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- 2 legislative and regulatory developments and economic conditions;
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- 6 increased government pricing pressures;
- 7 interruptions in production;
- 8 loss of or inability to obtain adequate protection for intellectual property rights;
- 9 litigation;
- 10 loss of key executives or other employees; and
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**Roche**

**Q1 2025 sales**

*Basel, 24 April 2025*



## **Group**

*Thomas Schinecker*  
*Chief Executive Officer*

**Performance**

**Outlook**

# Q1 2025: Group sales growth at +6%

## Q1 sales all at CER

- Group sales growth +6%, +8% Pharma and 0% for Diagnostics (healthcare pricing reforms in China)
- LOE impact in line with guidance

## Key milestones achieved in Q1

- Pharma regulatory: EU approval Columvi in 2L+ DLBCL, US approval Susvimo in DME and TNKase in acute ischemic stroke, US & EU filing Gazvya in LN, EU filing Lunsumio SC in 3L+ FL
- Pharma readouts: Positive Ph III (SUNMO) Lunsumio + Polivy in 2L+ DLBCL
- Ph III decisions taken: trontinemab in AD (data presented at ADPD), NXT007 in Hemophilia A (data to be presented at upcoming medical conference)
- Business development: Zealand Pharma collaboration on petrelintide (long-acting amylin analog)\*
- Diagnostics regulatory: cobas liat CT/NG
- Diagnostics pipeline: Unveiling of novel SBX sequencing technology

## Significant newsflow in 2025 ahead

- Pivotal Ph III readouts: giredestrant in 1L ER+/HER2- mBC and in post CDKi ER+/HER2- mBC, Lunsumio in 2L+ FL, Venclexta in 1L MDS, PiaSky in aHUS, Ocrevus HD in PPMS, fenebrutinib in RMS and PPMS, astegolimab in COPD, Gazyva in SLE, vamikibart in UME
- Ph III enabling readouts: Evrysdi + GYM 329 in SMA, GYM 329 in FSHD, zilebesiran in HTN, CT-388 in obesity, CT-868 in T1D
- Diagnostics launches: Elecsys pTau181, Elecsys Troponin-T hs Generation 6, Elecsys Pro-C3 ADAPT, cobas i601 Mass Spectrometry wave 1 ipacks, cobas BV/CV, navify Digital Pathology 3.0, Elecsys Dengue Ag

\*pending deal closure; LOE: Loss of exclusivity includes global losses of Avastin, Herceptin, MabThera/Rituxan, Esbriet, Lucentis and Actemra; CER: Constant Exchange Rates (avg. full year 2024); AD: Alzheimer's disease; SC: subcutaneous; ER: Estrogen-receptor; HER2: Human epidermal growth factor; mBC: Metastatic breast cancer; DLBCL: Diffuse large B-cell lymphoma; FL: Follicular lymphoma; MDS: Myelodysplastic syndromes; aHUS: Atypical hemolytic uremic syndrome; HD: High dose; RMS/PPMS: Remitting/primary progressive multiple sclerosis; COPD: Chronic obstructive pulmonary disease; SLE: Systemic lupus erythematosus; UME: Uveitic macular edema; SMA: Spinal muscular atrophy; FSHD: Facioscapulohumeral muscular dystrophy; HTN: hypertension; LN: Lupus nephritis

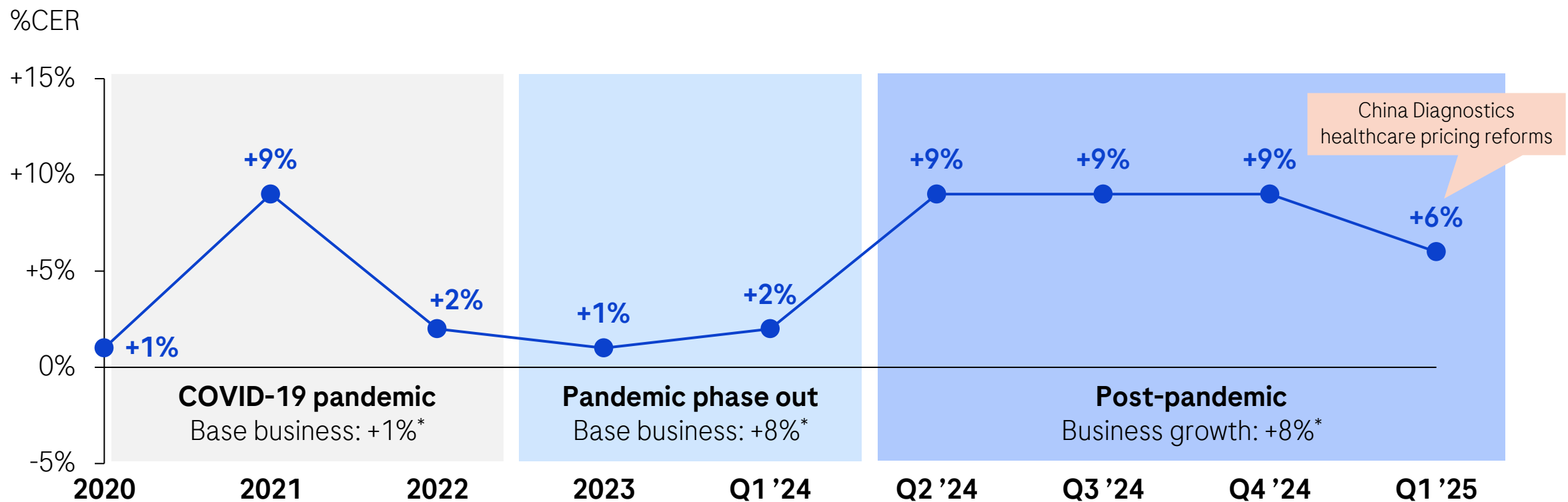
# Q1 2025: Strong Pharma sales driving Group growth

Diagnostics impacted by healthcare pricing reforms in China

	Q1 2025 CHFbn	Q1 2024 CHFbn	Change in % CHF	CER
Pharmaceuticals Division	11.9	10.9	9	8
Diagnostics Division	3.5	3.5	0	0
Roche Group	15.4	14.4	7	6

# Q1 2025: Consistent strong growth in the last four quarters

## Group sales growth



\*Average growth rate of quarterly CER growth rates for specified period; All growth rates at Constant Exchange Rates (avg. full year of respective years); Base business: Pharma excluding Ronapreve and Diagnostics excluding COVID-19 diagnostic tests



# Key growth drivers of the Roche portfolio

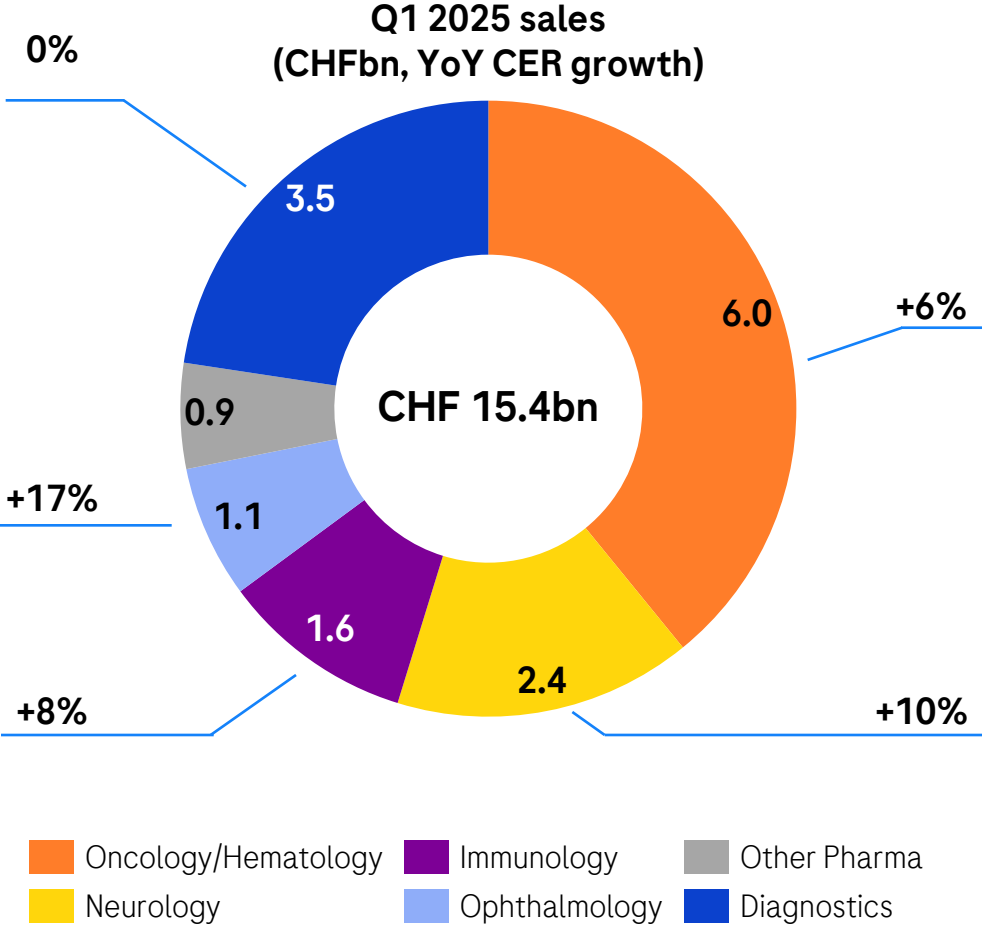
Diagnostics: Molecular Lab and Pathology Lab driving growth; China impacted by healthcare pricing reforms



Vabysmo: Continued market share expansion, incl. naïve pts; US impacted by branded market contraction



Xolair: >50k patients on treatment for food allergy



Phesgo: Conversion rate climbing to 47%  
Alecensa: Geographic expansion in adj. ALK+ NSCLC



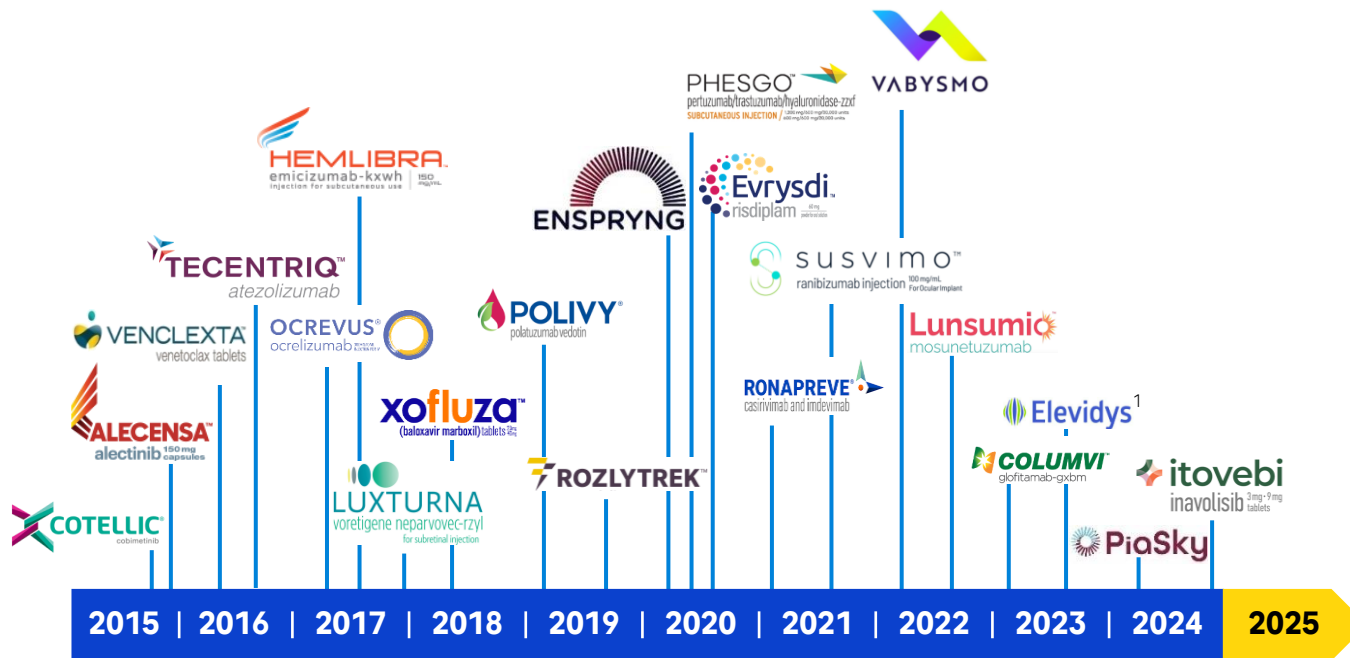
Columvi: EU approval in 2L+ DLBCL (STARGLO)  
Lunsumio+Polivy: Positive Ph III (SUNMO) in 2L+ DLBCL  
Hemlibra: Next-gen bispecific NXT007 to enter Ph III



Ocrevus Zunovo: Permanent J-Code granted April 1<sup>st</sup>  
Evrysdi: US approval for tablet formulation achieved

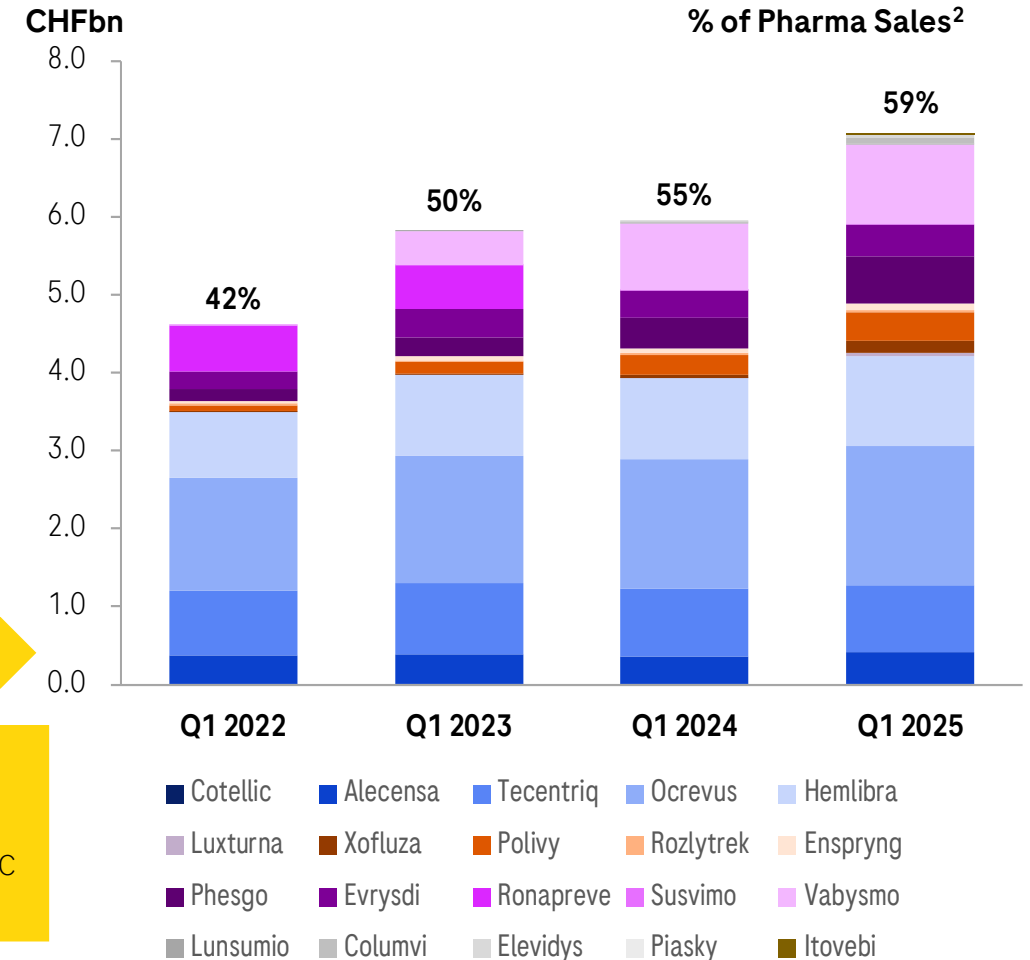
# Young portfolio to drive growth in the near- to mid-term

4 key pivotal NME readouts expected in 2025



## Pivotal NME readouts

- astegolimab in COPD
- vamikibart in UME
- giredestrant in ER+/HER2- BC
- fenebrutinib in RMS/PPMS

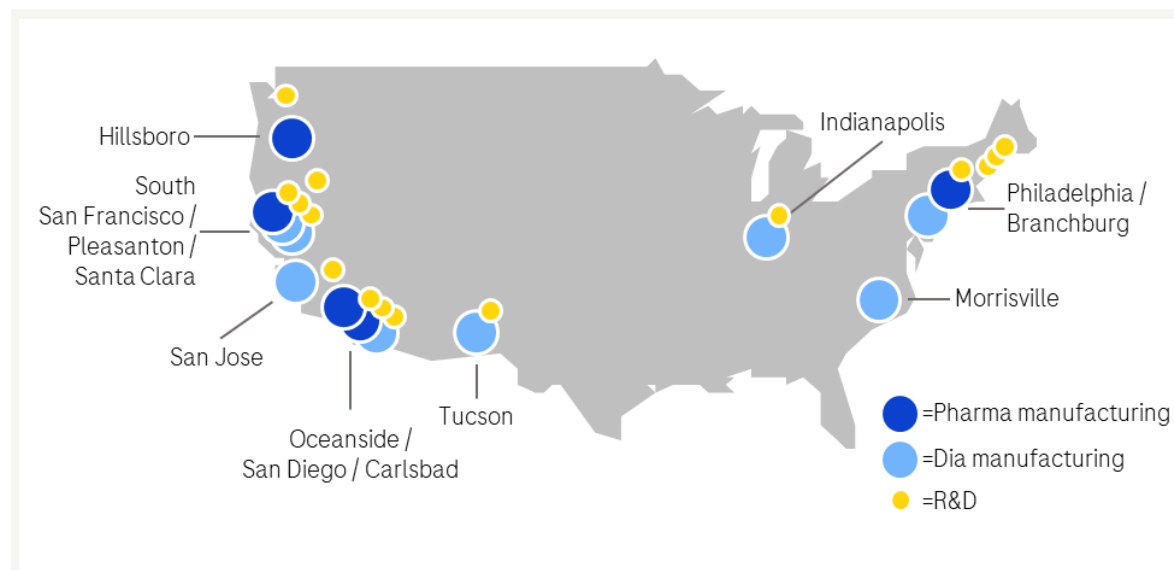


Young portfolio defined as all launches since end of 2015; 1. Elevidys: Accelerated US approval by partner company Sarepta; 2. Venclexta sales booked by AbbVie and therefore not included; NME: New molecular entity; COPD: Chronic obstructive pulmonary disorder; RMS/PPMS: Relapsing/primary progressive multiple sclerosis; ER: Estrogen receptor; HER2: Human epidermal growth factor 2 receptor; BC: Breast cancer; UME: Uveitic macular edema

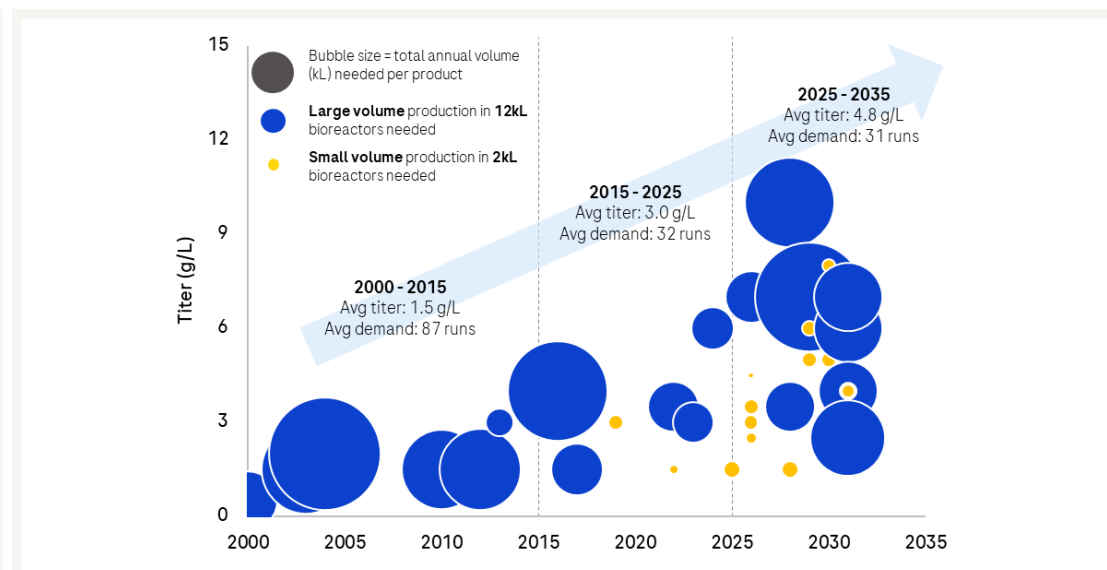
# Roche with full Pharma and Diagnostics value chains in the US

Commitment to invest USD 50bn into R&D and PP&E in the US until the end of the decade

## 13+1\* manufacturing and 15+1\* R&D sites in the US



## Biologics productivity evolution 2000 to 2030



- US investments of USD 67bn over the last 10 years, incl. USD 56bn in R&D and USD 11bn in PP&E
- Commitment to invest USD 50bn into R&D and PP&E in the US until the end of the decade (incl. one new R&D site and one new manufacturing site focusing on CVRM and AI/ML)
- Currently 50% drug substance capacity utilization in the US, due to a 5-fold biologics productivity increase from 2000 to 2030
- Manufacturing of key medicines already located in the US, with tech transfer for remaining key medicine ongoing
- IP for medicines invented in the US always held in the US

**Performance**

**Outlook**

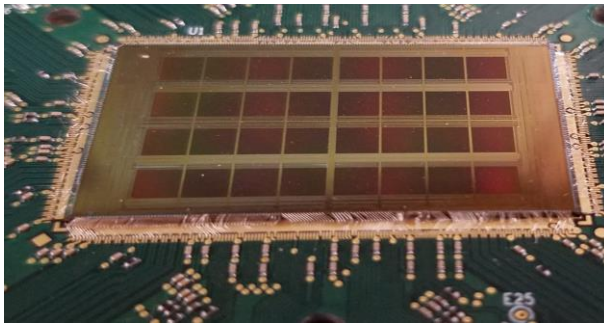
# Roche Sequencing Solution<sup>1</sup>

Combination of two powerful innovations creates a leap forward in sequencing

Presented at AGBT



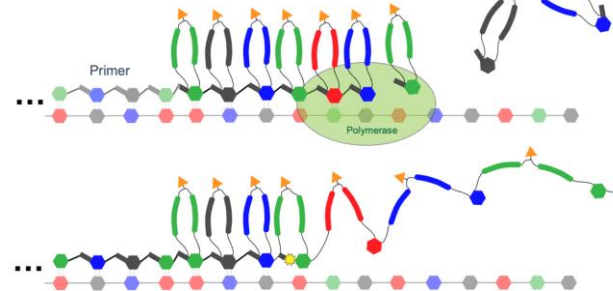
## High-throughput sensor module



- 8 million microwell array CMOS chip
- Significant improvement in measurement for single molecule sequencing

Acquired in 2014

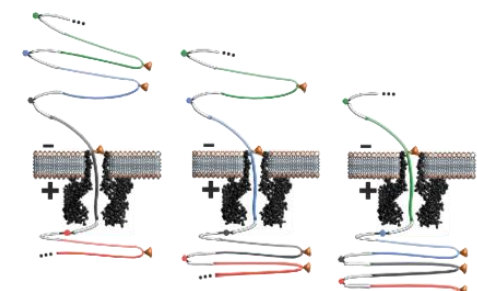
## SBX chemistry



- Novel chemistry from Stratos turns DNA into an expanded molecule 50x longer
- Significant improvement in signal-to-noise for single molecule sequencing

Acquired in 2020

## Unique benefits



- **Accuracy:** High accuracy, fit for clinical applications<sup>2</sup>
- **Speed:** Sample to VCF of a full human genome in under 7 hours
- **Throughput:** 7 human genomes in 1 hour at > 30X; 500M bases/second

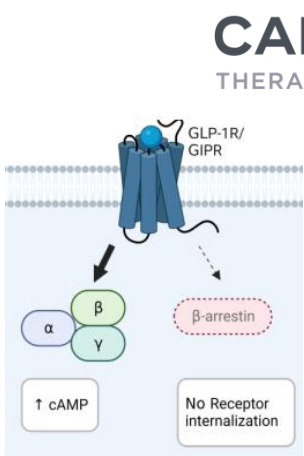
1. In development; 2. Accuracy as measured by F1 scores for calling SNV and InDels; SBX: Sequencing by expansion; CMOS: Complementary metal-oxide semiconductor; AGBT: Advances in Genome Biology and Technology; VCF: Variant calling file

# Roche's commitment to become a leader in CVRM

Complementing our obesity portfolio and laying the foundation for future innovation in CVRM


## Pharmaceuticals

## Diagnostics



**CARMOT<sup>\*</sup>**  
THERAPEUTICS

- CT-173 (PYY)
- CT-388 (GLP-1/GIP RA)
- CT-868 (GLP-1/GIP RA)
- CT-996 (GLP-1 RA)
- GYM 329 (anti-latent myostatin Ab)



**ZEAL&<sup>\*\*</sup>**  
ZEALAND PHARMA


Petrelintide (Long-acting amylin analogue)

Broad portfolio of differentiated assets to address unmet needs and develop unique combination in obesity, T1D/T2D and for comorbidities

Roche a leader in the CVM market

Leading cardiac/metabolic biomarker portfolio

Developing holistic diabetes/cardiac & comorbidity mgmt solutions, including ongoing CGM launch







**HARVARD<sup>\*\*\*</sup>**  
UNIVERSITY

*First industrial partner at the Boston innovation center*

Roche Genentech CVRM hub for innovation in drug discovery & development, and AI/ML

\*Carmot acquired by Roche in 2024; \*\*Zealand Pharma and Roche entered collaboration in 2025, pending deal closure; \*\*\*Harvard University and Roche announced launch of Roche Genentech Innovation Center Boston in 2025, based on existing partnership. First construction phase to complete in 2026; GLP-1: Glucagon-like peptide-1; GIP: Glucose-dependent insulinotropic polypeptide; RA: Receptor agonist; Ab: Antibody; T1D/T2D: Type 1/2 diabetes; CV(R)M: Cardiovascular, (renal) and metabolism; AI/ML: Artificial intelligence / machine learning; CGM: Continuous glucose monitoring

# 2025 Pharma pipeline

Q1 key updates: Ph III Go for trontinemab in AD and for NXT007 in hemophilia A; Zealand Pharma collaboration

## New Molecular Entities (NME)

<b>giredestrant</b> HR+ BC	<b>fenebrutinib</b> RMS, PPMS	<b>vamikibart</b> DME, UME
<b>Itovebi (inavolisib)</b> PI3Km BC	<b>Elevidys<sup>1</sup></b> DMD	<b>CT-388</b> Obesity +/- T2D
<b>divarasib</b> KRAS+ NSCLC, CRC	<b>GYM 329</b> SMA, FSHD, <i>obesity</i>	<b>CT-868</b> T1D with BMI ≥25
<b>tiragolumab</b> NSCLC, uHCC, <i>ESCC</i>	<b>afimkibart<sup>2</sup></b> IBD, <i>AtD</i> , <i>MASH</i>	<b>CT-996</b> Obesity +/- T2D
<b>trontinemab</b> Alzheimer's disease	<b>astegolimab</b> COPD	<b>petrelintide*</b> Obesity +/- T2D
<b>prasinezumab</b> Parkinson's disease	<b>sefaxersen</b> IgAN	<b>zilebesiran</b> Hypertension
		<b>NXT007</b> Hemophilia A

- 8+ NMEs with CHF >3bn peak sales potential per asset
- 5 NMEs with CHF 2-3bn peak sales potential per asset

## Line Extensions (LE)

<b>Columvi</b> 2L DLBCL, 1L DLBCL	<b>PiaSky</b> PNH, aHUS, SCD	<b>Enspryng</b> MOGAD, AIE, TED, <i>DMD</i>
<b>Lunsumio</b> 2L DLBCL, R/R FL, 1L FL	<b>Ocrevus<sup>3</sup></b> SC, <i>HC OBI</i> , <i>HD</i>	<b>Gazyva</b> LN, SLE, MN, PNS

- 6 marketed products with LEs that could add CHF 1-2bn peak sales potential per asset



\*Zealand Pharma and Roche entered collaboration in 2025, pending deal closure; Peak sales shown unadjusted; 1. Elevidys peak sales are ex-US; 2. anti-TL 1A; 3. Incremental peak sales opportunity for Ocrevus; AtD: Atopic dermatitis; CVRM: Cardiovascular, renal and metabolism; HC: High concentration; OBI: On-body injector

# 2025 guidance

LOE impact of CHF 1.2bn expected for 2025

## Group sales growth<sup>1</sup>

Mid single digit sales growth

## Core EPS growth<sup>1</sup>

High single digit Core EPS growth

## Dividend outlook

Further increase dividend in Swiss francs

1. At CER: Constant Exchange Rates (avg full year 2024); LOE: Loss of exclusivity includes global losses of Avastin, Herceptin, MabThera/Rituxan, Actemra, Esbriet and Lucentis





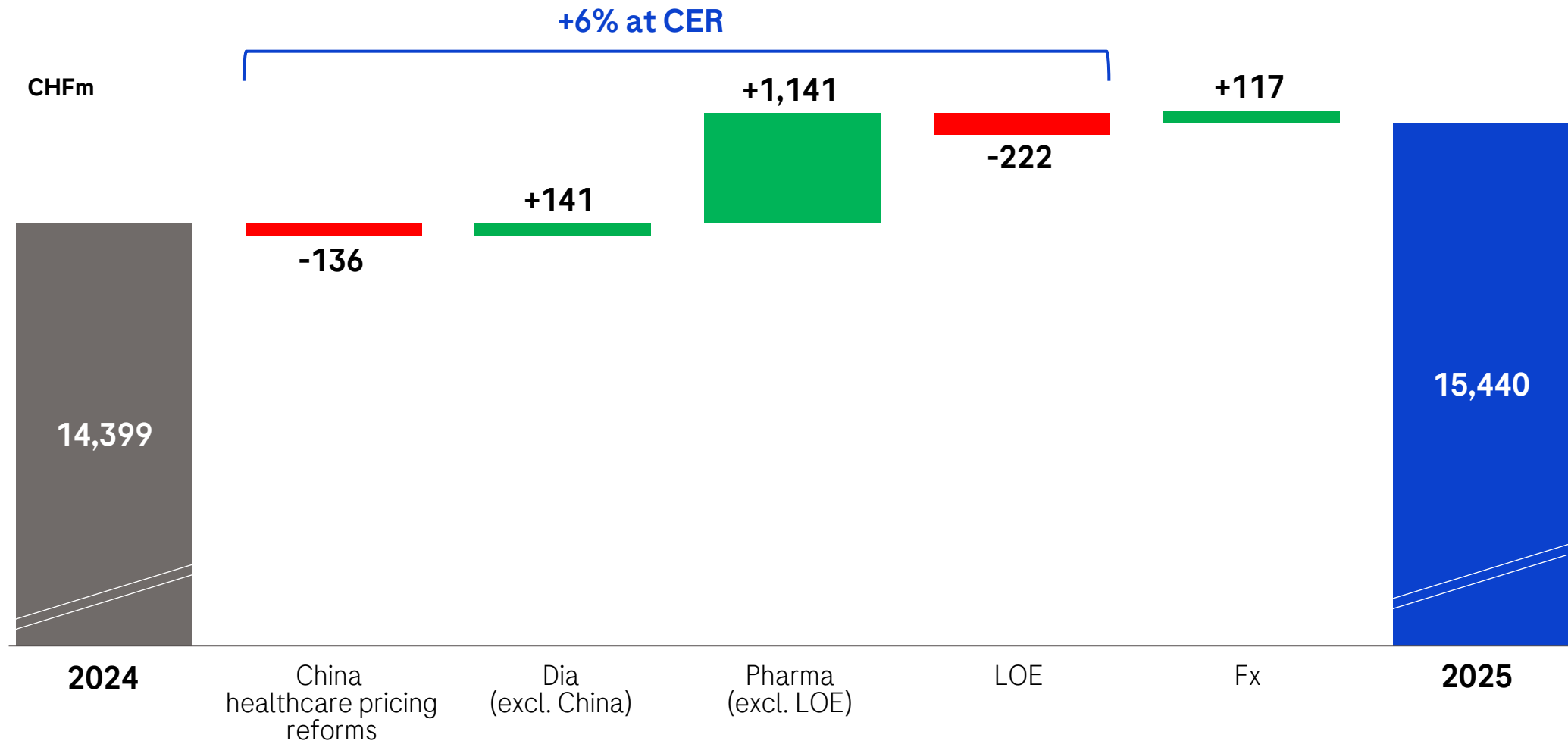
## **Finance**

*Alan Hippe*

*Chief Financial Officer*

# Q1 2025: Group growth at +6%

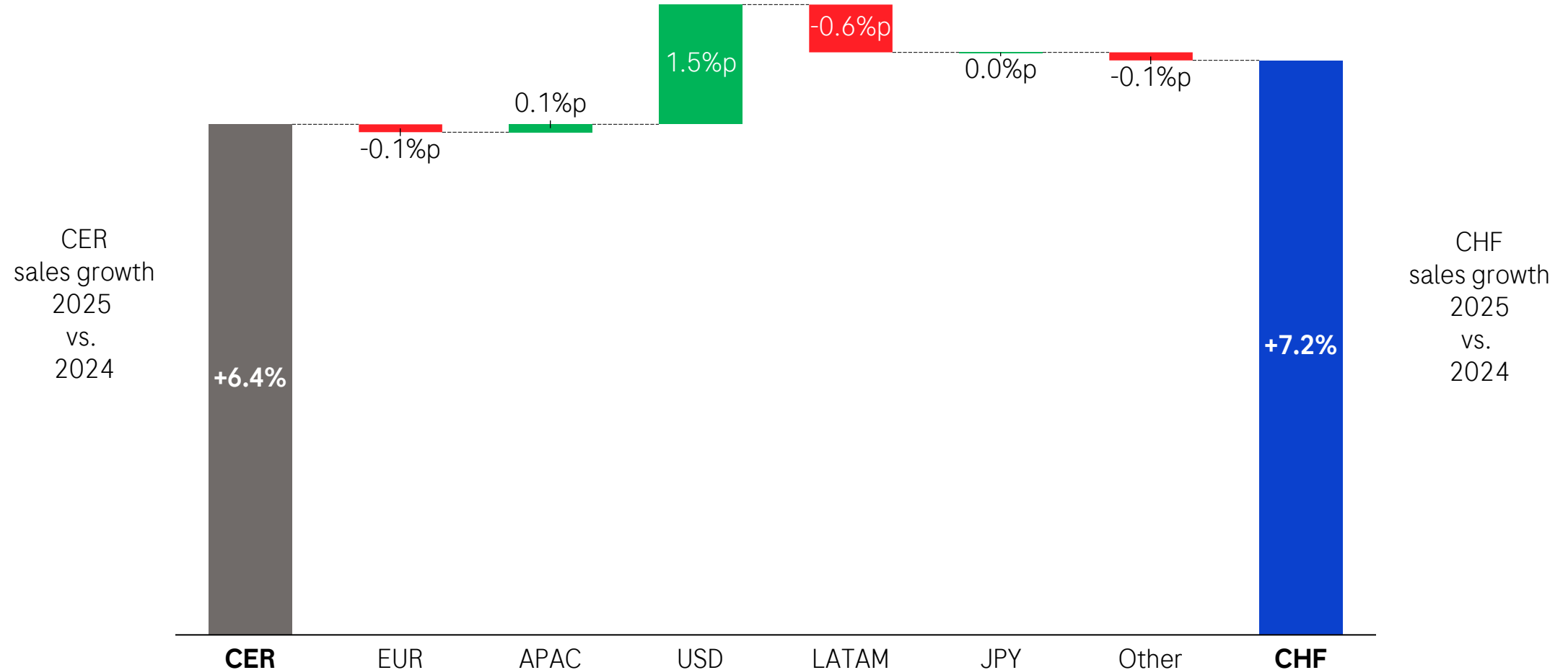
Pharma Division driving growth, Diagnostics Division stable due to healthcare pricing reforms in China



CER: Constant Exchange Rates (avg. full year 2024); LOE: Loss of exclusivity includes global losses of Avastin, Herceptin, MabThera/Rituxan, Actemra, Esbriet and Lucentis; Totals may include differences due to rounding

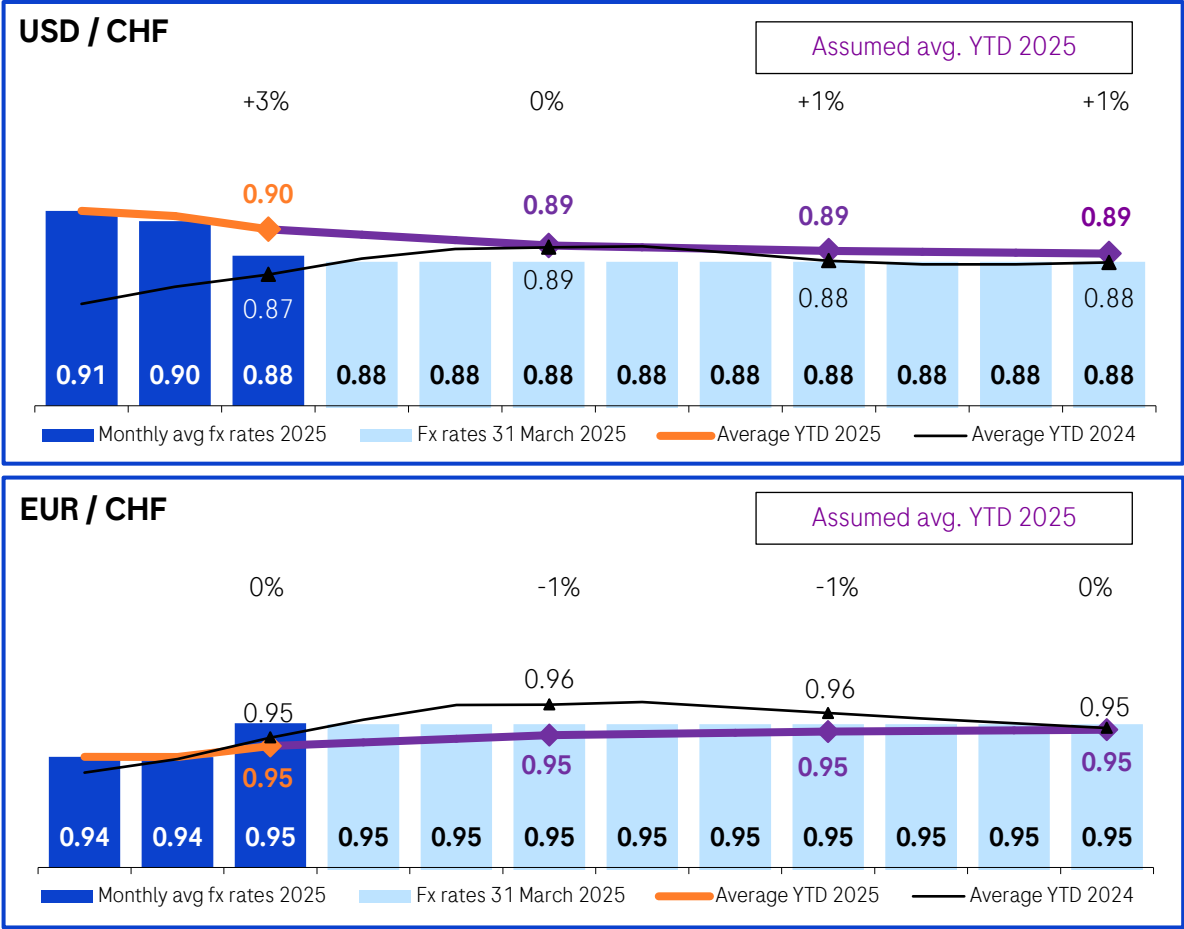
# Exchange rate impact on sales growth

Positive impact driven by the USD



# Expected 2025 currency impact

FY 2025 impact of -5%p on Group sales expected assuming 23 Apr 2025 rates remain stable until the end of 2025



Assuming the 31 March 2025 exchange rates remain stable until end of 2025,  
**2025 impact<sup>1</sup> is expected to be (%p):**

	Q1	Q2	Q3	Q4
Sales	+1	-3	+1	+1

	Q1	HY	Sep YTD	FY
Sales	+1	-1	-1	0
Core operating profit		-2		0
Core EPS		-3		0

1. On Group growth rates

# 2025 guidance

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## **Pharmaceuticals Division**

*Teresa Graham*

*CEO Roche Pharmaceuticals*

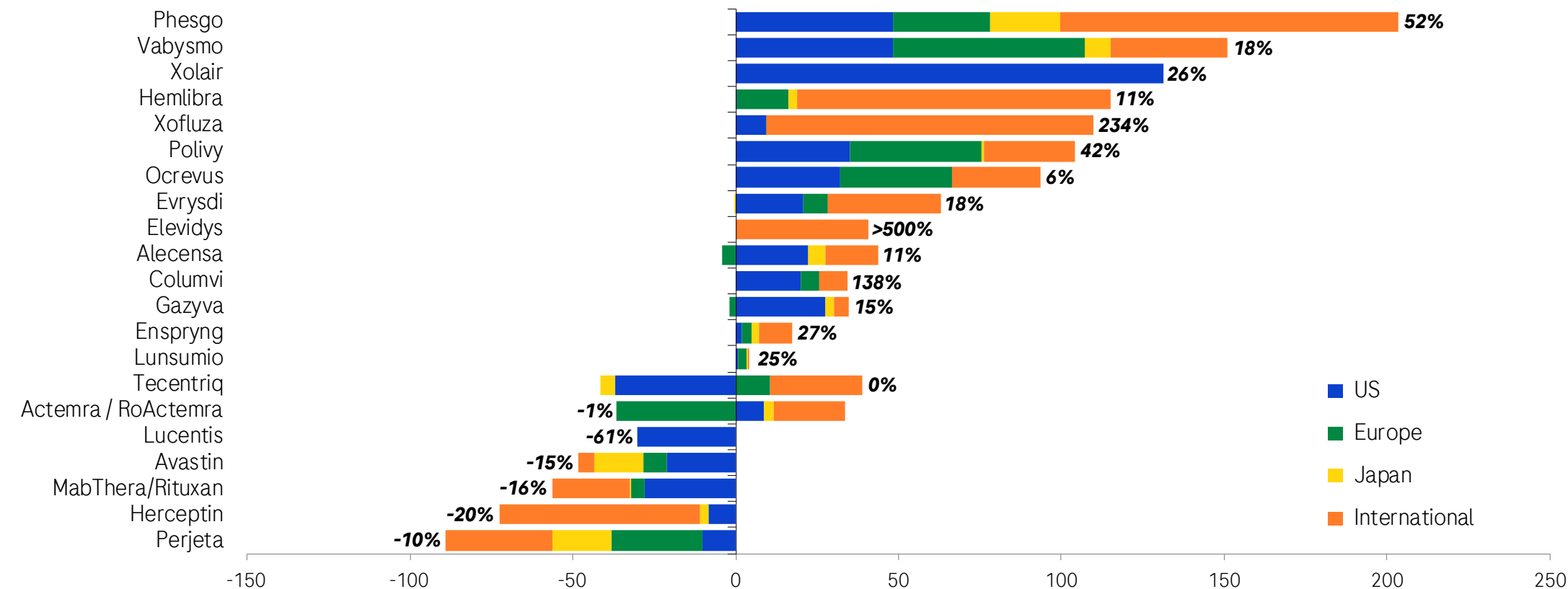
# Q1 2025: Pharmaceuticals sales

Continued strong growth in US, EU and International; Japan returning to growth

	Q1 2025 CHFm	Q1 2024 CHFm	Change in %	
			CHF	CER
<b>Pharmaceuticals Division</b>	<b>11,949</b>	<b>10,921</b>	<b>9</b>	<b>8</b>
United States	6,224	5,692	9	6
Europe	2,320	2,200	5	5
Japan	671	649	3	3
International	2,734	2,380	15	18

# Q1 2025: Young portfolio delivering strong growth

Growth across all regions with strong performance in International



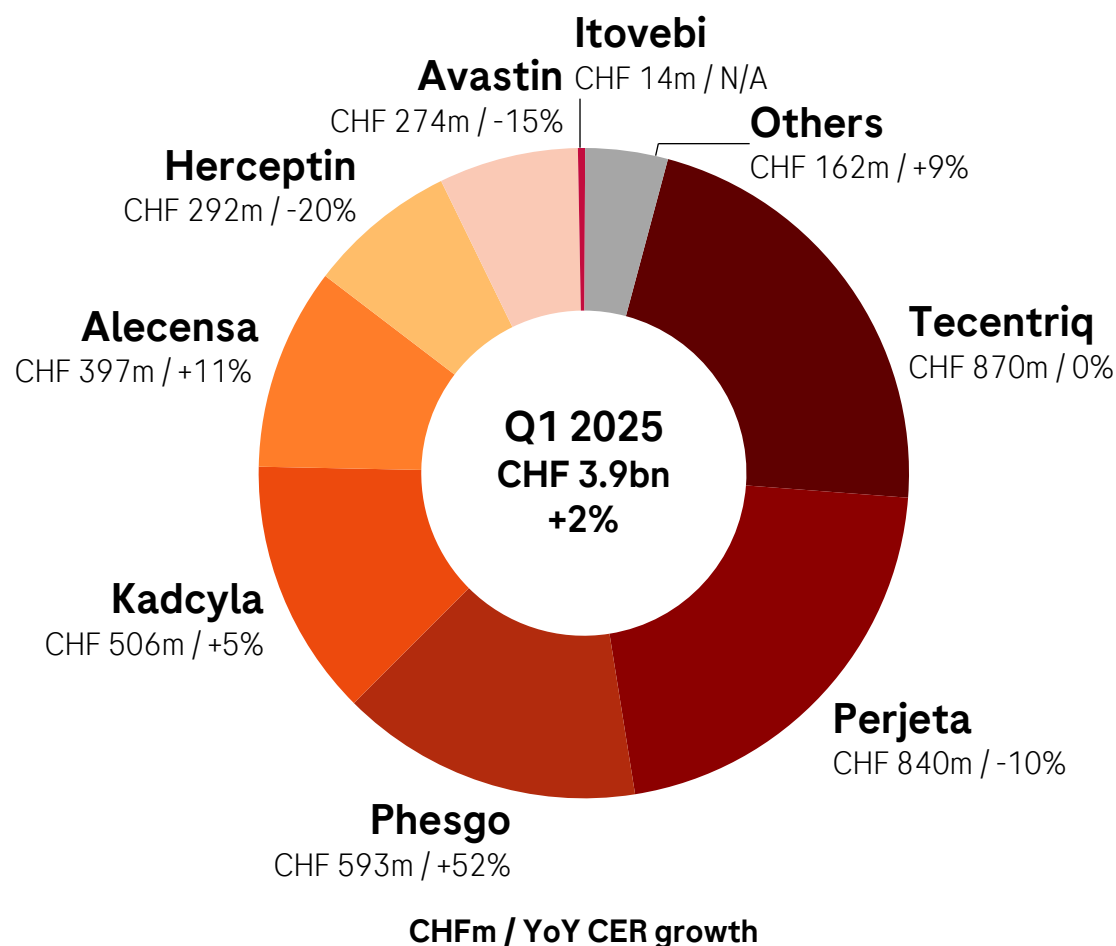
Absolute values and growth rates at Constant Exchange Rates (avg. full year 2024)





# Oncology growing +2% in Q1 driven by HER2 franchise

Phesgo conversion rate climbing to 47% in 58 launch countries\*



## Q1 update

- Phesgo: Strong uptake across all regions; strong growth in China following NRDL listing
- Perjeta: Conversion to Phesgo ongoing
  - Perjeta + Herceptin (APHINITY): Final OS analysis (≥11-year follow-up) to be presented at upcoming congress
- Kadcyla: Growth driven by adjuvant BC
- Itovebi: US launch in 1L *PIK3CA*-mut HR+ BC ongoing
- Tecentriq: Stable sales due to SCLC and HCC
- Alecensa: Growth driven by adjuvant ALK+ NSCLC

## Outlook 2025

- Itovebi in 1L *PIK3CA*-mut HR+ BC: EU approval
- Ph III (evERA) giredestrant in post CDKi ER+/HER2- mBC
- Ph III (persevERA) giredestrant in 1L ER+/HER2- mBC
- Ph III initiation for divarasib in 1L NSCLC

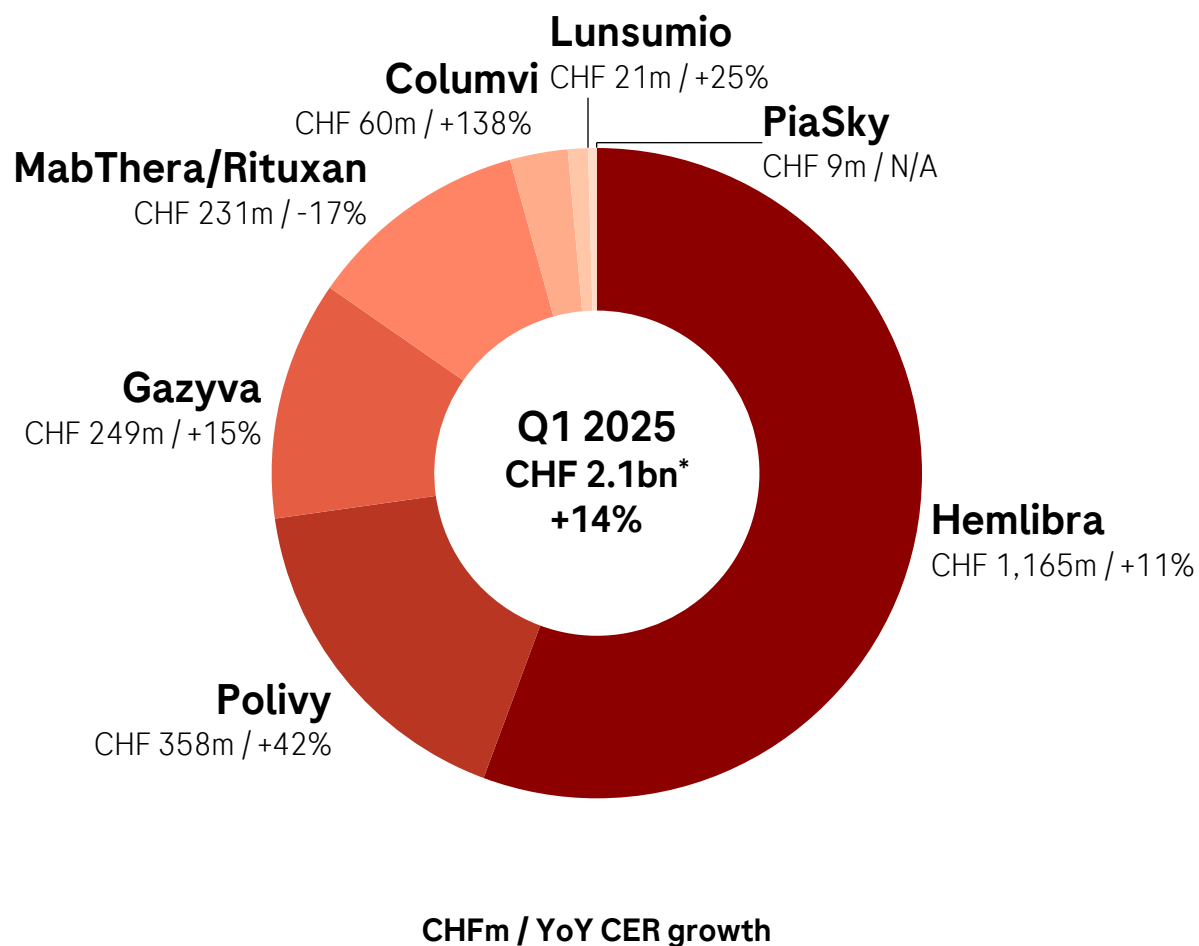
\*Perjeta/Phesgo conversion rate calculated using volumes, currently taking 58 launch countries into account; CER: Constant Exchange Rates (avg full year 2024); *PIK3CA*-mut: Phosphatidylinositol 3-kinase, catalytic, alpha polypeptide mutated; HR: Hormone receptor; ER: Estrogen receptor; HER2: Human epidermal growth factor 2; e/mBC: Early/metastatic breast cancer; SCLC: Small cell lung cancer; NSCLC: Non-small cell lung cancer; ALK: Anaplastic lymphoma kinase; HCC: Hepatocellular carcinoma; CDKi: Cyclin dependent kinase inhibitor; OS: Overall survival



# Polivy with strong global growth driven by 1L DLBCL

Positive Lunsumio Ph III (SUNMO) results in 2L+ DLBCL; Columvi EU approval achieved in 2L+ DLBCL

IR Hematology Update  
23 June



## Q1 update

- Hemlibra: Strong Q1 growth across all patient segments; US impacted by buying patterns
- Polivy: Strong 1L DLBCL uptake with >50k pts treated globally
  - POLARGO in r/r DLBCL data update at upcoming congress
- Gazyva: Growth driven by combinations in 1L CLL
- Columvi: Driven by 3L+ DLBCL launch; EU approval in 2L+ DLBCL (STARGLO) achieved
- Lunsumio: Driven by 3L+ FL launch
  - Positive Ph III (SUNMO) Lunsumio + Polivy in 2L+ DLBCL
- NXT007 in Hem A: Ph III decision taken; Ph II data to be presented

## Outlook 2025

- Columvi in 2L+ DLBCL (STARGLO): US PDUFA set for July 20
- Lunsumio SC in 3L+ FL: US PDUFA set for Sep 22
- Ph III (CELESTIMO) Lunsumio + lenalidomide in 2L+ FL
- Ph III (VERONA) Venclexta + azacitidine in 1L MDS
- Ph III (COMMUTE-a) PiaSky in aHUS

\*Venclexta sales booked by AbbVie and therefore not included; CER: Constant Exchange Rates (avg full year 2024); DLBCL: Diffuse large B cell lymphoma; CLL: Chronic lymphocytic leukemia; FL: Follicular lymphoma; SC: Subcutaneous; OS: Overall survival; MDS: Myelodysplastic syndromes; aHUS: Atypical hemolytic uremic syndrome



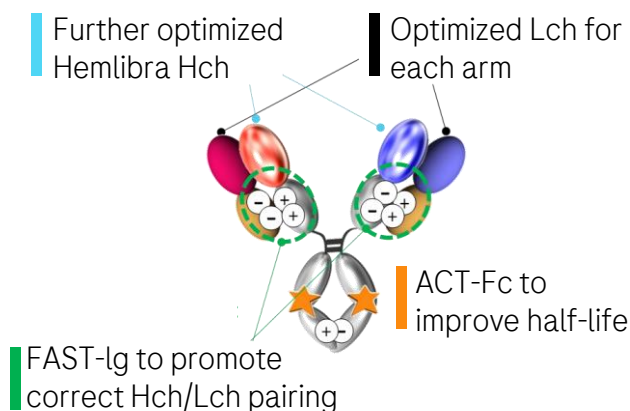
# NXT007: Next-gen Factor VIIIa mimetic bispecific mAb

Ph II data to be presented in 2025; Ph III program, including H2H vs. Hemlibra, to initiate in 2026

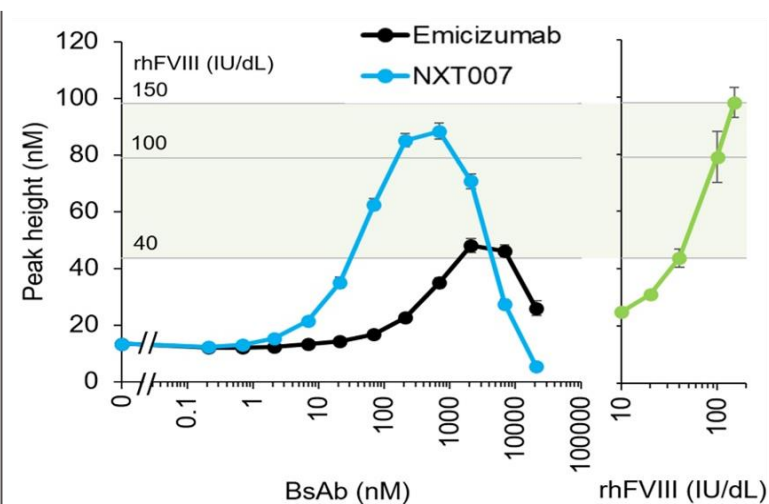
IR Hematology Update  
23 June

## NXT007 (FVIIIa mimetic bispecific mAb)

### Structure and function<sup>1</sup>



### NXT007, Hemlibra and FVIII thrombin generation<sup>2</sup>



- Potential to achieve zero treated bleeds for Hem A pts, without need for additional FVIII Tx
- Engineered based on Hemlibra, to enhance binding affinities, extend half-life, and allow for low volume, infrequent subcutaneous injections
- NXT007 is ~30-fold more potent than Hemlibra and in vitro assay indicates that thrombin generation is within the range of people without Hemophilia A<sup>2</sup>

## Clinical development

Ph I	Ph II	Ph III	Status
			Data in 2025
			Start exp. 2026
			Start exp. 2026
			Start exp. 2026

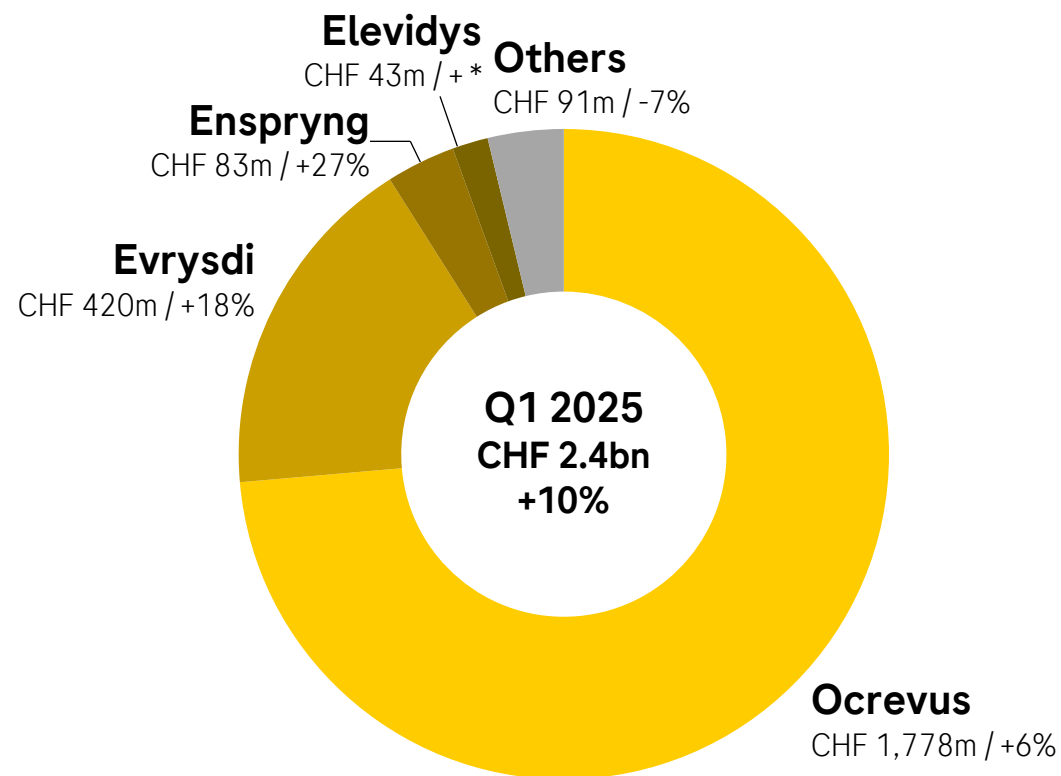
- Ph II data to be shared at upcoming medical conference in 2025
- Three Ph III trials, including H2H vs. Hemlibra, planned to start in 2026

1. Koga et al. MABS 2023, 15 (1), 2222441; 2. Teranishi-Ikawa et al. Journal of Thrombosis and Haemostasis 2024.22 (2):430-440; SoC: Standard of care; mAb: Monoclonal antibody; Lch: Light chain; Hch: Heavy chain; BsAb: Bispecific antibody; Tx: Treatment



# Ocrevus Zunovo permanent J-Code granted on April 1<sup>st</sup>

Achieved US approval for Evrysdi tablet formulation



CHFm / YoY CER growth

## Q1 update

- Ocrevus: ~50% Zunovo US starts naïve to Ocrevus
- Evrysdi: US approval for tablet formulation achieved; 5-year sustained efficacy & safety in Type 2&3 SMA patients shared at MDA
- Elevidys: Early launch momentum in ex-US/ex-EU to continue
  - Temporary clinical hold requested by EU regulators on ongoing studies
- Trontinemab: Positive update of Ph I/II (Brainshuttle™ AD) in AD presented at ADPD; Ph III to be initiated in 2025

## Outlook 2025

- Elevidys in DMD: EU approval
- Evrysdi tablet formulation in SMA: EU approval
- Ph III (GAVOTTE) Ocrevus HD in PPMS
- Ph III (FENTrepid) fenebrutinib in PPMS
- Ph III (FENhance 1/2) fenebrutinib in RMS
- Ph II (MANATEE) Evrysdi + GYM 329 in SMA
- Ph II (MANOEUVRE) GYM 329 in FSHD

\*Over 500%; CER: Constant Exchange Rates (avg full year 2024); RMS/PPMS: Relapsing/primary progressive multiple sclerosis; NTB: New to brand; SC: Subcutaneous; HD: High dose; SMA: Spinal muscular atrophy; AD: Alzheimer's disease; DMD: Duchenne muscular dystrophy; FSHD: Facioscapulohumeral muscular dystrophy

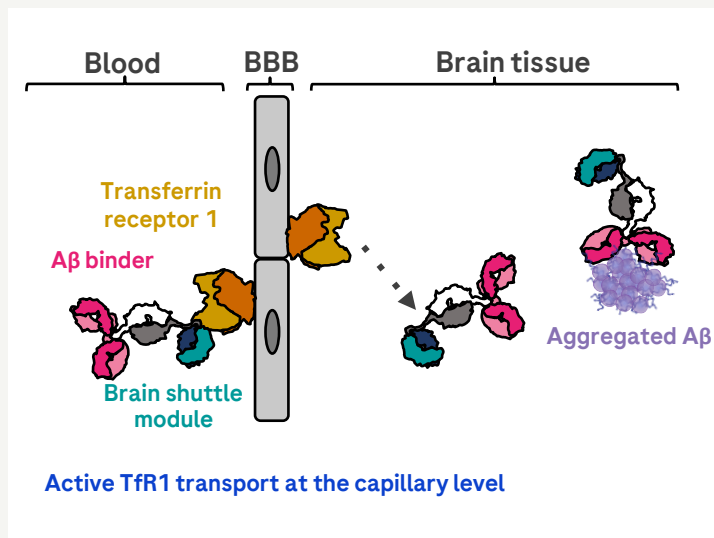


# Trontinemab: Rapid and deep amyloid clearance in AD

81% of patients on 3.6 mg/kg dose achieved amyloid PET negative within 28 weeks

AD/PD™ 2025  
ADVANCES IN SCIENCE & THERAPY

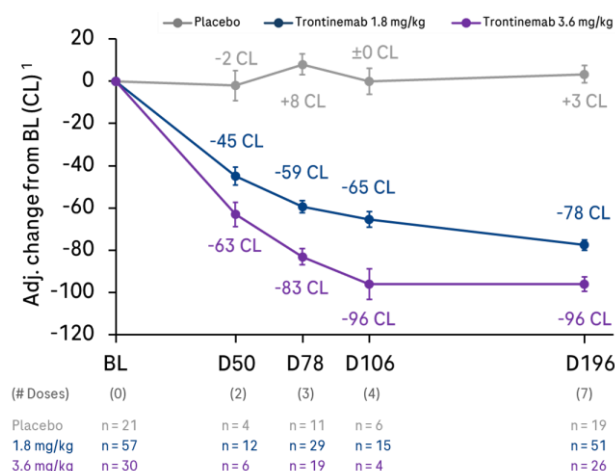
## Trontinemab (Brainshuttle™ bispecific 2+1 anti-A $\beta$ mAb)



- Trontinemab uses Roche's proprietary Brainshuttle™ technology, combining an A $\beta$  binding mAb with a transferrin receptor shuttle module
- Designed for efficient transport across the BBB to remove amyloid plaques in the brain

## Ph I/IIb (Brainshuttle™-AD): Updated results<sup>1</sup>

### Efficacy (Amyloid clearance)



### Safety (ARIA)

Total # with event [events/pt], (%)	Part 1+2 (Combined) (n=114)	
	Cohort 3 1.8 mg/kg or Pbo (n = 76)	Cohort 4 3.6 mg/kg or Pbo (n = 38)
ARIA-E	3 (3.9%)	0
ARIA-H	5 (6.6%)	1 (2.6%)
Concurrent ARIA-E + ARIA-H	0	0

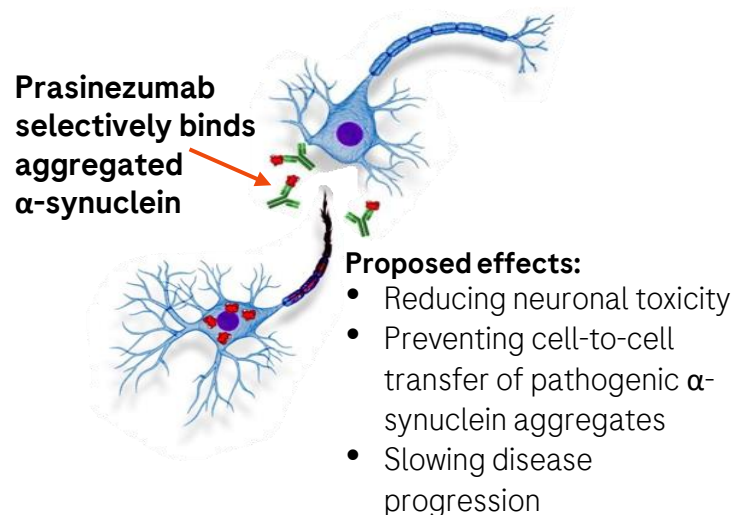
- Rapid amyloid depletion observed for 1.8 mg/kg and 3.6mg/kg doses, with all pts responding to treatment and 65% (1.8 mg/kg) / 81% (3.6 mg/kg) of pts achieving amyloid PET negative
- Favorable safety and tolerability profile with low ARIA incidence, limited & transient anemia and manageable IRR
- Ph III to initiate in 2025 with final readout expected in 2028



# Prasinezumab: Delay of confirmed motor progression in PD

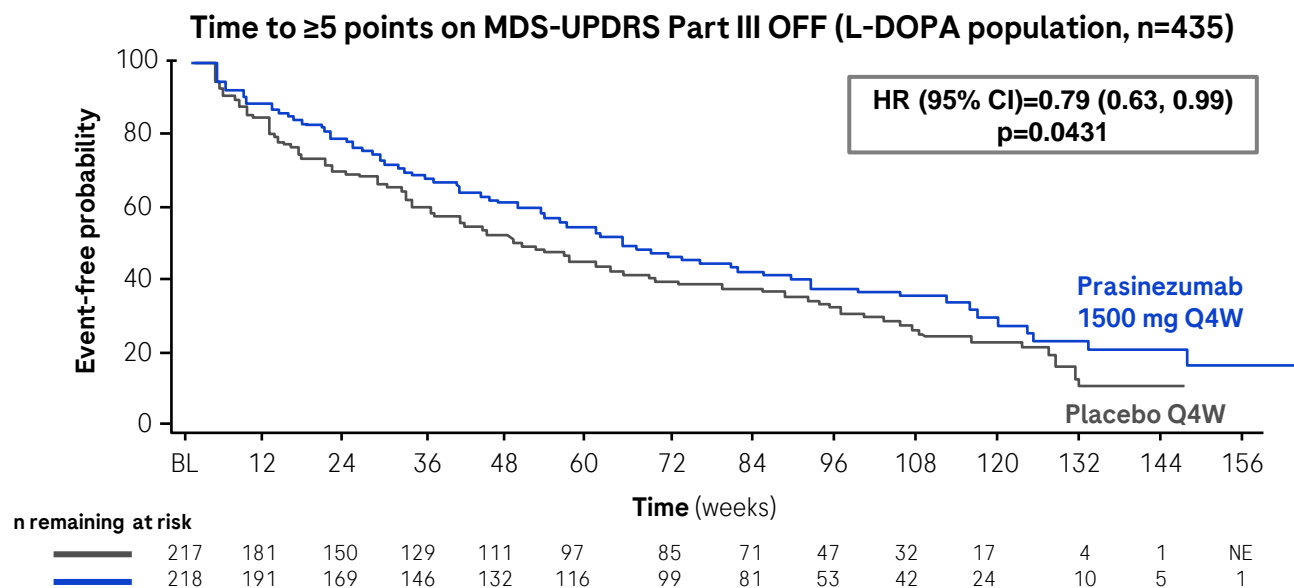
Additional OLE data and decision on next steps around mid-year

## Prasinezumab ( $\alpha$ -synuclein Ab)



- First potential disease modifying therapy in PD<sup>1, 2</sup>
- Parkinson's disease is one of the fastest growing neurological disorders with high unmet need, economic and societal burden

## Ph IIb (PADOVA) results<sup>3</sup>



- Prasinezumab showed a trend towards delaying motor progression; more pronounced effect (HR=0.79) in levodopa treated pts (~75% of population; prespecified analysis)
- Positive trends on multiple secondary and exploratory endpoints, including MRI biomarkers
- PASADENA and PADOVA OLE studies continuing with high retention / rollover

1. Pagano et al. Front Neurol. 2021; 12: 705407; 2. Pagano et al. N Engl J Med 2022 Aug 4;387(5):421-432; 3. Nikolcheva et al. ADPD 2025; IV: Intravenous; Q4W: Every 4 week; OLE: Open label extension; MDS-UPDRS: Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale; OFF: Practically defined OFF state; Ab: Antibody; PD: Parkinson's disease; L-DOPA: L-3,4-dihydroxyphenylalanine; MAOBI: Monoamine oxidase-B inhibitor; HR: Hazard ratio; CI: Confidence interval; In collaboration with Prothena



# Xolair with strong launch uptake in food allergy

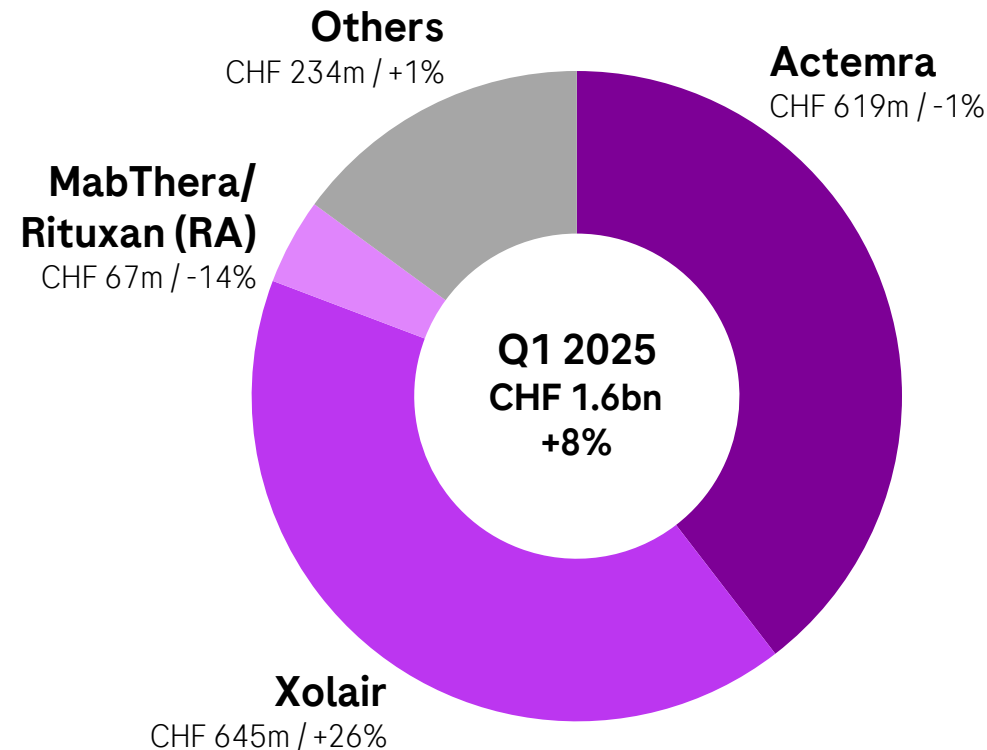
Three afimkibart (anti-TL 1A) trials initiated: Ph III in Crohn's disease, Ph II in atopic dermatitis and Ph I in MASH

## Q1 update

- Xolair: Strong food allergy launch with >50k patients on treatment
  - Updated Ph III (OUtMATCH) show Xolair is more effective and has less side effect vs. OIT for treating food allergy
  - No biosimilar launch expected in 2025
- Actemra: US biosimilar launch slower than expected
- Gazyva in LN: US & EU filing accepted; positive results presented at WCN and published in NEJM<sup>1</sup>
- Afimkibart (anti-TL 1A): Multiple trials initiated
  - Ph III (SIBERITE-1/2) in CD, Ph II in AtD, and Ph I in MASH

## Outlook 2025

- Gazyva in LN: US/EU approval; US PDUFA set for Oct
- Ph III (ALLEGORY) Gazyva in SLE
- Ph II/III (ALIENTO/ARNASA) astegolimab in COPD
- Ph II of anti-p40/TL 1A bispecific in IBD to initiate in H1



## CHFm / YoY CER growth

1. Furie RA, et al. Efficacy and safety of obinutuzumab in active lupus nephritis. NEJM.2025; CER: Constant Exchange Rates (avg full year 2024); RA: Rheumatoid arthritis; TL 1A: Tumor necrosis factor-like cytokine 1A; CD: Crohn's disease; LN: Lupus nephritis; SLE: Systemic lupus erythematosus; COPD: Chronic obstructive pulmonary disease; MASH: Metabolic dysfunction-associated steatohepatitis; IBD: Inflammatory bowel disease; AtD: Atopic dermatitis; OIT: Oral immunotherapy; anti-p40/TL 1A in collaboration with Pfizer





# Gazyva: Ph III results in LN show superiority over standard of care

Ph III results in SLE and INS expected in 2025

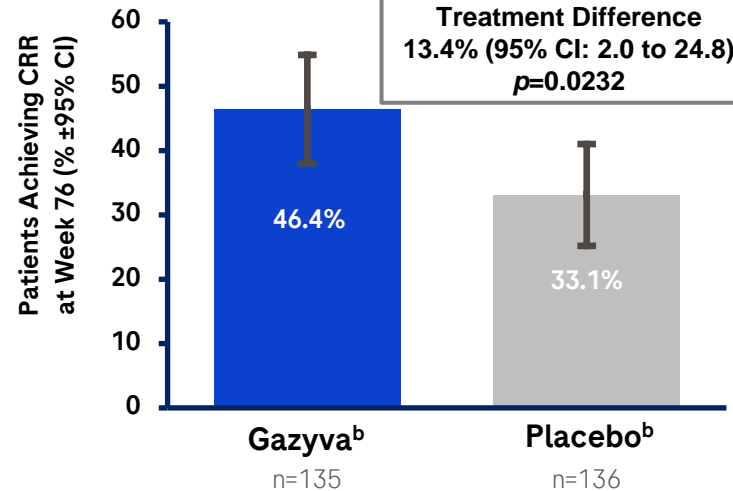
## Ph III (REGENCY) results: CRR at Week 76<sup>1</sup>



### Primary Endpoint: CRR at Week 76

Includes all of the following:

- UPCR <0.5 g/g
- eGFR ≥85% of baseline
- No intercurrent events of rescue therapy, treatment failure<sup>a</sup>, death and/or early study withdrawal



## Clinical development

Indication	Ph I	Ph II	Ph III	Status
LN		REGENCY		✓ Filing ongoing
SLE		ALLEGORY		Data exp 2025
MN		MAJESTY		Ongoing
INS		INShore		Data exp 2025

✓ Primary endpoint met

- Primary endpoint of CRR at week 76 achieved with statistically significant and clinically meaningful treatment difference of 13.5% (95% CI: 2.0 to 24.8)
- Safety was in line with the well-characterized profile of Gazyva and no new safety signals were identified
- US & EU filing has been completed and US PDUFA set for October
- Ph III readouts in SLE (REGENCY) and INS (INShore) are expected in 2025; Ph III (MAJESTY) in MN is ongoing

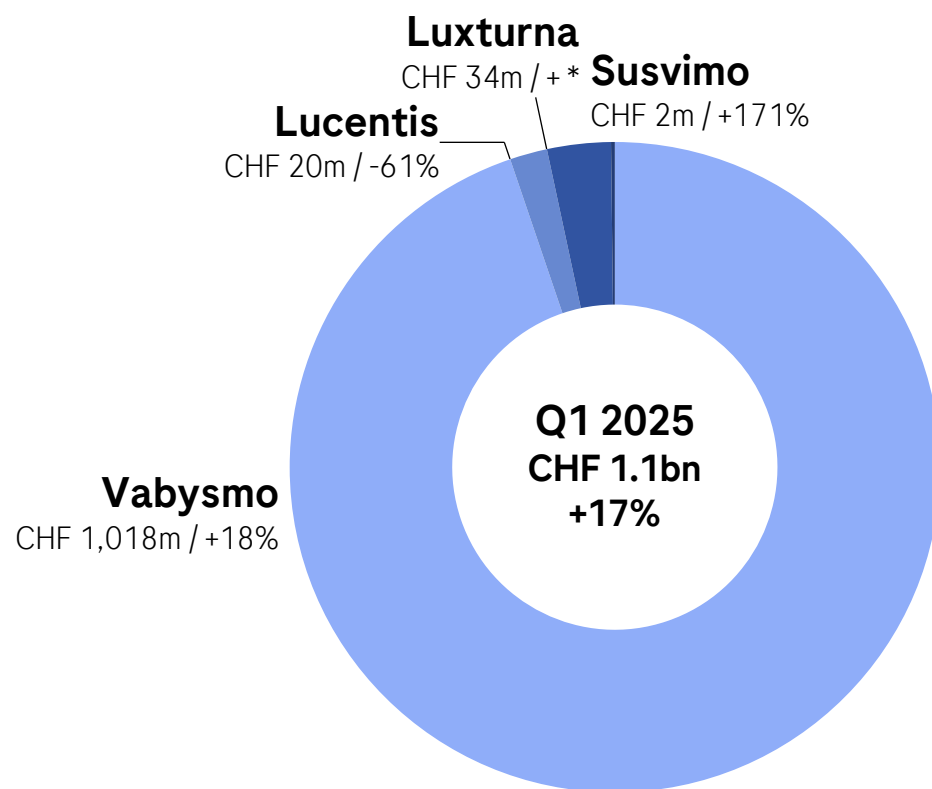
1. Rovin et al. WCN 2025; a Treatment failure definition (one or more): New ESKD or need for chronic dialysis or renal transplantation; clinically significant, sustained worsening of UPCR and/or eGFR from Week 24 onward that led the investigator to conclude the patient had failed the randomized treatment regimen; receipt of rescue therapy, except for glucocorticoid-only rescue; b Plus ST of mycophenolate mofetil plus glucocorticoids; LN: Lupus nephritis; SLE: Systemic lupus erythematosus; MN: Membranous nephropathy; INS: Idiopathic nephrotic syndrome (Childhood onset INS also known as PNS: Pediatric nephrotic syndrome); UPCR: Urine protein creatinine ratio; CI: Confidence interval; eGFR: Estimated glomerular filtration rate; CRR=complete renal response





# Vabysmo now the most prescribed therapy in nAMD in the US

Vabysmo continues to expand market shares across regions; US impacted by contraction of branded market



## Q1 update

- Vabysmo: Continued market share gains across early launch countries and ongoing global expansion
  - US market shares: 33% nAMD, 24% DME and 26% RVO\*\*;
  - Achieved market leadership in nAMD
  - ~60% of US patient starts are naïve
  - Strong uptake of pre-filled syringe, with US >95% and EU >70% conversion\*\*\*
  - China strong launch uptake following NRDL listing in Jan
- Susvimo: DME approval in US achieved

## Outlook 2025

- Susvimo in nAMD: EU filing
- Ph III (SANDCAT/MEERKAT) vamikibart in UME

## CHFm / YoY CER growth

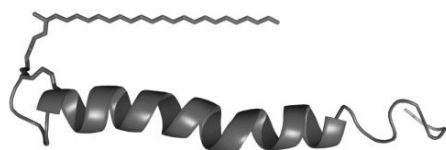
\*Over 500%; \*\*Data based on Feb 2025 Verana data. Disclaimer: Verana share valuations are derived from IRIS registry and are subject to restatement as additional data becomes available. \*\*\*Vabysmo vial/pre-filled syringe conversion rate calculated using volumes, EU conversion based on Germany and UK values; CER: Constant Exchange Rates (avg full year 2024); nAMD: Neovascular age-related macular degeneration; DME: Diabetic macular edema; RVO: Retinal vein occlusion; UME: Uveitic macular edema



# Petrelintide: BIC potential as monotherapy and FDC with CT-388

Strengthening our growing CVRM portfolio with a long-acting amylin analog

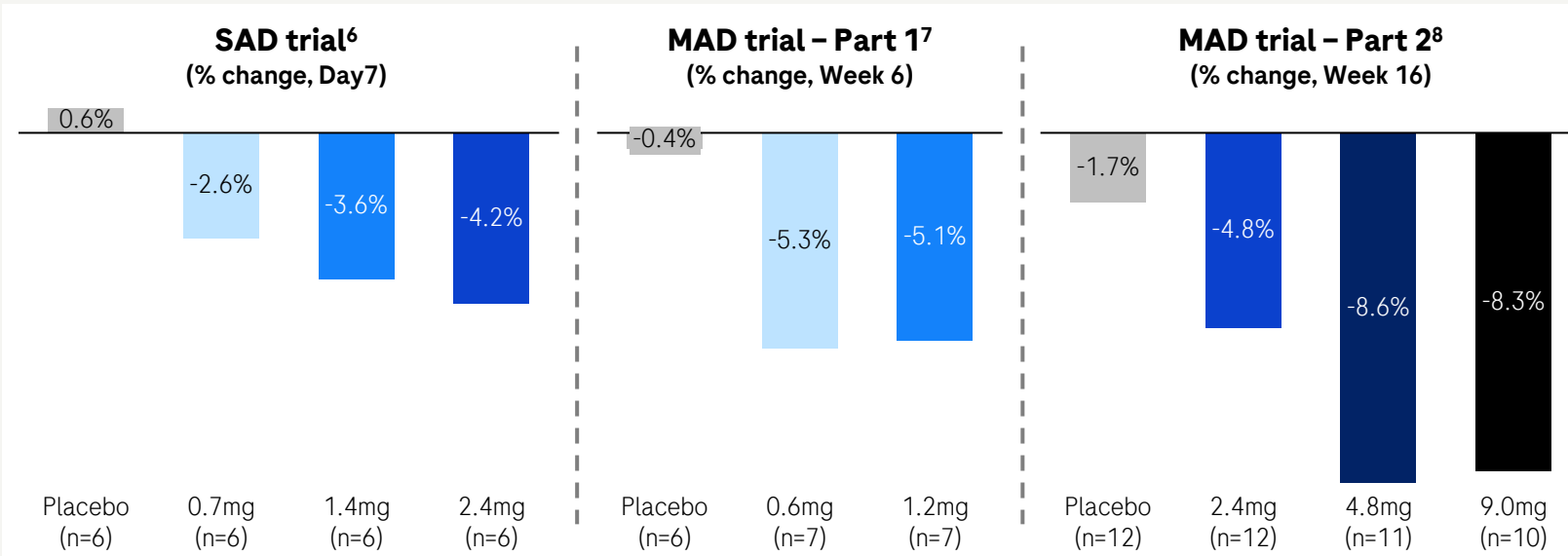
## Petrelintide



36 amino-acid acylated peptide

- A long-acting amylin analog, suitable for Q1W dosing<sup>1,2</sup>
- Potent balanced agonist effect on amylin and calcitonin receptors<sup>1,3</sup>
- Favorable physicochemical properties, allow for co-formulation and co-administration with other peptides<sup>4,5</sup>

## Ph I results: Change in body weight from baseline



- After 16 weeks of treatment, mean weight loss was up to 8.6% with petrelintide vs 1.7% with placebo
- Petrelintide was well tolerated and safe: vast majority of TEAEs reported were mild
- Combined Ph I data suggest a potential for weight loss comparable to mono GLP-1, but with improved tolerability for a better patient experience and high-quality weight loss
- Ph IIb (ZUPREME-1) in obesity without type 2 diabetes ongoing

1. Data on file; 2. Brændholt Olsen et al. Poster 92-LB. Presented at ADA 83rd Scientific Sessions, June 23–26, 2023, San Diego, CA; 3. Eriksson et al. Presentation at ObesityWeek, November 1–4, 2022, San Diego, CA; 4. Skarbaliene et al. Poster 1406-P. Presented at ADA 82nd Scientific Sessions, June 3–7, 2022, New Orleans, LA; 5. Eriksson et al. Poster 532. Presented at ObesityWeek, November 1–4, 2022, San Diego, CA; 6. Brændholt Olsen et al. Poster 92-LB. Presented at ADA 83rd Scientific Sessions, June 23–26, 2023, San Diego, CA; 7. Brændholt Olsen et al. Poster presented at ObesityWeek, October 14–17, 2023, Dallas, TX; 8. Data presented at ObesityWeek 2024 in San Antonio, Texas; BIC: Best-in-class; FDC: Fixed dose combination; SAD/MAD: Single/multiple ascending dose; (TE)AE: (Treatment emergent) adverse event; AE: Adverse event; Petrelintide in collaboration with Zealand Pharma (pending deal closure)



# Petrelintide complementing our growing CVRM portfolio

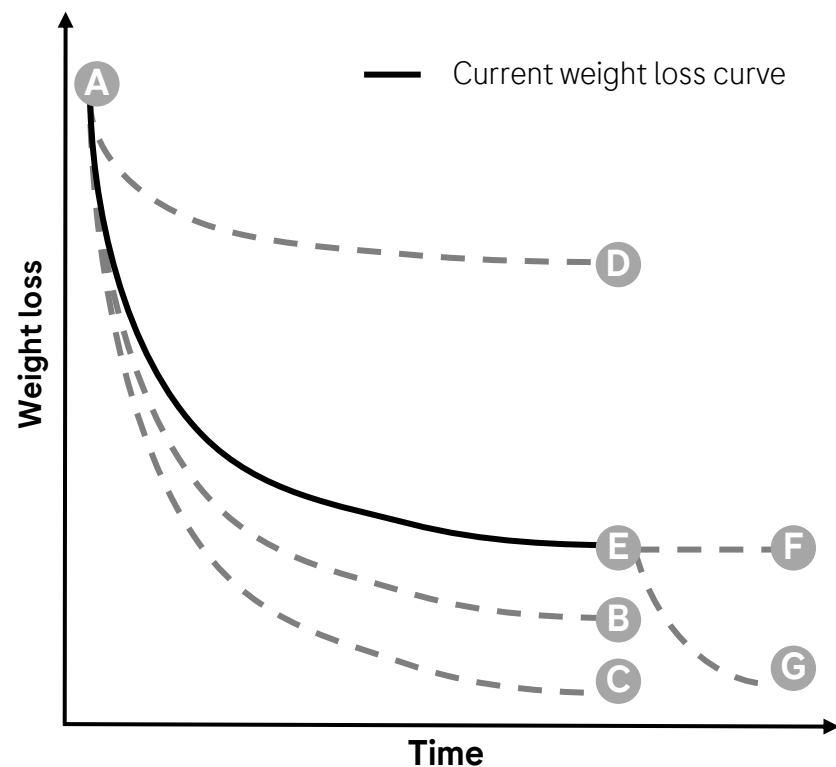
Several molecules to move ahead in 2025

## Obesity/Diabetes portfolio

		Ph I	Ph II
1	CT-388	103/104 (Obesity +/- T2D)	
2	CT-868	004 (T1D w. OW/OB as adjunct treatment)	
3	CT-996	201 (Obesity +/- T2D)	
4	CT-173 (PYY analogue)	Obesity	
5	GYM 329	Obesity	
6	Petrelintide	ZUPREME-1/2 (Obesity +/- T2D)	
7	CT-388 + petrelintide	Obesity +/- T2D	

- CT-388 Ph II final data in early 2026
- CT-388+ petre Ph II to initiate in early 2026
- CT-868 Ph II data expected in 2025
- CT-996 Ph II to initiate in 2025
- CT-173 Ph I in obesity to initiate in 2025
- GYM 329 Ph II combo to initiate in 2025

## Roche obesity portfolio: Potential to address unmet needs\*



	Unmet need	Roche asset	
A	Improved tolerability and/or simple up-titration	1	6
B	Better quality weight loss (muscle preservation)	5	6
C	Deeper weight loss (esp. in patients with higher BMI)	1	7
D	Non/inadequate responders	4	6
E	Improved convenience (orals) (equivalent efficacy to SC)	3	
F	Weight maintenance	3	4 6
G	Further weight loss once incretins achieve "plateau"	4	7

\*Illustration of the potential for individual Roche assets to address unmet needs in obesity; T1D/T2D: Type 1/2 diabetes; OW: Overweight; OB: Obese; FPI: First patient in; PYY: Peptide YY; BMI: Body mass index; SC: Subcutaneous; Petrelintide in collaboration with Zealand Pharma (pending deal closure)

# 2025: Significant key newsflow ahead\*

	Compound	Indication	Milestone
 Regulatory	Itovebi + palbociclib + fulvestrant	1L PIK3CA-mut HR+ BC	EU approval
	Columvi + GemOx	2L+ DLBCL	US/EU approval  (EU approval)
	Lunsumio SC	3L+ FL	US approval/EU filing  (EU filing)
	Elevidys	DMD	EU approval
	Gazyva	Lupus nephritis	US/EU filing; US approval  (US/EU filing)
	Susvimo	DME	US approval
	Susvimo	nAMD	EU filing
 Clinical results	giredestrant + palbociclib	1L ER+/HER2- mBC	Ph III persevERA
	giredestrant + everolimus	post CDKi ER+/HER2- mBC	Ph III evERA
	Lunsumio + Polivy	2L+ DLBCL	Ph III SUNMO
	Lunsumio + lenalidomide	2L+ FL	Ph III CELESTIMO
	Venclexta + azacitidine	1L MDS	Ph III VERONA
	PiaSky	aHUS	Ph III COMMUTE-a
	Ocrevus HD	RMS/PPMS	Ph III MUSETTE/GAVOTTE  (MUSETTE)
	fenebrutinib	RMS	Ph III FENhance 1/2
	fenebrutinib	PPMS	Ph III FENTrepid
	astegolimab	COPD	Ph II/III ALIENTO/ARNASA
	Gazyva	SLE	Ph III ALLEGORY
	vamikibart	UME	Ph III SANDCAT/MEERKAT
	NXT007	Hemophilia A	Ph II  (Moving to Ph III)
	trontinemab	AD	Ph I/II Brainshuttle™ AD  (Moving to Ph III)
	Evrysdi + GYM 329	SMA	Ph II MANATEE
	GYM 329	FSHD	Ph II MANOEUVRE
	zilebesiran	Hypertension	Ph II KARDIA-3
	CT-868 (QD SC)	T1D with Obesity	Ph II
	CT-996 (QD oral)	Obesity with T2D	Ph I (Arm 3)

\*Outcome studies are event-driven: timelines may change

## Additional 2025 newsflow:

- **TNKase** US approval in acute ischemic stroke



## **Diagnostics Division**

*Matt Sause*  
*CEO Roche Diagnostics*

# Q1 2025: Diagnostics sales

Diagnostics Division stable due to healthcare pricing reforms in China

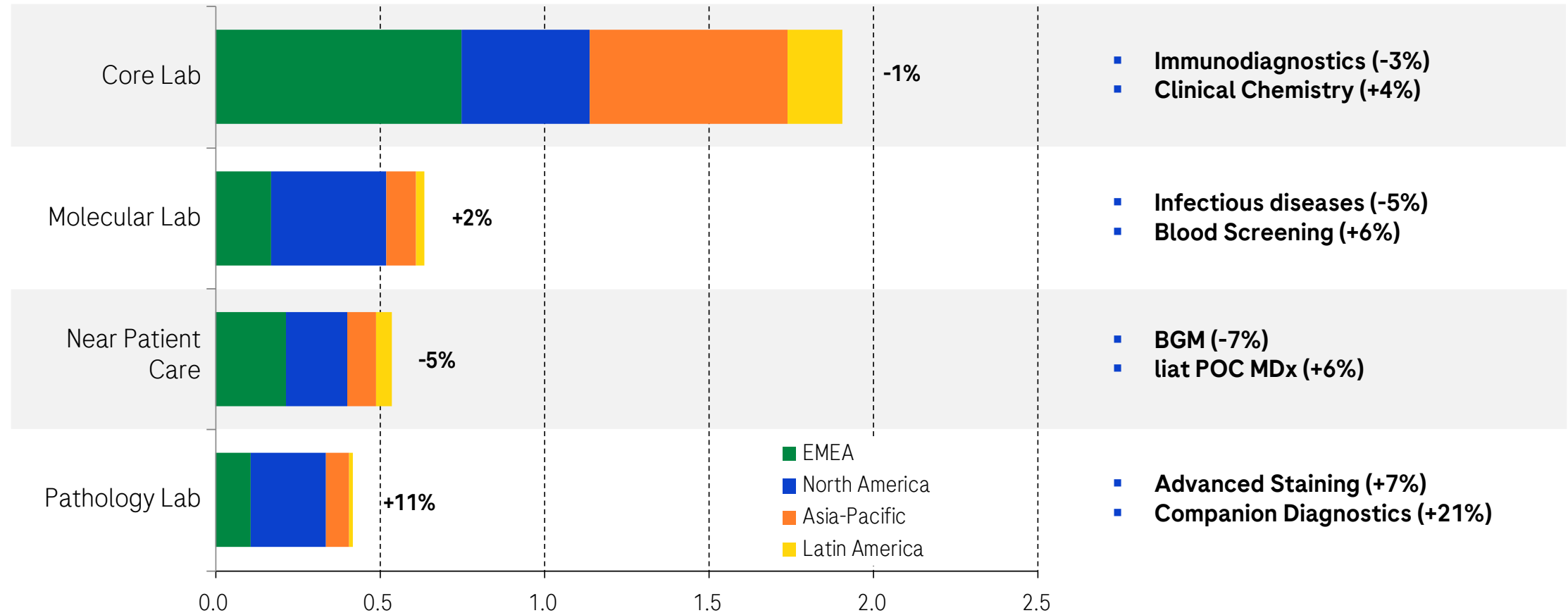
	Q1 2025 CHFm	Q1 2024 CHFm	Change in %	
			CHF	CER
<b>Diagnostics Division</b>	<b>3,491</b>	<b>3,478</b>	<b>0</b>	<b>0</b>
Core Lab	1,904	1,926	-1	-1
Molecular Lab	634	611	4	2
Near Patient Care	536	569	-6	-5
Pathology Lab	417	372	12	11

# Q1 2025: Diagnostics highlights

Diagnostics Division stable due to healthcare pricing reforms in China

CHFbn

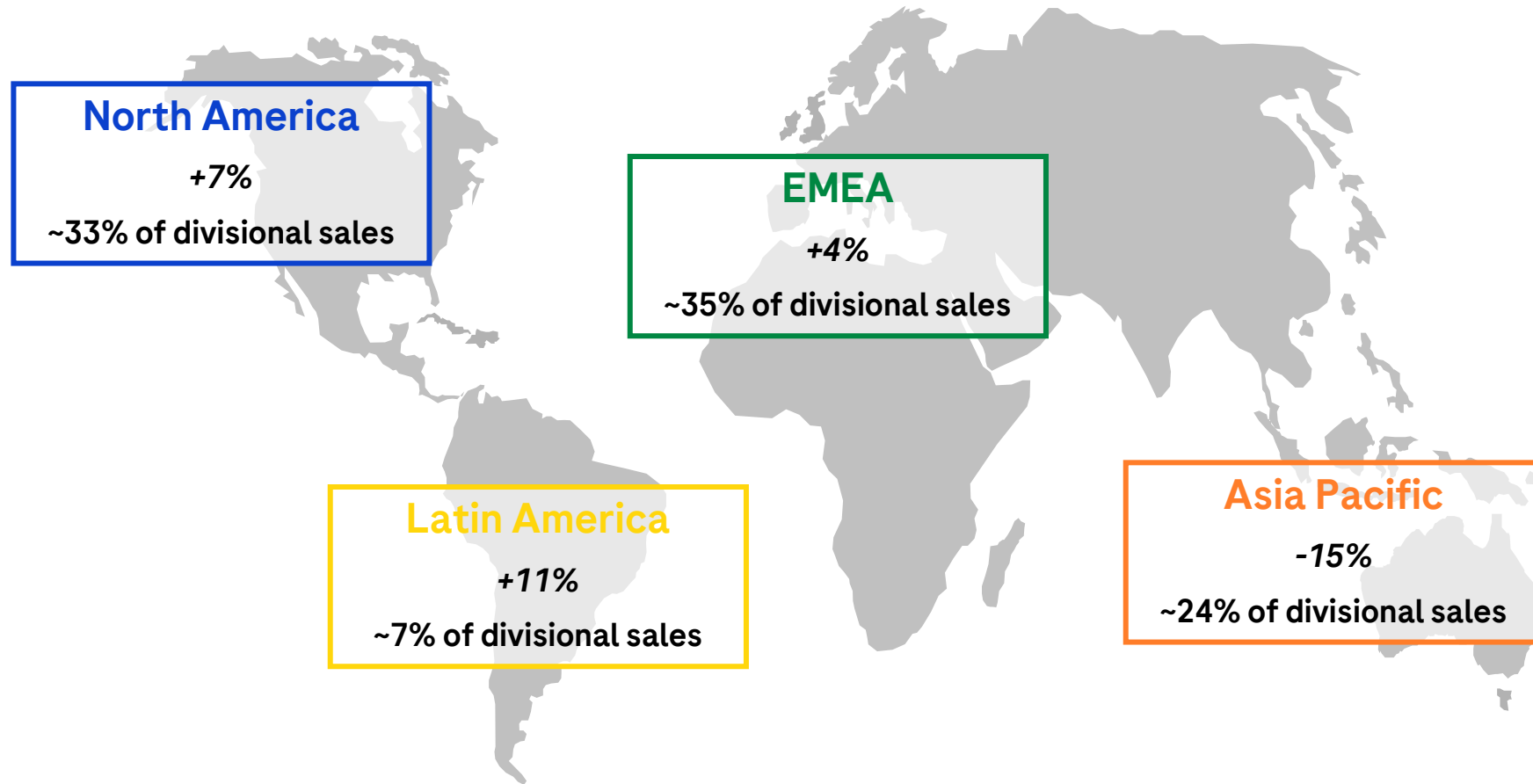
YoY CER growth





# Q1 2025: Diagnostics regional sales

Strong growth in North America, EMEA and Latin America





# Instrument placements

Continued strong growth of instrument placements in 2024

Non-exhaustive

## Core Lab



**+65%**  
cobas® pro and pure  
analytical units

## Molecular Lab



**+22%**  
cobas® 5800/6800/8800  
analytical units

## Pathology Lab



**+10%**  
BenchMark  
ULTRA/ULTRAPLUS



**+36%**  
DP200/600



**+4%**  
HE 600

## Near Patient Care



**+7%**  
cobas® liat

**+12%** Pre-analytical and connectivity systems

**+16%** navify® Laboratory Operations

# cobas® Mass Spec solution

The first fully automated IVD solution will revolutionize the Mass Spec segment of the clinical lab

## Key milestones

- ✓ Achieved CE launch for system and steroid 1 assays in December 2024 and for Vitamin D assays in February 2025
- ✓ Secured several key installations; expecting a strong pace of installations through 2025
- ✓ Initial sites reported fast installation and performance meeting specifications
- ✓ On track for CE launch of >40 wave 1 assays covering the majority of routine testing by the end of 2025

## Customer testimonials




*“This represents one of the **most significant innovations** in laboratory diagnostics over the past 40 years”*

LMU Munich,  
Feb 2025



*“It offers a **revolutionary technology** that enables mass spectrometry even for technicians without chromatographic expertise”*

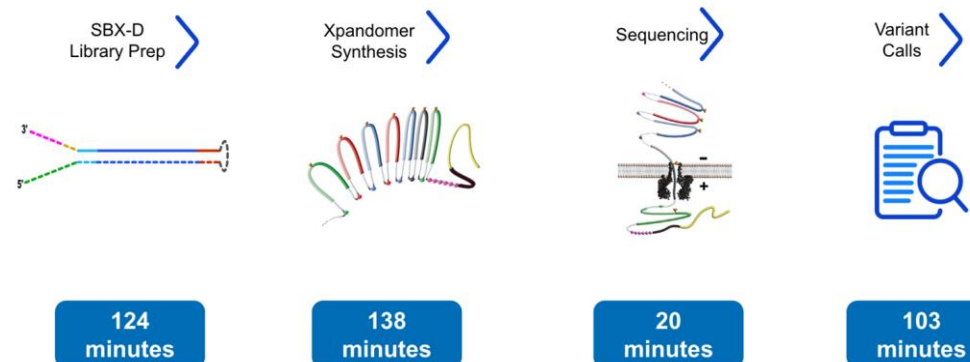
LSI Medience Tokyo<sup>1</sup>,  LSI Medience  
Dec 2024

# Roche Sequencing solution

Customer data demonstrates potential of SBX technology ahead of the 2026 commercial launch

## Early evaluation example: WGS in under 7 hours

**BROAD**  
CLINICAL LABS



## Market opportunity

- The NGS market is valued at USD 6.4bn (2024) and is projected to grow at +9% CAGR from 2024 to 2027<sup>1</sup>
- Strong growth in the clinical segment (+14%), driven by Tx selection and MRD in oncology, and in the biopharma segment (+7%)<sup>1</sup>

## SBX differentiation

- High speed: Library preparation through VCF in <7 hours for SBX-Fast workflow
- High accuracy when needed: Q39 average and F1 score of 99.8% (SNV) and 99.5% (InDel)
- Flexible operation to suit sample and application needs

1. DeciBio Report (December 2024); Note: Exemplary workflow refers to a time trial for a single sample performed at Broad Clinical Labs; CAGR: Compound annual growth rate; InDel: Insertions and deletions; MRD: Minimal residual disease; NGS: Next generation sequencing; SBX: Sequencing by expansion; SNV: Single nucleotide variations; Tx: Treatment; VCF: Variant call format; WGS: Whole genome sequencing; Roche Sequencing solution is in development

# cobas® liat CT/NG

First FDA cleared/CLIA waived molecular point of care diagnostic for CT/NG

## cobas® liat assay menu



**cobas® liat** CT/NG and CT/NG/MG



**cobas® liat** SARS-CoV-2, Influenza A/B, RSV  
(FDA EUA)



**cobas® liat** C. Diff



**cobas® liat** SARS-CoV-2



**cobas® liat** SARS-CoV-2 & Influenza A/B



**cobas® liat** Influenza A/B & RSV



**cobas® liat** Strep A

## Market opportunity

- The molecular STI market is valued at CHF 1bn (2023) and is projected to grow at +10% CAGR from 2023 to 2028<sup>1</sup>
- Chlamydia and gonorrhea affect >200m people / year worldwide<sup>2</sup>

## Differentiation

- Offer the only CLIA waived 20-min assay for CT and NG detection
- Expand menu of lab-equivalent point of care PCR solutions
- Leverage installed base of >13,500 analyzers to drive access

# Diagnostics key launches 2025

	Area	Product	Description	Market	Status
Tests	Core Lab	Elecsys® pTau 181	Non-invasive blood-based biomarker to enable earlier detection and rule out amyloid pathology	CE	
		Elecsys® Troponin-T hs Generation 6	High-sensitive test with greater precision at lower measurement ranges, enabling HCPs to confidently diagnose acute myocardial infarction	CE	
		Elecsys® Pro-C3 ADAPT	Solution to identify the severity of liver fibrosis in patients with MASLD/MASH	CE	
		cobas® i601 Mass Spectrometry wave 1 ipacks	Broad and comprehensive assay menu on the cobas i 601 mass spectrometry system (immunosuppressants, vitamin D, antiepileptics 1 and 2, therapeutic drug monitoring, antibiotics 1 and 2, steroids 2)	CE	
		Elecsys® Pepsinogen 1 and 2	Tests to identify individuals with advanced atrophic gastritis who are at increased risk for gastric cancer	CN	
	Molecular Lab	Elecsys® Dengue Ag	Test to aid in the diagnosis of early infection with any serotype of the dengue virus, enabling HCPs to implement appropriate patient management	CE	
		Elecsys® anti-AAVrh74	Test to enable selection of duchenne muscular dystrophy patients eligible to be treated with Elevidys	CE	
	Near Patient Care	cobas® BV/CV	Efficient and accurate molecular test to aid in the diagnosis of Bacterial Vaginosis (BV) and/or Candida Vaginitis (CV)	CE	
		cobas® liat lesion panel EUA	Rapid test to enable accurate detection and differential diagnosis of patients presenting with cutaneous and mucocutaneous lesions/ulcers to enable timely treatment and management. Supporting mpox health emergency	US EUA	
	Pathology Lab	cobas® liat CT/NG	Rapid test for the differential diagnosis of Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG)	US	✓
Digital solutions	Pathology Lab	VENTANA PTEN (SP218) Rx Dx	CDx IHC test intended for the assessment of PTEN protein loss in formalin-fixed paraffin-embedded prostate tissue to identify patients who may be eligible for treatment	US	
	Healthcare Insights	navify® Digital Pathology 3.0	Major update to the Roche Digital Pathology image management system with fully redesigned user experience and enhanced interoperability with third-party scanners	CE	
		Chest Pain Triage algorithm	Algorithm to triage chest pain patients in the emergency department	CE	✓
		Kidney Klinrisk algorithm	Algorithm to assess the likelihood of reaching end-stage renal disease	CE	✓

✓ On-market

AAVrh74: Adeno associated virus rhesus monkey 74; Ag: Antigen; CDx: Companion diagnostic; EUA: Emergency use authorization in US only; HCP: Healthcare practitioner; ICH: Immunohistochemistry; MASLD/MASH: Metabolic dysfunction-associated liver disease/metabolic dysfunction-associated steatohepatitis; PTEN: Phosphatase and tensin homolog

# Invitation to Roche Diagnostics Day 2025



## Roche Sequencing solution

### Roche Diagnostics Day on May 27

*London / hybrid event*

14:00 - 16:45 CEST / 13:00 - 15:45 BST  
08:00 - 10:45 am EDT / 05:00 - 07:45 am PDT

### Highlights:







- Deep-dive into the product portfolio and pipeline
- Roche SBX Sequencing solution updates and applications

### Presenters include:

- **Matt Sause**, CEO Roche Diagnostics
- **Palani Kumaresan**, Head of RDS
- **Moritz Hartmann**, Head of RIS
- **Josh Lauer**, Head of Molecular Lab
- **Ildikó Amann-Zalán**, Head of Research and Development RDS
- **Jill German**, Head of Pathology Lab
- **Benjamin Lilienfeld**, LCL SWA Systems
- **Olivier Gillieron**, LCL Cardiometabolic and Neurology

# IR events currently planned for 2025

Additional events driven by readouts

 <b>Immunology/WCN</b> <b>7 Feb</b> 16:30-17:30 CET Virtual event	 <b>Update on NGS</b> <b>20 Feb</b> 20:30-21:30 CET Virtual event	 <b>Neurology Update</b> <b>4 Apr</b> 16:00-17:30 CEST Virtual event	 <b>Diagnostics Day</b> <b>27 May</b> 14:00-16:45 CEST London & virtual	 <b>Hematology Update</b> <b>23 June</b> 19:00-20:15 CEST Virtual event	 <b>Pharma Day</b> <b>22 Sep</b> tbd London & virtual
<ul style="list-style-type: none"> <li>Update on immunology kidney portfolio ✓</li> <li>Focus on data presented at World Congress of Nephrology: Gazyva (REGENCY) in lupus nephritis</li> </ul>	<ul style="list-style-type: none"> <li>Update on Sequencing by Expansion (SBX) technology ✓</li> </ul>	<ul style="list-style-type: none"> <li>Neurology franchise update ✓</li> <li>Focus on data presented at MDA: Elevidys (EMBARK) 2-year data in DMD</li> <li>Focus on data presented at ADPD: prasinezumab (PADOVA) in PD and trontinemab (Brainshuttle™ AD) in AD</li> </ul>	<ul style="list-style-type: none"> <li>Deep-dive into the product portfolio and pipeline</li> <li>Roche SBX Sequencing solution updates and applications</li> </ul>	<ul style="list-style-type: none"> <li>Hematology franchise update</li> <li>Focus on key malignant hematology data from ASCO, EHA and ICML</li> <li>Focus on key benign hematology data from ISTH</li> </ul>	<ul style="list-style-type: none"> <li>Update on Pharma strategy and business performance</li> <li>Deep-dive into the current product portfolio</li> <li>Building blocks for future growth: Late stage portfolio update</li> <li>Update on R&amp;D excellence</li> </ul>

**Doing now what patients need next**



# Changes to the development pipeline

Q1 2025 update

New to phase I	New to phase II	New to phase III	New to registration
<p><b>2 NMEs:</b>  <b>RG6662</b> HTT miRNA GT (SPK-10001) – Huntington's disease  <b>CHU</b> MINT91 - solid tumors</p> <p><b>1 AI:</b>  <b>RG6631</b> afimkibart (anti-TL 1A) - MASH</p>	<p><b>2 NMEs:</b>  <b>RG6351</b> anti-Tie2 agonist - retinal disease  <b>RG6287</b> NME - immunology</p> <p><b>2 AIs:</b>  <b>RG6631</b> afimkibart (anti-TL 1A) – atopic dermatitis  <b>RG6168</b> Enspryng - DMD</p>	<p><b>2 AIs:</b>  <b>RG6631</b> afimkibart (anti-TL 1A) - Crohn's disease  <b>RG6114</b> Itovebi + CDK4/6i + letrozole - 1L ES  PIK3CA-mut. HR+ HER2- advanced BC</p>	
Removed from phase I	Removed from phase II	Removed from phase III	Approvals
<p><b>2 NMEs:</b>  <b>RG6315</b> NME - fibrosis  <b>RGXXXX</b> P-MUC1C-ALLO1 - solid tumors</p>		<p><b>1 AI:</b>  <b>RG6058</b> tiragolumab + T - locally advanced esophageal cancer</p>	<p><b>2 AIs (US):</b>  <b>RG6321</b> Susvimo – DME  <b>RG3625</b> TNKase – stroke</p> <p><b>1 AI (EU):</b>  <b>RG6026</b> Columvi + chemo - 2L+ DLBCL</p>

# Roche Group development pipeline

## Phase I (44 NMEs + 8 AIs)

<b>RG6026</b>	Columvi monotherapy + combos	heme tumors
<b>RG6076</b>	englumafusp alfa combos	heme tumors
<b>RG6114</b>	ltovebi	solid tumors
<b>RG6160</b>	cevostamab	r/r multiple myeloma
<b>RG6171</b>	giredestrant monotherapy + combos	solid tumors
<b>RG6221</b>	LTBR agonist	solid tumors
<b>RG6279</b>	eciskafusp alfa ± T	solid tumors
<b>RG6330</b>	divarasib monotherapy + combos	solid tumors
<b>RG6344</b>	mosperafenib (BRAF inhibitor (3))	solid tumors
<b>RG6411</b>	-	solid tumors
<b>RG6440</b>	anti-latent TGF-β1 (SOF10)	solid tumors
<b>RG6457</b>	WRN covalent inhibitor	solid tumors
<b>RG6468</b>	-	solid tumors
<b>RG6537</b>	AR degrader	mCRPC
<b>RG6538<sup>1</sup></b>	P-BCMA-ALLO1	r/r multiple myeloma
<b>RG6540<sup>1</sup></b>	P-CD19 x CD20 - ALLO1	heme tumors
<b>RG6561</b>	-	solid tumors
<b>RG6596<sup>2</sup></b>	HER2 TKI	HER2+ BC
<b>RG6614</b>	USP1 inhibitor	solid tumors
<b>RG6620</b>	KRAS G12D inhibitor	solid tumors
<b>RG6648<sup>3</sup></b>	cMET ADC	solid tumors
<b>RG7828</b>	Lunsumio monotherapy + combos	heme tumors
<b>RG6794</b>	CDK4/2i	(HR+) breast cancer
<b>RG6810<sup>4</sup></b>	DLL3 ADC	SCLC
<b>CHU</b>	DLL3 trispecific	solid tumors
<b>CHU</b>	codrituzumab	HCC
<b>CHU</b>	MINT91	solid tumors

<b>CHU</b>	CD137 switch	solid tumors
<b>CHU</b>	paluratide (RAS inhibitor)	solid tumors
<b>CHU</b>	anti-CLDN6 trispecific	CLDN6+ solid tumors
<b>CHU</b>	anti-CTLA-4 switch antibody	solid tumors
<b>RG6382</b>	CD19 x CD3	SLE
<b>RG6377</b>	-	IBD
<b>RG6418*</b>	selnoflast	inflammation
<b>RG6421</b>	TMEM16A potentiator	Muco-obstructive respiratory disease
<b>RG6631</b>	afimkibart (anti-TL 1A)	MASH
<b>RG7828</b>	Lunsumio	SLE
<b>CHU</b>	anti-HLA-DQ2.5 x gluten peptides	celiac disease
<b>CHU</b>	anti-C1s recycling antibody	immunology
<b>RG6237</b>	anti-latent myostatin (GYM 329)	obesity
<b>RG6652</b>	GLP-1 RA (CT-996)	obesity +/- T2D
<b>RG6035</b>	Brainshuttle™ CD20	multiple sclerosis
<b>RG6182</b>	MAGL inhibitor	multiple sclerosis
<b>RG6434</b>	-	neurodegenerative disorders
<b>RG6662</b>	HTT miRNA GT (SPK-10001)	Huntington's disease
<b>RG6120</b>	zifibancimig	nAMD
<b>RG6209</b>	-	retinal disease
<b>RG7921</b>	-	RVO
<b>RG6006</b>	zosurabalpin	bacterial infections
<b>RG6436</b>	LepB inhibitor	complicated urinary tract infection
<b>CHU</b>	REVN24	acute diseases
<b>CHU</b>	BRY10	chronic diseases

## Phase II (17 NMEs + 7 AIs)

<b>RG6107</b>	PiaSky	sickle cell disease
<b>RG6171</b>	giredestrant	endometrial cancer
<b>RG6180</b>	autogene cevumeran	solid tumors
<b>RG6797</b>	SPK-8011QQ	hemophilia A
<b>RG6512</b>	FIXa x FX (NXT007)	hemophilia
<b>RG6287</b>	-	immunology
<b>RG6536</b>	vixarelimab	IPF/SSc-ILD
<b>RG6631</b>	afimkibart (anti-TL 1A)	atopic dermatitis
<b>RG6615<sup>5</sup></b>	zilebesiran	hypertension
<b>RG6641</b>	GLP-1/GIP RA (CT-868)	T1D with BMI ≥ 25
<b>RG6640</b>	GLP-1/GIP RA (CT-388)	obesity +/- T2D
<b>RG6042</b>	tominersen	Huntington's
<b>RG6102</b>	trontinemab	Alzheimer's
<b>RG6168</b>	Enspryng	DMD
<b>RG6237</b>	anti-latent myostatin (GYM 329) + Evrysdi	SMA
	anti-latent myostatin (GYM 329)	FSHD
<b>RG6289</b>	nivegaceter (gamma-secretase modulator)	Alzheimer's
<b>RG6356</b>	Elevidys	0 to <4 year old DMD
<b>RG7816</b>	alogabat	Angelman syndrome
<b>RG7935</b>	prasinezumab	Parkinson's
<b>RG6179</b>	vamikibart	DME
<b>RG6351</b>	anti-Tie2 agonist	retinal disease
<b>RG6501</b>	OpRegen	geographic atrophy
<b>CHU</b>	anti-IL-8	endometriosis

New Molecular Entity (NME)  
 Additional Indication (AI)  
 Oncology / Hematology  
 Immunology

Cardiovascular, Renal & Metabolism  
 Neurology  
 Ophthalmology  
 Other

Status as of April 24, 2025

RG-No - Roche/Genentech; CHU - Chugai managed; <sup>1</sup>Poseida led studies undergoing integration into Roche portfolio; <sup>2</sup>Zion Pharma managed; <sup>3</sup>MediLink managed; <sup>4</sup>Innovent managed; <sup>5</sup>Alnylam Pharmaceuticals managed; \*also developed in neurology; T: Tecentriq; RA: Receptor agonist

# Roche Group development pipeline

## Phase III (8 NMEs + 31 AIs)

<b>RG3502</b>	Kadcyla + T	HER-2+ eBC high-risk	<b>RG6149</b>	astegolimab	COPD
<b>RG6026</b>	Columvi + Polivy + R-CHP	1L DLBCL	<b>RG6299</b>	sefaxersen (ASO factor B)	IgA nephropathy
	Columvi	r/r MCL	<b>RG6631</b>	afimkibart (anti-TL 1A)	ulcerative colitis
<b>RG6058</b>	tiragolumab + T	stage III unresectable 1L NSCLC		afimkibart (anti-TL 1A)	Crohn's disease
	tiragolumab + T + Avastin	1L HCC	<b>RG7159</b>	Gazyva	membranous nephropathy
<b>RG6107</b>	PiaSky	aHUS		Gazyva	systemic lupus erythematosus
<b>RG6114</b>	Itovebi + fulvestrant	post CDKi HR+ PIK3CA-mut. BC		Gazyva	childhood onset idiopathic nephrotic syndrome*
	Itovebi + Phesgo	1L HER2+ PIK3CA-mut. mBC	<b>RG1594</b>	Ocrevus higher dose	PPMS
	Itovebi + CDK4/6i + letrozole	1L ES PIK3CA-mut. HR+ HER2- advanced BC	<b>RG6168</b>	Enspryng	MOG-AD
<b>RG6171</b>	giredestrant + everolimus	post-CDK4/6 ER+/HER2- BC		Enspryng	autoimmune encephalitis
	giredestrant + palbociclib	1L ET sensitive ER+/HER2-mBC	<b>RG6356</b>	Elevidys	amb. 8 to <18y & non amb. DMD
	giredestrant	ER+ BC adj	<b>RG7845</b>	fenebrutinib	RMS
	giredestrant + Phesgo	1L ER+/HER2+ BC		fenebrutinib	PPMS
	giredestrant + CDK4/6i	1L ET resistant ER+/HER2- BC	<b>RG6168</b>	Enspryng	TED
<b>RG6330</b>	divarasib	2L NSCLC	<b>RG6179</b>	vamikibart	UME
<b>RG7446</b>	Tecentriq + platinum chemo	NSCLC periadj	<b>RG6321</b>	Susvimo	wAMD, 36-week
	Tecentriq + BCG	NMIBC, high-risk	<b>RG7716</b>	Vabysmo	CNV
	Tecentriq	ctDNA+ high-risk MIBC			
	Tecentriq + lurbinectedin	1L maintenance SCLC			
<b>RG7601</b>	Venclexta + azacitidine	1L MDS			
<b>RG7828</b>	Lunsumio + lenalidomide	2L+ FL			
	Lunsumio + Polivy	2L+ DLBCL			

## Registration US & EU (2 NME + 6 AIs)

<b>RG6026</b>	Columvi + chemo <sup>1</sup>	2L+ DLBCL
<b>RG6114</b>	Itovebi + palbociclib + fulv. <sup>2</sup>	1L HR+ PIK3CA-mut. mBC
<b>RG7828</b>	Lunsumio SC	3L+ FL
<b>RG7159</b>	Gazyva	lupus nephritis
<b>RG6152</b>	Xofluza <sup>3</sup>	influenza, pediatric (0-1 year)
<b>RG6152</b>	Xofluza <sup>4</sup>	influenza direct transmission
<b>RG6356</b>	Elevidys <sup>2,5</sup>	DMD
<b>RG6321</b>	Susvimo <sup>4</sup>	DR

T: Tecentriq

\*also known as pediatric nephrotic syndrome (PNS)

<sup>1</sup>Approved in EU, filed in US

<sup>2</sup>Approved in US, filed in EU

<sup>3</sup>Filed in EU

<sup>4</sup>Filed in US

<sup>5</sup>US rights with Sarepta

# Expected regulatory submissions\*

## New Molecular Entities: Lead and additional indications

New Molecular Entity (NME)	Cardiovascular, Renal & Metabolism
Additional Indication (AI)	Neurology
Oncology / Hematology	Ophthalmology
Immunology	Other

\*Filing timelines reflect the anticipated filing of a potential indication; projects shown are in phase II and phase III

✓ Indicates submission to health authorities has occurred

Unless stated otherwise submissions are planned to occur in US and EU

T: Tecentriq, RA: Receptor agonist

<sup>1</sup>Alnylam Pharmaceuticals managed

2025	RG6058	tiragolumab + T Stage III unresectable 1L NSCLC	RG6058	tiragolumab+T+ Avastin 1L HCC	RG6114	Itovebi + Phesgo 1L HER2+ PIK3CA-mut. mBC	2027	RG6356	Elevidys 0 to <4 year old DMD	RG6114	Itovebi + CDK4/6i + letrozole 1L ES PIK3CA-mut. HR+ HER2- advanced BC	RG6237	anti-latent myostatin (GYM 329) + Evrysdi SMA
	RG6171	giredestrant + everolimus post-CDK4/6 ER+/HER2- BC	RG6171	Itovebi + fulvestrant post CDKi HR+ PIK3CA-mut. BC	RG6171	giredestrant ER+ BC adj		RG6356	Elevidys amb. 8 to <18y & non amb. DMD	RG6171	giredestrant + Phesgo 1L ER+/HER2+ BC	RG6237	anti-latent myostatin (GYM 329) FSHD
	RG6149	astegolimab COPD	RG6171	giredestrant + palbociclib 1L ET sensitive ER+/HER2- mBC	RG6171	giredestrant endometrial cancer		RG6179	vamikibart DME	RG6171	giredestrant + CDK4/6i 1L ET resistant ER+/HER2- BC	RG7935	prasinezumab Parkinson's
	RG6321	Susvimo wAMD (EU)	RG7845	fenebrutinib RMS & PPMS	RG6171	giredestrant + CDK4/6i 1L ET resistant ER+/HER2- BC		RG6042	tominersen Huntington's	RG6179	divarasib 2L NSCLC	RG7816	alogabat ASD
2026			RG6179	vamikibart UME	RG6299	sefaxersen (ASO factor B) IgA nephropathy	2028 and beyond			RG6631	afimkibart (anti-TL1A) ulcerative colitis	RG6501	OpRegen geographic atrophy
			RG6321	Susvimo DME (EU)	RG6631	afimkibart (anti-TL1A) ulcerative colitis				RG6351	anti-Tie2 agonist retinal disease	RG6615 <sup>1</sup>	zilebesiran hypertension
2027							2028 and beyond			RG6640	GLP-1/GIP RA (CT-388) obesity +/- T2D		
										RG6641	GLP-1/GIP RA (CT-868) T1D with BMI ≥ 25		

# Expected regulatory submissions\*

Marketed products: Additional indications

New Molecular Entity (NME)	Cardiovascular, Renal & Metabolism
Additional Indication (AI)	Neurology
Oncology / Hematology	Ophthalmology
Immunology	Other

✓ Indicates submission to health authorities has occurred

Unless stated otherwise submissions are planned to occur in US and EU

\*Filing timelines reflect the anticipated filing of a potential indication; projects shown are in phase II and phase III

\*\*also known as pediatric nephrotic syndrome (PNS)

\*Unless stated otherwise submissions are planned to occur in US and EU  
 \*Filing timelines reflect the anticipated filing of a potential indication;  
 projects shown are in phase II and phase III  
 \*\*also known as pediatric nephrotic syndrome (PNS)

RG7828	Lunsumio + Polivy 2L+ DLBCL (US)								
RG7446	Tecentriq+ lurbinectedin 1L maintenance SCLC	RG7601	Venclexta + azacitidine 1L MDS	RG6107	PiaSky aHUS	RG3502	Kadcyla + Tecentriq HER-2+ eBC high-risk		
RG7446	Tecentriq ctDNA+ high-risk MIBC	RG1594	Ocrevus higher dose PPMS	RG7446	Tecentriq NSCLC periaj	RG6026	Columvi + Polivy + R-CHP 1L DLBCL		
				RG7828	Lunsumio + lenalidomide 2L FL+	RG6026	Columvi r/r MCL		
				RG7159	Gazyva membranous nephropathy	RG7446	Tecentriq + BCG High-risk NMIBC		
				RG7159	Gazyva systemic lupus erythematosus	RG7159	Gazyva childhood onset idiopathic nephrotic syndrome**		
				RG6168	Enspryng MOG-AD	RG6168	Enspryng autoimmune encephalitis	RG6107	PiaSky sickle cell disease
				RG6168	Enspryng TED	RG7716	Vabysmo CNV	RG6168	Enspryng DMD
<div> <div>2025</div> <div>2026</div> <div>2027</div> <div>2028 and beyond</div> </div>									

# Major pending approvals 2025

US		EU		China		Japan-Chugai	
RG6321	<b>Susvimo</b> DR (US) Filed April 2024	RG6114	<b>Itovebi + palbociclib + fulvestrant</b> 1L HR+ PIK3CA-mut. mBC Filed April 2024	RG6026	<b>Columvi + chemo</b> 2L DLBCL Filed August 2024	RG6356	<b>Elevidys</b> DMD Filed August 2024
RG6026	<b>Columvi + chemo</b> 2L DLBCL Filed Sept 2024	RG6356	<b>Elevidys</b> DMD (EU) Filed May 2024			RG7716	<b>Vabysmo</b> Angioid streaks Filed Sept 2024
RG6152	<b>Xofluza</b> influenza direct transmission Filed Nov 2024	RG6152	<b>Xofluza</b> influenza, pediatric (0-1 year) Filed June 2024			RG7446	<b>Tecentriq</b> ENKL Filed Oct 2024
RG7828	<b>Lunsumio SC</b> 3L+FL Filed Nov 2024	RG7828	<b>Lunsumio SC</b> 3L+FL Filed Nov 2024			RG99	<b>CellCept</b> refractory nephrotic syndrome Filed March 2025
RG7159	<b>Gazyva</b> lupus nephritis Filed Dec 2024	RG7159	<b>Gazyva</b> lupus nephritis Filed Jan 2025				

ENKL : extranodal natural killer/T-cell lymphoma, nasal type

Status as of April 24, 2025

	New Molecular Entity (NME)		Cardiovascular, Renal & Metabolism
	Additional Indication (AI)		Neurology
	Oncology / Hematology		Ophthalmology
	Immunology		Other

# Major granted approvals 2025

US		EU		China		Japan-Chugai	
RG3625	TNKase stroke Feb 2025	RG6026	Columvi + chemo 2L DLBCL April 2024	RG7828	Lunsumio 3L+ FL Dec 2024	RG7446	Tecentriq Alveolar Soft Part Sarcoma Feb 2025
RG6321	Susvimo DME (US) Feb 2025			RG6114	Itovebi + palbociclib + fulvestrant 1L HR+ PIK3CA-mut. mBC March 2025		
				RG1594	Ocrevus RMS & PPMS March 2025		

	New Molecular Entity (NME)		Cardiovascular, Renal & Metabolism
	Additional Indication (AI)		Neurology
	Oncology / Hematology		Ophthalmology
	Immunology		Other

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