



# Clinical Trials Appendix

FY 2025 Results Update

10 February 2026



# Pipeline at a glance

---

Across five focus therapy areas:



**Oncology**



**BioPharmaceuticals**

CVRM | R&I | V&I



**Rare Disease**

# 197

---

projects in our  
development pipeline

# 20

---

new molecular entities  
(NME) in our late-stage  
pipeline

# 125

---

new molecular entities  
(NME) or major lifecycle  
management (LCM) projects  
in Phase II or Phase III

# 43

---

regulatory approvals  
in major markets  
in FY 2025



# Key upcoming pipeline catalysts: 2026 and 2027

Oncology BioPharmaceuticals Rare Disease



## Regulatory decision<sup>1,2</sup>



## Key Phase III data readouts

### H1 2026

**Calquence** – CLL (1L fixed duration) (AMPLIFY) (US)  
**Enhertu** – neoadjuvant HER2+ Stage II or III breast cancer (DESTINY-Breast11)  
**Enhertu** – previously treated HER2+ solid tumours (DESTINY-PanTumour02) (JP)  
**Imfinzi + Imjudo** – NSCLC (1L) (POSEIDON) (CN)  
**Imfinzi + Imjudo** – HCC (1L) (HIMALAYA) (CN)  
**Imfinzi** – endometrial cancer (1L) (DUO-E) (CN)  
**Imfinzi** – resectable early-stage gastric and GEJ cancers (MATTERHORN) (EU, JP)  
**Imfinzi** – high-risk non-muscle invasive bladder cancer (POTOMAC)  
**Truqap** – PTEN-deficient mCRPC (CAPitello-281)  
**camizestrant** – *ESR1*m HR+ HER2- adv. breast cancer (1L switch) (SERENA-6)  
**Breztri** – uncontrolled asthma (KALOS/LOGOS)  
**Tezspire** – CRwNP (WAYPOINT) (JP, CN)  
**Tezspire** – severe asthma (DIRECTION) (CN)  
**Saphnelo** – SLE (subcutaneous) (TULIP-SC) (US, JP)  
**baxdrostat** – uncontrolled hypertension (BaxHTN)  
**Koselugo** – adult NF1-PN (KOMET) (CN)

**Imfinzi + Imjudo** – locoregional HCC ([EMERALD-3](#))  
**Imfinzi +/- Imjudo** – muscle-invasive bladder cancer ([VOLGA](#))  
**sonesitatur vedotin (AZD0901)** – CLDN18.2+ gastric cancer (2L+) ([CLARITY-Gastric01](#))  
**tozorakimab** – COPD ([OBERON/TITANIA/MIRANDA](#))  
**Ultomiris** – IgAN ([I CAN](#))  
**efzimfotase alfa** – hypophosphatasia ([HICKORY/CHESTNUT/MULBERRY](#))  
**Ultomiris** – HSCT-TMA ([TMA-313](#))

### H2 2026

**Datroway** – met. TNBC not candidate for IO (TROPION-Breast02)  
**Enhertu** – 1L HER2+ mBC (DESTINY-Breast09) (EU, JP, CN)  
**Enhertu** – previously treated HER2+ solid tumours (DESTINY-PanTumour02) (EU)  
**anselamimab** – AL amyloidosis (CARES)  
**gefurulimab** – generalised myasthenia gravis (PREVAIL)

**Datroway + Imfinzi** – NSQ/NSQ TROP2+ NSCLC (1L) ([AVANZAR](#))  
**Datroway** – NSQ/NSQ TROP2+ NSCLC (1L) ([TROPION-Lung07](#))  
**Datroway +/- Tagrisso** – EGFRm NSCLC (2L) ([TROPION-Lung15](#))  
**Imfinzi + oleclumab/monalizumab** – unresectable stage III NSCLC ([PACIFIC-9](#))  
**Tagrisso + Orpathys** – EGFRm NSCLC (2L) ([SAFFRON](#))  
**camizestrant** – HR+ HER2- adv. breast cancer (1L) ([SERENA-4](#))  
**Tezspire** – eosinophilic esophagitis (EoE) ([CROSSING](#))  
**Wainua** – ATTR-CM ([CARDIO-TTRansform](#))  
**tozorakimab** – LRTD ([TILIA](#))  
**Ultomiris** – CSA-AKI ([ARTEMIS](#))

### 2027

**Enhertu** – previously treated HER2+ solid tumours (DESTINY-PanTumour02) (EU)  
**Saphnelo** – SLE (subcutaneous) (TULIP-SC) (CN)

**Datroway + Imfinzi** – TNBC with residual disease (post-neoadj) ([TROPION-Breast03](#))  
**Datroway + Imfinzi** – PD-L1 CPS ≥10 TNBC (1L) ([TROPION-Breast05](#))  
**Truqap** – 1L early relapse/ET resistant advanced HR+ BC ([CAPitello-292](#))  
**Tagrisso** – stage IA2-IA3 EGFRm NSCLC ([ADAURA-2](#))  
**camizestrant** – adj. switch HR+ HER2- early breast cancer ([CAMBRIA-1](#))  
**puxi-sam** – B7-H4+ endometrial cancer (2-3L) ([Bluestar-Endometrial01](#))  
**volrustomig** – high-risk locally advanced cervical cancer ([eVOLVE-Cervical](#))  
**volrustomig** – mNSCLC (1L) ([eVOLVE-Lung02](#))  
**Saphnelo** – lupus nephritis ([IRIS](#))  
**Saphnelo** – systemic sclerosis ([DAISY](#))  
**Saphnelo** – myositis ([JASMINE](#))  
**Saphnelo** – CLE ([LAVENDER](#))  
**bacli/dapa** – HF with renal impairment ([BalanceD-HF](#))  
**zibo/dapa** – CKD and high proteinuria ([ZENITH](#))  
**laroprovstat** – dyslipidemia ([AZURE-LDL/AZURE-HeFH](#))  
**cliramitug** – ATTR-CM ([DepleTTR-CM](#))

Key upcoming pipeline catalysts are defined by a threshold of non-risk adjusted global peak year revenue expectations as of 10 February 2026.

<sup>1</sup>Regulatory decision includes programmes under review in a major market

<sup>2</sup>Inclusion dependent on status of regulatory submission and/or submission acceptance in regions in which submission acceptance is granted

3 As of 10 February 2026.

Appendix: [Glossary](#).



# Clinical Trials Appendix: selected highlights

## BioPharmaceuticals



balcinrenone/dapagliflozin (MR antagonist/modulator / SGLT2)

baxdrostat (aldosterone synthase inhibitor)

baxdrostat/dapagliflozin (ASI/SGLT2)

laroprovstat (oPSCK9)

zibotentan/dapagliflozin (ETA receptor antagonist/SGLT2)

tozorakimab (IL-33 ligand mAb)

## Oncology



camizestrant (next generation oral SERD)

puxitatug samroscan (AZD8205, B7H4 ADC)

rilvegostomig (PD-1/TIGIT bispecific)

saruparib (PARP1 inhibitor)

sonesitatug vedotin (AZD0901, CLDN18.2 ADC)

surovatamig (AZD0486, CD19/CD3 TCE)

torvutatug samroscan (AZD5335, FRα TOP1i ADC)

volrustomig (PD-1/CTLA-4 bispecific)

## Rare Disease



clirimitug (ALXN2220, TTR depleter)

efzimfotase alfa (enzyme replacement therapy)

eneboparatide (PTH 1 agonist)

gefurulimab (C5 inhibitor)

Approved medicines:  
key LCM

Next-wave pipeline:  
registrational studies ongoing



# Project movements since Q3 2025 update

New to Phase I	New to Phase II	New to pivotal trial	New to registration
<p><b><u>NME</u></b>  <b>AZD3632</b>            MENIN inhibitor haematological malignancies</p> <p><b>AZD3974</b>            anti-inflammatory and anti-fibrotic mechanism cirrhosis</p> <p><b>AZD4063</b>            PLN R14del dilated cardiomyopathy</p> <p><b>AZD9750</b>            AR PROTAC prostate cancer</p> <p><b><u>Additional indication</u></b>  <b>AZD0120</b>            CD19/BCMA CAR-T autoimmune disease</p> <p><b>AZD0120</b>            CD19/BCMA CAR-T multiple sclerosis</p> <p><b>surovatamig</b>            CD19/CD3 T-cell engager B-cell driven autoimmune disease</p>	<p><b><u>NME</u></b>  <b>ALXN2030 CONCORD</b>            siRNA targeting complement C3 antibody mediated rejection</p> <p><b>AZD0292</b>            pseudomonas Psl-PcrV bispecific mAb bronchiectasis</p> <p><b>AZD1163</b>            anti-PAD2/4 bispecific antibody rheumatoid arthritis</p> <p><b>AZD3470</b>            PRMT5 inhibitor classic Hodgkin lymphoma</p> <p><b>AZD5148</b>            anti-clostridioides difficile TcdB mAb reduction of <i>C. diff</i> recurrence</p> <p><b>tarperprumig I TRANSCEND</b>            kinase inhibitor ANCA-associated vasculitis</p> <p><b><u>Additional indication</u></b>  <b>surovatamig SYRUS</b>            CD19/CD3 T-cell engager B-cell acute lymphoblastic leukaemia</p>	<p><b><u>NME</u></b>  <b>torvutatug samrotecan (AZD5335) TREVI-OC-01</b>            anti-FRα TOP1i ADC ovarian cancer</p> <p><b><u>Additional indication</u></b>  <b>rilvegostomig ARTEMIDE-Biliary02#</b>            PD-1/TIGIT bispecific mAb metastatic biliary tract cancer</p> <p><b>surovatamig SOUNDTRACK-D2</b>            CD19/CD3 T-cell engager 1L elderly DLBCL</p> <p><b><u>Life-cycle management</u></b>  <b>Enhertu DESTINY-Endometrial02#</b>            HER2 TOP1i ADC adjuvant endometrial cancer</p>	<p><b><u>NME</u></b>  <b>anselamimab CARES</b>            fibril-reactive mAb amyloid light-chain amyloidosis</p> <p><b>baxdrostat BaxHTN Bax24</b>            aldosterone synthase inhibitor hypertension</p> <p><b><u>Life-cycle management</u></b>  <b>Datroway TROPION-Breast02#</b>            TROP2 TOP1i ADC 1L TNBC</p>

Phase progressions based on first subject in achievement

# Partnered and/or in collaboration

As of 10 February 2026.

Appendix: [Glossary](#).



# Project movements since Q3 2025 update

Removed from Phase I	Removed from Phase II	Removed from Phase III	Approved/removed from registration
<p><b><u>NME</u></b>  <b>AZD0233</b>  CX3CR1 dilated cardiomyopathy</p> <p><b>mRNA VLP vaccine</b>  mRNA-VLP vaccine prevention of COVID-19</p>	<p><b><u>NME</u></b>  <b>AZD3427</b>  relaxin mimetic heart failure</p> <p><b><u>Additional indication</u></b>  <b>ceralasertib</b>  ATR inhibitor solid tumours</p>	<p><b><u>NME</u></b>  <b>ceralasertib + Imfinzi LATIFY</b>  ATR inhibitor + PDL-1 mAb 2L NSCLC</p> <p><b><u>Life-cycle management</u></b>  <b>Datroway + rilvegostomig TROPION-Lung12<sup>#</sup></b>  TROP2 TOP1i ADC + PD-1/TIGIT bispecific mAb  ctDNA+ / high risk Stage I adenocarcinoma  NSCLC</p> <p><b><i>Lynparza + Imfinzi + bevacizumab DUO-O<sup>#1</sup></i></b>  PARP inhibitor + PD-L1 mAb + VEGF inhibitor  1L ovarian cancer</p>	<p><b><u>Life-cycle management</u></b>  <b>Enhertu + pertuzumab DESTINY-Breast09<sup>#</sup></b>  HER2 TOP1i ADC 1L HER2+ breast cancer</p> <p><b><i>Enhertu DESTINY-Gastric04<sup>#</sup></i></b>  HER2 TOP1i ADC 2L HER2+ gastric cancer</p> <p><b><i>Imfinzi + CRT PACIFIC-5 (China)<sup>#</sup></i></b>  PD-L1 mAb +CRT locally advanced stage III  NSCLC</p> <p><b><i>Imfinzi + FLOT MATTERHORN<sup>#</sup></i></b>  PD-L1 mAb + CTx resectable early gastric  cancer</p> <p><b><i>Saphnelo TULIP-SC<sup>#</sup></i></b>  type I IFN receptor mAb systemic lupus  erythematosus (subcutaneous)</p>

Phase progressions based on first subject in achievement

<sup>#</sup> Partnered and/or in collaboration

<sup>1</sup> Complete; decision taken to not progress with regulatory filings in US, Europe, China or Japan

As of 10 February 2026.

Appendix: [Glossary](#).



# Q4 2025 Oncology new molecular entity<sup>1</sup> pipeline

Phase I 23 New Molecular Entities		Phase II 19 New Molecular Entities		Phase III 23 New Molecular Entities	
surovatamig CD19/CD3 TCE r/r B-cell non-Hodgkin lymphoma	surovatamig SOUNDTRACK-E CD19/CD3 TCE mature B-cell malignancies	camizestrant ngSERD HR+ HER2- breast cancer	FPI-2265# PSMA actinium RC prostate cancer	<i>Imfinzi</i> +/- oleclumab +/- monalizumab PACIFIC-9# PD-L1 mAb +/- CD73 mAb +/- NKG2A mAb unresectable stage III NSCLC	camizestrant + palbociclib SERENA-4 ngSERD + CDK4/6i 1L HR+ HER2- advanced breast cancer
volrustomig eVOLVE-RCC02 PD-1/CTLA-4 bispecific mAb 1L advanced clear cell renal cell carcinoma	volrustomig + lenvatinib PD-1/CTLA-4 bispecific mAb + VEGFi advanced RCC	IPH5201 + <i>Imfinzi</i> # CD39 mAb + PD-L1 mAb neoadjuvant/adjuvant NSCLC	rilvegostomig ARTEMIDE-01# PD-1/TIGIT bispecific mAb solid tumours	camizestrant +/- abemaciclib CAMBRIA-2 ngSERD + CDK4/6i adjuvant HR+ HER2- early breast cancer	camizestrant CAMBRIA-1 ngSERD adjuvant switch HR+ HER2- early breast cancer
AZD0240 KRAS G12D armoured TCR-T solid tumours	AZD0516 STEAP2 TOP1i ADC prostate cancer	puxitatug samrotecan B7-H4 TOP1i ADC solid tumours	sonesitatug vedotin CLDN18.2 MMAE ADC solid tumours	puxitatug samrotecan Bluestar-Endometrial01 B7-H4 TOP1i ADC 2-3L B7-H4+ endometrial cancer	rilvegostomig ARTEMIDE-Lung03# PD-1/TIGIT bispecific mAb 1L PD-L1 TC ≥1% NSQ NSCLC
AZD0754 STEAP2 CAR-T prostate cancer	AZD2068 EGFR/cMET actinium radioconjugate solid tumours	saruparib PARP1 inhibitor solid tumours	surovatamig SYRUS CD19/CD3 TCE B-cell acute lymphoblastic leukaemia	rilvegostomig + bevacizumab +/- <i>Imjudo</i> ARTEMIDE-HCC01# PD-1/TIGIT bispecific mAb +VEGFi +/- CTLA-4 mAb 1L HCC	rilvegostomig + CTx ARTEMIDE-Biliary01# PD-1/TIGIT bispecific mAb + CTx adjuvant biliary tract cancer
AZD2284 STEAP2 actinium RC prostate cancer	AZD2962 IRAK4 inhibitor haematological malignancies	surovatamig SOUNDTRACK-B CD19/CD3 TCE B-cell non-Hodgkin lymphoma	torvutatug samrotecan (AZD5335) anti-FRα TOP1i ADC ovarian cancer, solid tumours	rilvegostomig + CTx ARTEMIDE-Lung02# PD-1/TIGIT bispecific mAb + CTx 1L PD-L1 TC ≥1% SQ NSCLC	rilvegostomig + <i>Enhertu</i> ARTEMIDE-Gastric01# PD-1/TIGIT bispecific mAb + HER2 TOP1i ADC 1L HER2+ gastric cancer
AZD3632 MENIN inhibitor haematological malignancies	AZD4360 CLDN18.2 TOP1i ADC solid tumours	tilatamig samrotecan EGFR/cMET TOP1i ADC solid tumours	volrustomig CANTOR PD-1/CTLA-4 bispecific mAb colorectal cancer (mCRC)	rilvegostomig ARTEMIDE-Biliary02# PD-1/TIGIT bispecific mAb metastatic biliary tract cancer	rilvegostomig ARTEMIDE-Lung04# PD-1/TIGIT bispecific mAb 1L PD-L1≥50% NSCLC
AZD4512 CD22 TOP1i ADC relapsed/refractory B-cell non-Hodgkin lymphoma	AZD5492 CD20 TITAN T-cell engager haematology	volrustomig PD-1/CTLA-4 bispecific mAb solid tumours	volrustomig eVOLVE-02 PD-1/CTLA-4 bispecific mAb cervical cancer, head and neck squamous cell carcinoma	saruparib + ADT +/- abiraterone EvoPAR-Prostate02 PARP1i + ADT +/- NHA localised/locally advanced BRCAm prostate cancer	saruparib + camizestrant EvoPAR-Breast01 PARP1i + ngSERD BRCA/PALB2m HR+ HER2- metastatic breast cancer
AZD5863 CLDN18.2/CD3 bispecific antibody solid tumours	AZD6621 STEAP2 TCE prostate cancer	volrustomig eVOLVE-01 PD-1/CTLA-4 bispecific mAb NSCLC	AZD0305 GPRC5D MMAE ADC relapsed/refractory multiple myeloma	saruparib + NHA EvoPAR-Prostate01 PARP1i + NHA HRRm/non-HRRm mCSPC	sonesitatug vedotin CLARITY-Gastric01 CLDN18.2 MMAE ADC 2L+ CLDN18.2+ gastric cancer
AZD6750 CD8-guided IL2 solid tumours	AZD7003 (China) GPC3 CAR-T hepatocellular carcinoma/squamous non-small cell lung cancer	AZD0120 CD19/BCMA CAR-T multiple myeloma	AZD9574 PARP1 inhibitor advanced solid malignancies	surovatamig SOUNDTRACK-D2 CD19/CD3 TCE 1L elderly DLBCL	surovatamig SOUNDTRACK-F1 CD19/CD3 TCE follicular lymphoma
AZD8421 CDK2 inhibitor solid tumours	AZD9750 AR PROTAC prostate cancer	AZD3470 PRMT5i classic Hodgkin lymphoma, solid tumours		torvutatug samrotecan (AZD5335) TREVI-OC-01 anti-FRα TOP1i ADC ovarian cancer	volrustomig eVOLVE-Cervical PD-1/CTLA-4 bispecific mAb high-risk locally advanced cervical cancer
AZD9793 GPC3 TCE solid tumours	NT-112 KRAS G12D armoured TCR-T solid tumours			volrustomig eVOLVE-HNSCC PD-1/CTLA-4 bispecific mAb unresected locally advanced HNSCC	volrustomig eVOLVE-Lung02 PD-1/CTLA-4 bispecific mAb 1L metastatic NSCLC
NT-175 TP53 R175H armoured TCR-T solid tumours				volrustomig eVOLVE-Meso PD-1/CTLA-4 bispecific mAb 1L unresectable malignant pleural mesothelioma	
				<b>Under review</b> 1 New Molecular Entity	
				camizestrant + CDK4/6i SERENA-6 ngSERD + CDK4/6i 1L HR+ HER2- ESR1m advanced breast cancer	

Phase progressions based on first subject in achievement  
1. Includes additional indications for assets where the lead is not yet launched  
# Partnered and/or in collaboration  
As of 10 February 2026.  
Appendix: [Glossary](#).





# Q4 2025 Oncology lifecycle management<sup>1</sup> pipeline

Phase I 0 Projects	Phase II 9 Projects	Phase III 29 Projects	Under review 4 Projects		
	<i>Enhertu</i> DESTINY-PanTumor03 (China)# HER2 TOP1i ADC HER2 expressing solid tumours	<i>Calquence</i> + R-CHOP ESCALADE BTKi + R-CHOP 1L DLBCL	<i>Datroway</i> + <i>Imfinzi</i> CTx AVANZAR# TROP2 TOP1i ADC + PD-L1 mAb + CTx 1L NSQ/NSQ TROP2+ NSCLC	<i>Datroway</i> + <i>Imfinzi</i> TROPION-Breast04# TROP2 TOP1i ADC + PD-L1 mAb neo/adjuvant TNBC or HR-low/HER2- breast cancer	<i>Datroway</i> TROPION-Breast02# TROP2 TOP1i ADC 1L TNBC not candidates for IO
	<i>Enhertu</i> (platform) DESTINY-Breast07# HER2 TOP1i ADC HER2+ breast cancer	<i>Datroway</i> + pembrolizumab TROPION-Lung07# TROP2 TOP1i ADC + PD-1 mAb 1L PD-L1 <50% NSQ NSCLC	<i>Datroway</i> + <i>Imfinzi</i> TROPION-Breast05# TROP2 TOP1i ADC + PD-L1 mAb 1L PD-L1 CPS ≥10 TNBC	<i>Datroway</i> + pembrolizumab TROPION-Lung08# TROP2 TOP1i ADC + PD-1 mAb 1L PD-L1 TPS ≥50% NSQ NSCLC	<i>Enhertu</i> followed by THP DESTINY-Breast11# HER2 TOP1i ADC neoadjuvant high-risk HER2+ early breast cancer
	<i>Enhertu</i> DESTINY-PanTumor01# HER2 TOP1i ADC HER2m solid tumours	<i>Datroway</i> + rilvegostomig TROPION-Lung10# TROP2 TOP1i ADC + PD-1/TIGIT bispecific mAb 1L PD-L1 ≥50% NSQ NSCLC	<i>Datroway</i> + <i>Tagrisso</i> TROPION-Lung14# TROP2 TOP1i ADC + EGFR TKI 1L EGFRm NSCLC	<i>Datroway</i> + <i>Tagrisso</i> TROPION-Lung15# TROP2 TOP1i ADC + EGFR TKI 2L EGFRm NSCLC	<i>Imfinzi</i> + BCG POTOMAC PD-L1 mAb + BCG non-muscle invasive bladder cancer
	<i>Imfinzi</i> combinations BEGONIA PD-L1 mAb + paclitaxel/novel oncology therapies 1L TNBC	<i>Enhertu</i> + rilvegostomig DESTINY-BTC01# HER2 TOP1i ADC + PD-1/TIGIT bispecific mAb 1L HER2+ biliary tract cancer	<i>Datroway</i> +/- <i>Imfinzi</i> TROPION-Breast03# TROP2 TOP1i ADC +/- PD-L1 mAb post-neoadjuvant TNBC with residual disease	<i>Enhertu</i> + rilvegostomig/pembrolizumab DESTINY-Endometrial01# HER2 TOP1i ADC + PD-1/TIGIT bispecific mAb/PD-1 mAb 1L HER2+ pMMR endometrial cancer	<i>Truqap</i> + abiraterone CAPitello-281 AKTi + NHA PTEN deficient mHSPC
	<i>Imfinzi</i> combinations HUDSON PD-L1 mAb + novel oncology therapies post-IO NSCLC	<i>Enhertu</i> DESTINY-Breast05# HER2 TOP1i ADC post-neoadjuvant high-risk HER2+ early breast cancer	<i>Enhertu</i> DESTINY-Endometrial02# HER2 TOP1i ADC adjuvant endometrial cancer	<i>Enhertu</i> DESTINY-Lung04# HER2 TOP1i ADC 1L HER2m NSCLC	
	<i>Imfinzi</i> combinations NeoCOAST-2# PD-L1 mAb + novel oncology therapies resectable NSCLC	<i>Imfinzi</i> + domvanalimab following cCRT PACIFIC-8# PD-L1 mAb + TIGIT following cCRT unresectable stage III NSCLC	<i>Imfinzi</i> + CRT KUNLUN PD-L1 mAb + CRT locally advanced ESCC	<i>Imfinzi</i> + EV +/- <i>Imjudo</i> VOLGA PD-L1 mAb + nectin-4 targeting MMAE ADC +/- CTLA-4 mAb muscle invasive bladder cancer (cis-ineligible/refusal)	
	<i>Tagrisso</i> + <i>Orpathys</i> SAVANNAH# EGFR TKI +METi advanced EGFRm NSCLC	<i>Imfinzi</i> + <i>Imjudo</i> + SoC NILE PD-L1 mAb + CTLA-4 mAb + SoC 1L urothelial cancer	<i>Imfinzi</i> + <i>Imjudo</i> + TACE +/- lenvatinib EMERALD-3 PD-L1 mAb +CTLA4 mAb +/- chemoembolisation +VEGFi locoregional HCC	<i>Imfinzi</i> + SBRT PACIFIC-4# PD-L1 mAb + SBRT stage I/II NSCLC	
	<i>Tagrisso</i> combinations ORCHARD# EGFR TKI + multiple novel ONC therapies 2L EGFRm osimertinib-resistant NSCLC	<i>Imfinzi</i> +/- bevacizumab EMERALD-2 PD-L1 mAb +/- VEGFi adjuvant HCC	<i>Imfinzi</i> + VEGF + TACE EMERALD-1 PD-L1 mAb +VEGFi +TACE locoregional HCC	<i>arza</i> MONO-OLA1# PARPi 1L BRCAwt ovarian cancer	
	<i>Truqap</i> AKTi prostate cancer	<i>Orpathys</i> + <i>Imfinzi</i> SAMETA# METi + PD-L1 mAb 1L papillary renal cell carcinoma	<i>Tagrisso</i> + <i>Orpathys</i> SAFFRON# EGFR TKI +METi advanced EGFRm NSCLC	<i>Tagrisso</i> +/- CTx NeoADAURA EGFR TKI +/- CTx neoadjuvant stage II/III resectable EGFRm NSCLC	
		<i>Truqap</i> + <i>Faslodex</i> + palbociclib CAPItello-292 AKTi + SERD + CDK4/6i 1L early relapse/ET resistant advanced HR+ breast cancer	<i>Tagrisso</i> ADAURA2 EGFR TKI EGFRm NSCLC stage Ia2-Ia3 following complete tumour resection		

Phase progressions based on first subject in achievement

1. Includes significant lifecycle management projects and parallel indications for assets beyond Phase III

# Partnered and/or in collaboration

As of 10 February 2026.

Appendix: [Glossary](#).





# Q4 2025 BioPharmaceuticals new molecular entity<sup>1</sup> pipeline

Phase I 14 New Molecular Entities		Phase II 17 New Molecular Entities		Phase III 8 New Molecular Entities
surovatamig CD19/CD3 TCE B-cell driven autoimmune disease	AZD0120 CD19/BCMA CAR-T systemic lupus erythematosus	atuliflapon FLAP inhibitor asthma	balcinrenone/dapagliflozin MR antagonist/modulator + SGLT2 inhibitor CKD	balcinrenone/dapagliflozin MR antagonist/modulator + SGLT2 inhibitor heart failure with CKD
AZD0120 CD19/BCMA CAR-T autoimmune diseases	AZD0120 CD19/BCMA CAR-T multiple sclerosis	elecoglipron (AZD5004) oral GLP-1 receptor agonist T2D/chronic weight management	opemalirsen podocyte health nephropathy	baxdrostat BaxPA aldosterone synthase inhibitor primary aldosteronism
AZD1613 PAPPA-1 mAb ADPKD	AZD1705 lipid lowering cardiovascular disease	tozorakimab IL-33 mAb asthma	AZD0292 pseudomonas Psl-PcrV bispecific mAb bronchiectasis	baxdrostat/dapagliflozin aldosterone synthase inhibitor and reversible inhibitor of SGLT2 CKD
AZD3974 anti-inflammatory and anti-fibrotic mechanism cirrhosis	AZD4063 PLN R14del dilated cardiomyopathy	AZD1163 anti-PAD2/4 bispecific antibody rheumatoid arthritis	AZD2389 anti-fibrotic mechanism metabolic dysfunction-associated steatohepatitis	baxdrostat/dapagliflozin aldosterone synthase inhibitor and reversible inhibitor of SGLT2 prevention of heart failure
AZD4144 NLRP3 cardiorenal disease	AZD4248 NNMT inhibitor cardiorenal disease	AZD4604 inhaled JAK1 inhibitor asthma	AZD5148 anti-clostridioides difficile TcdB mAb reduction of C.diff recurrence	laroprovstat AZURE PCSK9 dyslipidemia
AZD4954 Lp(a) inhibitor dyslipidaemia	AZD5492 CD20 TITAN T-cell engager systemic lupus erythematosus	AZD5462# RXFP1 agonist heart failure	AZD6234 peptide chronic weight management in overweight or obesity	tozorakimab OBERON TITANIA PROSPERO MIRANDA IL-33 mAb COPD
AZD6912 siRNA rheumatoid arthritis	AZD8965 inhibition of arginase enzyme idiopathic pulmonary fibrosis	AZD6793 IRAK4 inhibitor COPD	AZD7760 mAb combination targeting S aureus virulence factors prevention of Staph aureus infection	tozorakimab TILIA IL-33 mAb severe viral lower respiratory tract disease
		AZD7798 humanised monoclonal antibody targets T-cells subset Crohn's disease	AZD8630# inhaled TSLP Fab asthma	zibotentan/dapagliflozin endothelin A receptor antagonist/SGLT2i CKD with high proteinuria
		AZD9550 + AZD6234 GLP-1R glucagon dual agonist obesity		
				<b>Under review</b> 1 New Molecular Entity
				baxdrostat BaxHTN Bax24 BaxAsia aldosterone synthase inhibitor hypertension

Phase progressions based on first subject in achievement

1. Includes additional indications for assets where the lead is not yet launched

# Partnered and/or in collaboration

As of 10 February 2026.

Appendix: [Glossary](#).



# Q4 2025 BioPharmaceuticals life cycle management<sup>1</sup> pipeline

Phase I 0 Projects	Phase II 0 Projects	Phase III 9 Projects	Under review 2 Projects
		<i>Breztri/Trixeo</i> ATHLOS LABA/LAMA/ICS COPD cardiopulmonary exercise trial	<i>Breztri/Trixeo</i> (PT010) KALOS LOGOS LABA/LAMA/ICS asthma
		<i>Breztri/Trixeo</i> THARROS# LABA/LAMA/ICS cardiopulmonary outcomes trial in COPD	<i>Fasenra</i> NATRON IL-5R mAb hypereosinophilic syndrome
		<i>Saphnelo</i> DAISY# type I IFN receptor mAb systemic sclerosis	
		<i>Saphnelo</i> IRIS# type I IFN receptor mAb lupus nephritis	
		<i>Saphnelo</i> JASMINE# type I IFN receptor mAb myositis	
		<i>Saphnelo</i> LAVENDER# type I IFN receptor mAb cutaneous lupus erythematosus	
		<i>Tezspire</i> CROSSING# TSLP mAb eosinophilic esophagitis	
		<i>Tezspire</i> EMBARK, JOURNEY# TSLP mAb chronic obstructive pulmonary disease	
		<i>Wainua</i> # ligand-conjugated antisense ATTR-cardiomyopathy	

Phase progressions based on first subject in achievement  
1. Includes significant lifecycle management projects and parallel indications for assets beyond Phase III  
# Partnered and/or in collaboration  
As of 10 February 2026.  
Appendix: [Glossary](#)



# Q4 2025 Rare Disease pipeline<sup>1</sup>

Phase I 4 Projects	Phase II 4 Projects	Phase III 7 Projects	Under review 2 Projects
ALXN2080 oral factor D healthy volunteers	tarperprumig I TRANSCEND kinase inhibitor ANCA-associated vasculitis	cliramtig DepleTTR-CM# TTR depleter transthyretin amyloid cardiomyopathy	anselamimab CARES fibril-reactive mAb amyloid light-chain amyloidosis
ALXN2350 DCMRestore AAV gene therapy BAG3-associated dilated cardiomyopathy	ALXN1920 AUTUMN kidney-targeted factor H fusion protein nephrology	efzimfotase alfa Hickory (301), Mulberry (305), Chestnut (303) next generation TNSALP ERT hypophosphatasia	gefurulimab PREVAIL novel anti-C5, dual binding, nanobody generalised myasthenia gravis
AZD0120 ALACRITY CD19/BCMA CAR-T amyloid light-chain amyloidosis	ALXN2030 CONCORD siRNA targeting complement C3 antibody mediated rejection	eneboparatide CALYPSO parathyroid hormone receptor 1 hypoparathyroidism	
AZD1390 AGILE ATM inhibitor glioblastoma	ALXN2420 ASTERIA growth hormone receptor antagonist acromegaly	Ultomiris anti-complement C5 mAb haematopoietic stem cell transplant-associated thrombotic microangiopathy	
		Ultomiris ARTEMIS anti-complement C5 mAb cardiac surgery-associated acute kidney injury	
		Ultomiris AWAKE anti-complement C5 mAb delayed graft function	
		Ultomiris I CAN anti-complement C5 mAb immunoglobulin A nephropathy	

Phase progressions based on first subject in achievement

1. Includes new molecular entities and significant lifecycle management projects

# Partnered and/or in collaboration

As of 10 February 2026.

Appendix: [Glossary](#).



# Active designations in our pipeline

3	6	13	3	20
Priority Review	Breakthrough / PRIME <sup>1</sup> / Sakigake <sup>2</sup>	Fast Track	Qualified infectious disease product	Orphan
baxdrostat HTN (US)	AZD0292 Psl-PcrV N3Y NCFBE (EU)	AZD0292 Psl-PcrV N3Y NCFBE (US)	AZD0292 Psl-PcrV N3Y NCFBE (US)	Fasenra HES NATRON (US)
Datroway 1L TNBC TROPION-Breast02 (US)	Tezspire COPD EMBARK, JOURNEY (US)	AZD7760 Staph aureus mAbs-Hemodialysis (US)	AZD5148 C. difficile mAb - Prevention of Recurrence (US)	Saphnelo myositis JASMINE (US)
clirimitug DepleTTR-CM (JP)	tozorakimab severe viral LRTD TILIA (CN)	balci/dapa HF with CKD (US)	AZD7760 prevention of Staph aureus infection (US)	Saphnelo systemic sclerosis (US)
	camizestrant 1L HR+ HER2- ESR1m breast cancer SERENA-6 (US)	opemalirsen nephropathy (US)		Tezspire EoE CROSSING (US)
	Enhertu post-neoadjuvant high-risk HER2+ early breast cancer DESTINY-Breast05 (US)	tozorakimab COPD (US)		surovatamig follicular lymphoma SOUNDTRACK-F1 (EU)
	Ultomiris HSCT-TMA paed (US)	tozorakimab severe viral LRTD (US)		surovatamig lymphoblastic leukaemia SYRUS (EU)
		Wainua ATTR-Cardiomyopathy (US)		surovatamig lymphoblastic leukaemia SYRUS (US)
		camizestrant 1L HR+ HER2- ESR1m breast cancer SERENA-6 (US)		anselamimab AL amyloidosis CAEL101-301/2 (US)
		Orpathys + Tagrisso NSCLC SAVANNAH/SAFFRON (US)		anselamimab AL amyloidosis CAEL101-301/2 (EU)
		anselamimab AL amyloidosis CAEL101-301/2 (US)		clirimitug DepleTTR-CM (US)
		clirimitug DepleTTR-CM (US)		clirimitug DepleTTR-CM (EU)
		efzimfotase alfa s.c. HPP (US)		clirimitug DepleTTR-CM (JP)
		eneboparatide HypoPT (US)		efzimfotase alfa s.c. HPP (US)
				efzimfotase alfa s.c. HPP (JP)
				eneboparatide HypoPT (EU)
				eneboparatide HypoPT (US)
				gefurulumab myasthenia gravis PREVAIL (US)
				Koselugo NF1 adult 1L KOMET (CN)
				Ultomiris HSCT-TMA ALXN1210-TM-313 (US)
				Ultomiris HSCT-TMA ALXN1210-TM-313 (JP)

ACCELERATED APPROVAL, these regulations allowed medicines for serious conditions that addressed an unmet medical need to be approved based on a surrogate endpoint

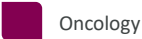
BREAKTHROUGH DESIGNATION is a process designed to expedite the development and review of medicines which may demonstrate substantial improvement over available therapy. <sup>1</sup>PRIME is a scheme launched by the EMA to enhance support for the development of medicines that target an unmet medical need. <sup>2</sup>SAKIGAKE is aimed at early introduction of innovative medicines, medical devices, etc. that are initially developed in Japan

FAST TRACK is a process designed to facilitate the development, and expedite the review of medicines to treat serious conditions and fill an unmet medical need

PRIORITY REVIEW DESIGNATION is the US FDA's goal to take action on an application within 6 months

ORPHAN DRUG DESIGNATION, intended for treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 patients in the US, or that affect more than 200,000 patients but are not expected to recover the costs of developing and marketing a treatment drug

QUALIFIED INFECTIOUS DISEASE PRODUCT designation confers particular advantages, including priority review by the US Food and Drug Administration (FDA) and fast-track designation, which can accelerate development of a product, as well as an additional five years' market exclusivity if a product is licensed.



Oncology

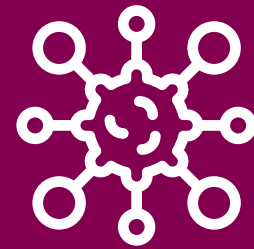
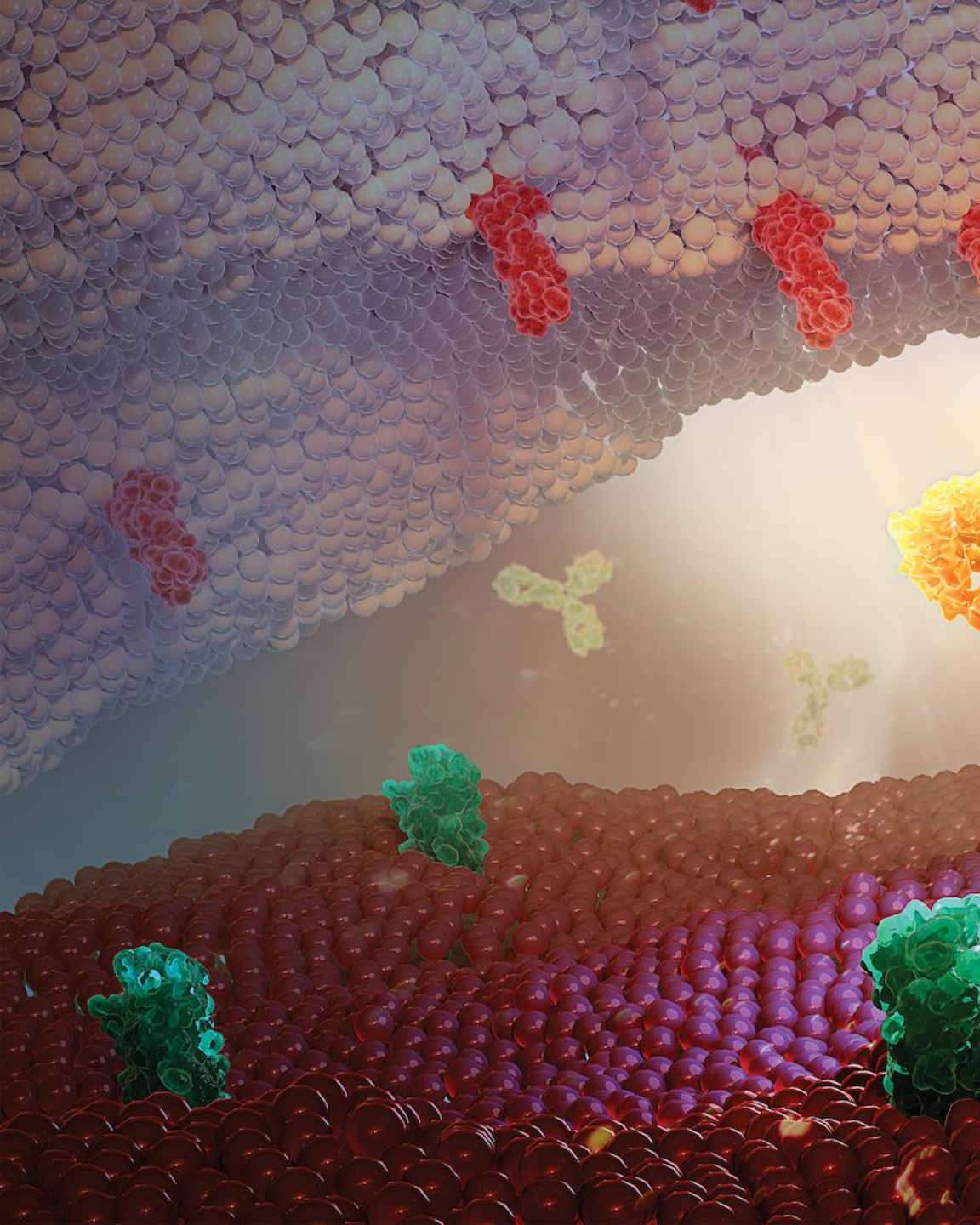


BioPharmaceuticals



Rare Disease





# Oncology:

approved medicines  
and late-stage  
pipeline



# Calquence (BTK inhibitor)

## Blood cancers

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

V&I

Rare Disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III AMPLIFY (ACE-CL-311) <a href="#">NCT03836261</a>	Previously untreated CLL	981	<ul style="list-style-type: none"> <li>Arm 1: <i>Calquence</i> + venetoclax</li> <li>Arm 2: <i>Calquence</i> + venetoclax + obinutuzumab</li> <li>Arm 3: FCR or BR</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: IRC PFS (Arm 1 vs. Arm 3)</li> <li>Secondary endpoints: IRC PFS (Arm 2 vs. Arm 3) and INV PFS (Arm 1 vs. Arm 3; Arm 2 vs. Arm 3)</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2019</li> <li>LPCD: Q3 2023</li> <li>Data readout: Q3 2024</li> <li>Primary endpoint met</li> </ul>
Phase III ECHO (ACE-LY-308) <a href="#">NCT02972840</a>	Previously untreated MCL	634	<ul style="list-style-type: none"> <li>Arm 1: <i>Calquence</i> + bendamustine + rituximab</li> <li>Arm 2: bendamustine + rituximab</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS by Lugano Classification for NHL</li> <li>Secondary endpoints: IA, PFS, ORR, DoR, time to response and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2017</li> <li>LPCD: Q1 2023</li> <li>Data readout: Q2 2024</li> <li>Primary endpoint met</li> </ul>
Phase III ESCALADE <a href="#">NCT04529772</a>	DLBCL	600	<ul style="list-style-type: none"> <li><i>Calquence</i> + rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>Data anticipated: 2027</li> </ul>
Phase III <a href="#">NCT04075292</a>	Untreated CLL	155	<ul style="list-style-type: none"> <li>Arm 1: <i>Calquence</i></li> <li>Arm 2: chlorambucil + rituximab</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoints: ORR and DoR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2020</li> <li>Data readout: Q2 2024</li> </ul>
Phase II TrAVeRse <a href="#">NCT05951959</a>	Treatment-naïve MCL	100	<ul style="list-style-type: none"> <li>Open-label, single-arm trial</li> <li><i>Calquence</i> + venetoclax + rituximab</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: MRD-negative CR at end of induction</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2024</li> <li>Data anticipated: &gt;2027</li> </ul>
Phase Ib ACE-LY-106 <a href="#">NCT02717624</a>	MCL	61	<ul style="list-style-type: none"> <li><i>Calquence</i> in combination with bendamustine and rituxumab</li> <li>Arm 1: treatment naïve</li> <li>Arm 2: R/R</li> <li>Arm 3: treatment naïve: <i>Calquence</i> + venetoclax + rituximab</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2016</li> <li>LPCD: Q2 2022</li> <li>Data readout: Q1 2023</li> </ul>
Phase I ACE-LY-003 <a href="#">NCT02180711</a>	R/R follicular lymphoma	89	<ul style="list-style-type: none"> <li>Arm 1: <i>Calquence</i></li> <li>Arm 2: <i>Calquence</i> + rituximab</li> <li>Arm 3: <i>Calquence</i> + rituximab + lenolidomide</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2015</li> <li>Data readout: Q1 2024</li> </ul>



# Datroway (datopotamab deruxtecan, TROP2 ADC)

## Breast cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase III TROPION-Breast02 <a href="#">NCT05374512</a> Partnered (Daiichi Sankyo)	Locally recurrent inoperable or metastatic TNBC not candidates for IO	600	<ul style="list-style-type: none"> <li>Open-label, randomised trial</li> <li>Arm 1: <i>Datroway</i></li> <li>Arm 2: investigator's choice of chemotherapy (paclitaxel, nab-paclitaxel, carboplatin, capecitabine, eribulin mesylate)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PFS (BICR) and OS</li> <li>Secondary endpoints: PFS (Inv), ORR, DoR, PK parameters and ADA</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2022</li> <li>LPCD: Q2 2024</li> <li>Data readout: Q4 2025</li> <li>Dual primary endpoints met</li> </ul>
Phase III TROPION-Breast03 <a href="#">NCT05629585</a> Partnered (Daiichi Sankyo)	Stage I-III TNBC without pathological complete response following neoadjuvant therapy	1075	<ul style="list-style-type: none"> <li>Open-label, randomised trial</li> <li>Arm 1: <i>Datroway</i> + <i>Imfinzi</i></li> <li>Arm 2: <i>Datroway</i></li> <li>Arm 3: investigator's choice of therapy (capecitabine, pembrolizumab, or capecitabine + pembrolizumab)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: iDFS</li> <li>Secondary endpoints: DDFS, OS, PK parameters and ADA</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2022</li> <li>LPCD: Q4 2024</li> <li>Data anticipated: 2027</li> </ul>
Phase III TROPION-Breast04 <a href="#">NCT06112379</a> Partnered (Daiichi Sankyo)	Perioperative triple-negative or HR-low/HER2-negative breast cancer	1900	<ul style="list-style-type: none"> <li>Open-label, randomised</li> <li>Arm 1: <i>Datroway</i> + <i>Imfinzi</i></li> <li>Arm 2: pembrolizumab + chemotherapy</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: EFS</li> <li>Secondary endpoints: pCR, OS, DDFS and safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>LPCD: Q3 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
Phase III TROPION-Breast05 <a href="#">NCT06103864</a> Partnered (Daiichi Sankyo)	Patients with PD-L1-positive locally recurrent inoperable or metastatic TNBC	625	<ul style="list-style-type: none"> <li>Open-label, randomised</li> <li>Arm 1: <i>Datroway</i> + <i>Imfinzi</i></li> <li>Arm 2: investigator's choice of chemotherapy in combination with pembrolizumab (paclitaxel, nab-paclitaxel, or gemcitabine + carboplatin)</li> <li>Arm 3: <i>Datroway</i></li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS (BICR)</li> <li>Secondary endpoints: OS, PFS (inv), ORR, DoR, DCR and safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>Data anticipated: 2027</li> </ul>





# Datroway (datopotamab deruxtecan, TROP2 ADC)

## NSCLC

Trial	Population	Patients	Design	Endpoints	Status
Phase III AVANZAR NCT05687266	1L NSCLC	1350	<ul style="list-style-type: none"> <li>Arm 1: <i>Datroway</i> + <i>Imfinzi</i> + carboplatin</li> <li>Arm 2: pembrolizumab + CTx</li> </ul>	<ul style="list-style-type: none"> <li>Co-primary endpoints: PFS and OS in NSQ ITT and NSQ TROP2 biomarker-positive</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2023</li> <li>Data anticipated: H2 2026</li> </ul>
Phase III TROPION-Lung01 NCT04656652 Partnered (Daiichi Sankyo)	Previously treated advanced or metastatic NSCLC with or without actionable genomic alterations	590	<ul style="list-style-type: none"> <li>Randomised, open-label, parallel assignment</li> <li>Arm 1: <i>Datroway</i></li> <li>Arm 2: docetaxel</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PFS and OS</li> <li>Secondary endpoints: ORR, DoR, TTR, DCR, PK parameters and ADA</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>LPCD: Q4 2022</li> <li>Data readout: Q3 2023</li> <li>Dual primary endpoint met (PFS)</li> </ul>
Phase III TROPION-Lung07 NCT05555732 Partnered (Daiichi Sankyo)	1L patients with PD-L1 TPS <50% and advanced or metastatic NSCLC without actionable genomic alterations	1170	<ul style="list-style-type: none"> <li>Randomised, open-label</li> <li>Arm 1: <i>Datroway</i> + pembrolizumab + platinum chemotherapy</li> <li>Arm 2: <i>Datroway</i> + pembrolizumab</li> <li>Arm 3: pembrolizumab + pemetrexed + platinum chemotherapy</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PFS and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2023</li> <li>Data anticipated: H2 2026</li> </ul>
Phase III TROPION-Lung08 NCT05215340 Partnered (Daiichi Sankyo)	Treatment-naïve patients with PD-L1-high advanced or metastatic NSCLC without actionable genomic alterations	740	<ul style="list-style-type: none"> <li>Randomised, open-label</li> <li>Arm 1: <i>Datroway</i> + pembrolizumab</li> <li>Arm 2: pembrolizumab</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PFS and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2022</li> <li>Data anticipated: H2 2026</li> </ul>
Phase III TROPION-Lung10 NCT06357533 Partnered (Daiichi Sankyo)	Locally advanced or metastatic non-squamous NSCLC with high PD-L1 expression (TC ≥50%) and without actionable genomic alterations	675	<ul style="list-style-type: none"> <li>Randomised, open-label, sponsor-blinded, parallel assignment</li> <li>Arm 1: <i>Datroway</i> + rilvegostomig</li> <li>Arm 2: rilvegostomig</li> <li>Arm 3: pembrolizumab</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PFS and OS in TROP2 biomarker-positive participants</li> <li>Secondary endpoints: PFS and OS in the ITT population, ORR, DoR, TTD, PK parameters, immunogenicity and PFS2</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2024</li> <li>Data anticipated: &gt;2027</li> </ul>
Phase III TROPION-Lung12 NCT06564844 Partnered (Daiichi Sankyo)	Stage I adenocarcinoma NSCLC who are ctDNA-positive or have high-risk pathological features	24	<ul style="list-style-type: none"> <li>Randomised trial</li> <li>Arm 1: <i>Datroway</i> + rilvegostomig</li> <li>Arm 2: rilvegostomig</li> <li>Arm 3: standard of care</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: DFS (BICR)</li> <li>Secondary endpoint: OS, QoL and PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>Trial discontinued due to strategic portfolio prioritisation</li> </ul>



# Datroway (datopotamab deruxtecan, TROP2 ADC)

## NSCLC

Trial	Population	Patients	Design	Endpoints	Status
Phase III TROPION-Lung14 <a href="#">NCT06350097</a> Partnered (Daiichi Sankyo)	EGFRm locally advanced or metastatic NSCLC	562	<ul style="list-style-type: none"> <li>Arm 1: <i>Tagrisso</i> + <i>Datroway</i></li> <li>Arm 2: <i>Tagrisso</i> monotherapy</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS (BICR)</li> <li>Secondary endpoints: OS, PFS by Inv., ORR, DoR; DCR; PFS of CNS met. patients; PFS2; safety; PK parameters and immunogenicity</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2024</li> <li>Data anticipated: &gt;2027</li> </ul>
Phase III TROPION-Lung15 <a href="#">NCT06417814</a> Partnered (Daiichi Sankyo)	Patients with advanced or metastatic EGFRm NSCLC whose disease has progressed on prior Osimertinib	744	<ul style="list-style-type: none"> <li>Open-label, sponsor blind, randomised trial</li> <li>Arm 1: <i>Datroway</i> + <i>Tagrisso</i></li> <li>Arm 2: <i>Datroway</i></li> <li>Arm 3: Platinum-based doublet CTx</li> </ul>	<ul style="list-style-type: none"> <li>Dual primary endpoints: PFS (BICR) monotherapy vs. CTx and PFS (BICR) combination vs. CTx</li> <li>Secondary endpoints: OS, CNS PFS, PFS (Inv.), PFS2, ORR, DoR, DCR, TTR, safety and PRO</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>Data anticipated: H2 2026</li> </ul>
Phase III TROPION-Lung17 <a href="#">NCT07291037</a> Partnered (Daiichi Sankyo)	Non-squamous 2L+ TROP2 NMR+ NSCLC	400	<ul style="list-style-type: none"> <li>Ph3, 2-arm, randomised study assessing the efficacy and safety of Dato-DXd compared with docetaxel</li> </ul>	<ul style="list-style-type: none"> <li>PFS, OS</li> </ul>	<ul style="list-style-type: none"> <li>Data anticipated: &gt;2027</li> </ul>
Phase II TROPION-Lung05 <a href="#">NCT04484142</a> Partnered (Daiichi Sankyo)	Advanced or metastatic NSCLC with actionable genomic alterations and progressed on or after kinase inhibitor therapy and platinum-based chemotherapy	137	<ul style="list-style-type: none"> <li>Single-arm, open-label</li> <li><i>Datroway</i></li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: ORR</li> <li>Secondary endpoints: DOR, PFS, OS, safety, PK parameters and ADA</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>LPCD: Q1 2022</li> <li>Data readout: Q1 2023</li> </ul>
Phase I TROPION-Lung02 <a href="#">NCT04526691</a> Partnered (Daiichi Sankyo)	Advanced or metastatic NSCLC	145	<ul style="list-style-type: none"> <li>Open-label, two-part (dose escalation and dose expansion), sequential assignment</li> <li><i>Datroway</i> + pembrolizumab +/- platinum chemotherapy</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: DLT and safety</li> <li>Secondary endpoints: ORR, DOR, PFS, OS, PK parameters and ADA</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2020</li> <li>LPCD: Q2 2023</li> <li>Data readout: Q4 2024</li> </ul>



# Datroway (datopotamab deruxtecan, TROP2 ADC)

## NSCLC

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase I</b> <b>TROPION-Lung04</b> <b><a href="#">NCT04612751</a></b> <b>Partnered (Daiichi Sankyo)</b>	Advanced or metastatic NSCLC	155	<ul style="list-style-type: none"> <li>Open-label, two-part (dose escalation, dose expansion), sequential assignment</li> <li><i>Datroway</i> + <i>Imfinzi</i> +/- platinum chemotherapy</li> <li>Cohort 1 &amp; 2: <i>Datroway</i> + <i>Imfinzi</i></li> <li>Cohort 3 &amp; 4: <i>Datroway</i> + <i>Imfinzi</i> + carboplatin</li> <li>Cohort 4a: <i>Datroway</i> + <i>Imfinzi</i> + carboplatin (SQ 1L only)</li> <li>Cohort 5 &amp; 6: <i>Datroway</i> + rilvegostomig</li> <li>Cohort 7 &amp; 8: <i>Datroway</i> + rilvegostomig + carboplatin</li> <li>Cohort 9 &amp; 10: <i>Datroway</i> + volrustomig + carboplatin</li> <li>Cohort 11: <i>Datroway</i> + volrustomig</li> <li>Cohort 12, 13 &amp; 14: <i>Datroway</i> + sabestomig</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: DLT and safety</li> <li>Secondary endpoints: ORR, DOR, PFS, OS, PK parameters and ADA</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>Data anticipated: H1 2026</li> </ul>



# Datroway (datopotamab deruxtecan, TROP2 ADC)

## Other cancers

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase II</b> <b>TROPION-PanTumor03</b> <b><a href="#">NCT05489211</a></b> <b>Partnered (Daiichi Sankyo)</b>	Endometrial cancer, gastric cancer, mCRPC, ovarian cancer, CRC, bladder cancer and BTC	606	<ul style="list-style-type: none"> <li>Sub-study 1 (endometrial cancer);</li> <li>Sub-study 1a: <i>Datroway</i> monotherapy</li> <li>Sub-study 2 (gastric cancer);</li> <li>Sub-study 2a: <i>Datroway</i> + capecitabine</li> <li>Sub-study 2b: <i>Datroway</i> + 5-fluorouracil</li> <li>Sub-study 3 (mCRPC);</li> <li>Sub-study 3a: <i>Datroway</i> (post-NHA)</li> <li>Sub-study 3c: <i>Datroway</i> + prednisone/prednisolone</li> <li>Sub-study 4 (ovarian cancer);</li> <li>Sub-study 4a: <i>Datroway</i></li> <li>Sub-study 4a (expansion): <i>Datroway</i> PSR/PRR (2-3L)</li> <li>Sub-study 4c: <i>Datroway</i> + carboplatin + bevacizumab PSR (2-3L)</li> <li>Sub-study 5 (CRC);</li> <li>Sub-study 5a1: <i>Datroway</i> (TROP2+ 3L+)</li> <li>Sub-study 5a2: <i>Datroway</i> (TROP2+ 2L+)</li> <li>Sub-study 5b: <i>Datroway</i> + 5-FU/leucovorin or capecitabine + bevacizumab (TROP2+ 1L)</li> <li>Sub-study 6 (bladder);</li> <li>Sub-study 6d: <i>Datroway</i> (2L+)</li> <li>Sub-study 6b: 1L cis-ineligible/2L <i>Datroway</i> + rilvegostomig (1L)</li> <li>Sub-study 6c: post-pembro/EV - <i>Datroway</i> + carbo/cisplatin (2L)</li> <li>Sub-Study 6E: 1L <i>Datroway</i> + rilvegostomig</li> <li>Sub-study 7 (BTC)</li> <li>Sub-study 7a: TROP2+ <i>Datroway</i> (2L+)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: ORR and safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2022</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase I/II</b> <b>TROPION-PanTumor02</b> <b><a href="#">NCT05460273</a></b> <b>Partnered (Daiichi Sankyo)</b>	NSCLC and TNBC and other solid tumours in Chinese patients	119	<ul style="list-style-type: none"> <li>Single-arm, multi-cohort trial with no blinding</li> <li><i>Datroway</i></li> <li>China only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: ORR</li> <li>Secondary endpoints: DoR, DCR, BOR, TTR PFS and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2022</li> <li>LPCD: Q2 2023</li> <li>Data readout: Q2 2024</li> </ul>
<b>Phase I</b> <b>TROPION-PanTumor01</b> <b><a href="#">NCT03401385</a></b> <b>Partnered (Daiichi Sankyo)</b>	Subjects with advanced solid tumours: NSCLC, TNBC, HR+ breast cancer, HER2-negative gastric/GEJ, oesophageal, urothelial, SCLC, CRPC, PDAC, HNSCC, HR+ HER2-low breast cancer and HER2-positive breast cancer	890	<ul style="list-style-type: none"> <li>Open-label, two-part (dose escalation, dose expansion), sequential assignment</li> <li><i>Datroway</i></li> <li>US and Japan</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: DLT and safety</li> <li>Secondary endpoints: PK parameters, anti-tumour activity and ADA</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2018</li> <li>Data readout: Q3 2025</li> </ul>



# Enhertu (trastuzumab deruxtecan, HER2 ADC)

## Breast cancer

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III DESTINY-Breast02 NCT03523585 Partnered (Daiichi Sankyo)</b>	HER2-positive, unresectable and/or metastatic breast cancer pretreated with prior SoC HER2 therapies including trastuzumab emtansine	600	<ul style="list-style-type: none"> <li>Randomised, open-label, parallel assignment</li> <li>Arm 1: <i>Enhertu</i></li> <li>Arm 2: physician's choice of lapatinib + capecitabine or trastuzumab + capecitabine</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoints: OS, ORR, DoR and CBR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2018</li> <li>LPCD: Q4 2020</li> <li>Data readout: Q3 2022</li> <li>Primary endpoint met</li> </ul>
<b>Phase III DESTINY-Breast03 NCT03529110 Partnered (Daiichi Sankyo)</b>	HER2-positive, unresectable and/or metastatic breast cancer previously treated with trastuzumab and taxane	524	<ul style="list-style-type: none"> <li>Randomised, open-label, parallel assignment</li> <li>Arm 1: <i>Enhertu</i></li> <li>Arm 2: ado-trastuzumab emtansine</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoints: OS, ORR, DoR and CBR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2018</li> <li>LPCD: Q2 2020</li> <li>Data readout: Q3 2021</li> <li>Primary endpoint met</li> </ul>
<b>Phase III DESTINY-Breast04 NCT03734029 Partnered (Daiichi Sankyo)</b>	HER2-low, unresectable and/or metastatic breast cancer	557	<ul style="list-style-type: none"> <li>Randomised, open-label, parallel assignment</li> <li>Arm 1: <i>Enhertu</i></li> <li>Arm 2: physician's choice of SoC chemotherapy (choice of capecitabine, eribulin, gemcitabine, paclitaxel or nab-paclitaxel)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoints: OS, DoR and ORR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2018</li> <li>LPCD: Q4 2020</li> <li>Data readout: Q1 2022</li> <li>Primary endpoint met</li> </ul>
<b>Phase III DESTINY-Breast05 NCT04622319 Partnered (Daiichi Sankyo)</b>	High-risk HER2-positive with residual invasive breast cancer following neoadjuvant therapy	1600	<ul style="list-style-type: none"> <li>Randomised, open-label, parallel assignment</li> <li>Arm 1: <i>Enhertu</i></li> <li>Arm 2: ado-trastuzumab emtansine</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: IDFS</li> <li>Secondary endpoints: DFS, OS, DRFI and BMFI</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2020</li> <li>Data readout: Q3 2025</li> <li>Primary endpoint met</li> </ul>
<b>Phase III DESTINY-Breast06 NCT04494425 Partnered (Daiichi Sankyo)</b>	HER2-low and -ultralow, HR+ breast cancer with disease progression on endocrine therapy in the metastatic setting	866	<ul style="list-style-type: none"> <li>Randomised, open-label, parallel assignment</li> <li>Arm 1: <i>Enhertu</i></li> <li>Arm 2: investigator's choice SoC chemotherapy (capecitabine, paclitaxel, nab-paclitaxel)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoints: OS, DoR and ORR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2020</li> <li>LPCD: Q2 2023</li> <li>Data readout: Q2 2024</li> <li>Primary endpoint met</li> </ul>
<b>Phase III DESTINY-Breast09 NCT04784715 Partnered (Daiichi Sankyo)</b>	HER2-positive, metastatic breast cancer with no prior therapy for advanced or metastatic disease	1157	<ul style="list-style-type: none"> <li>Randomised, parallel assignment</li> <li>Arm 1: <i>Enhertu</i> + placebo</li> <li>Arm 2: <i>Enhertu</i> + pertuzumab</li> <li>Arm 3: SoC</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoints: OS, DoR and ORR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2021</li> <li>Data readout: Q2 2025</li> <li>Primary endpoint met for <i>Enhertu</i> + pertuzumab arm</li> <li>Data anticipated for <i>Enhertu</i> monotherapy arm: H2 2026</li> </ul>



# Enhertu (trastuzumab deruxtecan, HER2 ADC)

## Breast cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase III DESTINY-Breast11 <a href="#">NCT05113251</a> Partnered (Daiichi Sankyo)	High-risk HER2-positive early non-metastatic breast cancer	927	<ul style="list-style-type: none"> <li>Randomised, open-label, parallel assignment</li> <li>Arm 1: <i>Enhertu</i></li> <li>Arm 2: <i>Enhertu</i> followed by THP</li> <li>Arm 3: doxorubicin and cyclophosphamide followed by THP</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: pCR</li> <li>Secondary endpoints: EFS, IDFS and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2021</li> <li>Data readout: Q2 2025</li> <li>Primary endpoint met</li> </ul>
Phase Ib/II DESTINY-Breast07 <a href="#">NCT04538742</a> Partnered (Daiichi Sankyo)	HER2-positive metastatic breast cancer	245	<ul style="list-style-type: none"> <li>Randomised, open-label, sequential assignment</li> <li>Arm 1: <i>Enhertu</i></li> <li>Arm 2: <i>Enhertu</i> + <i>Imfinzi</i></li> <li>Arm 3: <i>Enhertu</i> + pertuzumab</li> <li>Arm 4: <i>Enhertu</i> + paclitaxel</li> <li>Arm 5: <i>Enhertu</i> + <i>Imfinzi</i> + paclitaxel</li> <li>Arm 6: <i>Enhertu</i> + tucatinib</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: AE and SAE</li> <li>Secondary endpoints: ORR, PFS, DoR and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>Data readout: Q3 2025</li> </ul>
Phase Ib DESTINY-Breast08 <a href="#">NCT04556773</a> Partnered (Daiichi Sankyo)	HER2-low metastatic breast cancer	139	<ul style="list-style-type: none"> <li>Non-randomised, open-label parallel assignment</li> <li>Arm 1: <i>Enhertu</i> + capecitabine</li> <li>Arm 2: <i>Enhertu</i> + <i>Imfinzi</i> + paclitaxel</li> <li>Arm 3: <i>Enhertu</i> + <i>Truqap</i></li> <li>Arm 4: <i>Enhertu</i> + anastrozole</li> <li>Arm 5: <i>Enhertu</i> + <i>Faslodex</i></li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: AE and SAE</li> <li>Secondary endpoints: ORR, PFS, DoR and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>LPCD: Q1 2023</li> <li>Data readout: Q3 2023</li> </ul>



# Enhertu (trastuzumab deruxtecan, HER2 ADC)

## Gastric cancer

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>DESTINY-Gastric04</b> <b>NCT04704934</b> <b>Partnered (Daiichi Sankyo)</b>	HER2-positive gastric cancer or GEJ adenocarcinoma patients who have progressed on or after a trastuzumab-containing regimen and have not received any additional systemic therapy	490	<ul style="list-style-type: none"> <li>Open-label, randomised, parallel group assignment</li> <li>Arm 1: <i>Enhertu</i></li> <li>Arm 2: SoC chemotherapy</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: OS</li> <li>Secondary endpoints: ORR, DoR, PFS, DcR and safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2021</li> <li>Data readout: Q1 2025</li> </ul>
<b>Phase III</b> <b>DESTINY-Gastric05</b> <b>NCT06731478</b> <b>Partnered (Daiichi Sankyo)</b>	HER2+ 1L locally advanced or metastatic GC or GEJ adenocarcinoma	726	<ul style="list-style-type: none"> <li>Arm A (CPS ≥1): <i>Enhertu</i> + 5-FU or capecitabine + pembrolizumab</li> <li>Arm B (CPS ≥1): <i>Enhertu</i> + 5-FU or capecitabine + cisplatin or oxaliplatin + pembrolizumab</li> <li>Arm C (CPS &lt;1): <i>Enhertu</i> + 5-FU or capecitabine</li> <li>Arm D (CPS &lt;1): ToGA</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS (BICR) in ITT</li> <li>Secondary endpoints: OS, ORR, PFS (Inv.), DOR, safety and PRO</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase II</b> <b>DESTINY-Gastric06</b> <b>NCT04989816</b> <b>Partnered (Daiichi Sankyo)</b>	HER2-positive gastric cancer or GEJ adenocarcinoma patients who have progressed on two prior treatment regimens	95	<ul style="list-style-type: none"> <li>Open-label, single group assignment</li> <li><i>Enhertu</i></li> <li>China only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: ORR</li> <li>Secondary endpoints: PFS, ORR, DCR, OS, DoR and safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2021</li> <li>LPCD: Q2 2024</li> <li>Data readout: Q3 2023</li> <li>DESTINY-Gastric06 conditional approval converted to full approval on 20 Jan 2026</li> </ul>
<b>Phase Ib/II</b> <b>DESTINY-Gastric03</b> <b>NCT04379596</b> <b>Partnered (Daiichi Sankyo)</b>	Metastatic or unresectable HER2+ GC, GEJ, & esophageal adenocarcinoma Part 1: ≥ 2L following trastuzumab containing therapy Part 2, 3 and 4: Previously untreated metastatic or unresectable GC Part 3 and 4: HER2 expressing (IHC 3+,2+,1+) (local assess)	417	<ul style="list-style-type: none"> <li>Open-label, parallel assignment</li> <li>Part 1: to determine recommended Phase II combination dose</li> <li>5 Arms combining <i>Enhertu</i> with SoC chemotherapies (5-FU, capecitabine, oxaliplatin) and/or <i>Imfinzi</i></li> <li>Part 2 and 3: to assess efficacy of the selected combinations</li> <li>Arm 2A: standard chemotherapy</li> <li>Arm 2B: <i>Enhertu</i> monotherapy</li> <li>Arm 2C: <i>Enhertu</i> with chemotherapy</li> <li>Arm 2D: <i>Enhertu</i> with chemotherapy and pembrolizumab</li> <li>Arm 2E: <i>Enhertu</i> and pembrolizumab</li> <li>Arm 2F: <i>Enhertu</i>, chemotherapy and pembrolizumab</li> <li>Arm 3A (HER2+): <i>Enhertu</i>, chemotherapy and volrustomig</li> <li>Arm 3B (HER2low): <i>Enhertu</i>, chemotherapy and volrustomig</li> <li>Arm 4A (HER2+): <i>Enhertu</i>, chemotherapy and rilvegostomig</li> <li>Arm 4B (HER2low): <i>Enhertu</i>, chemotherapy and rilvegostomig</li> <li>Arm 5 (HER2low): <i>Enhertu</i>, chemotherapy and volrustomig (priming dose)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint (Part 1): safety, RP2D and ORR</li> <li>Secondary endpoints: DoR, DCR, PFS, OS, PK parameters and presence of ADAs</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2020</li> <li>Data anticipated: 2027</li> </ul>



# Enhertu (trastuzumab deruxtecan, HER2 ADC)

## Other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III DESTINY-BTC01 <a href="#">NCT06467357</a> Partnered (Daiichi Sankyo)	Advanced treatment-naïve HER2-expressing BTC	620	<ul style="list-style-type: none"> <li>Arm A: <i>Enhertu</i> + rilvegostomig</li> <li>Arm B: <i>Enhertu</i></li> <li>Arm C: gemcitabine and cisplatin + <i>Imfinzi</i></li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: OS</li> <li>Secondary endpoint: OS (ITT), PFS (INV), ORR (ONV), DOR (INV) Safety, PRO</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>Data anticipated: &gt;2027</li> </ul>
Phase III DESTINY-Endometrial01 <a href="#">NCT06989112</a> Partnered (Daiichi Sankyo)	Stage III, Stage IV, or recurrent, histologically-confirmed endometrial cancer	600	<ul style="list-style-type: none"> <li>Open label, randomized, global</li> <li>Arm A: <i>Enhertu</i> + rilvegostomig</li> <li>Arm B: <i>Enhertu</i> + pembrolizumab</li> <li>Arm C: carboplatin/paclitaxel + pembrolizumab</li> </ul>	<ul style="list-style-type: none"> <li>Primary: PFS (BICR) in ITT</li> <li>Secondary: OS, PFS (Investigator), ORR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
Phase III DESTINY-Endometrial02 <a href="#">NCT07022483</a> Partnered (Daiichi Sankyo)	Endometrial cancer excluding sarcoma Stage IIC or III FIGO 2023	710	<ul style="list-style-type: none"> <li>Randomised, open label, parallel assignment</li> <li>Arm 1: <i>Enhertu</i> +/- radiotherapy</li> <li>Arm 2: SoC chemotherapy +/- radiotherapy</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: DFS ITT (BICR or pathology)</li> <li>Secondary endpoints: OS ITT, DFS ITT (INV), DDFS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
Phase III DESTINY-Lung06 <a href="#">NCT06899126</a> Partnered (Daiichi Sankyo)	No prior therapy for locally advanced unresectable or metastatic NSCLC, HER2- over expressing and PD-L1 TPS <50% without known AGA that have locally available therapies targeting their AGAs in first-line advanced/metastatic	686	<ul style="list-style-type: none"> <li>Arm A: <i>Enhertu</i> + pembrolizumab</li> <li>Arm B: pembrolizumab + pemetrexed + platinum CTX (cis or carbo)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS by BICR</li> <li>Secondary endpoint: OS, PFS (Inv.), ORR per RECIST v1.1, DOR, safety and tolerability, PROs</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
Phase III DESTINY-Lung04 <a href="#">NCT05048797</a> Partnered (Daiichi Sankyo)	HER2-mutated, unresectable, locally advanced/metastatic NSCLC	450	<ul style="list-style-type: none"> <li>Randomised, parallel group assignment</li> <li>Arm 1: <i>Enhertu</i></li> <li>Arm 2: SoC (platinum, pemetrexed and pembrolizumab)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoints: OS, CNS-PFS, PFS (INV), ORR, DoR, safety, PK parameters, ADA, PRO-tolerability and PRO- pulmonary symptoms</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2021</li> <li>Data anticipated: H1 2026</li> </ul>
Phase III DESTINY-Ovarian01 <a href="#">NCT06819007</a> Partnered (Daiichi Sankyo)	(HER2)-expressing (immunohistochemistry [IHC] 3+/2+/1+) advanced high-grade epithelial ovarian cancer	582	<ul style="list-style-type: none"> <li>DS-unilateral</li> <li>Phase 3, open label, randomised</li> <li>Arm 1: <i>Enhertu</i> + bevacizumab</li> <li>Arm 2: bevacizumab</li> </ul>	<ul style="list-style-type: none"> <li>Primary: PFS (BICR) in IHC 2+/3+</li> <li>Secondary: PFS (BICR) in ITT (3/2/1+), OS ICH 2+/3+, OS ITT</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
Phase II DESTINY-CRC02 <a href="#">NCT04744831</a> Partnered (Daiichi Sankyo)	HER2-overexpressing advanced or metastatic colorectal cancer	122	<ul style="list-style-type: none"> <li>Randomised, parallel group assignment</li> <li>Arm 1: <i>Enhertu</i> 6.4mg/kg</li> <li>Arm 2: <i>Enhertu</i> 5.4mg/kg</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: ORR</li> <li>Secondary endpoints: ORR, PFS, OS, DoR, DCR and PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>Data readout: Q1 2023</li> <li>Primary endpoint met</li> </ul>



# Enhertu (trastuzumab deruxtecan, HER2 ADC)

## Other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase II DESTINY-Lung02 <a href="#">NCT04644237</a> Partnered (Daiichi Sankyo)	HER2-mutated, unresectable and/or metastatic NSCLC	152	<ul style="list-style-type: none"> <li>Randomised, parallel group assignment</li> <li>Arm 1: <i>Enhertu</i> 6.4mg/kg</li> <li>Arm 2: <i>Enhertu</i> 5.4mg/kg</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: ORR</li> <li>Secondary endpoints: DoR, DCR, PFS, OS and PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>Data readout: Q1 2023</li> <li>Primary endpoint met</li> </ul>
Phase II DESTINY-Lung05 <a href="#">NCT05246514</a> Partnered (Daiichi Sankyo)	HER2-mutant metastatic NSCLC who have disease progression on or after at least one-line of treatment	80	<ul style="list-style-type: none"> <li>Open-label, single-arm trial</li> <li>China only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: ORR</li> <li>Secondary endpoints: investigator and ICR assessed DCR, DoR and PFS, investigator assessed ORR, OS, ICR assessed NS-PFS, PK parameters, immunogenicity and safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2022</li> <li>LPCD: Q1 2023</li> <li>Data readout: Q4 2023</li> <li>Primary endpoint met</li> </ul>
Phase II DESTINY-PanTumor01 <a href="#">NCT04639219</a> Partnered (Daiichi Sankyo)	HER2-mutated tumours	102	<ul style="list-style-type: none"> <li>Non-randomised, single group assignment</li> <li><i>Enhertu</i></li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: ORR</li> <li>Secondary endpoints: DoR, DCR, PFS and PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>LPCD: Q2 2022</li> <li>Data readout: Q2 2023</li> </ul>
Phase II DESTINY-PanTumor02 <a href="#">NCT04482309</a> Partnered (Daiichi Sankyo)	HER2-expressing tumours	468	<ul style="list-style-type: none"> <li>Non-randomised, single group assignment</li> <li><i>Enhertu</i></li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: ORR</li> <li>Secondary endpoints: DoR, DCR, PFS and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2020</li> <li>Data readout: Q3 2023</li> </ul>
Phase II DESTINY-PanTumor03 <a href="#">NCT06271837</a> Partnered (Daiichi Sankyo)	HER2 expressing tumours	125	<ul style="list-style-type: none"> <li>Non-randomised single group assignment</li> <li><i>Enhertu</i></li> <li>China only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: ORR</li> <li>Secondary endpoints: DoR, DCR, PFS, OS, safety and tolerability, PK</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>Data readout: Q1 2026</li> </ul>



# Enhertu (trastuzumab deruxtecan, HER2 ADC)

## Other cancers

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase Ib</b> <b>DESTINY-Lung03</b> <b>NCT04686305</b> <b>Partnered (Daiichi Sankyo)</b>	HER2-over expressing, unresectable and/or metastatic NSCLC Part 1: 2L/3L advanced Parts 2/3/4/5: 1L advanced	244	<ul style="list-style-type: none"> <li>Non-randomised, parallel group assignment</li> <li>Part 1: to determine recommended combination dose</li> <li>3 Arms combine <i>Enhertu</i> with SoC chemotherapies (cisplatin, carboplatin or pemetrexed) and <i>Imfinzi</i>; Arm 1D: <i>Enhertu</i> monotherapy arm</li> <li>Part 2: to assess efficacy of the selected combinations with chemotherapies (cisplatin, carboplatin or pemetrexed) and <i>Imfinzi</i> not initiated</li> <li>Part 3 (2 arms): dose confirmation to assess safety and efficacy with volrustomig and volrustomig and chemotherapy (carboplatin)</li> <li>Part 4 (2 arms): dose confirmation to assess safety and efficacy with rilvegostomig and rilvegostomig and chemotherapy (carboplatin)</li> <li>Part 5: to evaluate priming approach ( <i>Enhertu</i>+ volru (500mg) followed by 250mg until progression)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: safety and RP2D</li> <li>Secondary endpoints: ORR, DoR, DCR, PFS, OS and PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2021</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase I</b> <b>Enhertu SubQ</b> <b>NCT07015697</b> <b>Partnered (Daiichi Sankyo)</b>	Part 1: pre-treated mBC Part 2: HER2-low mBC	76	<ul style="list-style-type: none"> <li>Non-Randomised, sequential assignment</li> <li>Part 1: Dose Escalation, s.c. T-DXd with hyaluronidase co-mixed</li> <li>Part 2: Expansion, s.c. T-DXd with hyaluronidase co-mixed flat dose</li> </ul>	<ul style="list-style-type: none"> <li>Part 1: DLT incidence, safety, PK</li> <li>Part 2: Primary endpoint: PK; Secondary endpoints: ORR, safety, tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase III</b> <b>DESTINY-Endometrial02</b> <b>NCT07022483</b> <b>Partnered (Daiichi Sankyo)</b>	Endometrial cancer excluding sarcoma Stage IIC or III FIGO 2023	710	<ul style="list-style-type: none"> <li>Randomised, open label, parallel assignment</li> <li>Arm 1: <i>Enhertu</i> +/- radiotherapy</li> <li>Arm 2: SoC chemotherapy +/- radiotherapy</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: DFS ITT (BICR or pathology)</li> <li>Secondary endpoints: OS ITT, DFS ITT (INV), DDFS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase III</b> <b>DESTINY-Lung06</b> <b>NCT06899126</b> <b>Partnered (Daiichi Sankyo)</b>	No prior therapy for locally advanced unresectable or metastatic NSCLC, HER2- over expressing and PD-L1 TPS <50% without known AGA that have locally available therapies targeting their AGAs in first-line advanced/metastatic	686	<ul style="list-style-type: none"> <li>Arm A: <i>Enhertu</i> + pembrolizumab</li> <li>Arm B: pembrolizumab + pemetrexed + platinum CTX (cis or carbo)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS by BICR</li> <li>Secondary endpoint: OS, PFS (Inv.), ORR per RECIST v1.1, DOR, safety and tolerability, PROs</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2025</li> <li>Data anticipated: &gt;2027</li> </ul>



# Imfinzi (PD-L1 mAb)

## Gastrointestinal cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase III EMERALD-1 <a href="#">NCT03778957</a>	Locoregional HCC	710	<ul style="list-style-type: none"> <li>Arm 1: TACE in combination with <i>Imfinzi</i></li> <li>Arm 2: TACE in combination with <i>Imfinzi</i> + bevacizumab</li> <li>Arm 3: TACE in combination with placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS (Arm 2 vs. Arm 3)</li> <li>Secondary endpoints: PFS (Arm 1 vs. Arm 3) and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2019</li> <li>LPCD: Q3 2021</li> <li>Data readout: Q4 2023</li> <li>Primary endpoint met</li> </ul>
Phase III EMERALD-2 <a href="#">NCT03847428</a>	HCC (adjuvant)	908	<ul style="list-style-type: none"> <li>Arm 1: <i>Imfinzi</i> + bevacizumab</li> <li>Arm 2: <i>Imfinzi</i> + placebo</li> <li>Arm 3: placebo + placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: RFS (Arm 1 vs. Arm 3)</li> <li>Secondary endpoints: RFS (Arm 2 vs. Arm 3), OS and RFS at 24 months</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2019</li> <li>LPCD: Q2 2022</li> <li>Data anticipated: H2 2026</li> </ul>
Phase III EMERALD-3 <a href="#">NCT05301842</a>	Locoregional HCC	725	<ul style="list-style-type: none"> <li>Arm 1: <i>Imfinzi</i> + <i>Imjudo</i> + TACE + lenvatanib</li> <li>Arm 2: <i>Imfinzi</i> + <i>Imjudo</i> + TACE</li> <li>Arm 3: TACE</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoint: OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2022</li> <li>Data anticipated: H1 2026</li> </ul>
Phase III HIMALAYA <a href="#">NCT03298451</a>	1L HCC	1324	<ul style="list-style-type: none"> <li>Arm 1: <i>Imfinzi</i> + <i>Imjudo</i></li> <li>Arm 2: <i>Imfinzi</i></li> <li>Arm 3: sorafenib</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: OS</li> <li>Secondary endpoints: PFS, TTP and ORR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2017</li> <li>LPCD: Q4 2019</li> <li>Data readout: Q4 2021</li> </ul>
Phase III KUNLUN <a href="#">NCT04550260</a>	Locally advanced, unresectable ESCC	640	<ul style="list-style-type: none"> <li>Arm 1: <i>Imfinzi</i> + definitive CRT</li> <li>Arm 2: placebo + definitive CRT</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoint: OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2020</li> <li>LPCD: Q3 2023</li> <li>Data anticipated: H2 2026</li> </ul>
Phase III MATTERHORN <a href="#">NCT04592913</a>	Resectable GC/GEJC	900	<ul style="list-style-type: none"> <li>Arm 1: <i>Imfinzi</i> + FLOT</li> <li>Arm 2: placebo + FLOT</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: EFS</li> <li>Secondary endpoints: OS (Arm 1 vs. Arm 2) and pCR (Arm 1 vs. Arm 2)</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2020</li> <li>LPCD: Q3 2022</li> <li>Data readout: Q1 2025</li> <li>Primary endpoint met</li> </ul>



# Imfinzi (PD-L1 mAb)

## Lung cancer

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III ADJUVANT BR.31 NCT02273375 Partnered (CCTG)</b>	Adjuvant NSCLC patients, Stage Ib (≥4cm) - Stage IIIa resected (incl. EGFR/ALK-positive)	1415	<ul style="list-style-type: none"> <li>Arm 1: <i>Imfinzi</i> mg/kg i.v. Q4W x 12 months</li> <li>Arm 2: placebo</li> <li>Global trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: DFS</li> <li>Secondary endpoint: OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2015</li> <li>LPD: Q1 2020</li> <li>Data readout: Q2 2024</li> </ul>
<b>Phase III ADRIATIC NCT03703297</b>	Limited-stage SCLC 1L following platinum-based concurrent chemoradiation therapy	730	<ul style="list-style-type: none"> <li>Arm 1: <i>Imfinzi</i> + <i>Imjudo</i> (4 doses)</li> <li>Arm 2: <i>Imfinzi</i></li> <li>Arm 3: placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PFS and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2018</li> <li>Data readout: Q2 2024</li> <li>Primary endpoint met</li> </ul>
<b>Phase III PACIFIC-4 NCT03833154</b>	<i>Imfinzi</i> with SBRT in unresected, Stage I/II NSCLC	630	<ul style="list-style-type: none"> <li>Arm 1: <i>Imfinzi</i> i.v. Q4W with definitive SBRT</li> <li>Arm 2: placebo with definitive SBRT</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoint: OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2019</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase III PACIFIC-5 NCT03706690</b>	Unresected, locally advanced NSCLC	407	<ul style="list-style-type: none"> <li>Arm 1: <i>Imfinzi</i> i.v. Q4W following chemotherapy/RT</li> <li>Arm 2: placebo following chemotherapy/RT</li> <li>Global trial (ex-US with China focus)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoint: OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2019</li> <li>LPD: Q2 2022</li> <li>Data readout: Q3 2024</li> <li>Primary endpoint met</li> </ul>
<b>Phase III PACIFIC-8 NCT05211895 Partnered (Arcus Biosciences)</b>	Unresected, locally advanced NSCLC	860	<ul style="list-style-type: none"> <li>Arm 1: <i>Imfinzi</i> + domvanalimab following chemotherapy/RT</li> <li>Arm 2: <i>Imfinzi</i> + placebo following chemotherapy/RT</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoint: OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2022</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase III PACIFIC-9 NCT05221840 Partnered (Innate Pharma)</b>	Patients with locally advanced (Stage III), unresectable NSCLC who have not progressed following platinum-based CRT	999	<ul style="list-style-type: none"> <li>Arm 1: <i>Imfinzi</i> + oleclumab</li> <li>Arm 2: <i>Imfinzi</i> + monalizumab + placebo</li> <li>Arm 3: <i>Imfinzi</i> + placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoints: OS, ORR, DoR, PFS2 and TFST</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2022</li> <li>Data anticipated: H2 2026</li> </ul>



# Imfinzi (PD-L1 mAb)

## Lung cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

V&I

Rare Disease

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase II</b> <b>HUDSON</b> <a href="#">NCT03334617</a>	NSCLC, patients who progressed on an anti-PD-1/PD-L1-containing therapy	531	<ul style="list-style-type: none"> <li>Open-label, biomarker-directed, multi-centre trial</li> <li>Module 1: <i>Imfinzi</i> + <i>Lynparza</i></li> <li>Module 2: <i>Imfinzi</i> + danvatirsen</li> <li>Module 3: <i>Imfinzi</i> + ceralasertib</li> <li>Module 4: <i>Imfinzi</i> + vistusertib</li> <li>Module 5: <i>Imfinzi</i> + oleclumab</li> <li>Module 6: <i>Imfinzi</i> + <i>Enhertu</i></li> <li>Module 7: <i>Imfinzi</i> + cediranib</li> <li>Module 8: ceralasertib</li> <li>Module 9: <i>Imfinzi</i> + ceralasertib</li> <li>Module 10: <i>Imfinzi</i> + ceralasertib</li> <li>Module 11: ceralasertib</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: ORR</li> <li>Secondary endpoints: efficacy including OS, PFS, DCR, safety and tolerability and DoR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2018</li> <li>LPCD: Q3 2023</li> <li>Data readout: Q4 2024</li> </ul>
<b>Phase II</b> <b>NeoCOAST-2</b> <a href="#">NCT05061550</a>	Early-stage, resectable NSCLC (Stage II to Stage IIIA)	630	<ul style="list-style-type: none"> <li>Open-label trial</li> <li>Arm 1: <i>Imfinzi</i> + oleclumab + platinum doublet chemotherapy</li> <li>Arm 2: <i>Imfinzi</i> + monalizumab + platinum doublet chemotherapy</li> <li>Arm 3: volrustomig + platinum doublet chemotherapy</li> <li>Arm 4: <i>Datroway</i> + single agent platinum chemotherapy</li> <li>Arm 5: AZD0171 + platinum doublet chemotherapy</li> <li>Arm 6: rilvegostomig + platinum doublet chemotherapy</li> <li>Arm 7: <i>Datroway</i> + rilvegostomig + single agent platinum chemotherapy</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: pCR and safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2022</li> <li>Data anticipated: 2027</li> </ul>



# Imfinzi (PD-L1 mAb)

## Other cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

V&I

Rare Disease

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>NIAGARA</b> <a href="#">NCT03732677</a>	Muscle-invasive bladder cancer eligible for cisplatin	1063	<ul style="list-style-type: none"> <li>Arm 1: <i>Imfinzi</i> in combination with gemcitabine + cisplatin, <i>Imfinzi</i> maintenance</li> <li>Arm 2: gemcitabine + cisplatin</li> </ul>	<ul style="list-style-type: none"> <li>Co-primary endpoints: pCR and EFS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2018</li> <li>LPCD: Q3 2021</li> <li>Data readout: Q2 2024</li> </ul>
<b>Phase III</b> <b>NILE</b> <a href="#">NCT03682068</a>	1L bladder cancer	1246	<ul style="list-style-type: none"> <li>Arm 1: <i>Imfinzi</i> + <i>Imjudo</i> + SoC</li> <li>Arm 2: <i>Imfinzi</i> + SoC</li> <li>Arm 3: SoC</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2018</li> <li>LPCD: Q2 2021</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase III</b> <b>POTOMAC</b> <a href="#">NCT03528694</a>	Non-muscle-invasive bladder cancer	1018	<ul style="list-style-type: none"> <li>Arm 1: BCG (induction + maintenance)</li> <li>Arm 2: <i>Imfinzi</i> + BCG (induction only)</li> <li>Arm 3: <i>Imfinzi</i> + BCG (induction + maintenance)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: DFS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2018</li> <li>LPCD: Q4 2020</li> <li>Data readout: Q2 2025</li> </ul>
<b>Phase III</b> <b>SAMETA</b> <a href="#">NCT05043090</a> Partnered (HUTCHMED)	MET-driven, unresectable and locally advanced or metastatic papillary renal cell carcinoma	200	<ul style="list-style-type: none"> <li>Arm 1: <i>Orpathys</i> + <i>Imfinzi</i></li> <li>Arm 2: sunitinib</li> <li>Arm 3: <i>Imfinzi</i> monotherapy</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoints: OS, ORR, DoR and DCR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2021</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase III</b> <b>VOLGA</b> <a href="#">NCT04960709</a>	Muscle-invasive bladder cancer ineligible to cisplatin	712	<ul style="list-style-type: none"> <li>Arm 1: <i>Imfinzi</i> + <i>Imjudo</i> + enfortumab vedotin</li> <li>Arm 2: <i>Imfinzi</i> + enfortumab vedotin</li> <li>Arm 3: SoC cystectomy</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety, EFS and pCR</li> <li>Secondary endpoint: OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2021</li> <li>LPCD: Q1 2025</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase II</b> <b>BEGONIA</b> <a href="#">NCT03742102</a>	1L mTNBC	243	<ul style="list-style-type: none"> <li>Arm 1: <i>Imfinzi</i> + paclitaxel</li> <li>Arm 2: <i>Imfinzi</i> + paclitaxel + <i>Truqap</i></li> <li>Arm 5: <i>Imfinzi</i> + paclitaxel + oleclumab</li> <li>Arm 6: <i>Imfinzi</i> + <i>Enhertu</i></li> <li>Arm 7: <i>Imfinzi</i> + <i>Datroway</i></li> <li>Arm 8: <i>Imfinzi</i> + <i>Datroway</i> (PD-L1-high)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> <li>Secondary endpoints: ORR, PFS, DoR, OS, PK and ADA</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2019</li> <li>Data readout: Q2 2025</li> </ul>





# Lynparza (PARP inhibitor)

## Imfinzi combinations

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III DUO-E</b> <a href="#">NCT04269200</a>	1L advanced and recurrent endometrial cancer	805	<ul style="list-style-type: none"> <li>Arm 1: chemotherapy + <i>Imfinzi</i> placebo followed by <i>Imfinzi</i> placebo + <i>Lynparza</i> placebo</li> <li>Arm 2: chemotherapy + <i>Imfinzi</i> followed by <i>Imfinzi</i> + <i>Lynparza</i> placebo</li> <li>Arm 3: chemotherapy + <i>Imfinzi</i> followed by <i>Imfinzi</i> + <i>Lynparza</i></li> <li>Global trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoints: OS, PFS2, ORR and DoR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2020</li> <li>LPCD: Q2 2023</li> <li>Data readout: Q2 2023</li> <li>Primary endpoint met</li> </ul>
<b>Phase III DUO-O</b> <a href="#">NCT03737643</a>	1L advanced ovarian cancer	1407	<ul style="list-style-type: none"> <li>Non-tBRCAm (tumour BRCA) patients</li> <li>Arm 1: chemotherapy + bevacizumab + <i>Imfinzi</i> placebo followed by bevacizumab + <i>Imfinzi</i> placebo + <i>Lynparza</i> placebo</li> <li>Arm 2: chemotherapy + bevacizumab + <i>Imfinzi</i> followed by bevacizumab + <i>Imfinzi</i> + <i>Lynparza</i> placebo</li> <li>Arm 3: chemotherapy + bevacizumab + <i>Imfinzi</i> followed by bevacizumab + <i>Imfinzi</i> + <i>Lynparza</i></li> <li>tBRCAm patients</li> <li>chemotherapy + bevacizumab (optional) + <i>Imfinzi</i> followed by bevacizumab (optional) + <i>Imfinzi</i> + <i>Lynparza</i></li> <li>Global trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoints: OS and PFS2</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2019</li> <li>LPCD: Q2 2023</li> <li>Data readout: Q2 2023</li> <li>Primary endpoint met</li> </ul>
<b>Phase II OlympiaN</b> <a href="#">NCT05498155</a>	HER2 negative BRCAm neoadjuvant breast cancer	50	<ul style="list-style-type: none"> <li>Non-randomised 2 cohort study</li> <li>Cohort A: lower-risk population receive neoadjuvant <i>Lynparza</i> monotherapy for 4-6 cycles</li> <li>Cohort B: higher-risk population receive neoadjuvant <i>Lynparza</i> + <i>Imfinzi</i> for 4-6 cycles</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: pCR (central review)</li> <li>Secondary endpoints: pCR (local pathology review), RCB, percentage change in tumour volume, EFS, safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2022</li> <li>LPCD: Q2 2024</li> <li>Data readout: Q3 2025</li> <li>Primary endpoint met.</li> </ul>



# Lynparza (PARP inhibitor)

## Other cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase III MONO-OLA1 <a href="#">NCT04884360</a>	BRCAwt advanced ovarian cancer, 1L maintenance	366	<ul style="list-style-type: none"><li>Arm 1: Lynparza BID 24-month duration</li><li>Arm 2: placebo BID 24-month duration</li><li>Global trial – 12 countries</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: PFS (BRCAwt HRD-positive) and PFS (BRCAwt)</li><li>Secondary endpoints: OS, TFST and PFS2</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2021</li><li>LPCD: Q1 2024</li><li>Data anticipated: H2 2026</li></ul>



# Orpathys (savolitinib, MET inhibitor)

## Gastric cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT04923932 Partnered (HUTCHMED)	Locally advanced or metastatic gastric cancer and esophagogastric junction adenocarcinoma patients with MET gene amplifications	75	<ul style="list-style-type: none"><li>Single-arm, multi-cohort, multi-centre, open-label trial</li><li>Orpathys</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: ORR</li><li>Secondary endpoints: PFS and safety</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2021</li><li>LPCD: Q2 2025</li><li>Data readout: Q4 2025</li></ul>



# Tagrisso (highly-selective, irreversible EGFR inhibitor)

## NSCLC

Approved medicines
Late-stage development
Early development

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III ADAURA2</b> <a href="#">NCT05120349</a>	Adjuvant EGFRm NSCLC Stage IA2 to IA3 following complete tumour resection	380	<ul style="list-style-type: none"> <li>Arm 1: <i>Tagrisso</i></li> <li>Arm 2: placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: DFS</li> <li>Secondary endpoints: DFS rate, OS, OS rate and QoL</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2022</li> <li>LPCD: Q4 2024</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase III LAURA</b> <a href="#">NCT03521154</a>	Maintenance therapy in patients with locally advanced, unresectable EGFRm Stage III NSCLC whose disease has not progressed following platinum-based chemoradiation therapy	216	<ul style="list-style-type: none"> <li>Arm 1: <i>Tagrisso</i></li> <li>Arm 2: placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS (BICR)</li> <li>Secondary endpoints: CNS PFS, OS, DoR, ORR and DCR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2018</li> <li>LPCD: Q3 2022</li> <li>Data readout: Q1 2024</li> <li>Primary endpoint met</li> </ul>
<b>Phase III NeoADAURA</b> <a href="#">NCT04351555</a>	Neoadjuvant EGFRm NSCLC	351	<ul style="list-style-type: none"> <li>Arm 1: placebo + pemetrexed/carboplatin or pemetrexed/cisplatin</li> <li>Arm 2: <i>Tagrisso</i> + pemetrexed/carboplatin or pemetrexed/cisplatin</li> <li>Arm 3: <i>Tagrisso</i></li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: mPR</li> <li>Secondary endpoints: cPR, EFS, DFS and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>LPCD: Q4 2023</li> <li>Data readout: Q4 2024</li> <li>Primary endpoint met</li> </ul>



# Tagrisso (highly-selective, irreversible EGFR inhibitor)

## NSCLC, combinations

Trial	Population	Patients	Design	Endpoints	Status
Phase III SACHI <a href="#">NCT05015608</a> Partnered (HUTCHMED)	Locally advanced or metastatic NSCLC with MET amplification after failure of the first-line EGFR inhibitor therapy	250	<ul style="list-style-type: none"> <li>Arm 1: <i>Tagrisso</i> + <i>Orpathys</i></li> <li>Arm 2: pemetrexed + platinum</li> <li>China only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2021</li> <li>Data readout: Q3 2024</li> <li>primary endpoint met</li> </ul>
Phase III SAFFRON <a href="#">NCT05261399</a> Partnered (HUTCHMED)	EGFRm, MET-overexpressed and/or amplified, locally advanced or metastatic NSCLC patients who have progressed on first- or second-line treatment with <i>Tagrisso</i>	324	<ul style="list-style-type: none"> <li>Arm 1: <i>Tagrisso</i> + <i>Orpathys</i></li> <li>Arm2: pemetrexed with either cisplatin or carboplatin</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoints: OS, ORR, PK, DCR and DoR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2022</li> <li>Data anticipated: H2 2026</li> </ul>
Phase III SANOVO <a href="#">NCT05009836</a> Partnered (HUTCHMED)	1L EGFRm, MET+ locally advanced or metastatic NSCLC	320	<ul style="list-style-type: none"> <li>Arm 1: <i>Tagrisso</i> + <i>Orpathys</i></li> <li>Arm 2: <i>Tagrisso</i> + placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2021</li> <li>Data anticipated: H2 2026</li> </ul>
Phase II ORCHARD <a href="#">NCT03944772</a>	Advanced EGFRm NSCLC patients who have progressed on first-line <i>Tagrisso</i> treatment	250	<ul style="list-style-type: none"> <li>Modular design platform trial:</li> <li>Module 1: <i>Tagrisso</i> + <i>Orpathys</i> (cMET)</li> <li>Module 2: <i>Tagrisso</i> + gefitinib (EGFRm)</li> <li>Module 3: <i>Tagrisso</i> + necitumumab (EGFRm)</li> <li>Module 4: carboplatin + pemetrexed + <i>Imfinzi</i></li> <li>Module 5: <i>Tagrisso</i> + alectinib (ALK)</li> <li>Module 6: <i>Tagrisso</i> + selpercatinib (RET fusion)</li> <li>Module 7: <i>Imfinzi</i> + etoposide + carboplatin or cisplatin</li> <li>Module 8: <i>Tagrisso</i> + pemetrexed + carboplatin or cisplatin</li> <li>Module 9: <i>Tagrisso</i> + <i>Koselugo</i></li> <li>Module 10: <i>Tagrisso</i> + <i>Datroway</i></li> <li>No intervention: observational cohort</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: ORR</li> <li>Secondary endpoints: PFS, DoR, OS, safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2019</li> <li>LPCD: Q4 2023</li> <li>Data readout: Q4 2025</li> </ul>
Phase II SAVANNAH <a href="#">NCT03778229</a> Partnered (HUTCHMED)	EGFRm/MET+, locally advanced or metastatic NSCLC who have progressed following treatment with <i>Tagrisso</i>	360	<ul style="list-style-type: none"> <li>Protocol v1-6: single-arm, open-label trial</li> <li>Protocol v7: randomised, double-blind trial</li> <li>Arm 1: <i>Tagrisso</i> + <i>Orpathys</i></li> <li>Arm 2: placebo + <i>Orpathys</i></li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: ORR</li> <li>Secondary endpoints: PFS, DoR and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2019</li> <li>LPCD: Q1 2024</li> <li>Data readout: Q3 2024</li> <li>Clinically meaningful ORR</li> </ul>



# Truqap (capivasertib, AKT inhibitor)

## Breast cancer and prostate cancer

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>CAPitello-280</b> <a href="#">NCT05348577</a>	mCRPC prostate cancer	1033	<ul style="list-style-type: none"> <li>Double-blind, randomised, comparative trial</li> <li>Arm 1: <i>Truqap</i> + docetaxel</li> <li>Arm 2: placebo + docetaxel</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2022</li> <li>LPCD: Q3 2024</li> <li>Data readout: Q2 2025</li> <li>Trial discontinued due to lack of efficacy</li> </ul>
<b>Phase III</b> <b>CAPitello-281</b> <a href="#">NCT04493853</a>	De novo PTEN deficient metastatic hormone sensitive prostate cancer	1012	<ul style="list-style-type: none"> <li>Double-blind, randomised, comparative trial</li> <li>Arm 1: <i>Truqap</i> + abiraterone</li> <li>Arm 2: placebo + abiraterone</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: rPFS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2020</li> <li>LPCD: Q1 2024</li> <li>Data readout: Q4 2024</li> <li>Primary endpoint met</li> </ul>
<b>Phase III</b> <b>CAPitello-291</b> <a href="#">NCT04305496</a>	2L+ AI-resistant locally advanced (inoperable) or metastatic HR+ HER2-negative breast cancer	834	<ul style="list-style-type: none"> <li>Double-blind, randomised, comparative trial</li> <li>Arm 1: <i>Truqap</i> + <i>Faslodex</i></li> <li>Arm 2: placebo + <i>Faslodex</i></li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2020</li> <li>LPCD: Q4 2021</li> <li>Data readout: Q4 2022</li> <li>Both primary endpoints met</li> </ul>
<b>Phase Ib/III</b> <b>CAPitello-292</b> <a href="#">NCT04862663</a>	1L triplet in early relapse/endocrine-resistant locally advanced (inoperable) or metastatic HR+/HER2-negative breast cancer	793	<ul style="list-style-type: none"> <li>Double-blind, randomised, comparative trial</li> <li>Arm 1: <i>Truqap</i> + palbociclib + <i>Faslodex</i></li> <li>Arm 2: placebo + palbociclib + <i>Faslodex</i></li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2021</li> <li>Data anticipated: 2027</li> </ul>



# camizestrant (next-generation oral SERD)

## Breast cancer

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III SERENA-4 <a href="#">NCT04711252</a></b>	HR+ HER2-negative advanced breast cancer	1370	<ul style="list-style-type: none"> <li>Randomised, double-blind, comparative trial</li> <li>Arm 1: camizestrant + palbociclib</li> <li>Arm 2: anastrozole + palbociclib</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoints: OS and PFS2</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>LPCD: Q4 2023</li> <li>Data anticipated: H2 2026</li> </ul>
<b>Phase III SERENA-6 <a href="#">NCT04964934</a></b>	HR+ HER2-negative advanced breast cancer	312	<ul style="list-style-type: none"> <li>Randomised, double-blind, comparator trial</li> <li>Arm 1: camizestrant + palbociclib or abemaciclib or ribociclib</li> <li>Arm 2: anastrozole or letrozole + palbociclib or abemaciclib or ribociclib</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoint: OS and PFS2</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2021</li> <li>LPCD: Q3 2024</li> <li>Data readout: Q1 2025</li> <li>Primary endpoint met</li> </ul>
<b>Phase III CAMBRIA-1 <a href="#">NCT05774951</a></b>	ER+/HER2-negative early breast cancer patients who completed definitive locoregional therapy and standard adjuvant ET for at least 2 years and up to 5 years	4300	<ul style="list-style-type: none"> <li>Arm 1: continue standard ET of investigator's choice</li> <li>Arm 2: camizestrant</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: IBCFS</li> <li>Secondary endpoints: IDFS, DRFS and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2023</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase III CAMBRIA-2 <a href="#">NCT05952557</a></b>	ER+/HER2-negative early breast cancer with intermediate-high or high risk of recurrence that has completed definitive locoregional therapy and have no evidence of disease	5500	<ul style="list-style-type: none"> <li>Arm A: standard endocrine therapy of investigator's choice (aromatase inhibitors [exemestane, letrozole, anastrozole] or tamoxifen) ± abemaciclib</li> <li>Arm B: camizestrant ± abemaciclib</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: IBCFS</li> <li>Secondary endpoints: IDFS, DRFS and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase II SERENA-2 <a href="#">NCT04214288</a></b>	HR+ advanced breast cancer	240	<ul style="list-style-type: none"> <li>Randomised, open-label, parallel-group, multi-centre trial</li> <li>Arm 1: camizestrant (75mg)</li> <li>Arm 2: camizestrant (150mg)</li> <li>Arm 3: camizestrant (300mg)</li> <li>Arm 4: <i>Faslodex</i></li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2020</li> <li>LPCD: Q3 2021</li> <li>Data readout: Q4 2022</li> <li>Primary endpoint met at 75mg and 150mg doses</li> </ul>





# camizestrant (next-generation oral SERD)

## Breast cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I SERENA-1 <a href="#">NCT03616587</a>	HR+ HER2-negative advanced breast cancer	396	<ul style="list-style-type: none"> <li>Escalation phase: open-label multi-centre trial</li> <li>Cohort 1: camizestrant</li> <li>Cohort 2: camizestrant + palbociclib, everolimus, abemeciclib (+/- anastrozole), <i>Truqap</i>, ribociclib (+/- anastrozole) or anastrozole</li> <li>Expansion phase: randomised expansion cohort(s)</li> <li>Cohort 1: camizestrant</li> <li>Cohort 2: camizestrant + palbociclib, everolimus, abemeciclib (+/- anastrozole), <i>Truqap</i>, ribociclib (+/- anastrozole) or anastrozole</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> <li>Secondary endpoints: PK parameters and anti-tumour activity</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2018</li> <li>LPCD: Q1 2024</li> <li>Data readout: Q1 2025</li> </ul>
Phase I <a href="#">NCT04541433</a>	HR+ HER2-negative advanced breast cancer	10	<ul style="list-style-type: none"> <li>Open-label trial</li> <li>camizestrant</li> <li>Japan only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> <li>Secondary endpoint: PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2020</li> <li>LPCD: Q1 2022</li> <li>Data readout: Q1 2023</li> </ul>
Phase I <a href="#">NCT04818632</a>	HR+ HER2-negative metastatic breast cancer in Chinese patients	30	<ul style="list-style-type: none"> <li>Dose escalation: camizestrant</li> <li>Dose expansion:</li> <li>Cohort 1: camizestrant</li> <li>Cohort 2: camizestrant + palbociclib</li> <li>Cohort 3: camizestrant + everolimus</li> <li>China only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety, tolerability and PK parameters</li> <li>Secondary endpoint: anti-tumour activity</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>LPCD: Q1 2023</li> <li>Data readout: Q4 2023</li> </ul>



# ceralasertib (AZD6738, ATR inhibitor)

## Multiple cancers

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

V&I

Rare Disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III LATIFY <a href="#">NCT05450692</a>	Post-IO NSCLC	594	<ul style="list-style-type: none"> <li>Double-arm randomised</li> <li>Arm 1: ceralasertib + <i>Imfinzi</i></li> <li>Arm 2: docetaxel</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: OS</li> <li>Secondary endpoints: PFS, ORR, DoR, TTR, DCR, PFS2 and TTD</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2022</li> <li>Data readout: Q4 2025</li> <li>Primary endpoint not met</li> </ul>
Phase I/II <a href="#">NCT02264678</a>	Solid tumours	357	<ul style="list-style-type: none"> <li>Module 1: ceralasertib + carboplatin</li> <li>Module 2: ceralasertib dose escalation, ceralasertib + <i>Lynparza</i></li> <li>Module 3: ceralasertib + <i>Imfinzi</i></li> <li>Module 4: ceralasertib monotherapy + <i>Lynparza</i> + <i>Imfinzi</i> (food effect/QT)</li> <li>Module 5: ceralasertib + saruparib</li> <li>Global trial – North America, Europe and South Korea</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability, efficacy and PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2014</li> <li>Trial discontinued due to efficacy</li> </ul>



# puxitatug samrotecan (AZD8205, B7H4 ADC)

## Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase III Bluestar-Endometrial01 <a href="#">NCT07044336</a>	B7-H4 selected 2-3L endometrial cancer	700	<ul style="list-style-type: none"><li>Randomised, single-open label</li><li>puxitatug samrotecan 2.4mg/kg Q3W</li><li>docetaxel/paclitxel</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: PFS, OS</li><li>Secondary endpoints: ORR, DoR, PFS2, TFST, TSST, TDT</li></ul>	<ul style="list-style-type: none"><li>Data anticipated: 2027</li></ul>
Phase I/II BLUESTAR <a href="#">NCT05123482</a>	Breast cancer, ovarian cancer, endometrial cancer, squamous NSCLC	370	<ul style="list-style-type: none"><li>Open-label dose escalation and expansion trial</li><li>Sub-study 1: puxitatug samrotecan monotherapy</li><li>Sub-study 2: puxitatug samrotecan + rilvegostomig</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: AE, SAE, DLTs, changes in lab and preliminary efficacy parameters</li><li>Secondary endpoints: ORR, DCR, DoR, PFS, OS, PK parameters and ADA</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2022</li><li>Data anticipated: 2027</li></ul>



# rilvegostomig (PD-1/TIGIT bispecific mAb)

## Gastrointestinal cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III ARTEMIDE-Biliary02 <a href="#">NCT07221253</a> Partnered (Compugen)	1L Advanced BTC	1100	<ul style="list-style-type: none"><li>Randomised, open label, Global, Multicenter</li><li>Arm 1: rilvegostomig + gemcitabine/cisplatin</li><li>Arm 2: <i>Imfinzi</i> + gemcitabine/cisplatin</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: OS</li><li>Secondary endpoints: PFS, ORR, DoR</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2025</li><li>Data anticipated: &gt;2027</li></ul>



# rilvegostomig (PD-1/TIGIT bispecific mAb)

## Lung cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

V&I

Rare Disease

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>ARTEMIDE-Lung02</b> <b><a href="#">NCT06692738</a></b> <b>Partnered (Compugen)</b>	squamous NSCLC 1L patients whose tumours express PD-L1 (TC >=1%)	880	<ul style="list-style-type: none"> <li>Randomised, double-blind, multicenter,</li> <li>Arm 1: rilvegostomig + platinum-based doublet chemotherapy followed by rilvegostomig maintenance.</li> <li>Arm 2: pembrolizumab + platinum-based doublet chemotherapy followed by pembrolizumab maintenance.</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PFS, OS</li> <li>Secondary endpoint: OS, ORR, DoR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase III</b> <b>ARTEMIDE-Lung03</b> <b><a href="#">NCT06627647</a></b> <b>Partnered (Compugen)</b>	Non-squamous NSCLC 1L patients whose tumours express PD-L1 (TC ≥1%)	878	<ul style="list-style-type: none"> <li>Randomised, double-blind, multi-centre trial</li> <li>Arm 1: rilvegostomig + platinum-based doublet chemotherapy followed by rilvegostomig monotherapy + pemetrexed in maintenance</li> <li>Arm 2: pembrolizumab + platinum-based doublet chemotherapy followed by pembrolizumab monotherapy + pemetrexed in maintenance</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PFS and OS</li> <li>Secondary endpoints: OS, ORR and DoR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase II</b> <b>LIBRA</b> <b><a href="#">NCT07098338</a></b> <b>Partnered (Daiichi Sankyo)</b>	Non-Small Cell Lung Cancer 1L non-AGA and 2L EGFRm	278	<ul style="list-style-type: none"> <li>Non-Randomised, Sequential Assignment, Open Label</li> <li>Sub-study 1: rilvegostomig ± ramucirumab, i.v.</li> <li>Sub-study 2: rilvegostomig + ramucirumab, i.v.</li> <li>Sub-study 3: <i>Datroway</i> + ramucirumab ± rilvegostomig, i.v.</li> </ul>	<ul style="list-style-type: none"> <li>Primary Endpoints: Safety and ORR</li> <li>Second Endpoints: BOR, PFS, DCR, DoR, OS, PK Parameters and ADA</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase I/II</b> <b>ALTAIR</b> <b><a href="#">NCT06996782</a></b>	Sub-study 2 population: Patients ≥ 18 years with histologically confirmed Stage IV NSCLC, No prior therapy for metastatic disease, PD-L1 results available (local or central, SP263 or 22C3), EGFR/ALK wild-type, ECOG PS 0 or 1.	116	<ul style="list-style-type: none"> <li>This is a multicentre, open-label study to evaluate the safety and efficacy of various combinations of study interventions in participants with advanced or metastatic NSCLC (mNSCLC).</li> <li>The study will include sub-studies and each sub-study focused on a specific treatment may include 2 parts - Part A consisting of one of more safety run-in cohorts to evaluate 2 or more dose levels to identify the recommended Phase 2 dose (RP2D) unless RP2D has been established then Part A will not be required; and Part B consisting of one or more expansion cohorts.</li> <li>The initial Sub-study 2 will evaluate the safety, tolerability, and anti-tumour activity of rilvegostomig plus standard of care (SoC) platinum-based chemotherapy, with or without ramucirumab.</li> </ul>	<ul style="list-style-type: none"> <li>Primary Endpoint: ORR</li> <li>Secondary Endpoint: Safety, DoR, DCR, PFS, PFS6/12 landmarks</li> <li>Exploratory Endpoint: Landmark OS, Molecular ctDNA response, Efficacy vs biomarker cut-off</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2025</li> <li>Data anticipated: &gt;2027</li> </ul>



# rilvegostomig (PD-1 /TIGIT bispecific mAb)

## Lung cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

V&I

Rare Disease

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II ARTEMIDE-01 <a href="#">NCT04995523</a> Partnered (Compugen)	NSCLC	210	<ul style="list-style-type: none"> <li>Open-label, dose escalation and dose expansion trial</li> <li>Part A: dose escalation in CPI-experienced NSCLC patients with rilvegostomig i.v. monotherapy</li> <li>Part B: dose expansion in CPI-experienced NSCLC patients with rilvegostomig i.v. monotherapy</li> <li>Part C: dose expansion in CPI-naïve NSCLC patients with rilvegostomig i.v. monotherapy</li> <li>Part D: randomised dose expansion in CPI-naïve NSCLC patients with rilvegostomig i.v. monotherapy</li> <li>Part E: dose expansion in CPI-naïve stage IV squamous NSCLC patients with rilvegostomig i.v. monotherapy</li> <li>Global trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints (Part A): safety, RP2D and MTD</li> <li>Primary endpoints (Part B): safety and efficacy (ORR)</li> <li>Primary endpoints (Part C): safety and efficacy (ORR)</li> <li>Primary endpoints (Part D): safety and efficacy (ORR)</li> <li>Primary endpoints (Part E): safety and efficacy (ORR)</li> <li>Secondary endpoints: PK parameters, PD (receptor occupancy), efficacy (DCR, DoR, DRR, PFS)</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2021</li> <li>Data anticipated: H2 2026</li> </ul>
Phase I ARTEMIDE-subQ <a href="#">NCT07161414</a> Partnered (Compugen)	Solid tumours	40	<ul style="list-style-type: none"> <li>Part 1 Dose finding: determine subcutaneous rilvegostomig dose co-administered with Recombinant Human Hyaluronidase (rHu) that yields drug exposure comparable with IV rilvegostomig. 2 planned dose levels (DL1 in Cohort A and DL2 in Cohort B).</li> <li>Part 2 Dose confirmation: Part 2 will be initiated once a dose has been identified based on Part 1.</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: AUCtau</li> <li>Secondary endpoint: safety, Ctrough, Cavg, serum rilvegostomig concentration</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2025</li> <li>Data anticipated: 2027</li> </ul>



# rilvegostomig (PD-1/TIGIT bispecific mAb)

## Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase III ARTEMIDE-Biliary01 <a href="#">NCT06109779</a> Partnered (Compugen)	adjuvant BTC with curative intent	750	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled, multicenter</li> <li>Arm 1: rilvegostomig + investigator's choice of chemotherapy (capecitabine, S-1 (tegafur/gimeracil/oteracil) or gemcitabine/cisplatin)</li> <li>Arm 2: placebo + investigator's choice of chemotherapy (capecitabine, S-1 (tegafur/gimeracil/oteracil) or gemcitabine/cisplatin)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: RFS</li> <li>Secondary endpoint: OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>LPCD: Q1 2026</li> <li>Data anticipated: &gt;2027</li> </ul>
Phase III ARTEMIDE-Gastric01 <a href="#">NCT06764875</a> Partnered (Compugen)	HER2-positive locally advanced or metastatic gastric or GEJ adenocarcinoma participants whose tumors express PD L1 CPS ≥ 1	840	<ul style="list-style-type: none"> <li>Randomised, multicentre</li> <li>Arm A: rilvegostomig in combination with fluoropyrimidine and <i>Enhertu</i></li> <li>Arm B: trastuzumab in combination with chemotherapy and pembrolizumab</li> <li>Arm C: trastuzumab in combination with chemotherapy and rilvegostomig</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PFS, OS</li> <li>Secondary endpoints: ORR, DoR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
Phase III ARTEMIDE-HCC01 <a href="#">NCT06921785</a> Partnered (Compugen)	Patients with advanced hepatocellular cancer who are not amenable to curative therapy or locoregional therapy	1220	<ul style="list-style-type: none"> <li>Randomised, open-label, sponsor-blinded, 3-arm, multicentre, global</li> <li>Arm A: <i>Imjudo</i>, rilvegostomig and bevacizumab</li> <li>Arm B: rilvegostomig and bevacizumab</li> <li>Arm C: atezolizumab and bevacizumab</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: OS</li> <li>Secondary endpoints: PFS, ORR, DoR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2022</li> <li>Data anticipated: &gt;2027</li> </ul>
Phase III ARTEMIDE-Lung04 <a href="#">NCT06868277</a> Partnered (Compugen)	NSCLC 1L patients whose tumours express PD-L1 (TC ≥/≤ 50%)	830	<ul style="list-style-type: none"> <li>randomised, double-blind, multicentre</li> <li>Arm A: rilvegostomig</li> <li>Arm B: pembrolizumab</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PFS, OS</li> <li>Secondary endpoints: ORR, DoR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2025</li> <li>Data anticipated: &gt;2027</li> <li>Initiating</li> </ul>





# rilvegostomig (PD-1/TIGIT bispecific mAb)

## Solid tumours

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

V&I

Rare Disease

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase IIb</b> <b>GEMINI-Gastric</b> <b><a href="#">NCT05702229</a></b> <b>Partnered (Compugen)</b>	Gastric cancer	360	<ul style="list-style-type: none"> <li>Open-label gastric platform trial</li> <li>Sub-study 1: volrustomig + XELOX or FOLFOX</li> <li>Sub-study 2: rilvegostomig + XELOX or FOLFOX</li> <li>Sub-study 3: sonestatug vedotin + volrustomig plus fluorouracil or capecitabine</li> <li>Sub-study 4: sonestatug vedotin + fluorouracil or capecitabine with or without rilvegostomig</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and efficacy (ORR and PFS6)</li> <li>Secondary endpoints: DoR, OS, PK, ADA and safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2023</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase IIb</b> <b>GEMINI-Hepatobiliary</b> <b><a href="#">NCT05775159</a></b> <b>Partnered (Compugen)</b>	HCC, BTC	294	<ul style="list-style-type: none"> <li>Open-label hepatobiliary platform trial</li> <li>HCC sub-study: <ul style="list-style-type: none"> <li>Cohort 1A: volrustomig monotherapy</li> <li>Cohort 1B: volrustomig combination with bevacizumab</li> <li>Cohort 1C: volrustomig combination with lenvatinib</li> <li>Cohort 1D: volrustomig combination with rilvegostomig and bevacizumab</li> <li>Cohort 1E: rilvegostomig combination with bevacizumab</li> </ul> </li> <li>BTC sub-study: <ul style="list-style-type: none"> <li>Cohort 2A: rilvegostomig combination with gemcitabine and cisplatin</li> <li>Cohort 2B: volrustomig combination with gemcitabine and cisplatin</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints (HCC sub-study): safety and efficacy (ORR)</li> <li>Primary endpoints (BTC sub-study): safety and efficacy (PFS6)</li> <li>Secondary endpoints: DoR, OS, PK and ADA</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2023</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase IIb</b> <b>GEMINI-PeriOp Gastric</b> <b><a href="#">NCT07069712</a></b> <b>Partnered (Compugen)</b>	Gastroesophageal Adenocarcinoma	150	<ul style="list-style-type: none"> <li>Open-label platform study</li> <li>Substudy 1: sonestatug vedotin + rilvegostomig and 5-FU or capecitabine</li> <li>Substudy 2: <i>Enhertu</i> + rilvegostomig and 5-FU or capecitabine</li> <li>Substudy 3: rilvegostomig +FLOT chemotherapy</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety, pCR rate</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2025</li> <li>Data anticipated: 2027</li> </ul>



# saruparib (AZD5305, PARP1 inhibitor)

## Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>EvoPAR-Breast01</b> <a href="#">NCT06380751</a>	BRCA1, BRCA2, or PALB2m, HR-positive, HER2-negative advanced breast cancer	500	<ul style="list-style-type: none"> <li>Randomised, open-label trial</li> <li>Arm 1: saruparib + camizestrant</li> <li>Arm 2: physician's choice CDK4/6i + physician's choice ET</li> <li>Arm 3: physician's choice CDK4/6i + camizestrant</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS (BICR)</li> <li>Secondary endpoints: PFS2 and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase III</b> <b>EvoPAR-Prostate01</b> <a href="#">NCT06120491</a>	HRRm and non-HRRm mCSPC	1800	<ul style="list-style-type: none"> <li>Randomised, placebo-controlled trial</li> <li>Arm 1: saruparib + physician's choice NHA (abiraterone, darolutamide or enzalutamide)</li> <li>Arm 2: placebo + physician's choice NHA (abiraterone, darolutamide or enzalutamide)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: rPFS</li> <li>Secondary endpoints: OS and PFS2</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase III</b> <b>EvoPAR-Prostate02</b> <a href="#">NCT06952803</a>	Adjuvant saruparib for high-risk BRCAm prostate cancer patients	700	<ul style="list-style-type: none"> <li>A Randomised, Double-blind, Placebo-controlled, Phase III Study of Adjuvant Saruparib (AZD5305) in Patients With BRCAm Localised High-Risk Prostate Cancer Receiving Radiotherapy With Androgen Deprivation Therapy (EvoPAR-Prostate02)</li> </ul>	<ul style="list-style-type: none"> <li>Primary: MFS by CI or PSMA-PET by BICR</li> <li>Key secondary: OS</li> </ul>	<ul style="list-style-type: none"> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase I/IIa</b> <b>PETRA</b> <a href="#">NCT04644068</a>	Advanced solid tumours	702	<ul style="list-style-type: none"> <li>Modular, open-label, multi-centre dose escalation and expansion trial</li> <li>Module 1: saruparib</li> <li>Module 2: saruparib + paclitaxel</li> <li>Module 3: saruparib + carboplatin +/- paclitaxel</li> <li>Module 4: saruparib + <i>Enhertu</i></li> <li>Module 5: saruparib + <i>Datroway</i></li> <li>Module 6: saruparib + camizestrant</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety, tolerability and PK parameters</li> <li>Secondary endpoint: efficacy</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2020</li> <li>LPCD: Q3 2025</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase I/IIa</b> <b>PETRANHA</b> <a href="#">NCT05367440</a>	Metastatic prostate cancer	175	<ul style="list-style-type: none"> <li>Multi-arm, open-label, non-randomised, multi-centre trial of saruparib in combination with new hormonal agents in patients with metastatic prostate cancer</li> <li>Arm 1: saruparib + enzalutamide</li> <li>Arm 2: saruparib + abiraterone acetate</li> <li>Arm 3: saruparib + darolutamide</li> <li>Arm 4: saruparib + apalutamide</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> <li>Secondary endpoints: PK parameters and efficacy</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2022</li> <li>LPCD: Q3 2025</li> <li>Data anticipated: &gt;2027</li> </ul>



# saruparib (AZD5305, PARP1 inhibitor)

## Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase I/II Ovarian Platform Study</b> <a href="#">NCT07060365</a>	Saruparib mono as neoadj. treatment in newly diagnosed BRCA1/2m Advanced/Recurrent Ovarian Cancer	30	<ul style="list-style-type: none"> <li>A Master Protocol Phase I/II Study to Investigate Biomarker Guided Novel Anticancer Agent(s) as Monotherapy or Combination Therapy for the Treatment of Participants with Advanced/Recurrent Ovarian Cancer (Ovarian Platform)</li> </ul>	<ul style="list-style-type: none"> <li>Primary : Safety [TEAEs, SAEs, AEs leading to dose discontinuation/reductions]</li> <li>Secondary : ORR, Complete resection rate, pCR, CA-125 response, PK</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2025</li> <li>Trial discontinued due to strategic portfolio prioritisation</li> </ul>
<b>Phase I ASCERTAIN</b> <a href="#">NCT05938270</a>	Newly diagnosed prostate cancer	120	<ul style="list-style-type: none"> <li>Open-label, randomised, multi-centre trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: to assess the effects of treatment on γH2AX change</li> <li>Secondary endpoints: safety and tolerability, impact on surgical feasibility and change in Ki67</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2023</li> <li>Data anticipated: H2 2026</li> </ul>
<b>Phase I</b> <a href="#">NCT05573724</a>	Locally advanced, unresectable or metastatic solid tumours	16	<ul style="list-style-type: none"> <li>Part A: to assess the effect of multiple doses of itraconazole on the single-dose PK parameters of saruparib which will last up to 13 days and follows a non-randomised, open-label, 2 intervention design</li> <li>Part B: option to continue with saruparib monotherapy after completing Part A and whilst obtaining clinical benefit</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PK parameters</li> <li>Secondary endpoints: safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2022</li> <li>LPCD: Q2 2023</li> <li>Data readout: Q4 2023</li> <li>Primary endpoint met</li> </ul>



# sonesitug vedotin (AZD0901, CLDN18.2 MMAE ADC)

## Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>CLARITY- Gastric 01</b> <a href="#">NCT06346392</a>	2L+ advanced or metastatic gastric or GEJ adenocarcinoma expressing CLDN18.2	572	<ul style="list-style-type: none"> <li>Multi-centre, open-label, sponsor-blinded, randomised trial</li> <li>Arm 1: sonesitug vedotin dose level 1 via i.v. infusion treatment</li> <li>Arm 2: sonesitug vedotin dose level 2 via i.v. infusion treatment</li> <li>Arm 3: investigator's choice chemotherapies</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PFS and OS</li> <li>Secondary endpoints: OS, PFS for 3L+, ORR, ORR for 3L+, DoR, MMAE, safety and tolerability, PK parameters and prevalence of ADAs</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2024</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase II</b> <b>CLARITY-PanTumour01</b> <a href="#">NCT06219941</a>	Locally advanced unresectable or metastatic solid tumours expressing CLDN18.2	224	<ul style="list-style-type: none"> <li>Open-label, multi-centre trial</li> <li>Sub-study 1: sonesitug vedotin monotherapy (Gastric Cancer)</li> <li>Sub-study 2: sonesitug vedotin and anti-cancer agents (Pancreatic Cancer)</li> <li>Sub-study 3: sonesitug vedotin monotherapy (Biliary Tract Cancer)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: AEs, SAEs and ORR</li> <li>Secondary endpoints: OS, PFS, DoR, DCR, PK parameters and prevalence of ADAs</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2024</li> <li>Data anticipated: 2027</li> </ul>



# surovatamig (AZD0486, CD19/CD3 T-cell engager)

## Haematologic malignancies

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>SOUNDTRACK-D2</b> <a href="#">NCT07215585</a>	B-cell non-Hodgkin lymphoma, diffuse large B-cell lymphoma (Elderly)	420	<ul style="list-style-type: none"> <li>Multi-centre, randomised</li> <li>Safety Run-in</li> <li>Arm 1: R-mini-CHOP followed by surovatamig</li> <li>Arm 2: R-mini-CHOP</li> </ul>	<ul style="list-style-type: none"> <li>Primary: PFS</li> <li>Key secondary: OS</li> </ul>	<ul style="list-style-type: none"> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase III</b> <b>SOUNDTRACK-F1</b> <a href="#">NCT06549595</a>	Previously untreated follicular lymphoma	1015	<ul style="list-style-type: none"> <li>Multi-centre, randomised, open-label trial</li> <li>Arm 1: rituximab + surovatamig followed by observation</li> <li>Arm 2: rituximab + surovatamig followed by maintenance AZD0486</li> <li>Arm 3: Investigator's choice of RCHOP/RCVP/BR followed by standard of care maintenance or observation</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoint: CR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase II</b> <b>SOUNDTRACK-B</b> <a href="#">NCT06526793</a>	B-cell non-Hodgkin lymphoma, follicular lymphoma and diffuse large B-cell lymphoma	240	<ul style="list-style-type: none"> <li>Multi-centre, single-arm, open-label trial</li> <li>Module 1 Follicular Lymphoma</li> <li>Module 2 Diffuse large B-cell lymphoma</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: ORR</li> <li>Secondary endpoints: DoR, CR and PFS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase I/IIb</b> <b>SYRUS</b> <a href="#">NCT06137118</a>	R/R B-ALL	163	<ul style="list-style-type: none"> <li>Multi-centre, open-label, single-arm dose escalation and dose optimisation trial</li> </ul>	<ul style="list-style-type: none"> <li>Ph1 primary endpoints: DLT, and safety</li> <li>Ph2 primary endpoint: CR</li> <li>Secondary endpoints: ORR, DoR, CR rate at any time during trial, EFS, OS, subsequent alloSCT, CR MRD-negative rate, PK parameters and ADA</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2024</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase I/II</b> <b>SOUNDTRACK-E</b> <a href="#">NCT06564038</a>	Mature B-cell malignancies (chronic lymphocytic leukaemia/small lymphocytic leukaemia, mantle-cell lymphoma, and large B-cell lymphoma)	180	<ul style="list-style-type: none"> <li>Multi-centre, open-label trial</li> <li>Sub-study 1 (RR CLL/SLL): surovatamig in IV or SC</li> <li>Sub-study 2 (RR MCL): surovatamig in IV or SC</li> <li>Sub-study 3 (RR LBCL): surovatamig IV + R-CHOP</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: DLT and safety</li> <li>Secondary endpoints: ORR, CR rate, DoR, Cmax, AUC, Cmin, Tmax, Ctrough, half-life of AZD0486, clearance of AZD0486 and ADA</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>Data anticipated: H2 2026</li> </ul>
<b>Phase I</b> <a href="#">NCT04594642</a>	R/R B-cell non-Hodgkin lymphoma	317	<ul style="list-style-type: none"> <li>Multi-centre, open-label, dose escalation and dose expansion trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability, MTD and/or RP2D and PK parameters</li> <li>Secondary endpoints: clinical activity of AZD0486 monotherapy and ADA titers for AZD0486 monotherapy</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>Data anticipated: H2 2026</li> </ul>



# torvutatug samrotecan (torvu-sam, AZD5335, anti-FR $\alpha$ TOP1i ADC)

## Ovarian cancer, solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase III Trevi-OC-01 <a href="#">NCT07218809</a> -	Previously treated FR $\alpha$ platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer.	1100	<ul style="list-style-type: none"> <li>Randomised, open-label</li> <li>FR<math>\alpha</math>-high cohort: torvu-sam or MIRV</li> <li>FR<math>\alpha</math>-low cohort: torvu-sam or IC ctx</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS</li> <li>Secondary endpoint: OS, ORR, Safety &amp; tolerability, HRQoL</li> </ul>	<ul style="list-style-type: none"> <li>Data anticipated: &gt;2027</li> <li>Initiating</li> </ul>
Phase I/II FONTANA <a href="#">NCT05797168</a>	Advanced solid tumour malignancies	506	<ul style="list-style-type: none"> <li>Module 1: torvu-sam monotherapy</li> <li>Module 2: torvu-sam + saruparib</li> <li>Module 3: torvu-sam + bevacizumab</li> <li>Module 4: torvu-sam + carboplatin +/- bevacizumab</li> <li>Module 5: torvu-sam + AZD9574</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> <li>Secondary endpoints: efficacy and PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2023</li> <li>Data anticipated: &gt;2027</li> </ul>



# volrustomig (PD-1/CTLA-4 bispecific mAb)

## Solid tumours

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

V&I

Rare Disease

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>eOLVE-Cervical</b> <a href="#">NCT06079671</a>	High-risk locally advanced cervical cancer with no progression following platinum-based cCRT	800	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled, multi-centre trial</li> <li>Arm 1: volrustomig</li> <li>Arm 2: placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS (Inv, ITT)</li> <li>Secondary endpoints: OS, ORR, DoR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase III</b> <b>eOLVE-HNSCC</b> <a href="#">NCT06129864</a>	Unresected, locally advanced HNSCC	1145	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled, multi-centre trial</li> <li>Arm 1: volrustomig</li> <li>Arm 2: observational</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PFS (BICR, PD-L1 expressing tumours)</li> <li>Secondary endpoints: PFS (BICR, ITT), landmark PFS, OS (PD-L1 expressing tumours), landmark OS and OS (ITT)</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2024</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase III</b> <b>eOLVE-Lung02</b> <a href="#">NCT05984277</a>	1L mNSCLC with PD-L1 <50%	1200	<ul style="list-style-type: none"> <li>Double-arm randomised, open-label trial</li> <li>Arm 1: volrustomig + chemotherapy</li> <li>Arm 2: pembrolizumab + chemotherapy</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: OS and PFS (PD-L1 &lt; 1%)</li> <li>Secondary endpoints: PFS (ITT), ORR and DoR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase III</b> <b>eOLVE-Meso</b> <a href="#">NCT06097728</a>	1L unresectable malignant pleural mesothelioma	825	<ul style="list-style-type: none"> <li>Double-arm, randomised, open-label trial</li> <li>Arm 1: volrustomig + chemotherapy</li> <li>Arm 2: chemotherapy or nivolumab + ipilimumab</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: OS</li> <li>Secondary endpoints: PFS, landmark OS, landmark PFS and ORR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase IIb</b> <b>eOLVE-01</b> <a href="#">NCT06448754</a>	NSCLC	180	<ul style="list-style-type: none"> <li>Platform, randomised, open-label, multicenter, global trial</li> <li>Substudy 1: mNSCLC (non-squamous). Participants randomized in two treatment arms: Arm 1A and Arm 1B.</li> <li>Arm 1A: volrustomig dose regimen 1 + chemotherapy</li> <li>Arm 1B: volrustomig dose regimen 2 + chemotherapy</li> <li>Substudy 2: mNSCLC. Participants enroll to Arm 2A only.</li> <li>Arm 2A: volrustomig dose regimen 2 + ramucirumab + chemotherapy</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety, &amp; tolerability, ORR</li> <li>Secondary endpoints: DCR, DOR, PFS, OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>Data anticipated: 2027</li> </ul>





# volrustomig (PD-1/CTLA-4 bispecific mAb)

## Solid tumours

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

V&I

Rare Disease

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase II</b> <b>CANTOR</b> <a href="#">NCT06792695</a>	Colorectal Cancer (mCRC)	120	<ul style="list-style-type: none"> <li>Platform, randomised, open-label, multicenter, global trial</li> <li>Arm A: Volrustomig + FOLFIRI + bevacizumab group</li> <li>Arm B: FOLFIRI + bevacizumab group</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PFS, safety</li> <li>Secondary endpoints: OS, ORR, DCR, DOR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase II</b> <b>eVOLVE-02</b> <a href="#">NCT06535607</a>	Advanced/metastatic solid tumours	110	<ul style="list-style-type: none"> <li>Platform, multi-centre trial</li> <li>Sub-study 1: volrustomig monotherapy in participants with cervical cancer</li> <li>Sub-study 2: volrustomig monotherapy in participants with head and neck squamous cell carcinoma</li> <li>Sub-study 3: volrustomig in combination with chemotherapy in participants with head and neck squamous cell carcinoma</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: ORR and safety</li> <li>Secondary endpoints: DOR, PFS, TTR, OS, PK parameters and immunogenicity</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase Ib/III</b> <b>eVOLVE-RCC02</b> <a href="#">NCT07000149</a> Partnered (Arcus Biosciences)	1L advanced clear cell renal cell carcinoma (ccRCC)	60	<ul style="list-style-type: none"> <li>Randomised, open-label, multicenter, global trial</li> <li>Ph1b:</li> <li>Arm 1 - volrustomig Dose 1 + casdatifan</li> <li>Arm 2 - volrustomig Dose 2 + casdatifan</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: AEs, SAEs</li> <li>Secondary endpoints: ORR, DoR, PFS, DCR, PK parameters and immunogenicity, TTR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase Ib</b> <a href="#">NCT04522323</a>	Advanced renal cell carcinoma	67	<ul style="list-style-type: none"> <li>Open-label, dose escalation and dose expansion trial</li> <li>Arm 1: volrustomig + axitinib</li> <li>Arm 2: volrustomig + lenvatanib</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints (escalation): safety, MTD, RP2D, tolerability and anti-tumour activity of combination (ORR)</li> <li>Secondary endpoints: PK parameters, ADA and anti-tumour activity (PFS, OR, DoR, DCR, TTR, OS)</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2020</li> <li>LPCD: Q2 2023</li> <li>Data anticipated: H1 2026</li> </ul>

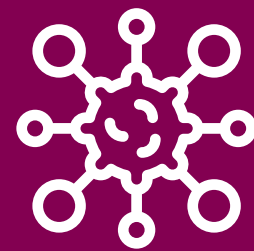
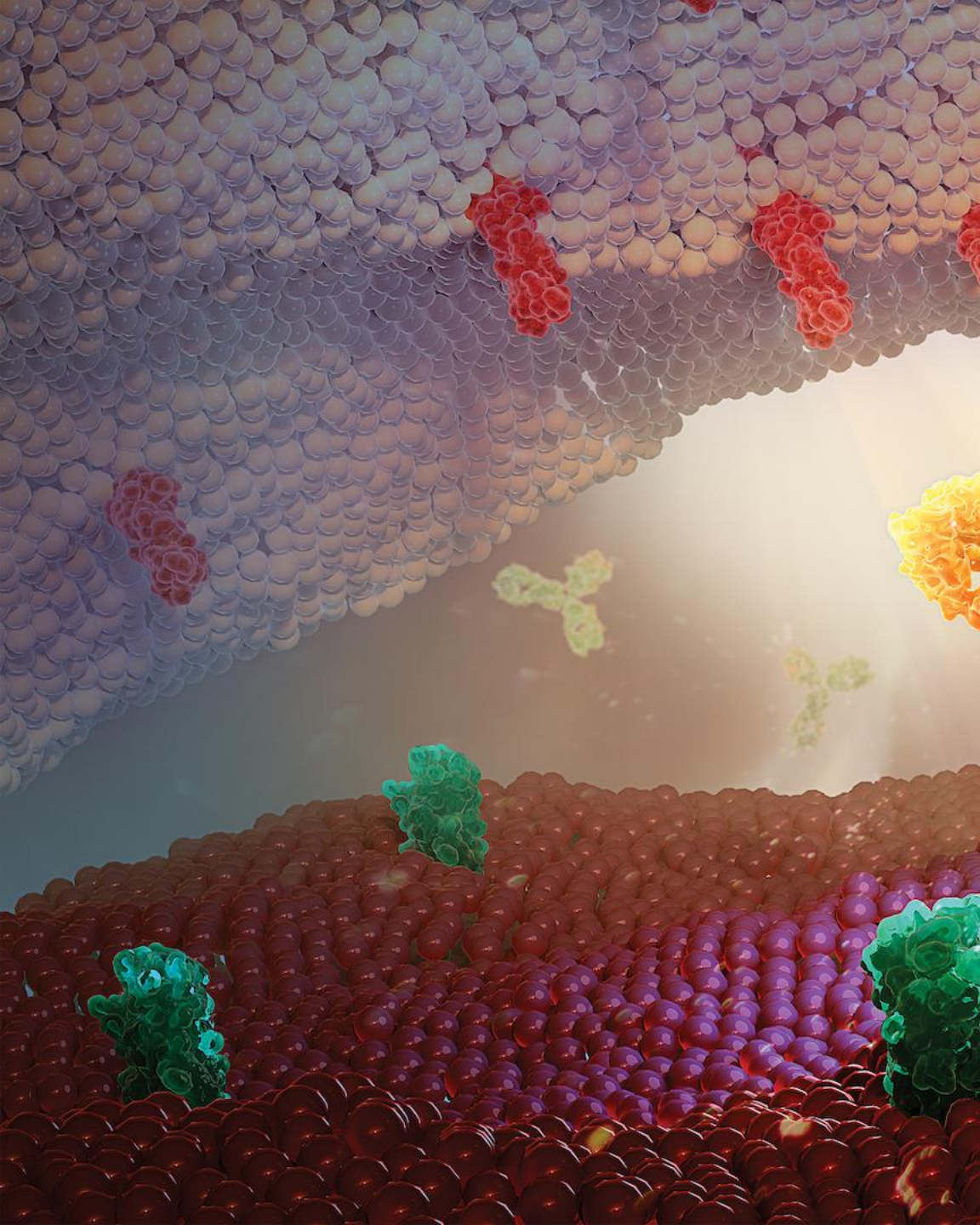


# volrustomig (PD-1/CTLA-4 bispecific mAb)

## Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT03530397</a>	Advanced solid tumours	400	<ul style="list-style-type: none"><li>Open-label, dose escalation and dose expansion trial</li><li>Dose escalation: volrustomig i.v.</li><li>Dose expansion: volrustomig i.v. as monotherapy and + chemotherapy</li><li>Arm 1: volrustomig i.v.</li><li>Arm 2: volrustomig i.v., pemetrexed + carboplatin</li><li>Arm 3: pembrolizumab, pemetrexed + carboplatin</li><li>Arm 4: volrustomig i.v., taxane (paclitaxel or nab-paclitaxel) + carboplatin</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints (escalation): safety and tolerability, MTD, OBD and HPDD</li><li>Primary endpoint (expansion): antitumour activity based on ORR</li><li>Secondary endpoints: PK parameters, ADA, tumoural baseline PD-L1, anti-tumour activity (OR, DoR, DCR, PFS, OS)</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2018</li><li>LPCD: Q4 2023</li><li>Data anticipated: H1 2026</li></ul>





# Oncology: early-stage development

# FPI-2265 (PSMA radioconjugate)

## Prostate cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase II AlphaBreak <a href="#">NCT06402331</a> Partnered (Fusion)	PSMA-positive mCRPC previously treated with lutetium-PSMA therapy	100	<ul style="list-style-type: none"><li>Open-label, randomised, multi-centre trial</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: PSA50 and safety</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2024</li><li>Data anticipated: H2 2026</li></ul>



# IPH5201 (CD39 mAb)

## Solid tumours

Approved medicines

Late-stage development

Early development

Oncology

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase I</b> <b>NCT04261075</b> Partnered (Innate Pharma)	Advanced solid tumours	57	<ul style="list-style-type: none"><li>• Open-label, dose escalation trial to determine MTD of IPH5201 as monotherapy, or in combination with <i>Imfinzi</i> +/- oleclumab</li><li>• Part 1: IPH5201 monotherapy dose escalation to MTD</li><li>• Part 2: IPH5201 + <i>Imfinzi</i> dose escalation to MTD</li><li>• Part 3: IPH5201 + <i>Imfinzi</i> + oleclumab dose escalation to MTD</li><li>• Route of administration: i.v.</li><li>• Global trial – US and EU</li></ul>	<ul style="list-style-type: none"><li>• Primary endpoints: AE, SAE and DLT</li><li>• Secondary endpoints: OR, DC, PK parameters and ADA</li></ul>	<ul style="list-style-type: none"><li>• FPCD: Q1 2020</li><li>• LPCD: Q2 2022</li><li>• Data readout: Q2 2023</li></ul>

CVRM

R&I

V&I

Rare Disease



# NT-112 (KRAS G12D specific TCR)

## Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT06218914</a>	Unresectable, advanced and/or metastatic non-small cell lung cancer, colorectal adenocarcinoma, pancreatic adenocarcinoma, endometrial cancer or any solid tumour histology positive for KRAS G12D mutation	24	<ul style="list-style-type: none"><li>Open-label, single-arm, multi-centre trial with dose escalation</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: incidence of DLTs, TEAEs and SAEs</li><li>Secondary endpoints: ORR per RECIST v.1.1, BOR, DOR, CBR (CR, PR, SD), TTR, PFS and OS</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2024</li><li>Data anticipated: H2 2026</li></ul>



# NT-125 (autologous, multi-specific neoantigen-targeting TCR-T)

## Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase I</b> <b>EudraCT: 2021-006406-73</b>	Adults with recurrent or metastatic NSCLC, melanoma, colorectal adenocarcinoma, HNSCC, bladder carcinoma, TNBC, cervical squamous cell carcinoma and adenocarcinoma or microsatellite instability-high/mismatch repair-deficient solid tumours	42	<ul style="list-style-type: none"> <li>Open-label, single-arm, single-centre trial with dose escalation and dose expansion components</li> <li>Arm 1: NT-125</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint (Phase Ia): incidence of AEs defined as DLTs</li> <li>Primary endpoint (Phase Ib): ORR per RECIST v.1.1</li> <li>Secondary endpoints (Phase Ia): percentage of pre-screened and enrolled subjects that receive treatment</li> <li>Secondary endpoints (Phase Ib): percentage change tumour size, best percentage change tumour size, DoR, clinical benefit rate, TTP, PFS and OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2023</li> <li>LPCD: Q4 2023</li> <li>Trial discontinued due to strategic portfolio prioritisation</li> </ul>





# NT-175 (TP53-armored TCR)

## Multiple cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT05877599</a>	Unresectable, advanced, and/or metastatic solid tumours positive for HLA-A*02:01 and TP53 R175H mutation	162	<ul style="list-style-type: none"><li>Open-label, single-arm, multi-centre trial with dose escalation and dose expansion components</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: Incidence of DLTs, TEAEs and SAEs</li><li>Secondary endpoints: ORR per RECIST v.1.1, BOR, DOR, CBR (CR, PR, SD), TTR, PFS and OS</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2023</li><li>Data anticipated: H2 2026</li></ul>



# tilatamig samrotercan (AZD9592, EGFR-cMET TOP1i ADC)

## Lung cancer

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase I EGRET</b> <a href="#">NCT05647122</a>	Advanced solid tumours including NSCLC, HNSCC and CRC	403	<ul style="list-style-type: none"> <li>Escalation phase, open-label, multi-centre trial</li> <li>Arm 1: tilatamig samrotercan</li> <li>Arm 2: tilatamig samrotercan + <i>Tagrisso</i></li> <li>Arm 3: tilatamig samrotercan + 5FU + bevacizumab</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints (escalation): safety and tolerability</li> <li>Primary endpoints (expansion): safety, tolerability and anti-tumour activity</li> <li>Secondary endpoints (escalation): PK parameters, immunogenicity and anti-tumour activity</li> <li>Secondary endpoints (expansion): PK parameters and immunogenicity</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2023</li> <li>Data anticipated: 2027</li> </ul>



# AZD0120 (GC012F, autologous anti-CD19 and anti-BCMA CAR-T)

## Blood cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase II DURGA-3 <a href="#">NCT06235229</a>	Relapsed/refractory multiple myeloma	20	<ul style="list-style-type: none"> <li>Open-label, multi-centre, non-randomised trial</li> <li>PhII dose expansion</li> <li>China only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint (PIb): safety and tolerability measures</li> <li>Secondary endpoints (PIb): PK parameters</li> <li>Primary endpoint (PII): ORR</li> <li>Secondary endpoints (PII): PFS, OS, MRD, DOR, TTR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2025</li> <li>Data anticipated: H1 2026</li> <li>Initiating</li> </ul>
Phase I DURGA-2 <a href="#">NCT07073547</a>	Newly diagnosed multiple myeloma (NDMM) ; Early relapsed or primary refractory multiple myeloma	40	<ul style="list-style-type: none"> <li>Open-label, single-arm, multi-centre trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: incidence of AEs, SAEs and DLTs</li> <li>Secondary endpoints: ORR, CRR, DoR, TTR, MRD negative status at 9 months, AEs and PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2025</li> <li>Data anticipated: H2 2026</li> </ul>
Phase I/II DURGA-1 <a href="#">NCT05850234</a>	Relapsed/refractory multiple myeloma	162	<ul style="list-style-type: none"> <li>Open-label, single-arm, multi-centre trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: ORR</li> <li>Secondary endpoints: DOR, PFS, OS, MRD negative rate, AEs</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2023</li> <li>Data anticipated: 2027</li> </ul>



# AZD0305 (GPRC5D ADC)

## Blood cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II <a href="#">NCT06106945</a>	R/R multiple myeloma	226	<ul style="list-style-type: none"><li>Open-label, dose escalation and dose expansion trial</li><li>Phase I: AZD0305 in monotherapy or in combination with other anticancer agents, prescribed at specified dose levels</li><li>Phase II: AZD0305 monotherapy prescribed as RP2D</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: occurrence of dose-limiting toxicities and incidence and severity of AEs and SAEs</li><li>Secondary endpoints: ORR, DoR, PFS, OS, PK parameters and immunogenicity</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2023</li><li>Data anticipated: 2027</li></ul>



# AZD0516 (STEAP2 ADC)

## Prostate cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II SEACLIFF <a href="#">NCT07181161</a> -	mCRPC	177	<ul style="list-style-type: none"><li>Open-label multi-centre, modular dose escalation and dose optimisation trial</li></ul>	<ul style="list-style-type: none"><li>Primary: safety and tolerability</li><li>Secondary: efficacy, PK and immunogenicity</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2025</li><li>Data anticipated: &gt;2027</li><li>Initiating</li></ul>



# AZD0754 (STEAP2 dnTGFβRII-armoured CAR-T)

## Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II APOLLO <a href="#">NCT06267729</a>	Metastatic castration resistance prostate cancer with prior NHA and taxane exposure	60	<ul style="list-style-type: none"><li>Open-label, single-arm, multi-centre trial with dose escalation and dose expansion components</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints (Phase I): DLT, AEs (including AESI and SAEs), determination of recommended dose for expansion phase</li><li>Secondary endpoints (Phase I): PSA related changes (PSA50, PSA90), radiological assessment according to RECIST v1.1 and PCWG3 (ORR, BOR, DRR, DCR, TTR, rPFS, OS), PK parameters (Cmax, Tmax, Tlast, AUC)</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2024</li><li>Data anticipated: 2027</li></ul>



# AZD2068 (FPI-2068, EGFR cMET radioconjugate)

## Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT06147037</a>	Advanced solid tumours	110	<ul style="list-style-type: none"><li>Multicentre, open-label dose escalation trial</li><li>Part A: optimisation of FPI-2053 dose (treatment with dose level 1 of [225Ac]-AZD2068 - fixed dose)</li><li>Part B: dose escalation of [225Ac]-AZD2068 with optimal FPI-2053</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: safety and tolerability</li><li>Secondary endpoints: anti-tumour activity, immunogenicity and PK parameters</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2024</li><li>Data anticipated: 2027</li></ul>





# AZD2284 (STEAP2 radioconjugate)

## Prostate cancer

Approved medicines

Late-stage development

Early development

Oncology

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase I</b> <b><u>NCT06879041</u></b>	mCRPC	134	<ul style="list-style-type: none"><li>Part A (Imaging):</li><li>Part A (Cold Antibody Exploration): aims to determine the optimal dosing regimen, with or without unconjugated antibody (AZD2275) pre-administration to improve the biodistribution of AZD2284</li><li>Part B (Therapeutic):</li><li>Part B (Actinium-225 Dose Escalation): aims to assess the safety, tolerability, and efficacy of escalating doses of AZD2284 informed by the optimal dosing regimen identified in Part A</li><li>Part B Expansion Cohorts 1 and 2: aims to explore efficacy of AZD2284</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: safety and tolerability</li><li>Secondary endpoints: anti-tumour activity, PK parameters and immunogenicity</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2025</li><li>Data anticipated: 2027</li></ul>

CVRM

R&I

V&I

Rare Disease



# AZD2962 (IRAK4 inhibitor)

## Blood cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT07064122</a>	Haematologic neoplasms	72	<ul style="list-style-type: none"><li>Modular, open-label, mutli-centre</li><li>AZD2962 orally QD dose escalation</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: DLT, AEs, duration of exposure, relative dose intensity</li><li>Secondary endpoints: OR, DoR, TTR, OS, time to progression, PK measures</li></ul>	<ul style="list-style-type: none"><li>Data anticipated: &gt;2027</li><li>Initiating</li></ul>



# AZD3470 (PRMT5)

## Solid tumours and blood cancer

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase I/II PRIMROSE</b> <a href="#">NCT06130553</a>	MTAP-deficient advanced solid tumours Arm 2: 2L+ NSCLC	234	<ul style="list-style-type: none"><li>Open-label, multi-centre</li><li>Arm 1: Phase 1 AZD3470</li><li>Arm 2: Phase 2 Proof of concept AZD3470 + <i>Datroway</i></li></ul>	<ul style="list-style-type: none"><li>Arm 1: Primary endpoints: safety and tolerability</li><li>Secondary endpoints: PK parameters and clinical efficacy</li><li>Arm 2: Primary endpoints: PFS, Safety</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2024</li><li>Data anticipated: 2027</li></ul>
<b>Phase I PRIMAVERA</b> <a href="#">NCT06137144</a>	R/R haematologic malignancies	110	<ul style="list-style-type: none"><li>Modular Phase I/II open-label dose escalation and expansion trial</li><li>Module 1 – Part A (dose escalation): AZD3470 monotherapy</li><li>Module 1 – Part B (dose expansion/optimisation): AZD3470 monotherapy</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: safety and tolerability</li><li>Secondary endpoints: PK parameters and clinical efficacy</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2024</li><li>Data anticipated: H1 2026</li></ul>



# AZD3632 (menin inhibitor)

## Blood cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II MOMENTUM <a href="#">NCT07155226</a>	R/R AML, ALL and HR MDS with KMT2Ar, NPM1m, or other genotypes associated with homeobox (HOX) overexpression	84	<ul style="list-style-type: none"><li>Module 1 is a dose escalation of AZD3632 monotherapy.</li><li>Module 2 will investigate the safety, PK, and tolerability when co-administered with posaconazole.</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: safety and tolerability</li><li>Secondary endpoints: preliminary efficacy (CR, CRh, TTR, DoR, TI, EFS, OS), PK parameters</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2026</li><li>Data anticipated: &gt;2027</li></ul>



# AZD4360 (CLDN18.2 ADC)

## Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II CONCLUDE <a href="#">NCT06921928</a>	Histologically confirmed advanced or metastatic Pancreatic ductal adenocarcinoma (PDAC), Gastric or Gastroesophageal junction cancer (G/GEJC), and Biliary tract cancer (BTC) with documented positive CLDN18.2 expression	117	<ul style="list-style-type: none"><li>Open-label, multi-centre trial with FIH modular protocol design</li><li>Module 1: AZD4360 monotherapy</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: safety</li><li>Secondary endpoints: efficacy, PK, immunogenicity</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2025</li><li>Data anticipated: 2027</li></ul>



# AZD4512 (CD22 ADC)

## Blood cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II ALLight <a href="#">NCT07109219</a>	Acute Lymphoblastic Leukemia (ALL)	83	<ul style="list-style-type: none"> <li>Modular phase I/II, open-label multi-centre study</li> <li>Module 1: Dose Escalation</li> <li>Module 2: Dose Expansion</li> </ul>	<ul style="list-style-type: none"> <li>Module 1:                             <ul style="list-style-type: none"> <li>Primary endpoints: safety</li> <li>Secondary endpoints: PK, safety, ORR, DoR, EFS, OS</li> </ul> </li> <li>Module 2:                             <ul style="list-style-type: none"> <li>Primary endpoints: ORR, safety</li> <li>Secondary endpoints: DoR, EFS, OS, PK, safety</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
Phase I/II Lumi-NHL <a href="#">NCT07123454</a>	Relapsed/Refractory B-cell Non-Hodgkin Lymphoma (B-NHL)	91	<ul style="list-style-type: none"> <li>Modular, open-label, non-randomised, multi-centre, dose escalation and expansion</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety measures</li> <li>Secondary endpoints: ORR, CR, DoR, PFS, OS</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2025</li> <li>Data anticipated: &gt;2027</li> </ul>



# AZD5492 (CD20 TITAN TCE)

## Blood cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase I TITANIUM <a href="#">NCT06542250</a>	CLL, MCL, LBCL, FL	176	<ul style="list-style-type: none"><li>Module 1: AZD5492 monotherapy</li><li>AZD5492 monotherapy for r/r B-cell malignancies</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: safety and tolerability</li><li>Secondary endpoints: preliminary efficacy (ORR, CRR, DoR, PFS, OS), PK parameters and immunogenicity</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2024</li><li>Data anticipated: H2 2026</li></ul>



# AZD5863 (CLDN18.2 CD3 bispecific antibody)

## Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT06005493</a>	Advanced or metastatic solid tumours with CLDN18.2 expression	280	<ul style="list-style-type: none"><li>Part A: dose escalation phase to determine the safety, tolerability, RP2D, and/or MTD of AZD5863</li><li>Part B: dose expansion phase to further characterise the safety profile and evaluate anti-tumour activity of AZD5863</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints (Part A): safety and tolerability</li><li>Primary endpoints (Part B): safety, tolerability and preliminary anti-tumour activity</li><li>Secondary endpoints: preliminary anti-cancer activity, PK parameters and immunogenicity</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2023</li><li>Data anticipated: H2 2026</li></ul>





# AZD6621 (STEAP2 T-cell engager)

## Prostate cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II ACTIVATED-4-PC <a href="#">NCT07192614</a> -	mCRPC	52	<ul style="list-style-type: none"><li>Open-label, multi-centre, modular dose escalation and dose optimisation trial.</li></ul>	<ul style="list-style-type: none"><li>Primary: safety, tolerability</li><li>Secondary: efficacy, PK, immunogenicity</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2025</li><li>Data anticipated: &gt;2027</li><li>Initiating</li></ul>



# AZD6750 (CD8 guided IL-2)

## Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II <a href="#">NCT07115043</a>	Select advanced or metastatic solid tumors	60	<ul style="list-style-type: none"><li>Open-label, dose escalation and expansion study</li><li>Module 1: AZD6750 monotherapy</li><li>Module 2: AZD6750 + rilvegostomig</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: Safety and efficacy measures</li><li>Secondary endpoints: PK/PD parameters, immunogenecity, efficacy</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2025</li><li>Data anticipated: &gt;2027</li></ul>



# AZD7003 (GPC3 CAR-T)

## Hepatocellular carcinoma (HCC)

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II STARLIGHT <a href="#">NCT06590246</a>	GPC3-positive advanced/recurrent HCC	121	<ul style="list-style-type: none"><li>Open-label, single-arm, multi-centre trial with dose escalation and dose expansion components</li><li>China only</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints (Phase I): DLT, AEs (including AESI and SAEs), determination of recommended dose for expansion phase</li><li>Secondary endpoints (Phase I): ORR per RECIST v. 1.1, TTR, DCR, DRR, BoR, DoR, PFS and OS; PK parameters (Cmax, Tmax, Tlast, AUC)</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2024</li><li>Data anticipated: &gt;2027</li></ul>



# AZD8421 (CDK2 inhibitor)

## Breast cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II CYCAD-1 <a href="#">NCT06188520</a>	ER+ HER2-negative advanced breast cancer	204	<ul style="list-style-type: none"><li>Module 1: AZD8421</li><li>Module 2: AZD8421+ camizestrant + one or more of abemaciclib or ribociclib or palbociclib</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: safety and tolerability</li><li>Secondary endpoints: PK parameters</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2023</li><li>Data anticipated: H2 2026</li></ul>



# AZD9574 (PARP1-selective BBB inhibitor)

## Solid tumours

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

V&I

Rare Disease

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase I/IIa CERTIS-1</b> <a href="#">NCT05417594</a>	Advanced solid malignancies	695	<ul style="list-style-type: none"><li>Modular, open-label, multi-centre dose escalation and expansion trial</li><li>Module 1: AZD9574 monotherapy</li><li>Module 2: AZD9574 + temozolomide</li><li>Module 3: [11C]AZ14193391 + AZD9574 or [11C]AZ14193391 + AZD9574 + temozolomide</li><li>Module 4: AZD9574 + <i>Enhertu</i></li><li>Module 5: AZD9574 + <i>Datroway</i></li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: safety and tolerability of AZD9574 as monotherapy and in combination with anti-cancer agents, determination of PARP1 occupancy in brain by AZD9574 at examined doses and plasma concentration and evaluation of safety of radioligand [11C]AZ14193391</li><li>Secondary endpoints: PK parameters and efficacy of AZD9574 as monotherapy and in combination with anti-cancer agents</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2022</li><li>Data anticipated: 2027</li></ul>



# AZD9750 (AR PROTAC)

## Prostate cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II ANDROMEDA <a href="#">NCT07336446</a>	Metastatic prostate cancer	300	<ul style="list-style-type: none"><li>Open-label, multicenter</li><li>Part A: monotherapy dose escalation or combination dose finding</li><li>Part B: monotherapy dose optimisation and expansion or combination dose expansion)</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: Safety and tolerability, Clinical efficacy (Part B)</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2026</li><li>Data anticipated: &gt;2027</li><li>Initiating</li></ul>

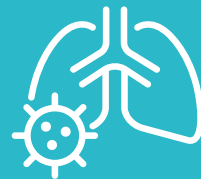
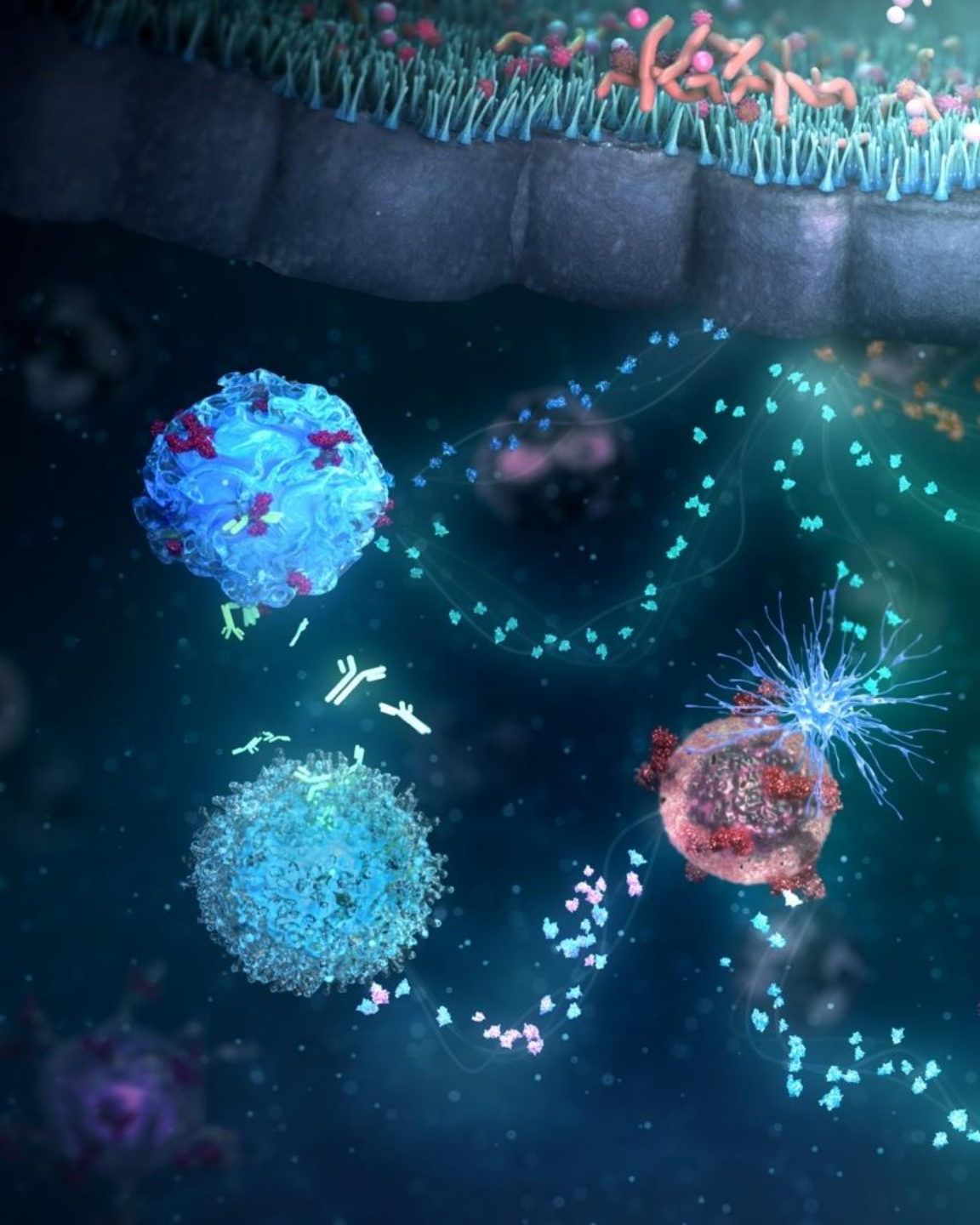


# AZD9793 (GPC3 TITAN T-cell engager)

## Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II RHEA-1 <a href="#">NCT06795022</a>	Metastatic solid tumours	304	<ul style="list-style-type: none"><li>Open label, non randomised, multi-centre, dose escalation and expansion</li><li>Module 1: intravenous AZD9793</li><li>Module 2: subcutaneous AZD9793</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: safety and tolerability</li><li>Secondary endpoints: ORR, BOR, DRR, DoR, TTR, PFS, OS, PK Parameters</li></ul>	<ul style="list-style-type: none"><li>Data anticipated: &gt;2027</li><li>Active</li></ul>





# BioPharmaceuticals: approved medicines and late-stage development



# Wainua (eplontersen, ligand-conjugated antisense)

## ATTR

Trial	Population	Patients	Design	Endpoints	Status
Phase III CARDIO-TTRansform <a href="#">NCT04136171</a> Partnered (Ionis Pharmaceuticals, Inc.)	Hereditary or wild-type transthyretin-mediated amyloid cardiomyopathy (ATTR-CM)	1438	<ul style="list-style-type: none"> <li>Arm 1: Wainua s.c.</li> <li>Arm 2: placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: composite outcome of CV mortality and recurrent CV clinical events at Week 140</li> <li>Secondary endpoints: 6MWT, KCCQ, CV events and CV mortality, all cause mortality, composite outcome of CV mortality and recurrent CV clinical events in subgroup of patients treated with tafamidis at baseline</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2020</li> <li>Data anticipated: H2 2026</li> </ul>
Phase III EPIC-ATTR <a href="#">NCT06194825</a>	ATTR-CM	64	<ul style="list-style-type: none"> <li>Arm 1: Wainua s.c. Q4W</li> <li>Arm 2: placebo</li> <li>China only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint (at week 24): percent change from baseline in serum TTR concentration</li> <li>Secondary endpoints: PK, immunogenicity, disease biomarkers (NT pro-BNP, hsTnT)</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>Data anticipated: H1 2026</li> </ul>
Phase III NEURO-TTRansform <a href="#">NCT04136184</a> Partnered (Ionis Pharmaceuticals, Inc.)	Hereditary transthyretin-mediated amyloid polyneuropathy (ATTRv-PN)	168	<ul style="list-style-type: none"> <li>Arm 1: Wainua s.c.</li> <li>Arm 2: inotersen s.c.</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints (at Week 35): change from baseline in mNIS+7 and percent change from baseline in TTR concentration</li> <li>Secondary endpoint (Week 35): changes from baseline in Norfolk QOL</li> <li>Primary endpoints (at Week 66): change from baseline in mNIS+7, change from baseline in the Norfolk QoL-DN Questionnaire and percent change from baseline in TTR concentration</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2020</li> <li>LPD: Q3 2023</li> <li>Data readout: Q2 2022</li> <li>Co-primary endpoints met at Week 35 and Week 66</li> </ul>



# balcinrenone/dapagliflozin (MR antagonist/modulator + SGLT2 inhibitor)

## Heart failure, CKD

Trial	Population	Patients	Design	Endpoints	Status
Phase III BalanceD-HF <a href="#">NCT06307652</a>	Heart failure patients with renal impairment (eGFR 20-60 ml/min) with heart failure event within the last 6 months	4800	<ul style="list-style-type: none"><li>Randomised, double-blind, parallel-group, double-dummy, active-controlled, event-driven trial</li><li>Arm 1: balcinrenone/dapagliflozin 15mg/10mg</li><li>Arm 2: balcinrenone/dapagliflozin 40mg/10mg</li><li>Arm 3: dapagliflozin 10mg</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: time to first occurrences of any the components of the composite of CV death, HF hospitalisation and HF event without hospitalisation</li><li>Secondary endpoints: total occurrences (first and recurrent) of the components of the composite of CV death, HF hospitalisation and HF event without hospitalisation; time to CV death; the hierarchical composite endpoint of death from any cause, total HF events, and change from baseline in KCCQ total symptom score to 24-week post-randomisation; and time do death from any cause</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2024</li><li>Data anticipated: 2027</li></ul>
Phase IIb MIRO-CKD <a href="#">NCT06350123</a> -	CKD	300	<ul style="list-style-type: none"><li>Multicentre, randomised, double-blind, dose-finding, parallel group, double-dummy trial</li><li>Arm 1: balcinrenone/dapagliflozin 15 mg/10 mg once daily</li><li>Arm 2: balcinrenone/dapagliflozin 40 mg/10 mg once daily</li><li>Arm 3: dapagliflozin 10 mg once daily</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: Relative change in UACR from baseline to Week 12</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2024</li><li>LPCD: Q4 2024</li><li>Data readout: Q3 2025</li><li>Primary endpoint met</li></ul>



# baxdrostat (selective aldosterone synthase inhibitor)

## Hypertension

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>Bax24</b> <a href="#">NCT06168409</a>	Patients with resistant hypertension on three or more antihypertensive medications	218	<ul style="list-style-type: none"> <li>Arm 1: baxdrostat 2mg QD</li> <li>Arm 2: placebo QD</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: effect of baxdrostat vs. placebo on ambulatory 24-hour average systolic blood pressure at Week 12</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2024</li> <li>LPCD: Q2 2025</li> <li>Data readout: Q4 2025</li> <li>Primary endpoint met</li> </ul>
<b>Phase III</b> <b>BaxAsia</b> <a href="#">NCT06344104</a>	Patients with uncontrolled hypertension on two or more antihypertensive medications including patients with resistant hypertension	326	<ul style="list-style-type: none"> <li>Arm 1: baxdrostat 1mg QD</li> <li>Arm 2 baxdrostat 2mg QD</li> <li>Arm 3: placebo QD</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: effect of baxdrostat vs. placebo on seated systolic blood pressure at Week 12</li> <li>Secondary endpoints: effect of baxdrostat vs. placebo on seated systolic blood pressure at 8 weeks after randomised withdrawal, safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2024</li> <li>LPCD: Q1 2025</li> <li>Data readout: Q1 2026</li> <li>Primary endpoint met</li> </ul>
<b>Phase III</b> <b>BaxHTN</b> <a href="#">NCT06034743</a>	Patients with uncontrolled hypertension on two or more antihypertensive medications including patients with resistant hypertension	796	<ul style="list-style-type: none"> <li>Arm 1: baxdrostat 1mg QD</li> <li>Arm 2: baxdrostat 2mg QD</li> <li>Arm 3: placebo QD</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: effect of baxdrostat vs. placebo on seated systolic blood pressure at Week 12</li> <li>Secondary endpoints: effect of baxdrostat vs. placebo on seated systolic blood pressure at 8 weeks after randomised withdrawal, safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2024</li> <li>LPCD: Q1 2025</li> <li>Data readout: Q3 2025</li> <li>Primary endpoint met</li> </ul>
<b>Phase II</b> <b>FigHTN</b> <a href="#">NCT05432167</a>	Patients with uncontrolled hypertension and CKD	194	<ul style="list-style-type: none"> <li>Arm 1: baxdrostat (low dose)</li> <li>Arm 2: baxdrostat (high dose)</li> <li>Arm 3: placebo</li> <li>US only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: change from baseline in mean seated systolic blood pressure vs. placebo at Week 26</li> <li>Secondary endpoint: to evaluate the treatment effect on SBP at Week 26 by dosing strategy</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2022</li> <li>LPCD: Q2 2024</li> <li>Data readout: Q3 2024</li> </ul>
<b>Phase II</b> <b>HALO-OLE</b> <a href="#">NCT05459688</a>	Patients with uncontrolled hypertension who have completed CIN-107-124	175	<ul style="list-style-type: none"> <li>Arm 1: baxdrostat 2mg QD</li> <li>US only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2022</li> <li>LPCD: Q3 2022</li> <li>Data readout: Q2 2024</li> </ul>



# baxdrostat (selective aldosterone synthase inhibitor)

## Hypertension

Approved medicines
Late-stage development
Early development

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase II</b> <a href="#">NCT06336356</a>	Patients with uncontrolled hypertension on one or more antihypertensive medications	45	<ul style="list-style-type: none"> <li>Arm 1: baxdrostat 2mg QD</li> <li>Arm 2: placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: individual cortisol level before and after ACTH stimulation test at baseline and Week 8</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2024</li> <li>LPCD: Q3 2024</li> <li>Data readout: Q1 2025</li> </ul>
<b>Phase I</b> <a href="#">NCT06194032</a>	Healthy volunteers	28	<ul style="list-style-type: none"> <li>Arm 1: baxdrostat 16mg (single dose)</li> <li>Arm 2: baxdrostat 32mg (single dose)</li> <li>Arm 3: placebo (single dose)</li> <li>Arm 4: moxifloxacin 400mg (single dose)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: placebo-corrected change from baseline QTcF</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2024</li> <li>LPCD: Q2 2024</li> <li>Data readout: Q3 2024</li> </ul>
<b>Phase I</b> <a href="#">NCT06357520</a>	Healthy volunteers	14	<ul style="list-style-type: none"> <li>Arm 1: baxdrostat 2mg and itraconazole 200mg</li> <li>US only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: AUCinf and Cmax</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2024</li> <li>LPCD: Q2 2024</li> <li>Data readout: Q3 2024</li> </ul>
<b>Phase I</b> <a href="#">NCT06657105</a>	Healthy volunteers	22	<ul style="list-style-type: none"> <li>Arm1: baxdrostat 2mg and ethiny estradiol/levonorgestrel 0.06/0.3mg</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: AUCinf, AUClast and Cmax</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>LPCD: Q4 2024</li> <li>Data readout: Q2 2025</li> </ul>

Oncology

CVRM

R&I

V&I

Rare Disease



# baxdrostat (selective aldosterone synthase inhibitor)

## Primary aldosteronism

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>BaxPA</b> <a href="#">NCT07007793</a>	Primary aldosteronism	180	<ul style="list-style-type: none"> <li>Multicentre, randomised, double-blind, placebo-controlled, parallel-group</li> <li>Arm 1: baxdrostat QD</li> <li>Arm 2: placebo QD</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: change from baseline in seated systolic blood pressure and achieving normalization of the renin angiotensin aldosterone system at week 8</li> <li>Secondary endpoints: effect of baxdrostat vs. placebo on seated systolic blood pressure and plasma renin activity at 8 weeks after randomised withdrawal.</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase II</b> <b>SPARK</b> <a href="#">NCT04605549</a>	Patients with primary aldosteronism	18	<ul style="list-style-type: none"> <li>Arm 1: baxdrostat 2-8mg QD</li> <li>US only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability in patients with PA at doses from 2 to 8mg per day for 12 weeks and the reduction in SBP patients with PA after 12 weeks</li> <li>Secondary endpoints: reduction in DBP as a function of dose in patients with PA after 12 weeks of treatment, change in serum potassium and requirement for potassium supplementation and change in serum sodium and requirement for fluid or mineral replacement</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2022</li> <li>LPCD: Q2 2023</li> <li>Data readout: Q1 2025</li> </ul>



# baxdrostat/dapagliflozin (selective ASI/SGLT2)

## CKD/Prevention of heart failure

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>BaxDuo-Arctic</b> <b><a href="#">NCT06268873</a></b>	CKD and high blood pressure	2500	<ul style="list-style-type: none"> <li>Arm 1: baxdrostat/dapagliflozin QD</li> <li>Arm 2: dapagliflozin/placebo QD</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: change from baseline in eGFR to post-treatment</li> <li>Secondary endpoints: change from baseline in SBP and UACR, kidney HCE and eGFR</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2024</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase III</b> <b>BaxDuo-Pacific</b> <b><a href="#">NCT06742723</a></b>	CKD and high blood pressure	5000	<ul style="list-style-type: none"> <li>Arm 1: baxdrostat/dapagliflozin QD</li> <li>Arm 2: dapagliflozin/placebo QD</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: Time to the first occurrence of any of the components of the composite of Kidney disease progression (<math>\geq 50\%</math> sustained decline in eGFR, Onset of kidney failure), CV events (HF with or without hospitalisation CV death)</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase III</b> <b>PREVENT-HF</b> <b><a href="#">NCT06677060</a></b>	T2D, history of hypertension and established CVD and risk factor(s)	11300	<ul style="list-style-type: none"> <li>Arm 1: baxdrostat/dapagliflozin QD</li> <li>Arm 2: dapagliflozin/placebo QD</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: Time to first occurrence of any of the components of the composite of: Hospitalisation for HF, HF without hospitalisation, CV death</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase II</b> <b>BaxDuo-Baltic</b> <b><a href="#">NCT07222917</a></b> -	CKD and high blood pressure	218	<ul style="list-style-type: none"> <li>Arm 1: baxdrostat/dapagliflozin</li> <li>Arm 2: baxdrostat/Placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: change from baseline in UACR at 12 weeks</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2025</li> <li>Data anticipated: 2027</li> </ul>



# Iaroprovstat (AZD0780, PCSK9 inhibitor)

## Dyslipidaemia

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

V&I

Rare Disease

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>AZURE-HeFH</b> <b><u>NCT07000136</u></b>	Heterozygos familial hypercholesterolemia	405	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled, parallel-group trial</li> <li>Arm 1: Iaroprovstat</li> <li>Arm 2: placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: Relative change in LDL-C from baseline to 12 weeks</li> <li>Secondary endpoint: Relative change in LDL-C from baseline to 12 weeks in patients on a statin, indicator for LDL-C &lt; 70 mg/dL (&lt; 1.8 mmol/L) at 12 weeks</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase III</b> <b>AZURE-LDL</b> <b><u>NCT07000123</u></b>	Patients with dyslipidaemia and history of clinical ASCVD or at risk for a first ASCVD event	2800	<ul style="list-style-type: none"> <li>Randomised, double-Blind, placebo-controlled, parallel-group trial</li> <li>Arm 1: Iaroprovstat</li> <li>Arm 2: placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: Relative change in LDL-C from baseline to 12 weeks</li> <li>Secondary endpoints: Relative change in LDL-C from baseline to 12 weeks in patients on statins</li> <li>Indicator for LDL-C &lt; 70 mg/dL (&lt; 1.8 mmol/L) at 12 weeks</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase III</b> <b>AZURE-Outcomes</b> <b><u>NCT07000357</u></b>	Patients with dyslipidaemia and established ASCVD or at high risk for a first ASCVD event	15100	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled, parallel-group trial</li> <li>Arm 1: Iaroprovstat</li> <li>Arm 2: placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: Time to first event of any component of MACE-PLUS</li> <li>Secondary endpoints: Time to first event of any component of 3P MACE, Time to first event of any component of MACE PLUS in patients with a history of ASCVD</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase II/III</b> <b>AZURE-China</b> <b><u>NCT06834932</u></b>	Participants with elevated LDL-C	360	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled, multi-centre</li> <li>China only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint (Part A) : PK parameters</li> <li>Secondary endpoint: (Part A) LDL-C at Week 4, To evaluate the effect of treatment with AZD0780 versus placebo on LDL-C at Week 4</li> <li>Primary Endpoint (Part B): To compare the effect of treatment with AZD0780 versus placebo on LDL-C at 12 weeks</li> <li>Secondary Endpoint (Part B):To evaluate the effect of treatment with AZD0780 versus placebo on LDL-C at Week 12</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>Data anticipated: 2027</li> </ul>



# Iaroprovstat (AZD0780, PCSK9 inhibitor)

## Dyslipidaemia

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase II</b> <b>PURSUIT</b> <b><a href="#">NCT06173570</a></b>	Dyslipidaemia	428	<ul style="list-style-type: none"><li>Randomised trial with equal distribution across five parallel treatment arms to either placebo or one of four AZD0780 doses</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: percent change in LDL-C level from baseline to Week 12</li><li>Secondary endpoints: percent change from baseline of LDL-C at Week 12, plasma concentrations summarised by sampling timepoint, percent change from baseline at Week 12 in other lipid parameters and inflammatory markers and safety and tolerability</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2024</li><li>LPCD: Q2 2025</li><li>Data readout: Q1 2025</li><li>Primary endpoint met</li></ul>
<b>Phase II</b> <b><a href="#">NCT06692764</a></b>	Participants with ASCVD or risk equivalents and LDL-C ≥70 mg/dL on stable medication	172	<ul style="list-style-type: none"><li>Multi-centre, randomised, double-blind, placebo-controlled, crossover trial</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: ambulatory 24-hour average systolic blood pressure at Week 4</li><li>Secondary endpoint: ambulatory 24-hour average diastolic blood pressure at Week 4</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2024</li><li>Data anticipated: H1 2026</li></ul>
<b>Phase I</b> <b><a href="#">NCT06576765</a></b>	Hepatic impairment and matched healthy controls	32	<ul style="list-style-type: none"><li>Multi-centre, single-dose, non-randomised, open-label, parallel-group trial</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: PK parameters</li><li>Secondary endpoints: safety and tolerability</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2024</li><li>LPCD: Q4 2024</li><li>Data readout: Q2 2025</li></ul>
<b>Phase I</b> <b><a href="#">NCT06592482</a></b>	Renal impairment and matched healthy controls	30	<ul style="list-style-type: none"><li>Multi-centre, single-dose, non-randomised, open-label, parallel-group trial</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: PK parameters</li><li>Secondary endpoints: safety and tolerability</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2024</li><li>LPCD: Q4 2024</li><li>Data readout: Q2 2025</li></ul>
<b>Phase I</b> <b><a href="#">NCT06671405</a></b>	Healthy volunteers	78	<ul style="list-style-type: none"><li>Open-label, fixed sequence trial to assess the PK of AZD0780 when administered in combination with itraconazole, carbamazepine, and the PK of midazolam and EE/LNG when administered with AZD0780</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: PK parameters</li><li>Secondary endpoints: safety and PK parameters</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2024</li><li>LPCD: Q1 2025</li><li>Data readout: Q4 2025</li></ul>
<b>Phase I</b> <b><a href="#">NCT06742853</a></b>	Healthy volunteers with elevated LDL-C	120	<ul style="list-style-type: none"><li>Randomised, single-blind, placebo-controlled trial</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: percent change in LDL-C at Week-4 and safety and tolerability</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2024</li><li>LPCD: Q3 2025</li><li>Data readout: Q4 2025</li></ul>
<b>Phase I</b> <b><a href="#">NCT07216131</a></b>	Healthy Volunteers	14	<ul style="list-style-type: none"><li>A fixed-sequence, Open-label PK trial of Iaroprovstat effect on metformin</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: PK measures</li><li>Secondary endpoint: safety and tolerability measures</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2025</li><li>LPCD: Q4 2025</li><li>Data anticipated: H1 2026</li></ul>





# zibotentan/dapagliflozin (ETA receptor antagonist/SGLT2 inhibitor)

## Chronic kidney disease

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>ZENITH High Proteinuria</b> <b><u>NCT06087835</u></b> -	CKD and high proteinuria	1835	<ul style="list-style-type: none"><li>Randomised, parallel, multi-centre, double-blind trial</li><li>Arm 1: zibotentan/dapagliflozin dose A or dose B</li><li>Arm 2: dapagliflozin</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: change in eGFR from baseline</li><li>Secondary endpoints: change in UPCR from baseline to each participant's mean level; change in UACR from baseline to each participant's mean level; time to the first occurrence of any of the components of the renal composite endpoint of 40% sustained decline in eGFR or ESKD or renal death</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2023</li><li>LPCD: Q4 2024</li><li>Data anticipated: 2027</li></ul>



# Airsupra (PT027, SABA/ICS, pMDI)

## Asthma

Approved medicines
Late-stage development
Early development

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase IIIb</b> <b>ACADIA</b> <b><u>NCT06307665</u></b> -	Adolescents with asthma	440	<ul style="list-style-type: none"> <li>Randomised, double-blind, multi-center, parallel-group</li> <li>Arm 1: BDA MDI 160/180µg prn</li> <li>Arm 2: AS MDI 180µg prn</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: severe asthma exacerbation rate (annualised)</li> <li>Secondary endpoints: time to first severe exacerbation, annualised total systemic corticosteroid exposure, safety (AEs and SAEs), PK sub-study (including Cmax, AUClast and AUCinf)</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2024</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase IIIb</b> <b>BATURA</b> <b><u>NCT05505734</u></b> <b>Managed by Avillion (Avillion)</b>	Adults and adolescents with mild asthma	2517	<ul style="list-style-type: none"> <li>Randomised, double-blind, multi-centre, parallel-group, decentralised</li> <li>12 to 52-week treatment period</li> <li>Arm 1: <i>Airsupra</i> MDI 160/180µg</li> <li>Arm 2: AS MDI 180µg</li> <li>US only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: time to first severe asthma exacerbation</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2022</li> <li>LPCD: Q1 2024</li> <li>Data readout: Q4 2024</li> <li>Primary endpoint met</li> </ul>
<b>Phase III</b> <b>BAIYUN</b> <b><u>NCT06471257</u></b>	Adult patients with asthma	790	<ul style="list-style-type: none"> <li>Randomised, double-blind, multi-centre, event-driven, parallel-group</li> <li>Arm 1: BDA MDI 160/180µg prn</li> <li>Arm 2: AS MDI 180µg prn</li> <li>China only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: time to first severe exacerbation</li> <li>Secondary endpoints: severe exacerbation rate (annualised), total systemic corticosteroid exposure, ACQ-5 responder, AQLQ+12 responder</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>Data anticipated: H2 2026</li> </ul>
<b>Phase II</b> <b>MITCHELL</b> <b><u>NCT06644924</u></b> -	Adults with asthma	102	<ul style="list-style-type: none"> <li>Randomised, single-dose, double-blind, placebo-controlled, 3-period, 3-treatment, crossover, multicenter</li> <li>Arm 1: AS MDI 180µg (double-blind)</li> <li>Arm 2: Placebo MDI (double-blind)</li> <li>Arm 3: Ventolin Evohaler 200µg (open-label)</li> <li>US Only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: Mean change from baseline in FEV1 AUC0-6 (Non-inferiority of AS MDI relative to Ventolin Evohaler)</li> <li>Secondary endpoints: FEV1 AUC0-6, Mean change from baseline in FEV1 AUC0-4, Safety (AEs and SAEs)</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>LPCD: Q2 2025</li> <li>Data readout: Q3 2025</li> <li>Primary endpoint met</li> </ul>
<b>Phase I</b> <b>PUTUO</b> <b><u>NCT06514157</u></b>	Healthy volunteers	14	<ul style="list-style-type: none"> <li>Open-label, single-dose, single-centre trial</li> <li>Treatment: BDA MDI 160µg/180µg (single dose)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PK parameters for budesonide and albuterol include AUClast, AUCinf, Cmax, tmax, tlast, t½λz, CL/F and Vz/F</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>LPCD: Q3 2024</li> <li>Data readout: Q1 2025</li> </ul>

Oncology

CVRM

R&I

V&I

Rare Disease



# Breztri, Trixeo (LAMA/LABA/ICS)

## Asthma

Approved medicines
Late-stage development
Early development

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III KALOS <a href="#">NCT04609878</a></b>	Uncontrolled asthma	2266	<ul style="list-style-type: none"> <li>Randomised, double-blind, double-dummy, parallel group and multi-centre trial</li> <li>Treatments (24- to 52-week variable length)</li> <li>Arm 1: BGF 320/28.8/9.6µg BID MDI</li> <li>Arm 2: BGF 320/14.4/9.6µg BID MDI</li> <li>Arm 3: <i>Symbicort</i> Aerosphere 320/9.6µg BID MDI</li> <li>Arm 4: <i>Symbicort</i> 320/9µg BID pMDI</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: change from baseline in FEV1 AUC0-3 at Week 24</li> <li>Secondary endpoint: change from baseline in morning pre-dose trough FEV1 at Week 24</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>Data readout: Q2 2025</li> <li>Primary endpoint met</li> </ul>
<b>Phase III LITHOS <a href="#">NCT05755906</a></b>	Inadequately controlled asthma despite treatment with low dose ICS or ICS/LABA	373	<ul style="list-style-type: none"> <li>Randomised, double-blind, parallel group and multi-centre</li> <li>Treatments (12-week)</li> <li>Arm 1: PT009 160/9.6µg BID MDI</li> <li>Arm 2: BD 160µg BID MDI</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: Change from baseline in forced expiratory volume in 1 second (FEV1) area under the curve 0 to 3 hours (AUC0-3) at Week 12</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2023</li> <li>Data readout: Q1 2025</li> </ul>
<b>Phase III LOGOS <a href="#">NCT04609904</a></b>	Uncontrolled asthma	2182	<ul style="list-style-type: none"> <li>Randomised, double-blind, double dummy, parallel group and multi-centre trial</li> <li>Treatments (24- to 52-week variable length)</li> <li>Arm 1: BGF 320/28.8/9.6µg BID MDI</li> <li>Arm 2: BGF 320/14.4/9.6µg BID MDI</li> <li>Arm 3: <i>Symbicort</i> Aerosphere 320/9.6µg BID MDI</li> <li>Arm 4: <i>Symbicort</i> 320/9µg BID pMDI</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: change from baseline in FEV1 AUC0-3 at Week 24</li> <li>Secondary endpoint: change from baseline in morning pre-dose trough FEV1 at Week 24</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>Data readout: Q2 2025</li> <li>Primary endpoint met</li> </ul>
<b>Phase III VATHOS <a href="#">NCT05202262</a></b>	Inadequately controlled asthma despite treatment with medium dose ICS or ICS/LABA	645	<ul style="list-style-type: none"> <li>Randomised, double-blind, parallel group, multi-centre trial</li> <li>Treatments (24-week)</li> <li>Arm 1: <i>Symbicort</i> Aerosphere 320/9.6µg BID MDI</li> <li>Arm 2: PT009 160/9.6µg BID MDI</li> <li>Arm 3: BD 320µg BID MDI</li> <li>Arm 4: open-label <i>Symbicort</i> Turbuhaler 320/9µg BID</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: change from baseline in FEV1 AUC0-3 at Week 24</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2022</li> <li>Data readout: Q2 2025</li> </ul>



# Breztri, Trixeo (LAMA/LABA/ICS)

## COPD

Trial	Population	Patients	Design	Endpoints	Status
Phase III ATHLOS <a href="#">NCT06067828</a>	COPD	180	<ul style="list-style-type: none"><li>Randomised, double-blind, three-treatment, three-period, crossover trial</li><li>Treatments (2-week treatment periods, 2-week washout between treatments)</li><li>Arm 1: <i>Breztri</i> 320/14.4/9.6µg BID MDI</li><li>Arm 2: <i>Symbicort</i> Aerosphere 320/9.6µg BID MDI</li><li>Arm 3: placebo BID MDI</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: change from baseline in isotime IC</li><li>Secondary endpoint: change from baseline in constant work rate cycle ergometry endurance time</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2023</li><li>Data anticipated: H1 2026</li></ul>
Phase III THARROS <a href="#">NCT06283966</a>	COPD	5000	<ul style="list-style-type: none"><li>Randomised, double blind, parallel group, multi-centre event-driven trial comparing BGF MDI 320/14.4/9.6µg BID with GFF MDI 14.4/9.6µg BID in participants with COPD who are at risk of a cardiopulmonary event</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: time to first severe cardiac or COPD event</li><li>Secondary endpoints: time to first severe COPD exacerbation event, time to first severe cardiac event, time to cardiopulmonary death, moderate/severe COPD exacerbation rate, time to MI hospitalisation or cardiac death and time to HF acute healthcare visit/hospitalisation or cardiac death</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2024</li><li>Data anticipated: &gt;2027</li></ul>



# Fasenra (IL-5R mAb)

## Other eosinophilic diseases

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>MANDARA</b> <b><u>NCT04157348</u></b>	Patients with r/r EGPA on corticosteroid therapy with or without stable immunosuppressive therapy; age 18 years and older	140	<ul style="list-style-type: none"><li>Arm 1: <i>Fasenra</i> 30mg Q4W s.c.</li><li>Arm 2: mepolizumab 300mg Q4W s.c.</li><li>52-week trial with a minimum 1-year open label extension</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: proportion of patients achieving remission (BVAS=0 and OCS dose ≤4mg/day) at Week 36 and Week 48</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2019</li><li>LPCD: Q3 2022</li><li>Data readout: Q3 2023</li><li>Primary endpoint met</li></ul>
<b>Phase III</b> <b>NATRON</b> <b><u>NCT04191304</u></b>	Patients with HES (history of persistent eosinophilia >1500 cells/μL with evidence of end organ manifestations attributable to eosinophilia) and signs or symptoms of HES worsening/flare at Visit 1; age 12 years and older	134	<ul style="list-style-type: none"><li>Arm 1: <i>Fasenra</i> 30mg Q4W s.c.</li><li>Arm 2: placebo Q4W s.c.</li><li>24-week trial with a minimum 1-year open label extension</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: time to first HES worsening/flare</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2020</li><li>LPCD: Q4 2024</li><li>Data readout: Q2 2025</li><li>Primary endpoint met</li></ul>



# *Saphnelo* (type I interferon receptor mAb)

## Lupus (SLE/LN)

Trial	Population	Patients	Design	Endpoints	Status
Phase III AZALEA-SLE <a href="#">NCT04931563</a> Partnered (BMS)	Moderate to severe SLE	276	<ul style="list-style-type: none"> <li>Arm 1: 300mg <i>Saphnelo</i> i.v. Q4W</li> <li>Arm 2: placebo i.v. Q4W</li> <li>Asia only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: BICLA at Week 52</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2021</li> <li>LPCD: Q2 2024</li> <li>Data readout: Q2 2025</li> <li>Primary endpoint met</li> </ul>
Phase III IRIS <a href="#">NCT05138133</a> Partnered (BMS)	Active, proliferative LN	360	<ul style="list-style-type: none"> <li>Arm 1: <i>Saphnelo</i> i.v.</li> <li>Arm 2: placebo i.v.</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: CRR at Week 52</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2022</li> <li>Data anticipated: 2027</li> </ul>
Phase III LAVENDER <a href="#">NCT06015737</a> Partnered (BMS)	Chronic and/or subacute CLE	302	<ul style="list-style-type: none"> <li>Arm 1: <i>Saphnelo</i> s.c.</li> <li>Arm 2: placebo s.c.</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: Clinical response based on CLASI-70 at week 24</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>Data anticipated: 2027</li> </ul>
Phase III TULIP-SC <a href="#">NCT04877691</a> Partnered (BMS)	Moderate to severe SLE	367	<ul style="list-style-type: none"> <li>Arm 1: <i>Saphnelo</i> s.c.</li> <li>Arm 2: placebo s.c.</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: BICLA at Week 52</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2021</li> <li>LPCD: Q3 2024</li> <li>Data readout: Q3 2025</li> <li>Primary endpoint met</li> </ul>



# Saphnelo (type I interferon receptor mAb)

## Sclerosis and other myopathies

Trial	Population	Patients	Design	Endpoints	Status
Phase III DAISY <a href="#">NCT05925803</a> Partnered (BMS)	Systemic sclerosis	306	<ul style="list-style-type: none"> <li>Arm 1: <i>Saphnelo</i> s.c.</li> <li>Arm 2: placebo s.c.</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: CRIS-25 at Week 52</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>LPCD: Q1 2026</li> <li>Data anticipated: 2027</li> </ul>
Phase III JASMINE <a href="#">NCT06455449</a> Partnered (BMS)	Idiopathic inflammatory myopathies	240	<ul style="list-style-type: none"> <li>Arm 1: <i>Saphnelo</i> s.c.</li> <li>Arm 2: placebo s.c.</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: Total Improvement Score ≥40 at Week 52</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>Data anticipated: 2027</li> </ul>



# Tezspire (TSLP mAb)

## CRSwNP, COPD and EoE

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III CROSSING</b> <b><u>NCT05583227</u></b> <b>Partnered (AMGEN)</b>	Adult and paediatric aged 12 years and older with eosinophilic esophagitis	360	<ul style="list-style-type: none"> <li>Arm 1: <i>Tezspire</i> s.c. low dose</li> <li>Arm 2: <i>Tezspire</i> s.c. high dose</li> <li>Arm 3: placebo</li> <li>52-week trial</li> </ul>	<ul style="list-style-type: none"> <li>Co-primary endpoints: histologic response of peak esophageal eosinophil per HPF count of <math>\leq 6</math> across all available esophageal levels and change from baseline in Dysphagia Symptom Questionnaire score</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2023</li> <li>LPCD: Q3 2025</li> <li>Data anticipated: H2 2026</li> </ul>
<b>Phase III EMBARK</b> <b><u>NCT06883305</u></b> <b>Partnered (Amgen)</b>	Adults with moderate to very severe COPD	990	<ul style="list-style-type: none"> <li>Randomized, double-blind, placebo-controlled</li> <li>Arm 1: <i>Tezspire</i> s.c. dose 1</li> <li>Arm 2: <i>Tezspire</i> s.c. dose 2</li> <li>Arm 3: placebo</li> <li>52-week treatment minimum</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: Annualized moderate to severe COPD exacerbations.</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase III JOURNEY</b> <b><u>NCT06878261</u></b> <b>Partnered (Amgen)</b>	Adults with moderate to very severe COPD	990	<ul style="list-style-type: none"> <li>Randomized, double-blind, placebo-controlled</li> <li>Arm 1: <i>Tezspire</i> s.c. dose 1</li> <li>Arm 2: <i>Tezspire</i> s.c. dose 2</li> <li>Arm 3: placebo</li> <li>52-week treatment minimum</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: Annualized moderate to severe COPD exacerbations</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase III WAYPOINT</b> <b><u>NCT04851964</u></b> <b>Partnered (AMGEN)</b>	Severe chronic rhinosinusitis with nasal polyps; age 18 years and older	416	<ul style="list-style-type: none"> <li>Arm 1: <i>Tezspire</i> s.c.</li> <li>Arm 2: placebo s.c.</li> <li>52-week trial</li> </ul>	<ul style="list-style-type: none"> <li>Co-primary endpoint: nasal polyp score and participant reported nasal congestion</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2021</li> <li>LPCD: Q4 2023</li> <li>Data readout: Q4 2024</li> <li>Co-primary endpoints met</li> </ul>





# Tezspire (TSLP mAb)

## Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III DIRECTION <a href="#">NCT03927157</a> Partnered (AMGEN)	Severe asthma; age 18 to 80 years	405	<ul style="list-style-type: none"><li>Arm 1: Tezspire s.c.</li><li>Arm 2: placebo s.c.</li><li>52-week trial</li><li>Regional trial (Asia) – 3 countries</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: annual asthma exacerbation rate</li><li>Secondary endpoints: change from baseline in pre-BD FEV1, asthma related QoL (AQLQ(S)+12) and asthma control (ACQ-6)</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2019</li><li>LPCD: Q2 2023</li><li>Data readout: Q3 2024</li><li>Primary endpoint met</li></ul>
Phase III NAVIGATOR <a href="#">NCT03347279</a> Partnered (AMGEN)	Severe asthma; age 12 to 80 years	1061	<ul style="list-style-type: none"><li>Arm 1: Tezspire s.c.</li><li>Arm 2: placebo s.c.</li><li>52-week trial</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: annual asthma exacerbation rate</li><li>Secondary endpoints: change from baseline in pre-BD FEV1, asthma related QoL (AQLQ(S)+12) and asthma control (ACQ-6)</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2018</li><li>LPCD: Q3 2019</li><li>Data readout: Q4 2020</li><li>Primary endpoint met</li></ul>



# tozorakimab (IL-33 ligand mAb)

## COPD

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III OBERON <a href="#">NCT05166889</a></b>	Adults with symptomatic COPD with a history of exacerbations	1132	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled, parallel-group</li> <li>Treatment: 52-week</li> <li>Arm 1: tozorakimab dose 1 s.c. + SoC</li> <li>Arm 2: tozorakimab dose 2 s.c. + SoC</li> <li>Arm 3: placebo s.c. + SoC</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: annualised rate of moderate to severe COPD exacerbations (former smokers)</li> <li>Secondary endpoints: annualised rate of moderate to severe COPD exacerbations (former or current smokers), annualised rate of COPD exacerbations requiring hospitalisation and/or ER/ED visits and change in pre/post-BD FEV1, E-RS:COPD and SGRQ</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2022</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase III TITANIA <a href="#">NCT05158387</a></b>	Adults with symptomatic COPD with a history of exacerbations	1174	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled, parallel-group</li> <li>Treatment: 52-week</li> <li>Arm 1: tozorakimab dose 1 s.c. + SoC</li> <li>Arm 2: tozorakimab dose 2 s.c. + SoC</li> <li>Arm 3: placebo s.c. + SoC</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: annualised rate of moderate to severe COPD exacerbations (former smokers)</li> <li>Secondary endpoints: annualised rate of moderate to severe COPD exacerbations (former or current smokers), annualized COPD exacerbations requiring hospitalisation and/or Emergency Room/Emergency Department and change in pre/post-BD FEV1, E-RS:COPD and SGRQ</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2022</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase III MIRANDA <a href="#">NCT06040086</a></b>	Adults with symptomatic COPD with a history of exacerbations	1454	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled, parallel group</li> <li>Arm 1: tozorakimab dose s.c. + SoC</li> <li>Arm 2: placebo s.c. + SoC</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: annualised rate of moderate to severe COPD exacerbations (former smokers)</li> <li>Secondary endpoints: annualised rate of moderate to severe COPD exacerbations (former or current smokers), annualised rate of severe COPD exacerbations (former and former or current smokers), COPD exacerbations requiring hospitalisation and/or Emergency Room (ER)/ Emergency Department (ED) visits and change in pre/post-BD FEV1, E-RS:COPD and SGRQ</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>Data anticipated: H1 2026</li> </ul>

Oncology

CVRM

R&I

V&I

Rare Disease



# tozorakimab (IL-33 ligand mAb)

## COPD

Trial	Population	Patients	Design	Endpoints	Status
Phase III PROSPERO <a href="#">NCT05742802</a>	Subjects who completed either OBERON or TITANIA will be offered the opportunity to consent (adults with symptomatic COPD with a history of exacerbations)	1713	<ul style="list-style-type: none"><li>Randomised, double-blind, placebo-controlled, parallel-group, long-term extension trial</li><li>Treatment: 52-weeks</li><li>Arm 1: tozorakimab dose 1 s.c. + SoC</li><li>Arm 2: tozorakimab dose 2 s.c. + SoC</li><li>Arm 3: placebo s.c. + SoC</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: annualised rate of severe COPD exacerbation in primary population of former smokers over the treatment period incorporating both the predecessor studies and PROSPERO</li><li>Secondary endpoint: annualised rate of severe COPD exacerbation in the overall population of current and former smokers, time to first severe COPD exacerbation in former smokers, annualised rate of COPD exacerbations requiring hospitalisation and/or ER/ED visits in former smokers.</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2023</li><li>Data anticipated: H1 2026</li></ul>



# tozorakimab (IL-33 ligand mAb)

## Severe viral LRTD, asthma

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III TILIA</b> <a href="#">NCT05624450</a>	Adults hospitalised for viral lung infection requiring supplemental oxygen	2870	<ul style="list-style-type: none"><li>Randomised, double-blind, placebo-controlled, parallel group</li><li>Arm 1: tozorakimab dose i.v. + SoC</li><li>Arm 2: placebo i.v. + SoC</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: progression to death or to invasive mechanical ventilation/extracorporeal membrane oxygenation</li><li>Secondary endpoints: safety and other efficacy measures</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2022</li><li>Data anticipated: H2 2026</li></ul>
<b>Phase II UMBRIEL</b> <a href="#">NCT06932263</a>	Adult participants with uncontrolled asthma on medium-to-high dose inhaled corticosteroids	540	<ul style="list-style-type: none"><li>Multi-centre, double-blind, placebo-controlled dose range finding</li><li>Arm 1: tozorakimab dose 1 s.c.</li><li>Arm 2: tozorakimab dose 2 s.c.</li><li>Arm 3: placebo s.c.</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: annualised rate of severe asthma exacerbations</li><li>Secondary endpoints: annualised rate of severe asthma exacerbations, time-to-first severe asthma exacerbation; pre and post BD FEV1, change in baseline ACQ- 6 and AQLQ(S), safety and other efficacy measures</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2025</li><li>Data anticipated: 2027</li><li>Enrolling</li></ul>

Oncology

CVRM

R&I

V&I

Rare Disease



# Next-generation propellant pMDI

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

V&I

Rare Disease

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b><u>NCT05755932</u></b>	Mucociliary clearance in healthy volunteers	30	<ul style="list-style-type: none"> <li>Randomised, double-blind, multi-site, two-way crossover trial with propellant only</li> <li>Arm 1: NGP pMDI; 6 inhalations BID for 7 days</li> <li>Arm 2: HFA pMDI; 6 inhalations BID for 7 days</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: change from baseline in MCC through 60 minutes following inhalation of 99m technetium sulfur colloid and gamma camera imaging</li> <li>Secondary endpoint: change from baseline in MCC at 3 hours following inhalation of 99m technetium sulfur colloid and gamma camera imaging</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2023</li> <li>Data readout: Q4 2024</li> </ul>
<b>Phase III</b> <b><u>NCT05850494</u></b>	Well-controlled or partially-controlled asthma	52	<ul style="list-style-type: none"> <li>Randomised, multi-centre double-blind, single-dose crossover trial</li> <li>Arm 1: NGP propellant only pMDI; 4 inhalations per dose</li> <li>Arm 2: HFA propellant only pMDI; 4 inhalations per dose</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: change from baseline FEV1 0 to 15 minutes post-dose, cumulative incidence of bronchospasm events and safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2023</li> <li>Data readout: Q1 2024</li> <li>Primary endpoint met</li> </ul>
<b>Phase III</b> <b><u>NCT06075095</u></b>	COPD	300	<ul style="list-style-type: none"> <li>Randomised, placebo-controlled, double-blind, multi-centre, 4-week, 3-way crossover pharmacodynamic trial to assess the equivalence of <i>Breztri</i> delivered by pMDI NGP vs. with <i>Breztri</i> delivered by MDI HFA</li> <li>Arm 1: <i>Breztri</i> pMDI NGP 320/14.4/9.6µg</li> <li>Arm 2: <i>Breztri</i> pMDI HFA 320/14.4/9.6µg</li> <li>Placebo: MDI HFA</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: changes in FEV1 AUC (0-4) and change in morning pre-dose trough FEV1</li> <li>Secondary endpoints: safety and efficacy</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2024</li> <li>Data readout: Q3 2025</li> <li>Primary endpoint met</li> </ul>
<b>Phase III</b> <b><u>NCT06502366</u></b>	Asthma	398	<ul style="list-style-type: none"> <li>Randomised, placebo-controlled, double-blind, multi-centre, 12-week, 3-way, partial-replicate crossover trial</li> <li>BDA MDI NGP 160/180µg</li> <li>BDA MDI HFA 160/180µg</li> <li>Placebo: MDI HFA</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: change from baseline in peak FEV1 in 0-60 minutes after dosing at Day 29</li> <li>Secondary endpoint: change from baseline in morning pre-dose trough FEV1</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase III</b> <b><u>NCT05573464</u></b>	Moderate to very severe COPD	542	<ul style="list-style-type: none"> <li>Randomised, double-blind, 12-week (with an extension to 52 weeks in a subset of participants), parallel-group, multi-centre trial</li> <li>Arm 1: <i>Breztri</i> MDI NGP 160/7.2/4.8µg (2 inhalations BID)</li> <li>Arm 2: <i>Breztri</i> MDI HFA 160/7.2/4.8µg (2 inhalations BID)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: number of participants with AEs/SAEs and potentially clinically significant changes in Digital 12-lead Holter ECG, laboratory values, blood pressure, pulse rate, respiratory rate and body temperature</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2022</li> <li>Data readout: Q4 2024</li> </ul>



# Next-generation propellant pMDI

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT05569421</a>	Healthy volunteers	108	<ul style="list-style-type: none"><li>Randomised, double-blind, single-dose, single-centre, partial-replicate, 3-way crossover trial</li><li>Arm 1: <i>Breztri</i> pMDI NGP 160/7.2/4.8µg (single dose of 4 inhalations)</li><li>Arm 2: <i>Breztri</i> pMDI HFA 160/7.2/4.8µg (single dose of 4 inhalations)</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: AUCinf, AUClast and Cmax</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2022</li><li>LPCD: Q2 2023</li><li>Data readout: Q1 2024</li><li>Primary endpoint met</li></ul>
Phase I <a href="#">NCT06139991</a>	Healthy volunteers	66	<ul style="list-style-type: none"><li>Randomised, double-blind, single-dose, crossover trial to assess the equivalence of <i>Airsupra</i> delivered by pMDI NGP vs. with <i>Airsupra</i> delivered by pMDI HFA</li><li>Arm 1: <i>Airsupra</i> pMDI NGP 80/90µg (single dose of 2 inhalations)</li><li>Arm B: <i>Airsupra</i> pMDI HFA 80/90µg (single dose of 2 inhalations)</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: AUClast and Cmax</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2023</li><li>LPCD: Q2 2024</li><li>Data readout: Q4 2024</li></ul>
Phase I <a href="#">NCT06297668</a>	Healthy volunteers	42	<ul style="list-style-type: none"><li>Randomised, partial double-blind, single dose, three-way crossover trial</li><li>Arm 1: BGF MDI HFA 160/7.2/4.8µg with spacer</li><li>Arm 2: BGF MDI NGP 160/7.2/4.8µg with spacer</li><li>Arm 3: BGF MDI NGP 160/7.2/4.8µg without spacer</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: AUClast of BGF MDI and Cmax of BGF MDI</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2024</li><li>LPCD: Q2 2024</li><li>Data readout: Q4 2024</li><li>Primary endpoint met</li></ul>
Phase I <a href="#">NCT06723756</a>	Healthy volunteers	105	<ul style="list-style-type: none"><li>Randomised, double-blind, single-dose, single-centre, 3-way crossover trial</li><li>Arm 1: <i>Breztri</i> pMDI NGP 160/14.4/4.8µg (single dose of 2 inhalations)</li><li>Arm 2: <i>Breztri</i> pMDI HFA 160/14.4/4.8µg (single dose of 2 inhalations)</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: AUClast and Cmax</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2025</li><li>Data readout: Q3 2025</li><li>Primary endpoint met</li></ul>
Phase I <a href="#">NCT05477108</a>	Healthy volunteers	108	<ul style="list-style-type: none"><li>Randomised, double-blind, single-dose, single-centre, partial-replicate, 3-way crossover trial</li><li>Arm 1: <i>Breztri</i> pMDI NGP 160/7.2/4.8µg (single dose of 4 inhalations)</li><li>Arm 2: <i>Breztri</i> pMDI HFA 160/7.2/4.8µg (single dose of 4 inhalations)</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: AUCinf, AUClast and Cmax</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2022</li><li>LPCD: Q1 2023</li><li>Data readout: Q4 2023</li><li>Primary endpoint met</li></ul>



# Beyfortus (nirsevimab, RSV mAb-YTE)

## Infection

Trial	Population	Patients	Design	Endpoints	Status
Phase III CHIMES <a href="#">NCT05110261</a>	Healthy infants (born 29 weeks 0 days or greater gestational age)	800	<ul style="list-style-type: none"><li>Randomised, double-blind, placebo-controlled</li><li>Arm 1: <i>Beyfortus</i> i.m.</li><li>Arm 2: placebo i.m.</li><li>China only</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: efficacy</li><li>Secondary endpoints: safety, PK parameters and ADA</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2021</li><li>LPCD: Q4 2024</li><li>Data anticipated: H1 2026</li></ul>



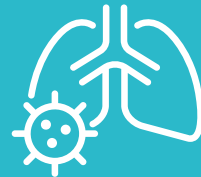
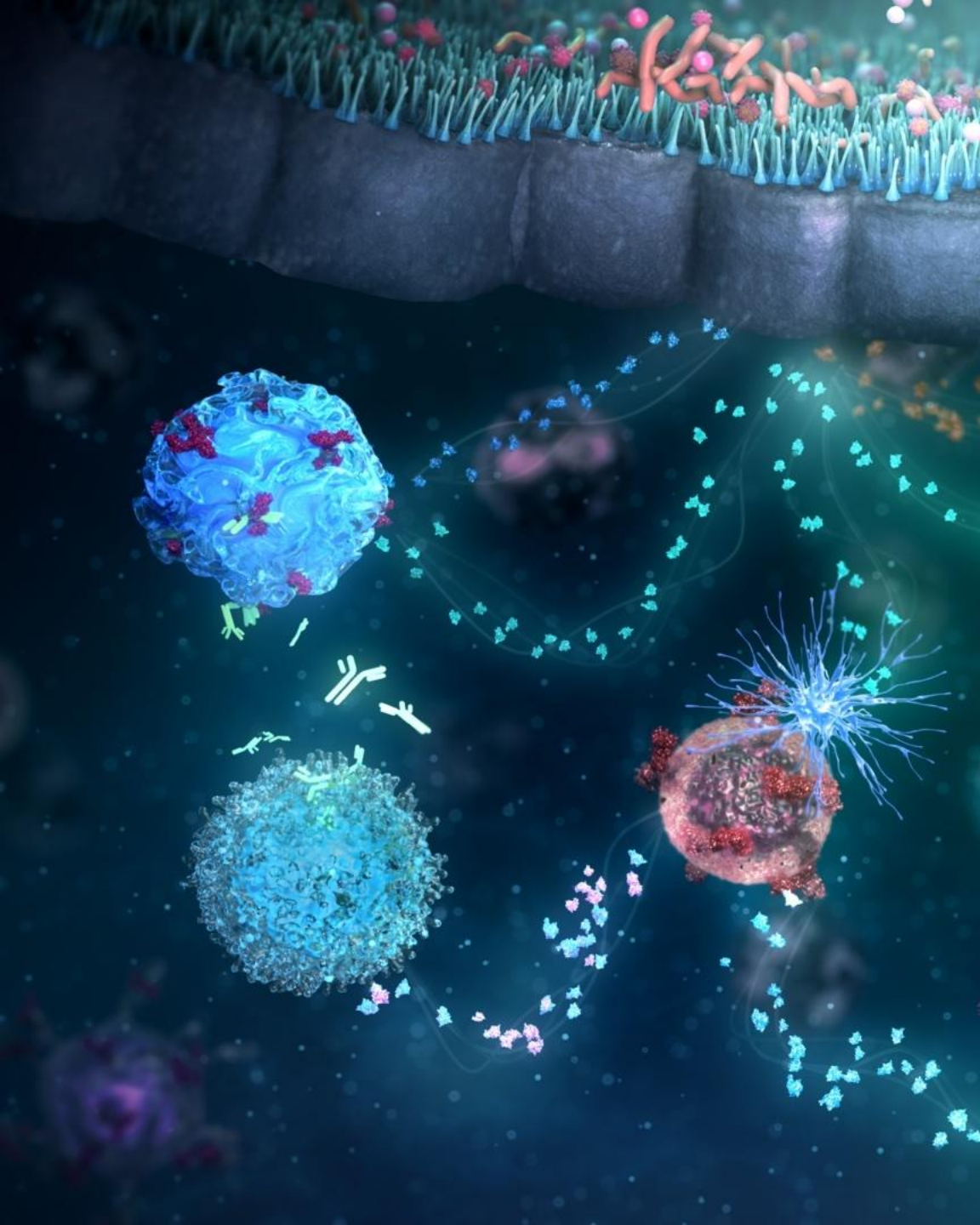
# Kavigale (sipavibart, SARS-CoV-2 LAAB)

## COVID-19

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>SUPERNOVA</b> <b><a href="#">NCT05648110</a></b>	Phase I: healthy adults; age 18 to 55 years Phase II: immuocompetent or immunoimpaired adults Phase III: 12 years of age or older with conditions causing immune impairment	3200	<ul style="list-style-type: none"> <li>2 parts (Phase I: sentinel safety cohort and Phase III: main cohort)</li> <li>Phase I (sentinel safety cohort): 56 healthy adults, age 18 to 55 years, randomised in a 5:2 ratio to receive AZD5156 or placebo</li> <li>Phase III (main cohort): randomised 1:1 to receive AZD3152 300mg or comparator (600mg <i>Evusheld</i> or placebo) administered i.m. in the anterolateral thigh on Day 1; participants will receive a second dose of their original randomised trial intervention 6 months after Visit 1</li> <li>Phase II (sub-study, open-label): participants randomised 2:1 to receive 1200mg i.v. AZD3152 or 300mg i.m. <i>Evusheld</i></li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints (Phase III main cohort): to evaluate the safety of AZD3152 and Evusheld and/or placebo and to compare the efficacy of AZD3152 to Evusheld and/or placebo in the prevention of symptomatic COVID-19</li> <li>Primary endpoints (Phase II sub-study): to evaluate the safety of AZD3152 and Evushled; to compare the nAb responses to the SARS-CoV-2 to a current variant of concern following AZD3152 administration vs. SARS-CoV-2 nAb responses to prior variants following Evusheld administration, to characterise the PK of AZD3152 and Evusheld in serum and to evaluate the ADA responses to AZD3152 and AZD7442 in serum</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2022</li> <li>LPCD: Q4 2023</li> <li>Data readout: Q2 2024</li> <li>Primary Endpoint met</li> </ul>
<b>Phase I</b> <b>LITTLE DIPPER</b> <b><a href="#">NCT05872958</a></b>	Healthy adult participants; age 18 to 55 years	96	<ul style="list-style-type: none"> <li>Phase I, double-blind, placebo-controlled, multi-centre, dose exploration trial</li> <li>to evaluate the safety and PK of AZD3152 in healthy adult participants across different dose levels and routes of administration</li> <li>participants randomised in a 10:2 ratio to receive either AZD3152 or placebo administered i.m. or i.v. across 5 fixed-dose cohorts</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: to evaluate the safety of i.m. or i.v. administration of AZD315 and to characterise the PK of AZD3152 in serum after a single i.m. or i.v. dose</li> <li>Secondary endpoint: to evaluate ADA responses to AZD3152</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2023</li> <li>LPCD: Q3 2023</li> <li>Data readout: Q4 2023</li> <li>Primary endpoint met</li> </ul>







# BioPharmaceuticals: early-stage development

# elecglipton (AZD5004, oral GLP-1 RA)

## Type 2 diabetes, obesity

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase IIb</b> <b>SOLSTICE</b> <a href="#">NCT06579105</a>	Type 2 diabetes	406	<ul style="list-style-type: none"> <li>Arm 1: AZD5004 tablet</li> <li>Arm 2: AZD5004 tablet</li> <li>Arm 3: AZD5004 tablet</li> <li>Arm 4: AZD5004 tablet</li> <li>Arm 5: AZD5004 tablet</li> <li>Arm 6: AZD5004 tablet</li> <li>Arm 7: active comparator semaglutide tablet</li> <li>Arm 8: placebo matching AZD5004 tablet</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: change in HbA1c from baseline at 26 weeks</li> <li>Secondary endpoints: change in fasting glucose from baseline, proportion of participants achieving HbA1c ≤6.5% and baseline HbA1c ≥7% and achieving &lt;7.0% and percent change in body weight from baseline</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>LPCD: Q2 2025</li> <li>Data readout: Q1 2026</li> <li>Primary endpoint met</li> </ul>
<b>Phase IIb</b> <b>VISTA</b> <a href="#">NCT06579092</a>	Obesity or overweight who have at least one weight-related comorbidity	310	<ul style="list-style-type: none"> <li>Arm 1: AZD5004 tablet</li> <li>Arm 2: AZD5004 tablet</li> <li>Arm 3: AZD5004 tablet</li> <li>Arm 4: AZD5004 tablet</li> <li>Arm 5: AZD5004 tablet</li> <li>Arm 6: placebo matching AZD5004 tablet</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: change in body weight from baseline at 26 weeks, proportion of participants with weight loss ≥5% from baseline weight at 26 weeks</li> <li>Secondary endpoints: change in body weight from baseline at 36 weeks, proportion of participants with weight loss ≥5% and absolute change from baseline in body weight at 26 and 36 weeks</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>LPCD: Q1 2025</li> <li>Data readout: Q1 2026</li> <li>Primary endpoints met</li> </ul>
<b>Phase I</b> <a href="#">NCT06555822</a>	Healthy volunteers	31	<ul style="list-style-type: none"> <li>Part A – Arm 1: AZD5004 oral tablet</li> <li>Part A – Arm 2: placebo oral tablet</li> <li>Part B: single dose, open label crossover</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints (Part A): safety and tolerability</li> <li>Secondary endpoints (Part A): PK and PD parameters</li> <li>Primary endpoint (Part B): PK parameters</li> <li>Secondary endpoints (Part B): safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>LPCD: Q1 2025</li> <li>Data readout: Q2 2025</li> </ul>
<b>Phase I</b> <a href="#">NCT06703658</a>	Healthy volunteers or participants with type 2 diabetes mellitus	35	<ul style="list-style-type: none"> <li>SAD: 3 cohorts to receive AZD5004 or placebo tablet</li> <li>MAD: 1 cohort to receive AZD5004 or placebo tablet</li> <li>Japan only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> <li>Secondary endpoints: PK and PD parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>LPCD: Q1 2025</li> <li>Data readout: Q3 2025</li> </ul>



# elecglipton (AZD5004, oral GLP-1 RA)

## Type 2 diabetes, obesity

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase I</b> <b><u>NCT06742762</u></b>	Healthy volunteers or participants with renal impairment	16	<ul style="list-style-type: none"> <li>Multi-centre, single-dose, non-randomised, open-label, parallel-group trial, Single oral dose of AZD5004</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PK parameters</li> <li>Secondary endpoints: safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>LPCD: Q2 2025</li> <li>Data readout: Q3 2025</li> </ul>
<b>Phase I</b> <b><u>NCT06813781</u></b>	Healthy volunteers or participants with hepatic impairment	33	<ul style="list-style-type: none"> <li>Multi-centre, single-dose, non-randomised, open-label, parallel-group trial, Single oral dose of AZD5004</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PK parameters</li> <li>Secondary endpoints: safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>LPCD: Q3 2025</li> <li>Data readout: Q1 2026</li> </ul>
<b>Phase I</b> <b><u>NCT06857695</u></b>	Healthy volunteers	8	<ul style="list-style-type: none"> <li>Part 1: A single dose of AZD5004 film-coated tablet and a single dose of AZD5004 solution for infusion</li> <li>Part 2: A single dose of AZD5004 oral solution</li> </ul>	<ul style="list-style-type: none"> <li>Part 1: absolute bioavailability</li> <li>Part 2: amount of AZD5004 excreted</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>LPCD: Q1 2025</li> <li>Data readout: Q3 2025</li> </ul>
<b>Phase I</b> <b><u>NCT06988553</u></b> <b>Partnered (Eccogene)</b>	Participants with overweight/obesity with/without T2D	45	<ul style="list-style-type: none"> <li>Randomized, parallel group, double-blind trial</li> <li>AZD5004 or placebo tablet</li> <li>China only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>LPCD: Q3 2025</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase I</b> <b><u>NCT06996886</u></b>	Healthy volunteers	16	<ul style="list-style-type: none"> <li>Open-label, randomized, 4-period, 4-treatment, single-dose crossover trial</li> <li>Different formulations as single dose of AZD5004</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PK profile (relative bioavailability)</li> <li>Secondary endpoints: PK profile (food effect)</li> <li>Safety endpoints: safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>LPCD: Q2 2025</li> <li>Data readout: Q4 2025</li> </ul>
<b>Phase I</b> <b><u>NCT06948747</u></b>	Healthy volunteers	49	<ul style="list-style-type: none"> <li>Open-label, fixed-sequence, single-centre trial</li> <li>Part A: AZD5004, Rosuvastatin and Erythromycin tablets</li> <li>Part B: AZD5004, Atorvastatin and Simvastatin tablets</li> <li>Part C: AZD5004 and Repaglinide tablets</li> </ul>	<ul style="list-style-type: none"> <li>Part A, B and C:</li> <li>Primary endpoints: PK profile</li> <li>Safety endpoints: safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>LPCD: Q3 2025</li> <li>Data readout: Q4 2025</li> </ul>
<b>Phase I</b> <b><u>NCT06942936</u></b>	Healthy volunteers	51	<ul style="list-style-type: none"> <li>Open-label, fixed-sequence, two-part study</li> <li>Part A: AZD5004 tablet and Itraconazole capsule</li> <li>Part B: AZD5004 and estradiol/ levonorgestrel tablets</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PK profile</li> <li>Safety endpoints: safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>LPCD: Q4 2025</li> <li>Data anticipated: H1 2026</li> </ul>



# opemalirsen (AZD2373, APOL1)

## Chronic kidney disease

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase IIb</b> <b>APPRECIATE</b> <b><u>NCT06824987</u></b> Partnered with Ionis Pharmaceuticals Inc	Participants diagnosed with APOL1 mediated kidney disease (AMKD), proteinuria, 18-65 years of age	96	<ul style="list-style-type: none"><li>Randomised, multi-centre, double-blind trial in US and UK followed by OLE</li><li>Arm 1: opemalirsen dose A</li><li>Arm 2: opemalirsen dose B</li><li>Arm 3: placebo</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: Dose-response effect of AZD2373 on placebo corrected percentage change in uACR from baseline to Week 30</li><li>Secondary endpoints: Safety and tolerability, proportion of patients achieving a 45% or greater reduction in uACR</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2025</li><li>Data anticipated: 2027</li></ul>
<b>Phase I</b> <b><u>NCT07154901</u></b> Partnered with Ionis Pharmaceuticals Inc	Healthy participants/renal impairment	50	<ul style="list-style-type: none"><li>Multicentre, single-dose, non-randomised, open-label, parallel-group</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: PK measures</li><li>Secondary endpoints: PK/PD, safety measures</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2025</li><li>Data anticipated: H2 2026</li></ul>



# AZD0233 (oral CX3CR1)

## Dilated cardiomyopathy

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT06381466</a>	Healthy volunteers	96	<ul style="list-style-type: none"><li>Randomised, SAD/MAD dose escalating trial</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: safety and tolerability</li><li>Secondary endpoints: PK parameters</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2024</li><li>Trial discontinued due to strategic portfolio prioritisation</li></ul>



# AZD1613 (PAPPA-1 mAb)

## ADPKD

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT06995820</a>	Healthy volunteers	136	<ul style="list-style-type: none"><li>Randomised, single-blind, placebo-controlled single and multiple ascending dose</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: safety and tolerability</li><li>Secondary endpoints: PK parameters, changes in plasma PD biomarkers</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2025</li><li>Data anticipated: H2 2026</li></ul>
Phase I <a href="#">NCT07228364</a>	ADPKD Patients	40	<ul style="list-style-type: none"><li>Single-blind, placebo-controlled, randomised</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: Safety, PK, PD biomarkers of PAPPA-1 inhibition</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2026</li><li>Data anticipated: 2027</li></ul>



# AZD1705 (Angptl3 inhibitor)

## Dyslipidaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT06238466</a>	Dyslipidaemia	112	<ul style="list-style-type: none"><li>Part A: single dose of AZD1705 with an in-clinic period of 3 days followed by an outpatient follow-up period of approximately 16 weeks</li><li>Part B: 2 doses of AZD1705 given 28 days apart with an in-clinic period followed by an outpatient follow-up period of approximately 20 weeks</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: AEs and SAEs</li><li>Secondary endpoints: AUCinf, AUClast, Cmax, Ae, fe, CLR, LDL-C, ApoB, triglycerides and target plasma protein</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2024</li><li>LPCD: Q2 2025</li><li>Data anticipated: H1 2026</li></ul>



# AZD2389 (anti-fibrotic mechanism)

## MASH

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase II</b> <b>BORANA</b> <b><u>NCT06750276</u></b>	Participants with liver fibrosis and compensated cirrhosis	40	<ul style="list-style-type: none"> <li>Randomised, single-blind, placebo-controlled trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>LPCD: Q3 2025</li> <li>Data readout: Q4 2025</li> </ul>
<b>Phase I</b> <b><u>NCT06138795</u></b>	Healthy volunteers	128	<ul style="list-style-type: none"> <li>Randomised, placebo-controlled SAD/MAD trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>LPCD: Q2 2025</li> <li>Data readout: Q4 2025</li> </ul>
<b>Phase I</b> <b><u>NCT06812780</u></b> -	Healthy volunteers or participants with hepatic impairment	36	<ul style="list-style-type: none"> <li>Multi-centre, single-dose, non-randomised, open-label, parallel-group trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PK parameters</li> <li>Secondary endpoints: safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>LPCD: Q3 2025</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase I</b> <b><u>NCT06846528</u></b>	Healthy volunteers	16	<ul style="list-style-type: none"> <li>Open-label, fixed-sequence trial</li> <li>AZD2389</li> <li>AZD2389 + itraconazole</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PK parameters, safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>LPCD: Q2 2025</li> <li>Data readout: Q3 2025</li> </ul>
<b>Phase I</b> <b><u>NCT06974565</u></b>	Healthy Volunteers	24	<ul style="list-style-type: none"> <li>Open-label, randomised, single dose, 2-way crossover</li> </ul>	<ul style="list-style-type: none"> <li>Pharmacokinetics, safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>LPCD: Q3 2025</li> <li>Data readout: Q4 2025</li> </ul>
<b>Phase I</b> <b><u>NCT06973005</u></b>	Healthy Volunteers	8	<ul style="list-style-type: none"> <li>Open label, fixed sequence, 3 period</li> </ul>	<ul style="list-style-type: none"> <li>Pharmacokinetics, safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>LPCD: Q3 2025</li> <li>Data readout: Q4 2025</li> </ul>

Oncology

CVRM

R&I

V&I

Rare Disease





# AZD3427 (relaxin)

## Heart failure

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase II</b> <b>Re-PHiRE</b> <b><u>NCT05737940</u></b>	HF and pulmonary hypertension due to left heart disease	260	<ul style="list-style-type: none"><li>Randomised, double-blind, placebo-controlled, multi-centre trial</li><li>Arm 1: AZD3427 (high dose)</li><li>Arm 2: AZD3427 (medium dose)</li><li>Arm 3: AZD3427 (low dose)</li><li>Arm 4: placebo</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: change in PVR from baseline to Week 25 vs. placebo as measured by right heart catheterisation</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2023</li><li>LPCD: Q1 2025</li><li>Data readout: Q4 2025</li><li>Trial discontinued due to efficacy</li></ul>
<b>Phase Ib</b> <b>RE-PERFUSE</b> <b><u>NCT06611423</u></b>	HFrEF patients with mild renal impairment	10	<ul style="list-style-type: none"><li>Eligible participants randomised equally</li><li>Arm 1: i.v. saline placebo followed by s.c. AZD3427</li><li>Arm 2: i.v. saline placebo followed by s.c. AZD3427 placebo</li><li>Arm 3: i.v. dopamine diluted in saline followed by s.c. AZD3427</li><li>Arm 4: i.v. dopamine diluted in saline followed by s.c. AZD3427 placebo</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: volumetric fraction of the renal cortex with increased perfusion from baseline to Day 8 compared to placebo as measured using PET</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2024</li><li>LPCD: Q3 2025</li><li>Data readout: Q4 2025</li></ul>



# AZD3974 (anti-inflammatory and anti-fibrotic mechanism) cirrhosis

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT07290283</a>	Healthy Volunteers	176	<ul style="list-style-type: none"><li>Single-blind, placebo-controlled, randomised</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: Safety/tolerability, PK</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2026</li><li>Data anticipated: H2 2026</li></ul>



# AZD4063 (PLN siRNA)

## Dilated cardiomyopathy

Trial	Population	Patients	Design	Endpoints	Status
Phase I PULSE <a href="#">NCT07241104</a> Partnered with Ionis Pharmaceuticals Inc (Ionis Pharmaceuticals Inc )	R14del dilated cardiomyopathy	31	<ul style="list-style-type: none"><li>Unblinded, SAD/MAD with 3 cohorts</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: Safety and tolerability measures</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2025</li><li>Data anticipated: 2027</li></ul>



# AZD4144 (NLRP3)

## Cardiorenal disease

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

V&I

Rare Disease

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase I</b> <b><u>NCT06122714</u></b>	Healthy participants	95	<ul style="list-style-type: none"> <li>Randomised, single-blind, placebo-controlled, SAD/MAD sequential group trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> <li>Secondary endpoints: PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>LPCD: Q4 2024</li> <li>Data readout: Q1 2025</li> </ul>
<b>Phase I</b> <b><u>NCT06491550</u></b>	Healthy participants	92	<ul style="list-style-type: none"> <li>Randomised, single-blind, placebo-controlled, SAD/MAD sequential group trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> <li>Secondary endpoints: PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>LPCD: Q2 2025</li> <li>Data readout: Q3 2025</li> </ul>
<b>Phase I</b> <b><u>NCT06693765</u></b>	Participants with renal impairment, end-stage kidney disease and healthy volunteers	41	<ul style="list-style-type: none"> <li>Single-dose, non-randomised, open-label, parallel-group trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety, tolerability and PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>LPCD: Q2 2025</li> <li>Data readout: Q4 2025</li> </ul>
<b>Phase I</b> <b><u>NCT06675175</u></b>	Participants with established ASCVD	28	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled, parallel group trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety, tolerability and PD parameters</li> <li>Secondary endpoints: PK and PD parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase I</b> <b><u>NCT06948006</u></b>	Healthy participants	32	<ul style="list-style-type: none"> <li>Open-label, randomized, single-dose, crossover trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PK and safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>LPCD: Q2 2025</li> <li>Data readout: Q3 2025</li> </ul>
<b>Phase I</b> <b><u>NCT06925854</u></b>	Healthy participants	12	<ul style="list-style-type: none"> <li>Open-label, 2-period, 2-sequence cross over trial</li> <li>Treatment A: single dose of rosuvastatin</li> <li>Treatment B: single dose of rosuvastatin in combination with AZD4144</li> <li>Participants will be randomized 1:1 ratio to receive treatment sequence AB or BA.</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PK and safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>LPCD: Q2 2025</li> <li>Data readout: Q3 2025</li> </ul>
<b>Phase I</b> <b><u>NCT06942923</u></b>	Healthy participants with obesity	28	<ul style="list-style-type: none"> <li>Placebo-controlled, parallel group study</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety, tolerability and PD parameters</li> <li>Secondary endpoints: PK and PD parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>Data anticipated: H1 2026</li> </ul>



# AZD4248 (NNMT)

## CKD

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT07024823</a>	Healthy volunteers	164	<ul style="list-style-type: none"><li>Randomised, single-blind, placebo-controlled</li><li>Part A: SAD in healthy volunteers</li><li>Part B: MAD in healthy volunteers</li><li>Part C: multiple dosing DKD</li><li>Part D: observational cohort</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: Safety and tolerability measures</li><li>Secondary endpoints: PK parameters</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2025</li><li>Data anticipated: H1 2026</li></ul>



# AZD4954 (Lp(a) inhibitor)

## Dyslipidaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT06980428</a>	Healthy volunteers	120	<ul style="list-style-type: none"><li>Randomised, placebo-controlled SAD/MAD trial</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: safety and tolerability</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2025</li><li>Data anticipated: H2 2026</li></ul>



# AZD5462 (oral relaxin)

## Heart failure

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase IIb</b> <b>LUMINARA</b> <a href="#">NCT06299826</a>	Stable patients with chronic heart failure	375	<ul style="list-style-type: none"> <li>Two cohort, randomised, double-blind, placebo-controlled, multi-centre trial</li> <li>Arm 1: AZD5462 (high dose)</li> <li>Arm 2: AZD5462 (medium dose)</li> <li>Arm 3: AZD5462 (low dose)</li> <li>Arm 4: placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: change in heart function from baseline to Week 25 compared to placebo</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>LPCD: Q3 2025</li> <li>Data anticipated: H2 2026</li> </ul>
<b>Phase Ib</b> <b>AURORA</b> <a href="#">NCT06639087</a>	Stable patients with heart failure and moderately impaired renal function	8	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled, multi-centre mechanistic trial</li> <li>Arm 1: AZD5462 + dapagliflozin</li> <li>Arm 2: placebo + dapagliflozin</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: change in fractional excretion of sodium from baseline to Day 1</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>LPCD: Q2 2025</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase I</b> <b>GLITTER</b> <a href="#">NCT06661733</a>	Participants with Severe Renal Impairment and participants Normal Renal Function	16	<ul style="list-style-type: none"> <li>Single centre, non-randomised, open-label, parallel group trial</li> <li>Cohort 1: AZD5462</li> <li>Cohort 2: AZD5462</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PK parameters, safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>LPCD: Q4 2024</li> <li>Data readout: Q3 2025</li> </ul>
<b>Phase I</b> <b>PHOTON</b> <a href="#">NCT06989983</a>	Healthy volunteers	8	<ul style="list-style-type: none"> <li>Open-label, two-part sequential human ADME trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: mass balance recovery, absorption, metabolism, excretion of [14C]AZD5462 and absolute bioavailability of AZD5462</li> <li>Secondary endpoints: safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>LPCD: Q2 2025</li> <li>Data anticipated: H1 2026</li> </ul>

Oncology

CVRM

R&I

V&I

Rare Disease



# AZD6234 (selective amylin receptor agonist)

## Obesity with related co-morbidities

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase II</b> <b>APRICUS</b> <a href="#">NCT06595238</a>	Participants living with obesity or overweight with co-morbidity	231	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: percent change in body weight from baseline to Week 26 and weight loss <math>\geq 5\%</math> from baseline weight to Week 26</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase II</b> <b>ARAY</b> <a href="#">NCT06851858</a>	adults with overweight or obesity and type 2 diabetes on stable GLP-1 RA therapy	64	<ul style="list-style-type: none"> <li>Randomised, parallel-group, double-blind, placebo-controlled trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: Percent change in body weight from baseline at Study Week 2; Weight loss <math>\geq 5\%</math> from baseline at Study Week 26</li> <li>Secondary endpoints: Weight loss, HbA1c, PK measures</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>Data anticipated: H2 2026</li> </ul>
<b>Phase I/II</b> <b>AGLOW</b> <a href="#">NCT07017179</a>	Chinese participants with obesity/overweight	48	<ul style="list-style-type: none"> <li>Sub study 1 - 3 periods totalling up to approximately 23 weeks</li> <li>Sub study 2 - 3 periods totalling up to approximately 36 weeks</li> </ul>	<ul style="list-style-type: none"> <li>Sub study 1 - To assess the safety and tolerability, PK, efficacy and immunogenicity of repeated subcutaneous (s.c.) doses of AZD6234 compared to placebo.</li> <li>Sub study 2 - To assess the safety and tolerability PK, efficacy and immunogenicity of repeated subcutaneous (s.c.) doses of AZD9550 and of AZD6234 in combination with AZD9550 compared to placebo.</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2022</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase I</b> <a href="#">NCT05511025</a>	Healthy participants who are overweight or obese	64	<ul style="list-style-type: none"> <li>SAD trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2022</li> <li>LPCD: Q4 2023</li> <li>Data readout: Q1 2024</li> </ul>
<b>Phase I</b> <a href="#">NCT06132841</a>	Overweight or obese participants	142	<ul style="list-style-type: none"> <li>Randomised, single-blind, placebo-controlled trial with repeated doses of AZD6234 or placebo via s.c. injection</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability of repeat doses</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>Data anticipated: H1 2026</li> </ul>





# AZD6234 (selective amylin receptor agonist)

## Obesity with related co-morbidities

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase I</b> <b><u>NCT06845813</u></b>	Participants include those with end-stage renal disease (ESRD) on intermittent haemodialysis (HD), severe renal impairment not on dialysis, and optional groups for moderate and mild renal impairment.	48	<ul style="list-style-type: none"> <li>Phase I multicentre, single-dose, non-randomised, open-label, parallel-group study aims to examine the pharmacokinetics, safety, and tolerability of AZD6234 in both male and female participants.</li> </ul>	<ul style="list-style-type: none"> <li>compare the plasma PK of a single SC dose of AZD6234 in participants with ESRD on HD, severe renal impairment (not on dialysis), moderate (optional), and mild (optional) renal impairment to those with normal renal function</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>LPCD: Q3 2025</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase I</b> <b><u>NCT07013643</u></b>	Healthy females of childbearing and non-childbearing potential	50	<ul style="list-style-type: none"> <li>Open-label, single-sequence, multiple-cohort study</li> </ul>	<ul style="list-style-type: none"> <li>To assess the effect of multiple doses of AZD6234 (cohort 1) and AZD6234 and AZD9550 in combination (cohort 2) on the PK of single doses of combined oral contraceptive EE/LEVO</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2025</li> <li>Data anticipated: H2 2026</li> </ul>



# AZD9550 (GLP-1-glucagon receptor agonist)

## MASH, Obesity

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase I/II CONTEMPO <a href="#">NCT06151964</a></b>	Overweight and obese participants with T2DM or without T2DM	118	<ul style="list-style-type: none"> <li>Randomised, single-blind, placebo-controlled, MAD trial with 4 parts (A to D)</li> <li>Part A: multiple repeat doses of AZD9550 or placebo given as 4 QW s.c. doses for 4 weeks to 2 sequential cohorts evaluating 2 low dose levels of AZD9550 or placebo</li> <li>Part B: QW up-titration over 5 doses of AZD9550 or placebo</li> <li>Part C: bi-weekly/monthly up-titration of AZD9550 or placebo for 24 weeks</li> <li>Part D: bi-weekly/monthly up-titration of AZD9550 or placebo for 24 weeks (Japan only)</li> <li>Part E: bi-weekly/monthly up-titration of AZD9550 and AZD6234 or placebo for 24 weeks</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety, tolerability and PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase I <a href="#">NCT05848440</a></b>	Healthy volunteers	64	<ul style="list-style-type: none"> <li>SAD trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2023</li> <li>LPCD: Q4 2023</li> <li>Data readout: Q2 2024</li> </ul>



# AZD9550+AZD6234 (GLP-1-glucagon receptor agonist + selective amylin receptor agonist)

## Obesity

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase IIb</b> <b>ASCEND</b> <b><u>NCT06862791</u></b>	Adults who are living with obesity or overweight with at least one of the following weight-related co-morbidities: hypertension, dyslipidemia or obstructive sleep apnoea	360	<ul style="list-style-type: none"> <li>Randomised, parallel-group, double-blind, placebo-controlled, multi-centre, reduced factorial design</li> <li>IMP injected subcutaneous, once weekly</li> <li>Arm 1: AZD9550 low dose + AZD6234 low dose or placebos</li> <li>Arm 2: AZD9550 medium dose + AZD6234 medium dose or placebos</li> <li>Arm 3: AZD9550 high dose + AZD6234 high dose or placebos</li> <li>Arm 4: AZD9550 low dose + AZD6234 medium dose or placebos</li> <li>Arm 5: AZD9550 medium dose + AZD6234 low dose or placebos</li> <li>Arm 6: AZD9550 high dose + AZD6234 medium dose or placebos</li> <li>Arm 7: AZD9550 medium dose + AZD6234 high dose or placebos</li> <li>Arm 8: AZD9550 high dose or placebo</li> <li>Arm 9: AZD6234 high dose or placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: percent change in body weight from baseline after 36 weeks of treatment, weight loss <math>\geq 5\%</math> from baseline after 36 weeks of treatment</li> <li>Secondary endpoints: absolute body weight change, weight loss <math>\geq 5\%/10\%/15\%</math> from baseline, ADA incidence/prevalence/titres</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>Data anticipated: H2 2026</li> </ul>



# atuliflapon (FLAP inhibitor)

## Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase IIa FLASH <a href="#">NCT05251259</a>	Patients with moderate-to-severe uncontrolled asthma	666	<ul style="list-style-type: none"><li>Randomised, placebo-controlled, double-blind, multi-centre trial with a lead-in PK cohort</li><li>Experimental lead-in PK cohort,: Arm 1: atuliflapon; Arm 2: placebo</li><li>Experimental Part 1: Arm 1: atuliflapon; Arm 2: placebo</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: time to first CompEx asthma event</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2022</li><li>Data anticipated: H1 2026</li></ul>



# surovatamig (AZD0486, CD19/CD3 T-cell engager)

## RA, SLE

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT07201558</a>	Adult Participants With Rheumatoid Arthritis or Systemic Lupus Erythematosus	48	<ul style="list-style-type: none"><li>Open-label Multicenter study</li><li>Part 1: SAD</li><li>Part 2: SUD</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: safety and tolerability measures</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2026</li><li>Data anticipated: &gt;2027</li></ul>



# AZD0120 (GC012F, autologous anti-CD19 and anti-BCMA CAR-T)

## autoimmune

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib AURORA <a href="#">NCT07295847</a>	Adult participants with systemic sclerosis (SSc), idiopathic inflammatory myopathies (IIM), or difficult-to-treat rheumatoid arthritis (D2T RA)	27	<ul style="list-style-type: none"><li>Open-label, multi-center, parallel-assignment, multi-cohort study</li></ul>	<ul style="list-style-type: none"><li>Primary: Incidence and severity of DLTs (over 28 days) and TEAS (over the study duration)</li><li>Secondary: Cellular kinetics, DAS28-CRP (RA), mRSS (SSc), TIS (IIM), ADA, RCL</li></ul>	<ul style="list-style-type: none"><li>Data anticipated: &gt;2027</li></ul>



# AZD0120 (GC012F, autologous anti-CD19 and anti-BCMA CAR-T)

## Neurology

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib ZENITH <a href="#">NCT07224373</a>	Adults with refractory active relapsing or progressive multiple sclerosis	24	<ul style="list-style-type: none"><li>Open-label, multi-center, parallel-assignment, randomized study</li></ul>	<ul style="list-style-type: none"><li>Primary: Incidence and severity of DLTs, AEs, SAEs, and TEAEs</li><li>Secondary: B-cell counts, Cellular Kinetics, ARR, CDP-12, CDP-24, CDI, 9HPT, T25FW, EDSS, SDMT, NEDA-3, PIRA, MRI parameters, SF-36v2, Neuro-QoL, RCL, ADA</li></ul>	<ul style="list-style-type: none"><li>Data anticipated: &gt;2027</li></ul>



# AZD0120 (GC012F, autologous anti-CD19 and anti-BCMA CAR-T)

## SLE

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/II PHOENIX <a href="#">NCT06897930</a>	Refractory systemic lupus erythematosus (SLE)	24	<ul style="list-style-type: none"><li>Single-arm, open-label, multi-center trial</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints (Phase I): safety and tolerability, determination of recommended dose for expansion phase</li><li>Secondary endpoints (Phase I): SRI-4, DORIS, LLDAS, BICLA, time from infusion to disease flare, PK parameters, LN-specific responses, disease related biomarker assessments, AZD0120 immunogenicity, RCL presence</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2025</li><li>Data anticipated: &gt;2027</li></ul>
Phase I/II <a href="#">NCT06530849</a>	Refractory systemic lupus erythematosus	21	<ul style="list-style-type: none"><li>Single-arm, open label, multi-centre trial</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint (Phase I): safety at 28 days</li><li>Primary endpoint (Phase II): efficacy (SRI-4 response) at Week 48</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2024</li><li>Data anticipated: 2027</li></ul>





# AZD1163 (anti-PAD2/4 bispecific antibody)

## Rheumatoid arthritis

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase IIb LaunchPAD-RA <a href="#">NCT07276581</a></b>	Moderate -to-severely active RA (≥ 18 years with ≥ 6 swollen joints, ≥ 6 tender joints, and CRP > ULN); Stratified - Population 1 : AZD1163 add-on to TNF SoC (approx. 50%), Population 2 : AZD1163 mono (approx. 50%).	320	<ul style="list-style-type: none"> <li>A 24-week multicentre, double-blind, 4-arm, randomised Ph2b study of AZD1163; 320 participants in total.</li> </ul>	<ul style="list-style-type: none"> <li>Primary: Change from baseline in DAS28-CRP at Week 12; Key Secondary: Percentage of participants achieving ACR20, ACR50, CDAI and SDAI at Week 12.</li> </ul>	<ul style="list-style-type: none"> <li>Data anticipated: 2027</li> </ul>
<b>Phase I <a href="#">NCT06103877</a></b>	Healthy volunteers	107	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled SAD/MAD trial</li> <li>Part 1 (SAD): 9 cohorts with 8 i.v. administered dose levels and 1 s.c. administered dose level of AZD1163</li> <li>Part 2 (MAD): 2 cohorts with 2 s.c. dose levels of AZD1163</li> <li>Part 3 (Ethnic cohorts): 1 cohort with 1 s.c. administered dose level of AZD1163 and 2 cohorts with 1 s.c. dose levels of AZD1163</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: incidence of AEs</li> <li>Secondary endpoint: PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>LPCD: Q2 2025</li> <li>Data anticipated: H1 2026</li> </ul>

Oncology

CVRM

R&I

V&I

Rare Disease



# AZD4604 (inhaled JAK-1 inhibitor)

## Asthma

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase IIa</b> <b>AJAX</b> <b><a href="#">NCT06020014</a></b>	Moderate-to-severe asthma uncontrolled on medium-to high-dose ICS-LABA	320	<ul style="list-style-type: none"> <li>Multi-centre, randomised, placebo-controlled, double-blind, parallel-group trial</li> <li>Arm 1: AZD4604</li> <li>Arm 2: placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: time to first CompEx asthma event</li> <li>Secondary endpoints: Pre-BD FEV1, CAAT, ACQ-6, average morning and average evening PEF, daily asthma symptom score, time to first CompEx acute worsening event, CompEx event rate and CompEx acute worsening event rate</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase IIa</b> <b>ARTEMISIA</b> <b><a href="#">NCT06435273</a></b>	Adult patients with moderate-to-severe asthma receiving treatment with medium-to-high dose ICS-LABA	48	<ul style="list-style-type: none"> <li>Multi-centre, randomised, placebo-controlled, double-blind, parallel-group trial</li> <li>Arm 1: AZD4604</li> <li>Arm 2: placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: gene expression in airway epithelial cells</li> <li>Secondary endpoints: STAT phosphorylation and cellular pathology</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase Ib</b> <b>ATALANTA</b> <b><a href="#">NCT06732882</a></b>	Adults With Mild Asthma	28	<ul style="list-style-type: none"> <li>Single blind, multi-center, randomised, placebo-controlled, parallel-group trial via the Turbuhaler and Genuair devices</li> <li>Arm 1: Genuair 1400 ug BID AZD4604</li> <li>Arm 2: Turbuhaler 1400 ug BID AZD4604</li> <li>Arm 3: Turbuhaler 150 ug BID AZD4604</li> <li>Arm 4: Genuair placebo</li> <li>Arm 5: Turbuhaler Placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: PK parameters</li> <li>Secondary endpoints: PD parameters, FeNO</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>LPCD: Q2 2025</li> <li>Data readout: Q4 2025</li> </ul>
<b>Phase I</b> <b><a href="#">NCT04769869</a></b>	Healthy volunteers and patients with mild asthma	137	<ul style="list-style-type: none"> <li>SAD/MAD/POM trial</li> <li>Part 1 SAD</li> <li>Part 2 MAD</li> <li>Part 3 POM</li> <li>UK only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> <li>Secondary endpoints: PK parameters and FENO</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2021</li> <li>LPCD: Q1 2023</li> <li>Data readout: Q1 2023</li> </ul>
<b>Phase I</b> <b><a href="#">NCT06519968</a></b>	Healthy volunteers	56	<ul style="list-style-type: none"> <li>Part 1a: SAD cohorts in healthy Japanese participants</li> <li>Part 1b: multiple dose cohort in healthy Japanese participants</li> <li>Part 2a: SAD cohort in healthy Chinese participants</li> <li>Part 2b: multiple dose cohort in healthy Chinese participants</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> <li>Secondary endpoints: PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>LPCD: Q4 2024</li> <li>Data readout: Q1 2025</li> </ul>

Oncology

CVRM

R&I

V&I

Rare Disease



# AZD5492 (CD20 TITAN TCE)

## SLE

Trial	Population	Patients	Design	Endpoints	Status
Phase I TITAN <a href="#">NCT06916806</a>	Systemic lupus erythematosus (SLE) or Idiopathic inflammatory myopathies (IIM) or Rheumatoid Arthritis (RA)	70	<ul style="list-style-type: none"><li>Open-label, multi-centre</li><li>Part 1: Single ascending dose with AZD5492</li><li>Part 2: Step-up dosing with AZD5492</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: safety and tolerability</li><li>Secondary endpoints: PK parameters</li></ul>	<ul style="list-style-type: none"><li>Data anticipated: 2027</li></ul>



# AZD6793 (IRAK4)

## COPD

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase II</b> <b>PRESTO</b> <b><u>NCT07082738</u></b>	moderate to very severe COPD	1160	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo controlled 4 arm study</li> <li>Dose 1 AZD6793</li> <li>Dose 2 AZD6793</li> <li>Dose 3 AZD6793</li> <li>Placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: annualised rate of moderate or severe COPD exacerbations</li> <li>Secondary endpoints: time to first exacerbations, annualised rate of severe exacerbations, CompEx, pre-BD FEV1, post-BD FEV1, BCSS, CAT, SGRQ</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase I</b> <b><u>NCT05662033</u></b>	Healthy volunteers	133	<ul style="list-style-type: none"> <li>Single-blind, randomised, placebo-controlled trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> <li>Secondary endpoint: PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2022</li> <li>LPCD: Q4 2024</li> <li>Data readout: Q3 2025</li> </ul>
<b>Phase I</b> <b><u>NCT06368440</u></b>	Healthy volunteers	40	<ul style="list-style-type: none"> <li>Single-blind, randomised, placebo-controlled trial</li> <li>Japanese and Chinese healthy participants</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: safety</li> <li>Secondary endpoints: PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2024</li> <li>LPCD: Q4 2024</li> <li>Data readout: Q2 2025</li> </ul>
<b>Phase I</b> <b><u>NCT06494644</u></b>	Healthy participants	17	<ul style="list-style-type: none"> <li>A single-group trial with a duration of up to 8 weeks (maximum of 53 days) including Screening, Period 1, Period 2, Period 3 and Follow-up to assess the pharmacokinetics of AZD6793 when administered alone and in combination with itraconazole in healthy participants</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: PK parameters (C<sub>max</sub>, AUC, CL/F, t<sub>1/2</sub>, t<sub>max</sub>, V<sub>z</sub>/F, RAUC)</li> <li>Secondary endpoint: safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>LPCD: Q4 2024</li> <li>Data readout: Q2 2025</li> </ul>

Oncology

CVRM

R&I

V&I

Rare Disease



# AZD6912 (siRNA)

## Rheumatoid arthritis

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT06115967</a>	Healthy volunteers	40	<ul style="list-style-type: none"><li>Randomised, double-blind, placebo-controlled SAD trial</li><li>5 cohorts with s.c. administered ascending dose level of AZD6912</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: incidence of AEs</li><li>Secondary endpoint: PK parameters</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2023</li><li>LPCD: Q4 2024</li><li>Data anticipated: H1 2026</li></ul>



# AZD7798 (humanised mAb)

## Crohn's disease

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase IIa</b> <b>AMALTHEA</b> <b><u>NCT06450197</u></b>	Moderate to severe Crohn's disease	107	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled trial</li> <li>Arm 1: AZD7798</li> <li>Arm 2: placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: Crohn's Disease Activity Index (CDAI) remission</li> <li>Secondary endpoints: endoscopic response, endoscopic remission, endoscopic score change from baseline, CDAI response, CDAI score change from baseline, symptomatic remission, PK parameters and ADA</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2024</li> <li>Data anticipated: H2 2026</li> </ul>
<b>Phase II</b> <b>CALLISTO</b> <b><u>NCT06681324</u></b>	Patients with active ileal Crohn's disease and an ileostomy	30	<ul style="list-style-type: none"> <li>A Participant- and Investigator-blind, Randomized, Placebo-controlled Phase II Study Arm 1: AZD7798</li> <li>Arm 2: Placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: safety</li> <li>Secondary endpoints: Simple Endoscopic Score for Crohn's Disease (SES-CD) , endoscopic response and remission, PK parameters, ADA</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase I</b> <b><u>NCT05452304</u></b>	Global, Japanese and Chinese healthy volunteers	112	<ul style="list-style-type: none"> <li>SAD, repeating dose trial</li> <li>Arm 1: AZD7798</li> <li>Arm 2: placebo</li> <li>s.c. and i.v. administration</li> <li>UK only</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> <li>Secondary endpoints: PK parameters and immunogenicity</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2022</li> <li>LPCD: Q3 2024</li> <li>Data readout: Q4 2023</li> </ul>

Oncology

CVRM

R&I

V&I

Rare Disease



# AZD8630 (inhaled TSLP)

## Asthma

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase II</b> <b>LEVANTE</b> <b><a href="#">NCT06529419</a></b> <b>Partnered (AMGEN)</b>	Adults with uncontrolled asthma at risk of exacerbations	516	<ul style="list-style-type: none"> <li>Randomised, placebo-controlled, double-blind, dose range-finding, multi-centre trial</li> <li>Arm 1: AZD8630 Dose A</li> <li>Arm 2: AZD8630 Dose B</li> <li>Arm 3: AZD8630 Dose C</li> <li>Arm 4: placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: time to first CompEx asthma event</li> <li>Secondary endpoints: change from baseline in pre-bronchodilator forced expiratory volume in 1 second and safety and tolerability</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>LPCD: Q4 2025</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase I</b> <b>APKiTA</b> <b><a href="#">NCT07065331</a></b> <b>Partnered (AMGEN)</b>	Adolescent participants with asthma aged 11 to 17	22	<ul style="list-style-type: none"> <li>Phase 1, open label, single dose study in adolescent participants with asthma where the participants will receive AZD8630 administered via dry powder inhaler</li> </ul>	<ul style="list-style-type: none"> <li>Area under the serum concentration-time curve from time zero to 24 hours (AUC0-24)</li> <li>Maximum observed drug concentration (Cmax)</li> <li>Time to reach peak or maximum observed concentration (Tmax)</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>LPCD: Q3 2025</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase I</b> <b><a href="#">NCT05110976</a></b> <b>Partnered (AMGEN)</b>	Healthy volunteers and patients with asthma	232	<ul style="list-style-type: none"> <li>SAD and MAD trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> <li>Secondary endpoints: PK parameters and FENO</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2022</li> <li>LPCD: Q3 2023</li> <li>Data readout: Q4 2023</li> <li>Primary and Secondary endpoints met</li> </ul>
<b>Phase I</b> <b><a href="#">NCT06531811</a></b> <b>Partnered (AMGEN)</b>	Healthy volunteers	32	<ul style="list-style-type: none"> <li>Randomised, open-label, 2-treatment, 2-period trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability</li> <li>Secondary endpoint: PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>LPCD: Q3 2024</li> <li>Data readout: Q2 2025</li> </ul>
<b>Phase I</b> <b><a href="#">NCT06795906</a></b> <b>Partnered (AMGEN)</b>	Adults with asthma on medium-to-high dose inhaled corticosteroids and long-acting beta-agonists	24	<ul style="list-style-type: none"> <li>Randomised, placebo-controlled, double-blind, parallel design</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety and tolerability, pharmacokinetic parameter</li> <li>Secondary endpoint : change from baseline in FeNO at weeks 1 and 2</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>LPCD: Q2 2025</li> <li>Data readout: Q4 2025</li> </ul>

Oncology

CVRM

R&I

V&I

Rare Disease



# AZD8965 (arginase enzyme inhibitor)

## IPF

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT06502379</a>	Healthy volunteers	163	<ul style="list-style-type: none"><li>Randomised, single-blind, SAD/MAD, placebo-controlled, AZD8965/placebo administered orally</li><li>PART 1: SAD cohorts</li><li>PART 2: MAD cohorts</li><li>PART 3a: Japanese and Chinese participants SAD cohorts</li><li>PART 3b: Japanese and Chinese participants SMAD cohorts</li><li>PART 4: food effect cohort</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints (Part 1, 2, 3): safety and tolerability measures</li><li>Primary endpoint (Part 4): PK parameters</li><li>Secondary endpoint (Part 1, 2, 3): PK parameters</li><li>Secondary endpoints (Part 4): safety and tolerability measures under fasted and fed condition</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2024</li><li>LPCD: Q4 2025</li><li>Data anticipated: H1 2026</li></ul>





# mRNA VLP vaccine

## COVID-19

Trial	Population	Patients	Design	Endpoints	Status
Phase I ARTEMIS-C <a href="#">NCT06147063</a>	Healthy volunteers ≥18+ with history of a SARS-CoV-2 infection and/or prior completion of primary series/booster vaccination at least 6 months prior to trial start	240	<ul style="list-style-type: none"> <li>Arm 1: dose 1 via i.m. injection AZD9838 in 18-64-year-olds</li> <li>Arm 2: dose 2 via i.m. injection AZD9838 in 18-64-year-olds</li> <li>Arm 3: i.m. dose of licensed mRNA vaccine in 18-64-year-olds</li> <li>Arm 4: dose 1 via i.m. injection AZD6563 in 18-64-year-olds</li> <li>Arm 5: dose 2 via i.m. injection AZD6563 in 18-64-year-olds</li> <li>Arm 6: dose 1 via i.m. injection in 65+ year olds</li> <li>Arm 7: dose 2 via i.m. injection in 65+ year olds</li> <li>Arm 8: i.m dose of licensed mRNA vaccine in 65+ year olds</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: safety as measured by AEs, ARs, SAEs, MAAEs, AESIs, GMTs of strain neutralising antibodies and GMFRs of strain neutralising antibodies</li> <li>Secondary endpoints: nAb responses to the SARS-CoV2 ancestral strain, Omicron BA.4/5, and Omicron XBB.1.5 in serum</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2023</li> <li>Trial discontinued due to strategic portfolio prioritisation</li> </ul>



# AZD0292 (Psl-PcrV N3Y-bispecific mAb)

## Bronchiectasis

Trial	Population	Patients	Design	Endpoints	Status
Phase IIb CLEAR <a href="#">NCT07088926</a>	Bronchiectasis patients ≥ 12 years of age, chronically colonized with PsA	435	<ul style="list-style-type: none"><li>Randomized, double-blind, placebo-controlled, parallel, multidose</li><li>2 dosage regimens (high dose, low dose) of AZD0292 IV vs placebo IV</li></ul>	<ul style="list-style-type: none"><li>Primary: efficacy</li><li>Secondary: safety, PK</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2025</li><li>Data anticipated: &gt;2027</li></ul>
Phase I <a href="#">NCT06311760</a>	Healthy volunteers	32	<ul style="list-style-type: none"><li>Randomised, single-blind, placebo-controlled trial</li><li>Arm 1: AZD0292 Dose 1 administered via i.v. infusion</li><li>Arm 2: AZD0292 Dose 2 administered via i.v. infusion</li><li>Arm 3: AZD0292 Dose 3 administered via i.v. infusion</li><li>Arm 4: AZD0292 Dose 4 administered via i.v. infusion</li><li>Arm 5: placebo administered via i.v. infusion</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: AEs and participants with AESI</li><li>Secondary endpoints: Cmax, AUClast, AUCinfinity and ADA</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2024</li><li>LPCD: Q3 2024</li><li>Data readout: Q2 2025</li></ul>



# AZD5148 (anti-TcdB mAb)

## Clostridium difficile

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase IIb</b> <b>PRISM</b> <b><a href="#">NCT07285213</a></b>	≥ 18 years, with a qualifying C. difficile infection episode at the time of providing informed consent	230	<ul style="list-style-type: none"> <li>Randomized, Double-blind, Placebo-controlled</li> <li>AZD5148 or placebo (1:1)</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: efficacy</li> <li>Secondary endpoint: safety, PK</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase I</b> <b><a href="#">NCT06469151</a></b>	Healthy volunteers	84	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled, dose escalation</li> <li>Cohort 1: AZD5148 (dose 1, i.m.) or placebo</li> <li>Cohort 2a: AZD5148 (dose 2, i.m.) or placebo</li> <li>Cohort 2b: AZD5148 (dose 2, i.m., Chinese participants) or placebo</li> <li>Cohort 3: AZD5148 (dose 2, i.v.) or placebo</li> <li>Cohort 4a: AZD5148 (dose 3, i.v.) or placebo</li> <li>Cohort 4b: AZD5148 (dose 3, i.v., Chinese participants) or placebo</li> <li>Cohort 5: AZD5148 (dose 4, i.v.) or placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: safety</li> <li>Secondary endpoint: PK parameters</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2024</li> <li>LPCD: Q4 2024</li> <li>Data anticipated: H1 2026</li> </ul>

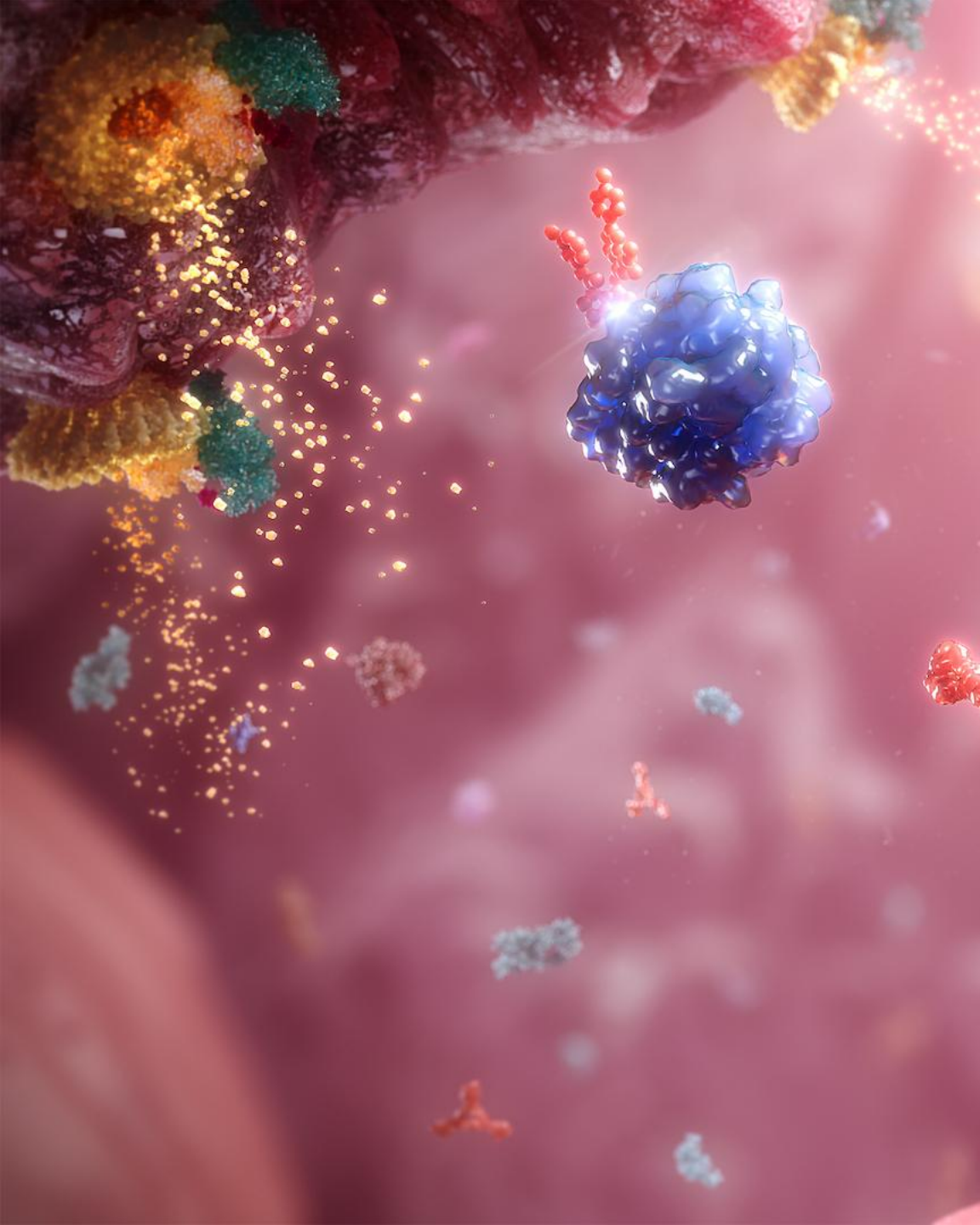


# AZD7760 (mAb combination targeting S aureus virulence factors)

## Prevention of Staph aureus infection

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase I/IIa</b> <a href="#">NCT06749457</a>	Phase I: healthy volunteers male and female participants aged 18 to 55 years Phase IIa: patients with ESKD receiving heamodialysis through a central venous catheter	231	<ul style="list-style-type: none"> <li>Phase I: randomised, double-blind, placebo-controlled, dose escalation trial to evaluate the safety and PK of AZD7760 to evaluate 3 doses</li> <li>Phase IIa: randomised, double-blind, placebo-controlled trialto evaluate the safety and PK of AZD7760</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint (Phase I): safety</li> <li>Primary endpoint (Phase IIa): safety</li> <li>Secondary endpoints (Phase I): PK parameters and ADA</li> <li>Secondary endpoints (Phase IIa): PA parameters, ADA and D451 safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2025</li> <li>Data anticipated: 2027</li> </ul>





# Rare Disease: approved medicines and late-stage development

# Beyonttra (acoramidis, ALXN2060)

## ATTR-CM

Trial	Population	Patients	Design	Endpoints	Status
Phase III ALXN2060-TAC-302 <a href="#">NCT04622046</a>	ATTR-CM	22	<ul style="list-style-type: none"><li>Arm 1: 800mg Beyonttra administered twice daily</li><li>Japan only</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: change from baseline to Month 12 of treatment in distance walked during the six-minute walk test, cause mortality and cardiovascular related hospitalisation over a 30-month period</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2020</li><li>Data readout: Q1 2024</li><li>Primary endpoint met</li></ul>



# Koselugo (selumetinib, MEK inhibitor)

## Neurofibromatosis type 1, solid tumours

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>KOMET</b> <a href="#">NCT04924608</a> Partnered (Merck Sharp & Dohme LLC)	Adult age ≥18 years with NF1 who have symptomatic, inoperable PN  Available baseline chronic target PN pain score	145	<ul style="list-style-type: none"> <li>Multi-centre, international trial with a parallel, randomised, double-blind, placebo-controlled, 2 arm design</li> <li>Arm 1: <i>Koselugo</i> 25mg/m2 BID</li> <li>Arm 2: placebo BID until end of Cycle 12, then crossover to <i>Koselugo</i> 25mg/m2 BID</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: ORR by end of Cycle 16 on <i>Koselugo</i> vs. placebo as determined by ICR per REiNS criteria</li> <li>Key secondary endpoint: change from baseline of chronic PN-pain intensity on <i>Koselugo</i> vs. placebo</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2021</li> <li>Data readout: Q3 2024</li> <li>Primary endpoint met</li> </ul>
<b>Phase I/II</b> <b>SPRINKLE</b> <a href="#">NCT05309668</a> Partnered (Merck Sharp & Dohme LLC)	Paediatric (age 1 to 7 years) diagnosed with NF1 with symptomatic, inoperable PN with at least one measurable PN, defined as a PN of at least 3cm, measured in one dimension	38	<ul style="list-style-type: none"> <li>Single-arm, open-label with <i>Koselugo</i> granule formulation</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: <i>Koselugo</i> AUC0-12 derived after single dose administration [time frame: pre-dose and 1, 2, 3, 4, 6, 8 and 10-12 hours after <i>Koselugo</i> single dose on the first day of treatment (Cycle 1 Day 1)]; AEs graded by CTCAE Ver 5.0 [time frame: from screening until 30 days after last dose]</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2022</li> <li>LPCD: Q1 2024</li> <li>Data readout: Q2 2024</li> <li>Primary endpoint met</li> </ul>



# Ultomiris (anti-C5 mAb)

## Haematology, nephrology, transplant

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III ARTEMIS</b> <a href="#">NCT05746559</a>	CSA-AKI	736	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled, multicentre trial</li> <li><i>Ultomiris</i> i.v. to protect patients with CKD from CSA-AKI and subsequent MAKE</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: to assess the efficacy of a single dose of <i>Ultomiris</i> i.v. vs. placebo in reducing the risk of the clinical consequences of AKI (MAKE) at 90 days in adult participants with CKD who undergo non-emergent cardiac surgery with CPB</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2023</li> <li>Data anticipated: H2 2026</li> </ul>
<b>Phase III AWAKE</b> <a href="#">NCT06830798</a>	Delayed graft function in high risk donor kidneys	450	<ul style="list-style-type: none"> <li>Arm1: Placebo</li> <li>Arm2: <i>Ultomiris</i></li> </ul>	<ul style="list-style-type: none"> <li>Primary: time to freedom from dialysis</li> <li>Secondary: DGF incidence, number of dialysis sessions, time to first occurrence of eGFR <math>\Rightarrow</math> 30 mL/min/1.73m<sup>2</sup>.</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2025</li> <li>Data anticipated: &gt;2027</li> </ul>
<b>Phase III I CAN</b> <a href="#">NCT06291376</a>	Immunoglobulin A nephropathy	510	<ul style="list-style-type: none"> <li>Arm 1: <i>Ultomiris</i> via weight-based i.v. infusion</li> <li>Arm 2: placebo via weight-based i.v. infusion</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoints: change from baseline in proteinuria based on 24-hour UPCR at Week 34 and eGFR over 106 weeks</li> <li>Secondary endpoints: reduction in UPCR <math>\geq</math> 50%, change in proteinuria at week 10, time to sustained <math>\geq</math> 30% eGFR decline, composite kidney endpoint</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2024</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase III TMA-313</b> <a href="#">NCT04543591</a>	Thrombotic microangiopathy-associated haematopoietic stem cell transplant	146	<ul style="list-style-type: none"> <li>Arm 1: <i>Ultomiris</i> Q8W</li> <li>Arm 2: placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: event free survival</li> <li>Secondary endpoints: overall survival, non-relapse mortality, number of TMA response criteria met</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2020</li> <li>LPCD: Q1 2025</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase III TMA-314</b> <a href="#">NCT04557735</a>	Paediatric thrombotic microangiopathy-associated haematopoietic stem cell transplant	41	<ul style="list-style-type: none"> <li>Arm 1: <i>Ultomiris</i> administered once every 4 to 8 weeks</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: proportion of participants with TMA response</li> <li>Secondary endpoints: time to TMA response, proportion of participants with TMA relapse</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2020</li> <li>LPCD: Q2 2024</li> <li>Data readout: Q1 2025</li> <li>Positive high-level results</li> </ul>
<b>Phase II SANCTUARY</b> <a href="#">NCT04564339</a>	Proliferative lupus nephritis or immunoglobulin A nephropathy	120	<ul style="list-style-type: none"> <li>Arm 1: LN cohort, <i>Ultomiris</i></li> <li>Arm 2: LN cohort, placebo</li> <li>Arm 3: IgAN cohort, <i>Ultomiris</i></li> <li>Arm 4: IgAN cohort, placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: percentage change in proteinuria from baseline to Week 26</li> <li>Secondary endpoints: percentage change in proteinuria from baseline to Week 50</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q1 2021</li> <li>LPCD: Q2 2025</li> <li>Data readout: Q2 2025</li> <li>Primary endpoint met (IgAN cohort)</li> <li>Primary endpoint not met (LN cohort)</li> </ul>





# Ultomiris (anti-C5 mAb)

## Neurology

Trial	Population	Patients	Design	Endpoints	Status
Phase II/III ALXN1210-NMO-317 <a href="#">NCT05346354</a>	Neuromyelitis optica spectrum disorder	12	<ul style="list-style-type: none"><li>Arm 1: <i>Ultomiris</i> Q8W</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: change from baseline in annualised relapse rate at Week 50</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2022</li><li>LPCD: Q1 2025</li><li>Data anticipated: H1 2026</li></ul>



# anselamimab (CAEL-101, fibril-reactive mAb)

## AL amyloidosis

Trial	Population	Patients	Design	Endpoints	Status
Phase III CARES-301 <a href="#">NCT04504825</a>	AL amyloidosis (Mayo Stage IIIb)	124	<ul style="list-style-type: none"><li>Arm 1: anselamimab combined with SoC for PCD</li><li>Arm 2: placebo combined with SoC for PCD</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: a hierarchical combination of time to all-cause mortality and frequency of cardiovascular hospitalisation, safety (TEAEs)</li><li>Secondary endpoint: quality of life measures</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2021</li><li>LPCD: Q4 2023</li><li>Data readout: Q3 2025</li><li>Primary endpoint not met</li></ul>
Phase III CARES-302 <a href="#">NCT04512235</a>	AL amyloidosis (Mayo Stage IIIa)	267	<ul style="list-style-type: none"><li>Arm 1: anselamimab combined with SoC for PCD</li><li>Arm 2: placebo combined with SoC for PCD</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: a hierarchical combination of time to all-cause mortality and frequency of cardiovascular hospitalisation, safety (TEAEs)</li><li>Secondary endpoint: quality of life measures</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2020</li><li>LPCD: Q4 2023</li><li>Data readout: Q3 2025</li><li>Primary endpoint not met</li></ul>
Phase II CAEL101-203 <a href="#">NCT04304144</a>	AL amyloidosis (Mayo Stage I, Stage II and Stage IIIa)	25	<ul style="list-style-type: none"><li>Arm 1: anselamimab combined with SoC CyBorD</li><li>Arm 2: placebo combined with SoC CyBorD and daratumumab</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: occurrence of DLT during the first 4 weeks of therapy</li><li>Secondary endpoint: AUC (plasma curve concentration)</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2020</li><li>Data readout: Q2 2024</li></ul>



# cliramitug (ALXN2220, TTR depleter)

## Amyloidosis

Trial	Population	Patients	Design	Endpoints	Status
Phase III DepleTTR-CM <a href="#">NCT06183931</a>	ATTR-CM (wild-type and variant)	1180	<ul style="list-style-type: none"><li>Arm 1: cliramitug via i.v. infusion Q4W for at least 24 months up to a maximum of 48 months</li><li>Arm 2: placebo via i.v. infusion Q4W for at least 24 months up to a maximum of 48 months</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: composite all-cause mortality and total CV events.</li><li>Secondary endpoints: KCCQ, 6MWT, all-cause mortality, CV mortality, CV events</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2024</li><li>LPCD: Q2 2025</li><li>Data anticipated: 2027</li></ul>



# efzimfotase alfa (ALXN1850, next-generation asfotase alfa)

## Hypophosphatasia

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase III</b> <b>CHESTNUT</b> <a href="#">NCT06079372</a>	Hypophosphatasia	40	<ul style="list-style-type: none"> <li>Arm 1: bodyweight-dependent doses of either 20mg, 35mg or 50mg of efzimfotase alfa Q2W via s.c. for 24 weeks</li> <li>Arm 2: 6mg/kg/week of Strensiq via s.c. injection as either 2mg/kg 3 times per week or 1mg/kg 6 times per week for 24 weeks</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: incidence of TEAEs</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2024</li> <li>LPCD: Q1 2025</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase III</b> <b>HICKORY</b> <a href="#">NCT06079281</a>	Hypophosphatasia	114	<ul style="list-style-type: none"> <li>Arm 1: placebo on Day 1 followed by Q2W via s.c. injection for 24 weeks</li> <li>Arm 2: bodyweight-dependent doses of either 20mg, 35mg or 50mg of efzimfotase alfa Q2W via s.c. injection for 24 weeks</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: change from baseline in 6MWT at Day 169</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q2 2024</li> <li>LPCD: Q1 2025</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase III</b> <b>MULBERRY</b> <a href="#">NCT06079359</a>	Hypophosphatasia	30	<ul style="list-style-type: none"> <li>Arm 1: bodyweight-dependent doses of either 25mg, 35mg, or 50mg of efzimfotase Q2W via s.c. injection for 24 weeks</li> <li>Arm 2: placebo Q2W for 24 weeks</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: Radiographic Global Impression of Change (RGI-C) Score at Day 169</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2024</li> <li>LPCD: Q3 2025</li> <li>Data anticipated: H1 2026</li> </ul>
<b>Phase I</b> <b>ALXN1850-HPP-101</b> <a href="#">NCT04980248</a>	Hypophosphatasia	15	<ul style="list-style-type: none"> <li>Arm 1: ALXN1850, 3 cohorts at low, medium and high dosages</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: incidence of TEAEs and TSEAEs</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q3 2021</li> <li>LPCD: Q2 2022</li> <li>Data readout: Q4 2022</li> <li>Primary endpoint met</li> </ul>



# eneboparatide (parathyroid hormone receptor 1 agonist)

## Hypoparathyroidism

Trial	Population	Patients	Design	Endpoints	Status
Phase III CALYPSO <a href="#">NCT05778071</a>	Chronic hypoparathyroidism	165	<ul style="list-style-type: none"><li>Arm 1: 20mcg eneboparatide administered once daily via s.c. injection</li><li>Arm 2: placebo administered once daily via s.c. injection</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: complete independence from active vitamin D, independence from therapeutic doses of oral calcium (i.e. taking oral elemental calcium supplements ≤600mg/day) and albumin-adjusted serum calcium within the normal range (8.3 to 10.6mg/dL) vs. placebo after 24 weeks of treatment</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2023</li><li>Data readout: Q1 2025</li><li>Primary endpoint met</li></ul>

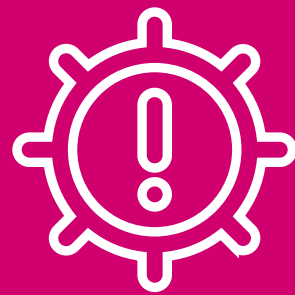
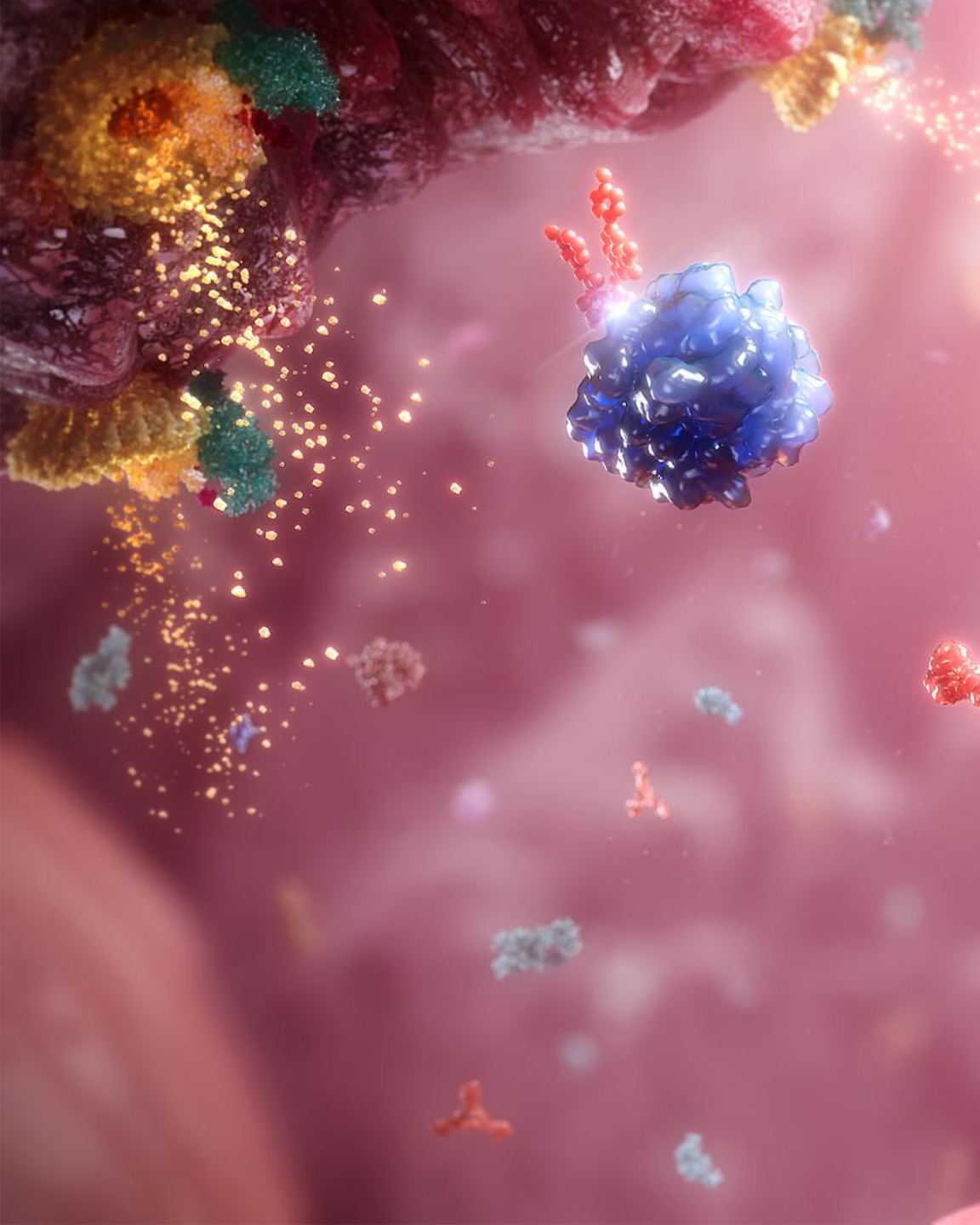


# gefurulimab (ALXN1720, anti-C5 dual-binding nanobody)

## Neurology, nephrology

Trial	Population	Patients	Design	Endpoints	Status
Phase III ALXN1720-MG-301 <a href="#">NCT05556096</a>	Generalised myasthenia gravis	260	<ul style="list-style-type: none"><li>Arm 1: weight-based maintenance treatment with gefurulimab on Day 1, followed by weight-based maintenance treatment of gefurulimab on Week 1 (Day 8) and Q1W thereafter for a total of 26 weeks</li><li>Arm 2: placebo</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: change from baseline in MG-ADL total score at Week 26</li><li>Key Secondary endpoints: Change from baseline in QMG total score, Change from baseline in the MGC total score</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q4 2022</li><li>LPCD: Q4 2024</li><li>Data readout: Q3 2025</li><li>Primary endpoint met</li></ul>





# Rare Disease: early-stage development

tarperprumig (ALXN1820, anti-properdin)

Anti-neutrophil cytoplasmic antibody (ANCA) associated vasculitis

Trial	Population	Patients	Design	Endpoints	Status
Phase II I-TRANSCEND <a href="#">NCT07160608</a>	Newly diagnosed or relapsing ANCA (Anti-Neutrophil Cytoplasmic Antibody)-associated vasculitis patients.	75	<ul style="list-style-type: none"> <li>Randomised, double-blind, placebo-controlled, parallel group</li> <li>taperprumig (dose regimen 1 or 2) placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: safety and tolerability</li> <li>Secondary endpoints: Remission at Week 26; Sustained Remission at Week 52; Change from baseline in eGFR, uPCR, uACR and hematuria; Number of participants achieving BVAS of 0 through week 52; Time to first relapse</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2025</li> <li>Data anticipated: &gt;2027</li> </ul>

Oncology

CVRM

R&I

V&I

Rare Disease





# ALXN1920 (kidney-targeted factor H fusion protein)

## Nephrology

Trial	Population	Patients	Design	Endpoints	Status
Phase II AUTUMN <a href="#">NCT07157787</a> -	Primary membranous nephropathy (PMN)	30	<ul style="list-style-type: none"><li>Randomised, double-blind, placebo-controlled</li><li>ALXN1920 SC infusion</li><li>Placebo SC infusion</li></ul>	<ul style="list-style-type: none"><li>Primary Endpoint: Change From Baseline in Proteinuria Based on 24-hour UPCR at Week 26</li><li>Secondary endpoints: Change From Baseline in Proteinuria Based on 24-hour UPCR, Change From Baseline in Proteinuria Based on Spot UPCR at Week 26, Change From Baseline in Serum Albumin at Week 26, Change From Baseline in Anti-phospholipase A2 Receptor (anti-PLA2R) Antibody Level at Week 26, Change From Baseline in Peripheral Cluster of Differentiation 20 (CD20+) B Cell Count at Week 4, Week 8, and Week 26, Change From Baseline biomarker level at Week 26</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q1 2026</li><li>Data anticipated: 2027</li><li>Initiating</li></ul>
Phase I ALXN1920-HV-101 <a href="#">NCT05751642</a>	Healthy adults	48	<ul style="list-style-type: none"><li>Randomised, double-blind, placebo-controlled SAD trial</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: safety and tolerability</li><li>Secondary endpoints: PK/PD parameters</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2023</li><li>LPCD: Q4 2023</li><li>Data readout: Q2 2024</li></ul>



# ALXN2030 (siRNA targeting complement C3)

## Transplant

Trial	Population	Patients	Design	Endpoints	Status
<b>Phase II</b> <b>CONCORD</b> <a href="#">NCT06744647</a>	Kidney transplant recipients with late active or chronic active antibody-mediated rejection (AMR)	45	<ul style="list-style-type: none"> <li>Randomised, controlled, double-blind</li> <li>ALXN2030 Dose A</li> <li>ALXN2030 Dose B</li> <li>Placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: Biopsy-proven histologic resolution at 52 weeks</li> <li>Secondary endpoints: Biopsy-proven histologic resolution at 28 weeks, change from baseline in biopsy-proven histologic scores at 28 and 52 weeks, eGFR, TEAEs, PK measures</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2025</li> <li>Data anticipated: 2027</li> </ul>
<b>Phase I</b> <b>ALXN2030-HV-101</b> <a href="#">NCT05501717</a>	Healthy volunteers	48	<ul style="list-style-type: none"> <li>Randomised, placebo-controlled SAD trial</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: safety</li> </ul>	<ul style="list-style-type: none"> <li>FPCD: Q4 2022</li> <li>LPCD: Q2 2025</li> <li>Data anticipated: H2 2026</li> </ul>



# ALXN2350 (AAV gene therapy)

## BAG3-associated dilated cardiomyopathy (DCM)

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II DCMRestore <a href="#">NCT07218887</a>	BAG3 mutation associated dilated cardiomyopathy	18	<ul style="list-style-type: none"> <li>Open-label, dose finding and dose expansion study</li> <li>ALXN2350 one of three doses as single IV infusion</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: Part A TEAEs, SAEs up to week 78</li> <li>Secondary endpoints: Part B TEAEs, SAEs, cardiac events, time to first event of death, heart transplant, mechanical circulating supporting or aborted sudden cardiac death, up to week 78</li> </ul>	<ul style="list-style-type: none"> <li>Data anticipated: &gt;2027</li> <li>Initiating</li> </ul>



# ALXN2420 (GH receptor antagonist)

## Acromegaly

Trial	Population	Patients	Design	Endpoints	Status
Phase IIb ASTERIA <a href="#">NCT07037420</a> -	Acromegaly	60	<ul style="list-style-type: none"><li>A Phase 2, randomised, double-blinded, placebo-controlled, dose range-finding, multicentre study to assess the efficacy, safety, and pharmacokinetics of ALXN2420, a growth hormone receptor antagonist, administered subcutaneously in combination with somatostatin analogs in adult participants with acromegaly.</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: Percentage change from baseline in serum IGF-1 level at Week 15</li><li>Secondary endpoints: Sserum IGF-1 level ≤ 1.3 ULN at Week 15, Achievement of serum IGF-1 level ≤ 1.0 ULN at Week 15, Change from baseline in symptoms, as assessed by AcroSD/IGF-1 scores, at Week 15, Change from baseline in SF-36 summary scores and subscores at Week 15, Change from baseline in EQ-5D-5L at Week 15, Change from baseline in AcroQoL at Week 15, Change from baseline in global impression of severity at Week 15 as assessed by PGIS scale, Global impression of change at Week 15 as assessed by PGIC scale</li></ul>	<ul style="list-style-type: none"><li>Data anticipated: 2027</li><li>Initiating</li></ul>



# AZD0120 (GC012F, autologous anti-CD19 and anti-BCMA CAR-T)

## AL amyloidosis

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II ALACRITY <a href="#">NCT07081646</a>	Relapsed or Refractory AL Amyloidosis	91	<ul style="list-style-type: none"><li>Open-label, multicentre, non-randomised trial</li></ul>	<ul style="list-style-type: none"><li>Primary endpoint: % of pts achieving complete hematologic response (CR) through 6 months</li><li>Secondary endpoints: % of patients achieving modified hematologic response (CR+VGPR+low dFLC response) through 6 months, MRD negativity through 6 months, OS, EFS</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q3 2025</li><li>Data anticipated: &gt;2027</li></ul>



# AZD1390 (ATM inhibitor)

## Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase I <a href="#">NCT03423628</a>	Recurrent glioblastoma eligible for re-irradiation, brain metastases and leptomeningeal disease, newly-diagnosed glioblastoma patients	180	<ul style="list-style-type: none"><li>Open-label trial</li><li>Arm 1: recurrent GBM, AZD1390 + RT in dose escalation cohorts (Japan safety/PK cohorts added); optional food effect cohort initiated</li><li>Arm 3: primary GBM, AZD1390 + RT in dose escalation cohorts</li></ul>	<ul style="list-style-type: none"><li>Primary endpoints: safety, tolerability and MTD</li><li>Secondary endpoints: PK parameters and preliminary assessment of anti-tumour activity</li></ul>	<ul style="list-style-type: none"><li>FPCD: Q2 2018</li><li>Data anticipated: H2 2026</li></ul>



# Glossary – 1 of 5

<b>14C</b>	Carbon 14
<b>1L, 2L, 3L</b>	1st-, 2nd- or 3rd-line
<b>5-FU</b>	5-fluorouracil
<b>6MWT</b>	6-minute walk test
<b>A2AR</b>	Adenosine A2A receptor
<b>AAV</b>	Adeno-associated virus
<b>ACE</b>	Angiotensin-converting enzyme
<b>AChR+</b>	Acetylcholine receptor-positive
<b>ACQ</b>	Asthma Control Questionnaire
<b>ACR</b>	American College of Rheumatology Response Scoring System
<b>ADA</b>	Anti-drug antibody
<b>ADC</b>	Antibody-drug conjugate
<b>ADP</b>	Adenosine diphosphate
<b>ADsCa</b>	Albumin-adjusted serum calcium
<b>AE</b>	Adverse event
<b>AER</b>	Annual exacerbation rate
<b>AEs</b>	Adverse effects
<b>AGA</b>	Actional genomic alteration
<b>aHUS</b>	Atypical haemolytic uraemic syndrome
<b>AI</b>	Auto-injector
<b>AI</b>	Aromatase inhibitor
<b>AKT</b>	Protein kinase B
<b>AL amyloidosis</b>	Light-chain amyloidosis
<b>ALK</b>	Anaplastic large-cell lymphoma kinase
<b>ALL</b>	Acute lymphocytic leukaemia
<b>alloSCT</b>	Allogeneic stem cell transplantation
<b>ALSFRS-R</b>	Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised
<b>AML</b>	Acute myeloid leukaemia
<b>AMR</b>	Antibody mediated rejection
<b>anti-FR<math>\alpha</math></b>	Anti-folate receptor alpha
<b>anti-PCD</b>	Anti-plasma cell dyscrasia
<b>APFS</b>	Accessorised pre-filled syringe
<b>APOL1</b>	Apolipoprotein L1
<b>APOL1 G0/G1/G2</b>	Sequences of the G0, G1, and G2 APOL1 variants from amino acids 339–398
<b>AQLQ</b>	Asthma Quality of Life Questionnaire
<b>AQP4+</b>	Aquaporin-4 antibody positive
<b>ARB</b>	Angiotensin receptor blockers
<b>AS</b>	Albuterol sulfate
<b>ASCO</b>	American Society of Clinical Oncology
<b>ASI</b>	Aldosterone synthase inhibitor

<b>ASO</b>	Antisense oligonucleotide
<b>ATM</b>	Ataxia telangiectasia mutated kinase
<b>ATR</b>	Ataxia telangiectasia and Rad3-related protein
<b>ATTR</b>	Transthyretin amyloidosis
<b>ATTR-CM</b>	Transthyretin amyloid cardiomyopathy
<b>ATTR-PN</b>	Transthyretin amyloid polyneuropathy
<b>ATTRv-PN</b>	Hereditary transthyretin-mediated amyloid polyneuropathy
<b>AUC</b>	Area under curve
<b>AUCinf</b>	Area under plasma concentration time curve from zero to infinity
<b>AUClast</b>	Area under plasma concentration curve from zero to the last quantifiable concentration
<b>AUCt</b>	Area under concentration-time curve
<b>AUEC</b>	Area under the effect-time curve
<b>Avb8</b>	Alpha v beta 8
<b>B7H4</b>	B7 homolog 4
<b>BA</b>	Bioavailability
<b>BAFF</b>	B-cell activating factor
<b>B-ALL</b>	B cell acute lymphoblastic leukaemia
<b>BBB</b>	Blood-brain barrier
<b>BCG</b>	Bacillus Calmette-Guérin
<b>BCL2</b>	B-cell leukemia/lymphoma 2 protein
<b>BCMA</b>	B-cell maturation antigen
<b>BDA</b>	Budesonide albuterol
<b>BFF</b>	Budesonide and formoterol fumarate
<b>BGF</b>	Budesonide, glycopyrronium and formoterol fumarate
<b>BICLA</b>	British Isles Lupus Assessment Group-based Composite Lupus Assessment
<b>BICR</b>	Blinded independent central review
<b>BID</b>	Twice per day
<b>BIG</b>	Big Ten Cancer Research Consortium
<b>BM</b>	Biomarker
<b>BMD</b>	Bone mineral density
<b>BMFI</b>	Bone metastasis-free interval
<b>BMI</b>	Body mass index
<b>BOR</b>	Best overall response rate
<b>BR</b>	Bendamustine and rituximab
<b>BRCA</b>	BRest CAncer gene
<b>BRCAm</b>	BRest CAncer gene-mutated
<b>BRCAwt</b>	BRest CAncer wild-type gene
<b>BRD4</b>	Bromodomain-containing protein 4
<b>BTC</b>	Biliary tract carcinoma
<b>BTC</b>	Biliary tract cancer

<b>BTK</b>	Bruton's tyrosine kinase
<b>BTKi</b>	Bruton's tyrosine kinase
<b>BVAS</b>	Birmingham Vasculitis Activity Score
<b>C3</b>	Complement component 3
<b>C5</b>	Complement component 5
<b>CA-125</b>	Cancer antigen-125
<b>CAAT</b>	Chronic Airways Assessment Test
<b>CAD</b>	Coronary artery disease
<b>CAGR</b>	Compound annual growth rate
<b>cAMR</b>	Chronic antibody-mediated rejection
<b>CAR-T</b>	Chimeric antigen receptor therapy
<b>CBP</b>	Cardiopulmonary bypass
<b>CBR</b>	Clinical benefit rate
<b>CD</b>	Cluster of differentiation
<b>CD123</b>	Interleukin 3 receptor $\alpha$
<b>CD19</b>	Cluster of differentiation 19
<b>CD3</b>	Cluster of differentiation 3
<b>CD39</b>	Cluster of differentiation 39
<b>CD73</b>	Cluster of differentiation 73
<b>CD8</b>	Cluster of differentiation 8
<b>CDAI</b>	Clinical Disease Activity Index
<b>CDK</b>	Cyclin-dependent kinase
<b>CDK2</b>	Cyclin-dependent kinase 2
<b>CDK4/6i</b>	Cyclin-dependent kinase 4/6 inhibitor
<b>CE</b>	Clinically evaluable
<b>CHD</b>	Coronary heart disease
<b>Chemo</b>	Chemotherapy
<b>CHF</b>	Chronic heart failure
<b>cHL</b>	Classic Hodgkin lymphoma
<b>CI</b>	Confidence interval
<b>CKD</b>	Chronic kidney disease
<b>CLD</b>	Chronic lung disease
<b>CLDN 18.2</b>	Claudin-18.2
<b>CLDN18.2</b>	Claudin 18.2
<b>CLL</b>	Chronic lymphocytic leukaemia
<b>cm</b>	Centimetre
<b>CM</b>	Cardiomyopathy
<b>CMAx</b>	Maximum observed plasma concentration
<b>cMET</b>	C-mesenchymal epithelial transition factor
<b>CMML</b>	Chronic myelomonocytic leukaemia



# Glossary – 2 of 5

[BACK](#)
[NEXT](#)

<b>CNS</b>	Central nervous system
<b>CNS-PFS</b>	Central nervous system progression-free survival
<b>CompEx</b>	Composite endpoint for exacerbations
<b>COPD</b>	Chronic obstructive pulmonary disease
<b>CPB</b>	Cardiopulmonary bypass
<b>CPI</b>	Checkpoint inhibitor
<b>CPI-experienced</b>	Checkpoint inhibitor-experienced
<b>CPI-naïve</b>	Checkpoint inhibitor-naïve
<b>cPR</b>	Central pathological review
<b>CR</b>	Complete response
<b>CRC</b>	Colorectal cancer
<b>CrCl</b>	Creatinine clearance
<b>CRR</b>	Complete response rate
<b>CRR</b>	Complete renal response
<b>CRSwNP</b>	Chronic rhinosinusitis with nasal polyps
<b>CRT</b>	Chemoradiotherapy
<b>CRwNP</b>	Chronic rhinosinusitis with nasal polyps
<b>CSA-AKI</b>	Cardiac surgery-associated acute kidney injury
<b>CTC</b>	Circulating tumour cell
<b>CTCAE</b>	Common Terminology Criteria for Adverse Events
<b>ctDNA</b>	Circulating tumor DNA
<b>CTLA4</b>	Cytotoxic T-lymphocyte associated protein 4
<b>CTLA-4</b>	Cytotoxic T-lymphocyte-associated antigen-4
<b>CTx</b>	Chemotherapy
<b>CV</b>	Cardiovascular
<b>CVOT</b>	Cardiovascular outcomes trial
<b>CVRM</b>	Cardiovascular, Renal and Metabolism
<b>CXCR2</b>	C-X-C Motif chemokine receptor 2
<b>CyBorD</b>	Cyclophosphamide, bortezomib and dexamethasone
<b>Dato-DXd</b>	Datopotamab deruxtecan
<b>DCR</b>	Disease control rate
<b>DDFS</b>	Distant disease-free survival
<b>DDI</b>	Drug-drug Interaction
<b>DDR</b>	DNA damage response
<b>dECG</b>	Differentiated electrocardiogram
<b>DFS</b>	Disease-free survival
<b>DGF</b>	Delayed graft function
<b>DLBCL</b>	Diffuse large B-cell lymphoma
<b>DLT</b>	Dose-limiting toxicity
<b>DMARDs</b>	Disease-modifying antirheumatic drugs

<b>DNA</b>	Deoxyribonucleic acid
<b>dNCC</b>	Directly measured non-ceruloplasmin-bound copper
<b>dnTGFb</b>	Dominant-negative transforming growth factor-beta
<b>DoCR</b>	Durability of complete response
<b>DoR</b>	Duration of response
<b>DPB</b>	Disease progression in bone
<b>DPI</b>	Dry powder inhaler
<b>dPTEN</b>	Phosphatase and tensin homolog deficient
<b>DRFI</b>	Disease recurrence-free interval
<b>DSQ</b>	Dysphagia Symptom Questionnaire
<b>DXA</b>	Dual energy X-ray absorptiometry
<b>EBITDA</b>	Earnings before interest, tax, depreciation and amortisation
<b>EBRT</b>	External beam radiation therapy
<b>ECG</b>	Electrocardiogram
<b>ED</b>	Emergency department
<b>EFS</b>	Event-free survival
<b>EG</b>	Eosinophilic gastritis
<b>EGE</b>	Eosinophilic gastroenteritis
<b>eGFR</b>	Estimated glomerular filtration rate
<b>eGFR</b>	Epidermal growth factor receptor-mutated
<b>EGFRi</b>	Epidermal growth factor receptor inhibitor
<b>EGFRm</b>	Epidermal growth factor receptor-mutated
<b>EGPA</b>	Eosinophilic granulomatosis with polyangiitis
<b>EM</b>	Emerging Markets
<b>EoE</b>	Eosinophilic oesophagitis
<b>EOS</b>	Eosinophil
<b>EPI</b>	Epigenetics
<b>ER</b>	Estrogen receptor
<b>ER+</b>	Estrogen receptor-positive
<b>ERK</b>	Extracellular signal-regulated kinase
<b>ERoW</b>	Established Rest of World
<b>E-RS:COPD</b>	Evaluating Respiratory Symptoms in Chronic Obstructive Pulmonary Disease
<b>ERT</b>	Enzyme replacement therapy
<b>ESAI</b>	Eczema Area and Severity Index
<b>ESCC</b>	Esophageal squamous cell carcinoma
<b>ESKD</b>	Early-stage kidney disease
<b>ESR1</b>	Estrogen receptor 1
<b>ESRD</b>	End-stage renal disease
<b>ET</b>	Endocrine therapy
<b>ETA</b>	Endothelin A

<b>ETA</b>	Endothelin A
<b>ETA RA</b>	Endothelin receptor A antagonist
<b>EU</b>	European Union
<b>EVH</b>	Extravascular haemolysis
<b>FAF</b>	Fundus autofluorescence
<b>FCR</b>	Fludarabine, cyclophosphamide and rituximab
<b>FDC</b>	Fixed-dose combination
<b>FeNO</b>	Fractional nitric oxide concentration in exhaled breath
<b>FEV</b>	Forced-expiratory volume
<b>FEV1</b>	Forced expiratory volume in 1 second
<b>FGFR</b>	Fibroblast growth factor receptor
<b>FL</b>	Follicular lymphoma
<b>FLAP</b>	5-lipoxygenase activating protein
<b>FLOT</b>	Fluorouracil, leucovorin, oxaliplatin and docetaxel
<b>FOLFOX</b>	Folinic acid, fluorouracil and oxaliplatin
<b>FOXP3</b>	Forkhead box P3
<b>FP</b>	5-fluorouracil/cisplatin
<b>FPCD</b>	First patient commenced dosing
<b>FPG</b>	Fasting plasma glucose
<b>FRα</b>	Folate receptor alpha
<b>FX</b>	Foreign exchange
<b>G7</b>	US, Japan, EU5
<b>GA</b>	Geographic atrophy
<b>GBM</b>	Glioblastoma
<b>gBRCAm</b>	Germline BRCA-mutated
<b>GC</b>	Gastric cancer
<b>GCB</b>	Germinal center B-cell
<b>GEJ</b>	Gastric/gastroesophageal junction
<b>GEJC</b>	Gastroesophageal junction cancer
<b>GFF</b>	Glycopyrronium and formoterol fumarate
<b>GI</b>	Gastrointestinal
<b>GLP-1</b>	Glucagon-like peptide-1
<b>GLP-1/glu</b>	Glucagon-like peptide 1 receptor/glucagon dual peptide agonist
<b>GLP-1RA</b>	Glucagon-like peptide 1 receptor agonist
<b>GMFR</b>	Geometric mean fold rise
<b>gMG</b>	Generalised myasthenia gravis
<b>GMT</b>	Geometric mean titer
<b>GN</b>	Glomerulonephritis
<b>GPC3</b>	Glypican-3
<b>GPC3-positive</b>	Glypican 3-positive





# Glossary – 3 of 5

<b>GPRC5D</b>	G protein-coupled receptor, class C, group 5, member D
<b>GU</b>	Genitourinary
<b>GYN</b>	Gynaecologic
<b>H1</b>	H1-antihistamine
<b>hADME</b>	Human mass balance
<b>HbA1c</b>	Glycated haemoglobin
<b>HCC</b>	Hepatocellular carcinoma
<b>HD</b>	High dose
<b>HDL-C</b>	High-density lipoprotein cholesterol
<b>HER2</b>	Human epidermal growth factor receptor 2
<b>HER2-low</b>	Human epidermal growth factor receptor 2-low
<b>HER2-negative</b>	Human epidermal growth factor receptor 2-negative
<b>HER2-positive</b>	Human epidermal growth factor receptor 2-positive
<b>HES</b>	Hyper eosinophilic syndrome
<b>HF</b>	Heart failure
<b>HFA</b>	Hydrofluoroalkane
<b>HFO</b>	Hydrofluoro-olefins
<b>HFpEF</b>	Heart failure with preserved ejection fraction
<b>HFrfEF</b>	Heart failure with reduced ejection fraction
<b>HGFR</b>	Met/hepatocyte growth factor receptor
<b>HGSC</b>	High-grade serous carcinoma
<b>hHF</b>	Hospitalisation for heart failure
<b>HIF-PH</b>	Hypoxia inducible factor-prolyl hydroxylase
<b>HK</b>	Hyperkalaemia
<b>HLA-A*02:01</b>	Human leukocyte antigen serotype within the HLA-A serotype group
<b>HLR</b>	High-level results
<b>hMPV</b>	Human metapneumovirus
<b>HNSCC</b>	Head and neck squamous-cell carcinoma
<b>HPD</b>	Hyperprogressive disease
<b>HPDD</b>	Highest protocol-defined dose
<b>HPF</b>	High-power field
<b>HPP</b>	Hypophosphatasia
<b>HR</b>	Hazard ratio
<b>HR+</b>	Hormone receptor-positive
<b>HRD</b>	Homologous recombination deficiency
<b>HRD+</b>	Homologous recombination deficiency-positive
<b>HR-low</b>	Hormone receptor-low
<b>HRR</b>	homologous recombination repair
<b>HRRm</b>	Homologous recombination repair-mutated
<b>HSCT-TMA</b>	hematopoietic stem cell transplantation-associated thrombotic microangiopathy

<b>HSD17B13</b>	Hydroxysteroid 17-beta dehydrogenase 13
<b>HVPG</b>	Hepatic venous pressure gradient
<b>i</b>	Inhibitor
<b>i.m.</b>	Intramuscular
<b>i.v.</b>	Intravenous
<b>IA</b>	Investigator-assessed
<b>IBD</b>	Inflammatory bowel disease
<b>ICR</b>	Independent central review
<b>ICS</b>	Inhaled corticosteroid
<b>ICS-LABA</b>	Inhaled corticosteroid long-acting beta-agonists
<b>ICU</b>	Intensive care unit
<b>IDFS</b>	Invasive disease-free survival
<b>IgAN</b>	Immunoglobulin A nephropathy
<b>IHF</b>	Impaired hepatic function
<b>IIT</b>	Investigated initiated trial
<b>iJAK1</b>	Inhaled Janus kinase
<b>IL</b>	Interleukin
<b>IL-12</b>	Interleukin-12
<b>IL-33</b>	Interleukin-33
<b>IL-5</b>	Interleukin-5
<b>IL-5R</b>	Interleukin-5 receptor
<b>IMAC-TIS</b>	International Myositis Assessment And Clinical Studies-Total Improvement Score
<b>IND</b>	Investigational new drug
<b>INV</b>	Investigator review
<b>IO</b>	Immuno-oncology
<b>IPF</b>	Idiopathic pulmonary fibrosis
<b>IPFS</b>	Invasive progression-free survival
<b>IRA</b>	Inflation Reduction Act
<b>IRAK4</b>	Interleukin-1 receptor-associated kinase 4
<b>IRC</b>	Independent review committee
<b>ISS</b>	Investigator-sponsored studies
<b>ISS7</b>	Itch-severity score (weekly)
<b>iTSLP</b>	Inhaled thymic stromal lymphopoietin
<b>ITT</b>	Intent-to-treat
<b>IVIg</b>	Intravenous immunoglobulin
<b>JAK-1</b>	Janus kinase 1
<b>K+</b>	Potassium
<b>KCCQ</b>	Kansas City Cardiomyopathy Questionnaire
<b>kg</b>	Kilogram
<b>Ki67</b>	Antigen Kiel 67

<b>LA amylin</b>	Long-acting amylin
<b>LAAB</b>	Long-acting antibody
<b>LABA</b>	Long-acting beta agonist
<b>LAMA</b>	Long-acting muscarinic agonist
<b>LCAT</b>	Lecithin-cholesterol acyltransferase
<b>LCM</b>	Lifecycle management
<b>LDH</b>	Lactate dehydrogenase
<b>LDL-C</b>	Low-density lipoprotein cholesterol
<b>LICA</b>	Ligand-conjugated ASO
<b>LIF</b>	Low-density lipoprotein cholesterol
<b>LN</b>	Lupus nephritis
<b>LoE</b>	Loss of exclusivity
<b>LOS</b>	Length of stay
<b>LPCD</b>	Last patient commenced dosing
<b>LS</b>	Last subject dosed
<b>LS-SCLC</b>	Limited stage small-cell lung cancer
<b>LV</b>	Left ventricle
<b>m</b>	Mutation
<b>mAb</b>	Monoclonal antibody
<b>MABA</b>	Muscarinic antagonist-beta2 agonist
<b>MACE</b>	Major adverse cardiac events
<b>MAD</b>	Multiple ascending dose
<b>MAKE</b>	Major adverse kidney events
<b>MASH</b>	Metabolic dysfunction-associated steatohepatitis
<b>MASLD</b>	Metabolic dysfunction-associated steatotic liver disease
<b>mBC</b>	Metastatic breast cancer
<b>MCC</b>	Mucociliary clearance
<b>MCL</b>	Mantle cell lymphoma
<b>mCRPC</b>	Metastatic castrate-resistant prostate cancer
<b>MDI</b>	Metered-dose inhaler
<b>mDOR</b>	Median duration of response
<b>MDS</b>	Myelodysplastic syndrome
<b>MEK</b>	Mitogen-activated protein kinase
<b>MET</b>	Mesenchymal epithelial transition factor
<b>mFOLFOX</b>	Modified folinic acid, fluorouracil and oxaliplatin
<b>mg</b>	Milligram
<b>mg/dL</b>	Milligrams per decilitre
<b>MG-ADL</b>	Myasthenia Gravis-Activities of Daily Living
<b>MGFA</b>	Myasthenia Gravis Foundation of America
<b>mHSPC</b>	Metastatic hormone sensitive prostate cancer



# Glossary – 4 of 5

[BACK](#)
[NEXT](#)

<b>MI</b>	Myocardial infarction
<b>mL</b>	Millilitre
<b>MM</b>	Multiple myeloma
<b>MMAE</b>	Monomethyl auristatin E
<b>MMT</b>	Mixed meal test
<b>MoA</b>	Mechanism of action
<b>mPFS</b>	Median progression-free survival
<b>MPO</b>	Myeloperoxidase
<b>mPR</b>	Major pathological response
<b>MR</b>	Mineralocorticoid receptor
<b>MRA</b>	Mineralocorticoid receptor antagonist
<b>MRD-negative</b>	Minimal residual disease-negative
<b>MRI</b>	Magnetic resonance imaging
<b>MRM</b>	Mineralocorticoid receptor modulator
<b>mRNA</b>	Messenger ribonucleic acid
<b>MSA</b>	Multiple system atrophy
<b>MTAP-deficient</b>	Methylthioadenosine phosphorylase-deficient
<b>MTD</b>	Maximum tolerated dose
<b>mTNBC</b>	Metastatic triple-negative breast cancer
<b>MZL</b>	Marginal zone lymphoma
<b>n/m</b>	Not material
<b>nAb</b>	Neutralising antibody
<b>NaC</b>	Sodium channel
<b>NAFLD</b>	Non-alcoholic fatty liver disease
<b>NASH</b>	Non-alcoholic fatty liver disease
<b>NBRx</b>	New-to-brand prescription
<b>NCFB</b>	Non-cystic fibrosis bronchiectasis
<b>NCI</b>	National Cancer Institute
<b>NCPV</b>	Noncalcified plaque volume
<b>Neo-adj</b>	Neoadjuvant
<b>NF1</b>	Neurofibromatosis type 1
<b>NF1-PN</b>	Neurofibromatosis type 1 with plexiform neurofibromas
<b>ng</b>	Next-generation
<b>NGF</b>	Nerve growth factor
<b>ngSERD</b>	Next-generation oral selective estrogen receptor degrader
<b>NHA</b>	Novel hormonal agent
<b>NHL</b>	Non-Hodgkin's lymphoma
<b>NIH</b>	National Institute of Health
<b>NKTCL</b>	Extranodal natural killer T-cell lymphoma
<b>NME</b>	New molecular entity

<b>NME</b>	New molecular entity
<b>NMOSD</b>	Neuromyelitis optica spectrum disorder
<b>NP</b>	Nasal polyps
<b>NRDL</b>	National Reimbursement Drug List
<b>NRG</b>	National Clinical Trials Network in Oncology
<b>NSCLC</b>	Non-small cell lung cancer
<b>NST</b>	Neoadjuvant systemic treatment
<b>NT-proBNP</b>	N-terminal pro-B-type natriuretic peptide
<b>NYHA</b>	New York Heart Association
<b>OBD</b>	Optimal biological dose
<b>OCS</b>	Oral corticosteroid
<b>OD</b>	Once daily
<b>oGLP1</b>	Oral glucagon-like receptor peptide 1
<b>OGTT</b>	Oral glucose tolerance test
<b>oPCSK9</b>	Oral protein convertase subtilisin/kexin type 9
<b>OR</b>	Objective response
<b>ORR</b>	Overall response rate
<b>oRXFP1</b>	Oral relaxin family peptide receptor 1
<b>OS</b>	Overall survival
<b>PA</b>	Primary aldosteronism
<b>PALB2m</b>	Partner and localizer of BRCA2-mutated
<b>PAR2</b>	Protease-activated receptor 2
<b>PARP</b>	Poly ADP ribose polymerase
<b>PARP1</b>	poly(ADP-ribose) polymerase-1
<b>PARP-1sel</b>	Poly ADP ribose polymerase-1 selective
<b>PARPi</b>	poly-ADP ribose polymerase inhibitor
<b>PASI</b>	Psoriasis area severity index
<b>PBD</b>	Pyrrolobenzodiazepine
<b>PCD</b>	Plasma cell dyscrasia
<b>pCR</b>	Pathological complete response
<b>PCSK9</b>	Proprotein convertase subtilisin/kexin type 9
<b>PD</b>	Pharmacodynamics
<b>PD1</b>	Programmed cell death protein 1
<b>PD-1</b>	Programmed cell death protein-1
<b>PDAC</b>	Pancreatic ductal adenocarcinoma
<b>PDE4</b>	Phosphodiesterase type 4
<b>PD-L1</b>	Programmed death-ligand 1
<b>PD-L1-high</b>	Programmed death-ligand 1-high
<b>Peak</b>	Maximum
<b>PET</b>	Positron-emission tomography

<b>PFS</b>	Progression-free survival
<b>PFS2</b>	Time to second disease progression or death
<b>PgR</b>	Progesterone receptor
<b>PI3K</b>	Phosphoinositide 3 kinase
<b>PIK3CA</b>	Phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit
<b>PK</b>	Pharmacokinetic
<b>PK/PD</b>	Pharmacokinetic/pharmacodynamic
<b>PLEX</b>	Plasma exchange
<b>PLL</b>	Prolymphocytic leukaemia
<b>pMDI</b>	Pressurised metered-dose inhaler
<b>PN</b>	Plexiform neurofibroma
<b>PN</b>	Polyneuropathy
<b>PNH</b>	Paroxysmal nocturnal haemoglobinuria
<b>PNH-EVH</b>	PNH with extravascular haemolysis
<b>PNPLA3</b>	Phospholipase domain-containing protein 3
<b>POC</b>	Proof-of-concept
<b>POM</b>	Proof-of-mechanism
<b>post-BD</b>	Post-bronchodilator
<b>PP</b>	Plasmapheresis
<b>pPCI</b>	Primary percutaneous coronary intervention
<b>PR</b>	Partial response
<b>pre-BD</b>	Pre-bronchodilator
<b>PRMT5</b>	Protein arginine methyltransferase 5
<b>PRO</b>	Patient reported outcome
<b>PRR</b>	Recurrent platinum resistant
<b>PS</b>	Propensity score
<b>PSA</b>	Prostate-specific antigen
<b>PSA50</b>	Prostate-specific antigen 50
<b>PSC</b>	Pulmonary sarcomatoid carcinoma
<b>PSMA</b>	Prostate-specific membrane antigen
<b>PSR</b>	Platinum-sensitive relapsed
<b>PTCL</b>	Peripheral T-cell lymphoma
<b>PTEN</b>	Phosphatase and tensin homolog gene
<b>PTH</b>	parathyroid hormone receptor
<b>PVR</b>	Pulmonary vascular resistance
<b>Q1W</b>	Every one week
<b>Q2W</b>	Every two weeks
<b>Q4W</b>	Every four weeks
<b>Q8W</b>	Every eight weeks
<b>QCS</b>	Quantitative continuous scoring



# Glossary – 5 of 5

<b>QD</b>	Once daily
<b>QID</b>	Four times per day
<b>QOD</b>	Every other day
<b>QoL</b>	Quality of life
<b>QoL-DN</b>	Norfolk Quality of Life-Diabetic Neuropathy
<b>QT</b>	Duration of ventricular electrical systole
<b>QTcF</b>	Corrected QT interval by Fredericia
<b>R&amp;I</b>	Respiratory and Immunology
<b>R/R</b>	Relapsed/refractory
<b>r/r</b>	Relapsed/refractory
<b>RA</b>	Rheumatoid arthritis
<b>RAAS</b>	Renin-angiotensin-aldosterone system
<b>RAGE</b>	Receptor for advanced glycation end products
<b>RC</b>	Radioconjugates
<b>RECIST</b>	Response Evaluation Criteria in Solid Tumours
<b>REiNS</b>	Response Evaluation in Neurofibromatosis and Schwannomatosis
<b>RET</b>	Rearranged during transfection
<b>RFS</b>	Relapse-free survival
<b>rhLCAT</b>	Recombinant human lecithin-cholesterol acyltransferase
<b>rNDV</b>	Recombinant Newcastle disease virus
<b>ROR<math>\gamma</math></b>	Related orphan receptor gamma
<b>RP2D</b>	Recommended Phase II dose
<b>rPFS</b>	Radiographic progression-free survival
<b>RR</b>	Response rate
<b>RSV</b>	Respiratory syncytial virus
<b>RT</b>	Radiation therapy
<b>s. asthma</b>	Severe asthma
<b>s.c.</b>	Subcutaneous
<b>SABA</b>	Short-acting beta2-agonist
<b>SAD</b>	Single ascending dose
<b>SAE</b>	Serious adverse event
<b>SARS-CoV-2</b>	Severe-acute-respiratory-syndrome-related coronavirus-19
<b>SBP</b>	Systolic blood pressure
<b>SBRT</b>	Stereotactic body radiation therapy
<b>SCCHN</b>	Squamous-cell carcinoma of the head and neck
<b>SCD</b>	Sickle cell disease
<b>SCLC</b>	Small cell lung cancer
<b>SD</b>	Stable disease
<b>SERD</b>	Selective estrogen receptor degrader
<b>SG&amp;A</b>	Selling, General and Administrative

<b>SGLT2</b>	Sodium-glucose transport protein 2
<b>SGLT2i</b>	Sodium/glucose cotransporter 2 inhibitor
<b>SGRM</b>	Selective glucocorticoid receptor modulator
<b>SGRQ</b>	Saint George Respiratory Questionnaire
<b>siRNA</b>	Small interfering ribonucleic acid
<b>SJC</b>	Swollen joint count
<b>sK</b>	Serum potassium
<b>SLE</b>	Systemic lupus erythematosus
<b>SLL</b>	Small lymphocytic lymphoma
<b>SMAD</b>	Single and multiple ascending dose trial
<b>SoC</b>	Standard-of-care
<b>sPGA</b>	Static Physician's Global Assessment Score
<b>SS</b>	Steady state
<b>ST2</b>	Suppression of tumorigenicity 2
<b>STAT3</b>	Signal transducer and activator of transcription 3
<b>Stg. I/II/III</b>	Stage I/II/III
<b>sUA</b>	Serum uric acid
<b>T2D</b>	Type-2 diabetes
<b>T2DM</b>	Type-2 diabetes mellitus
<b>T300</b>	Imfinzi plus Imjudo
<b>T790M</b>	Threonine 790 substitution with methionine
<b>TACE</b>	Transarterial chemoembolization
<b>tBRCAm</b>	Tumour (somatic) BRCA-mutated
<b>TCE</b>	T-cell engager
<b>TCR</b>	T-cell receptor
<b>TCR-T</b>	T-cell receptor therapy
<b>TDR</b>	Tumour drivers and resistance
<b>TEAE</b>	Treatment-emergent adverse event
<b>TESAE</b>	Treatment-emergent serious adverse event
<b>TFST</b>	Time to first subsequent therapy or death
<b>TGFbetaRIIDN</b>	Transforming growth factor-beta RIIDN
<b>THP</b>	Paclitaxel, trastuzumab and pertuzumab
<b>TID</b>	Three times per day
<b>TIGIT</b>	T-cell immunoreceptor with Ig and ITIM domains
<b>TIM3</b>	T-cell immunoglobulin and mucin domain 3
<b>TIM-3</b>	T-cell immunoglobulin and mucin domain-containing protein
<b>TJC</b>	Tender joint count
<b>TKI</b>	Tyrosine kinase Inhibitor
<b>TLR</b>	Toll-like receptor 9
<b>TMA</b>	Thrombotic microangiopathy

<b>Tmax</b>	Time to reach maximum observed plasma concentration
<b>TNBC</b>	Triple negative breast cancer
<b>TNF</b>	Tumour necrosis factor
<b>TNSALP</b>	Tissue-nonspecific alkaline phosphatase
<b>TOP1i</b>	Topoisomerase 1 inhibitor
<b>TP53</b>	Tumour protein 53
<b>TP53 R175H</b>	Tumour protein p53 with arginine at position 175 is replaced with histidine
<b>TPS</b>	Tumour proportion score
<b>Treg</b>	Regulatory T-cell
<b>TROP2</b>	Trophoblast cell surface antigen 2
<b>TSLP</b>	Thymic stromal lymphopoietin
<b>TTD</b>	Time to treatment discontinuation
<b>TTF</b>	Time to treatment failure
<b>TTNT</b>	Time to next therapy
<b>TTP</b>	Time to tumour progression
<b>TTR</b>	Time to treatment response
<b>TTR</b>	Transthyretin
<b>u/r HTN</b>	Uncontrolled or treatment resistant hypertension
<b>UACR</b>	Urinary albumin/creatinine ratio
<b>UK</b>	United Kingdom
<b>ULN</b>	Upper limit of normal
<b>u-LTE4</b>	Urinary leukotriene E4
<b>UMEC</b>	Umeclidinium
<b>UPCR</b>	Urine protein creatinine ratio
<b>URAT1</b>	Uric acid transporter 1
<b>US</b>	United States
<b>V&amp;I</b>	Vaccines and Immune Therapies
<b>VEGF</b>	Vascular endothelial growth factor
<b>VHH</b>	Single domain antibody
<b>VLP</b>	Virus-like particle
<b>XELOX</b>	Oxaliplatin and capecitabine

