Connect Biopharma Announces Positive Preliminary Topline Data from its Global Phase 2 Study of Rademikibart as an Add-on Treatment for Acute Exacerbations in Adult and Adolescent Participants with Asthma and Type 2 Inflammation

September 15, 2026

– Rademikibart meaningfully reduced the rate of treatment failure at 28 days by 66% compared to placebo –

–Rademikibart produced a rapid, statistically significant improvement in lung function at Day 7 compared to placebo –

– Rademikibart was well tolerated in asthma patients experiencing an acute exacerbation with a low incidence of adverse events–

– Data from Seabreeze STAT COPD study of rademikibart will be available later this month after which Connect plans to engage with the U.S. Food and Drug Administration (FDA) to gain alignment on a Phase 3 program –

– Company to host a conference call to discuss the data today, September 15 at 8:00 a.m. ET –

SAN DIEGO, Sept. 15, 2026 (GLOBE NEWSWIRE) -- Connect Biopharma Holdings Limited (Nasdaq: CNTB) (Connect Biopharma, Connect or the Company), a clinical-stage biopharmaceutical company focused on transforming care for the treatment of inflammatory diseases, today announced topline results from its global phase 2 study evaluating rademikibart, the Company's next-generation, potentially best-in-class anti-interleukin-4-receptor alpha (IL-4Rα) antibody as an add-on treatment for acute exacerbations in adult and adolescent participants with asthma and type 2 inflammation.

"Topline data from our Seabreeze STAT asthma trial for rademikibart supports its potential to meaningfully improve outcomes for patients in the critical period after an exacerbation," said Barry Quart, Pharm.D., CEO and Director of Connect Biopharma. "Today's data highlight the statistically significant rapid improvements in FEV_1 within one week post treatment as well as a 66% reduction in treatment failures at 28 days, although that endpoint did not reach statistical significance. The overall results of this study provide a clear roadmap for design of a Phase 3 program. Taken together with updated market research showing approximately 1.6M ED visits in 2025 for acute asthma exacerbation by high-T2 patients, we believe these results support the potential of rademikibart to deliver significant patient impact and reduce the health economic burden for patients and hospitals. Looking ahead, we intend to report topline data from our Phase 2 Seabreeze STAT chronic obstructive pulmonary disease (COPD) trial later this month. Following which we plan to engage with the FDA regarding a Phase 3 registrational development program for rademikibart as add-on treatment for acute exacerbations of asthma and COPD."

"Patients who experience acute exacerbations remain at an elevated risk for subsequent exacerbations and worsening of symptoms despite current standard-of-care," said Michael Wechsler, MD, Director of the Cohen Family Asthma Institute and Professor of Medicine at National Jewish Health in Denver, Colorado. "66% reduction in treatment failure is an exceptional outcome and is particularly impressive and shows a meaningful improvement over standard-of-care therapy alone. The ability to deliver this magnitude of benefit while also significantly improving lung function underscores the potential of rademikibart to improve outcomes and establish a new treatment paradigm for managing acute exacerbations in the hospital setting."

The Phase 2 Seabreeze STAT Asthma study (CBP-201-206) is a randomized, double-blind, placebo-controlled study that evaluated the safety and efficacy of rademikibart as an adjunct to standard of care for acute exacerbations in adult and adolescent participants with asthma and type 2 inflammation. The study enrolled 160 patients who were randomized 1:1 to receive either a 600mg dose of rademikibart (n=79) or placebo (n=81), administered subcutaneously in addition to standard of care. The primary endpoint was treatment failure, defined as death due to any cause, (re)admission to a hospital for asthma, emergency department (ED) (re)visit or unscheduled medical visit for worsening of asthma symptoms, or the necessity to intensify pharmacologic treatment within 28 days after randomization. The key secondary endpoint was absolute change from baseline in post-bronchodilator (post-BD) forced expiratory volume in one second (FEV_1) at Week 1, which is also the proposed primary endpoint for Phase 3.
Key topline results include:

- Rademikibart demonstrated a statistically significant increase from baseline in post-bronchodilator FEV_1 on Day 7 of 250 mL compared to 120 mL with placebo (130mL greater improvement compared to placebo; p=0.023)
- Rademikibart reduced the treatment failure rate by approximately 66% over 28 days compared to placebo (p=0.153).
    - The endpoint missed statistical significance due to an overall lower treatment failure rate than projected
- 50% reduction in emergency department visits or unscheduled medical visits for worsening asthma symptoms compared to placebo
- Rademikibart was well tolerated and no new safety signals were observed through the end of the study. The safety profile was comparable to placebo, with a low incidence of adverse events (AEs) in both arms, no individual AE occurring in more than 2 participants, no AEs leading to study discontinuation in either arm, and one serious adverse event (SAE) reported in the rademikibart arm compared to 3 SAEs in the placebo arm.

Connect expects to report topline data from the ongoing Phase 2 Seabreeze STAT COPD study (CBP-201-207) of rademikibart for the treatment of

acute exacerbations in COPD patients with type 2 inflammation later this month and plans to move quickly to meet with the FDA to gain alignment on a Phase 3 program.

Company-Hosted Conference Call and Webcast

Connect will host a conference call and webcast today, September 15, 2026, at 8:00 a.m. ET. To access the conference call, please pre-register through here to receive dial-in information and a personal PIN to access the live call. Participants may access the live webcast here or from the Investors section of the Connect website at investors.connectbiopharma.com. An archive of the webcast and presentation will be available for approximately 90 days after the event.

About the Seabreeze STAT Asthma Study

Seabreeze STAT Asthma is a Phase 2, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of rademikibart as an adjunct to standard of care for acute exacerbations in adult and adolescent participants with asthma and type 2 inflammation. The study has enrolled 160 participants globally with an eosinophil count of ≥300 cells/μL who have experienced an acute asthma exacerbation. Participants received either a single dose of rademikibart or placebo, administered subcutaneously. The primary endpoint is treatment failure rate over 28 days following an acute exacerbation. The key secondary endpoint is post-bronchodilator (post-BD) forced expiratory volume in one second (FEV_1) at Week 1. Other secondary endpoints include rate and time to new asthma exacerbations, change-from-baseline in asthma symptom score and nocturnal awakenings, post-BD FEV_1 at other timepoints, and incidence of adverse events for 8 weeks after dosing. For more information, please visit clinicaltrials.gov (identifier NCT06940141).

About Rademikibart

Rademikibart is a fully human monoclonal antibody targeting interleukin-4 receptor alpha (IL-4Rα), a common subunit of interleukin-4 receptor (IL-4) and interleukin-13 receptor (IL-13). We believe that by binding with IL-4Rα, rademikibart can block the functions of IL-4 and IL-13 effectively, thereby blocking the T helper 2 (Th2) inflammatory pathway to achieving the goal of treating Th2 related inflammatory diseases such as atopic dermatitis, asthma and COPD.

About Connect Biopharma

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 antibody designed to target IL-4Rα. The Company is currently conducting global clinical studies of rademikibart for the treatment of acute exacerbations of asthma and COPD, areas with significant unmet need. Connect has granted an exclusive license to Simcere Pharmaceutical Co., Ltd., for rademikibart in Greater China. Under the exclusive license and collaboration agreement, Connect is eligible to receive remaining milestone payments up to an aggregate amount of approximately $99 million upon the achievement of certain development, regulatory and commercial milestones. Connect is also eligible to receive royalties at tiered percentage rates up to low double-digit percentages on net sales in Greater China.

For more information visit www.connectbiopharma.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. Forward-looking statements are statements that are not of historical fact and include, without limitation, statements regarding future events, our future financial and operating results and related expectations, 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), statements regarding the timing or results of any interim analysis or interim, topline or preliminary data and whether such analysis or data is indicative of safety, efficacy, final trial results or likelihood of regulatory approval for our product candidates, planned or expected meetings with the FDA or any other regulatory authorities, planned or expected product approval applications or approvals, anticipated milestones and milestone payments, expected data readouts and enrollments and the timing thereof, 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, adequacy of existing cash and potential partnership funding to fund operations and capital expenditure requirements, anticipated patient populations, market opportunities and potential pricing strategies for our prospective products, if approved, our plans for rademikibart, including potential indications, 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; the timing and outcome of any meetings with the FDA or other regulatory authorities regarding further development of our product candidates, including with respect to a potential Phase 3 program for rademikibart; our ability to obtain and maintain regulatory approval of our product candidates; existing regulations and regulatory developments in the U.S., the People’s Republic of China, Europe and other jurisdictions; 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; the degree of market acceptance of our product candidates, if approved, by physicians, patients, healthcare payors and others in the medical community; the impact on our business of adverse global macroeconomic and geopolitical conditions, including high interest rates, the inflationary environment, recessionary fears, foreign exchange rate volatility, instability in financial institutions, government shutdowns, changes in monetary policy, changes in trade policies, including tariffs and other trade restrictions or the threat of such actions, and rising geopolitical instability, including the conflicts in the Middle East and the related volatility in the price of oil and other commodity prices; as well as the risks and uncertainties described in Part I, “Item 1A. Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2025, our subsequent Quarterly Reports on Form 10-Q and our other filings with the SEC .

Words such as “aim,” “anticipate,” “believe,” “commitments,” “continue,” “could,” “design,” “estimate,” “expect,” “feel,” “goal,” “intend,” “may,” “might,” “objective,” “optimistic,” “plan,” “potential,” “predict,” “promising,” “seek,” “should,” “target,” “will,” “would,” 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 or outcomes, or the timing of such results or outcomes, may differ materially from those expressed or implied in our forward-looking statements due to the risks and uncertainties described above. 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 herein. 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 hereof. 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.

This press release discusses our product candidate, rademikibart, which is under clinical investigation and has not yet been approved for marketing by the FDA, the NMPA, 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.

Investor Relations Contact:

Alex Lobo
Precision AQ
Alex.lobo@precisionaq.com
(212) 698-8802

Media Contact:

Ignacio Guerrero-Ros, Ph.D., or David Schull
Russo Partners, LLC
Ignacio.guerrero-ros@russopartnersllc.com
David.schull@russopartnersllc.com
(858) 717-2310 or (646) 942-5604