Cue Biopharma Expands Pipeline with Exclusive License from Ascendant Health Sciences Ltd. for Clinical-Stage Dual-Mechanism Anti-IgE Antibody

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Novel dual-mechanism anti-IgE antibody designed to improve upon existing and emerging therapies for IgE-mediated diseases

Cue Biopharma plans to initiate global Phase 2b trial in food allergy following anticipated results in 2H 2026 from Ascendant Health-led Phase 2 study in chronic spontaneous urticaria

Transaction establishes Cue Biopharma as a clinical-stage company with a robust portfolio of therapies targeting functional cures for immunological disorders

BOSTON, April 30, 2026 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of therapeutic biologics to selectively engage and modulate disease-specific T cells for the treatment of autoimmune and inflammatory diseases, today announced that it has entered into an exclusive license agreement with Ascendant Health Sciences Ltd. (Ascendant Health) to develop, manufacture and commercialize Ascendant-221, a Phase 2 clinical stage anti-IgE monoclonal antibody for the treatment of allergic diseases.

Under the terms of the license agreement, Cue was granted global rights excluding mainland China, Hong Kong, Macau and Taiwan to develop and commercialize Ascendant-221. As consideration for the license, Cue will pay Ascendant Health a $15 million upfront license fee, followed by up to an aggregate of $676.5 million in additional potential payments upon the achievement of various development, regulatory and commercial milestones, and tiered royalties on future sales of Ascendant-221.

Ascendant-221 is currently being evaluated by Ascendant Health's related company, Genesis Life Sciences, in a Phase 2 placebo and active comparator-controlled dose-ranging study in chronic spontaneous urticaria (CSU) in China (China Study) with clinical results expected in 2H 2026. Cue plans to initiate a global Phase 2b trial in food allergy, following completion of the China Study and review of the data.

"With the licensing of Ascendant-221, Cue aims to expand its portfolio of potentially transformative therapies enabling functional cures in immunological disorders including autoimmunity and allergy," said Shao-Lee Lin, M.D., Ph.D., chief executive officer of Cue Biopharma. "In a Phase 1 single ascending dose trial Ascendant-221 demonstrated a favorable safety and tolerability profile with rapid and durable suppression of free IgE for longer than twelve weeks with a single dose, consistent with its dual mechanism of action. We believe these findings support continued clinical development of Ascendant-221 with potential as a best-in-class anti-IgE approach, including the possibility for less frequent dosing as compared to standard of care and potential expansion into patients with high-IgE who are not adequately served by the limitations of current therapies."

Dr. Lin added, "The addition of Ascendant-221 enhances Cue's pipeline, alongside CUE-401, a bifunctional therapeutic that combines engineered IL-2 and TGF-beta signals to promote immune tolerance that has broad relevance in autoimmunity. Recent findings published in *Nature* provide compelling evidence supporting its mechanism of action, further reinforcing our confidence in its potential to transform the treatment landscape for serious autoimmune diseases."

"This investment is the culmination of our Board's review of options designed to maximize stockholder value and augment our portfolio with assets that have a functional impact on autoimmunity and immunology," said Pasha Sarraf, M.D., Ph.D., chairman of Cue Biopharma. "In parallel, Cue has strengthened its leadership team with the appointment of a seasoned pharmaceutical CEO with a track record of commercialized drug development in immunology and the addition of other experienced executive leaders to support a clinical stage company."

Additional details concerning the terms of the license agreement and associated consideration will be provided in a Current Report on Form 8-K to be filed with the Securities and Exchange Commission.

About Ascendant-221
Ascendant-221 is a humanized anti-IgE IgG1 monoclonal antibody that binds in a differentiated way to IgE leading to a distinct IgE conformation. Ascendant-221 has a dual mechanism of action; it neutralizes free IgE with picomolar potency and leverages the naturally occurring CD23-mediated IgE downregulation pathway to suppress new IgE synthesis. By targeting key drivers of IgE-mediated disease, Ascendant-221 is designed to enable deeper and more sustained control of free IgE levels, and therefore of allergic conditions. The program has completed a Phase 1 single ascending dose clinical trial and is currently being evaluated in a Phase 2 clinical trial in CSU. Ascendant-221 was formerly known as UB-221.

About CUE-401
CUE-401 is a novel bifunctional therapeutic that incorporates an innovative TGF-beta breathing-mask moiety with Cue Biopharma's clinically validated interleukin-2 (IL-2) mutein in a single injectable biologic. The design of CUE 401 was inspired by Nobel Prize winning science in 2025 for the role of IL-2 and TGF-beta as essential components in helping establish immune tolerance by regulating FOXP3 signaling. CUE-401 is designed to promote immune regulation and tolerance by three complementary mechanisms: 1. Direct regulation of proinflammatory mechanisms by TGF-beta, 2. Expansion of existing Tregs by IL-2, and 3. Conversion of FOXP3- conventional CD4+ T cells into FOXP3+ induced Tregs through the coordinated provision of TGF-beta and IL-2 signals, both of which are required for the de novo induction of FOXP3 expression.

About Cue Biopharma
Cue Biopharma (Nasdaq: CUE) is a clinical stage therapeutics company focused on advancing a portfolio of potentially transformative therapies aimed

at enabling functional cures across immunological disorders. Its lead asset is a novel anti-IgE antibody with a dual-mechanism of action, currently in Phase 2 development for allergic diseases. In addition, Cue developed the Immuno-STAT® platform which selectively targets disease-specific T cells in vivo without broad immune modulation. Its lead autoimmune candidate, CUE-401, is advancing towards Phase 1 and was designed to regulate inflammation and drive Treg-mediated tolerance. Cue is led by an experienced management team with deep expertise in identifying, acquiring, and advancing promising drug candidates.

For more information please visit www.cuebiopharma.com and follow us on X and LinkedIn.

About Ascendant Health
Ascendant Health is a privately-held biotechnology company committed to delivering transformative solutions to patients globally.

Cue Biopharma Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, those regarding: the potential benefits of the therapeutic approach to be developed pursuant to the license agreement with Ascendant Health; the potential for future milestone payments or payment of other consideration pursuant to the license agreement; the company's expectations as to timing of data from the Ascendant Health-led Phase 2 study of Ascendant-221 in CSU; the company's plans to initiate a global Phase 2b trial of Ascendant-221 in food allergy and the timing thereof; the safety and tolerability profile of Ascendant-221 and the potential for less frequent dosing as compared to standard of care and expansion into patients with high-IgE who are not adequately served by current therapies; the company's belief regarding the potential benefits and applications of its drug candidates and programs, including the company's plans to further advance its differentiating Immuno-STAT® platform, lead autoimmune asset, CUE-401, and Ascendant-221; and the company's business strategies, plans and prospects. Forward-looking statements, which are based on certain assumptions and describe the company's future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "project," "estimate," "anticipate," "strategy," "future," "likely," "promise," "potential," "possibility," or other comparable terms, although not all forward-looking statements contain these identifying words. All statements other than statements of historical facts included in this press release regarding the company's strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Important factors that could cause the company's actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the company's ability to maintain its license agreement with Ascendant Health; the company's ability to expand its pipeline with Ascendant-221; the company's limited operating history, limited cash and a history of losses; the company's ability to obtain adequate financing to fund its business operations in the near term and successfully remediate its current "going concern" determination that it does not have sufficient capital on hand to continue operations beyond the next twelve months; the company's ability to achieve profitability; potential setbacks in the company's research and development efforts including negative or inconclusive results from its preclinical studies or clinical trials or the company's ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates; serious and unexpected drug-related side effects or other safety issues experienced by participants in clinical trials; its ability to secure required U.S. Food and Drug Administration ("FDA") or other governmental approvals for its product candidates and the breadth of any approved indication; adverse effects caused by public health pandemics, including possible effects on the company's operations and clinical trials; delays and changes in regulatory requirements, policy and guidelines including potential delays in submitting required regulatory applications to the FDA; the company's reliance on licensors, collaborators, contract research organizations, suppliers and other business partners; the company's ability to obtain adequate financing to fund its business operations in the future and ability to continue as a going concern; the company's ability to maintain and enforce necessary patent and other intellectual property protection; competitive factors; general economic and market conditions and the other risks and uncertainties described in the Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations sections of the company's most recently filed Annual Report on Form 10-K and any subsequently filed Quarterly Report(s) on Form 10-Q. Any forward-looking statement made by the company in this press release is based only on information currently available to the company and speaks only as of the date on which it is made. The company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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