Connect Biopharma Initiates Phase 2 Seabreeze STAT COPD Study Evaluating Rademikibart for the Treatment of Acute Exacerbations in COPD

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– Expect to report topline data from the Seabreeze STAT COPD study in 1H 2026 –

SAN DIEGO, May 14, 2025 (GLOBE NEWSWIRE) -- Connect Biopharma Holdings Limited (Nasdaq: CNTB) (Connect Biopharma, Connect or the Company), a clinical-stage biopharmaceutical company focused on transforming acute and chronic care of asthma and chronic obstructive pulmonary disease (COPD), today announced the initiation of its Phase 2 Seabreeze STAT COPD study (NCT06940154) following written agreement on the final study protocol from the U.S. Food and Drug Administration. The study will evaluate the safety and efficacy of rademikibart as an adjunct to standard of care for acute exacerbations in participants with COPD and type 2 inflammation.

“The initiation of our second Phase 2 study in patients with inflammatory lung disease highlights our commitment to swiftly advancing the development of rademikibart for asthma and COPD,” said Barry Quart, Pharm.D., CEO and Director of Connect Biopharma. “In the current treatment landscape for patients experiencing an acute exacerbation with asthma or COPD, there are no approved biologics that can rapidly improve lung function and prevent further exacerbations over the short- and long-term. Based on our recently published Phase 2 data we believe rademikibart holds the potential to be the first biologic to deliver on this promise.”

The initiation of the Seabreeze STAT COPD study follows a post-hoc analysis in COPD-like patients from the Company’s previously completed global Phase 2b Asthma study. Data from the post-hoc analysis highlights the potential of rademikibart to improve outcomes for patients with COPD, with greatest improvements being observed in patients with elevated baseline eosinophil counts. Connect will present these data at the upcoming American Thoracic Society (ATS) 2025 International Conference, taking place May 18-21, 2025, in San Francisco.

“The arrival of biologics greatly advanced how we manage symptoms in COPD and asthma, but there remains a major unmet need for a fast, effective treatment immediately following acute exacerbations,” said Surya Bhatt, MD, Professor of Medicine in the Division of Pulmonary, Allergy and Critical Care Medicine at the University of Alabama at Birmingham School of Medicine. “Currently, 1.3 million patients visit the emergency department each year for a COPD flare-up and approximately 50% experience treatment failure within four weeks of an exacerbation. I am excited to take part in the Seabreeze STAT COPD study and evaluate whether rademikibart can deliver rapid, lasting relief for these patients.”

Seabreeze STAT COPD is a Phase 2, randomized, double-blind, placebo-controlled study evaluating rademikibart as an adjunct to standard of care for acute exacerbations in participants with COPD and type 2 inflammation. The study is expected to enroll approximately 160 participants globally who have an acute COPD exacerbation and type 2 inflammation, characterized by an eosinophil count of ≥300 cells/μL. Participants will receive either a single dose of rademikibart or placebo, administered subcutaneously. The primary endpoint is safety and efficacy of rademikibart as an adjunct to standard of care, as measured by the treatment failure rate over 28 days following an acute exacerbation. Secondary endpoints include rate and time to new moderate and severe COPD exacerbations, change-from-baseline in clinical respiratory symptoms of COPD, post- bronchodilator forced expiratory volume in one second (FEV_1), and incidence of adverse events.

About Connect Biopharma and Rademikibart

Connect Biopharma is a clinical-stage biopharmaceutical company dedicated to transforming care for asthma and COPD. Headquartered in San Diego, California, the company is advancing rademikibart, a next-generation, potentially best-in-class anti-interleukin-4-receptor alpha (IL-4Rα) antibody. With an initial focus on acute exacerbations amongst the approximately 1 million asthma patients and 1.3 million COPD patients in the U.S. who visit an emergency room annually for an acute exacerbation—an area with significant unmet need—rademikibart has the potential to be initiated in the acute setting and then continued for chronic maintenance therapy in asthma and COPD. In a prior Phase 2 trial for chronic asthma, rademikibart demonstrated strong efficacy and safety data, with clinically meaningful reductions in exacerbations and rapid, statistically significant improvements in FEV_1, observed within one week—and in most cases, within 24 hours via home spirometry.

For more information visit www.connectbiopharm.com.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended (the “Act”). Forward-looking statements are statements that are not of historical fact and include, without limitation, statements regarding future events, our future financial condition, results of operations, business strategy and plans, prospective products (as well as their potential to achieve a differentiated, competitive, or favorable benefit or profile or trend, including on safety, tolerability, improvement, maintenance, clinical response, dosing, efficacy and/or convenience), planned or expected product approval applications or approvals, anticipated milestones, expected data readouts and enrollments, research and development plans and costs, potential future partnerships, expectations about existing partnerships, timing and likelihood of success, objectives of management for future operations, future results of anticipated product development efforts, and adequacy of existing cash and potential partnership funding to fund operations and capital expenditure requirements, as well as statements regarding industry trends. These statements are based on management’s current expectations of future events only as of the date of this press release and are inherently subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond our control, including, among other things: the ability of our clinical trials to demonstrate safety and efficacy of our product candidates and other positive results; whether we will need expanded or additional trials in order to obtain regulatory approval for our product candidates; our ability to obtain and maintain regulatory approval of our product candidates; existing regulations and regulatory developments in the U.S., the PRC, Europe and other jurisdictions; the ability

of our current cash and investments position to support planned operations; our plans and ability to obtain, maintain, protect and enforce our intellectual property rights and our proprietary technologies, including extensions of existing patent terms where available; our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials; and the degree of market acceptance of our product candidates, if approved, by physicians, patients, healthcare payors and others in the medical community.

Words such as “aim,” “anticipate,” “believe,” “could,” “expect,” “feel,” “goal,” “intend,” “may,” “optimistic,” “plan,” “potential,” “promising,” “will,” and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. The inclusion of forward-looking statements should not be regarded as a representation by Connect Biopharma that any of its expectations, projections or plans will be achieved. Actual results may differ materially due to the risks and uncertainties inherent in our business and other risks described in our filings with the U.S. Securities and Exchange Commission (the “SEC”). Further information regarding these and other risks is included under the heading “Risk Factors” in our annual and periodic reports filed with the SEC. These forward-looking statements should not be taken as forecasts or promises nor should they be taken as implying any indication, assurance or guarantee that the assumptions on which such forward-looking statements have been made are correct or exhaustive or, in the case of the assumptions, fully stated in this presentation. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You are cautioned not to place undue reliance on the scientific data presented or these forward-looking statements, which speak only as of the date of this presentation. Except as required by law, Connect Biopharma undertakes no obligation to publicly update any forward-looking statements, whether because of new information, future events or otherwise. Connect Biopharma claims the protection of the safe harbor for forward-looking statements contained in the Act for all forward-looking statements.

This press release discusses our product candidate, rademikibart, which is under clinical investigation and has not yet been approved for marketing by the U.S. Food and Drug Administration or by any other regulatory agency. No representation is made as to the safety or effectiveness of rademikibart for the uses for which it is being studied. The trademarks included herein are the property of the owners thereof and are used for reference purposes only.

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