



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

September 30, 2026

- Rademikibart significantly reduced the rate of treatment failure compared to placebo through one month by 81% ($p=0.0122$) –*
- Rademikibart significantly reduced the rate of new moderate to severe COPD exacerbations through one month by 85% ($p=0.030$) –*
- Rademikibart significantly reduced the rate of hospitalizations or emergency department visits for new acute COPD exacerbations by 100% ($p=0.0137$) –*
- Rademikibart was well tolerated in COPD patients experiencing an acute exacerbation with a lower incidence of adverse events than placebo –*
- 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 30 at 8:00 a.m. ET –*

SAN DIEGO, Sept. 30, 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-4R α) antibody as an add-on treatment for acute exacerbations in adult participants with chronic obstructive pulmonary disease (COPD) and type 2 inflammation.

"Topline data from our Seabreeze STAT COPD trial for rademikibart provides overwhelming evidence of the potential benefit early treatment with rademikibart may provide to COPD patients experiencing an acute exacerbation," said Barry Quart, Pharm.D., CEO and Director of Connect Biopharma. "2025 claims data indicate that COPD patients going to the emergency department (ED) due to an acute exacerbation generate approximately \$6 billion in healthcare costs in the following 30 days due to return visits to the ED or hospital. This study demonstrated that rademikibart completely eliminated those return visits while decreasing new moderate to severe COPD exacerbations by 85% compared to placebo. These groundbreaking results provide a unique opportunity to differentiate rademikibart in COPD from all other approved biologics. We plan to engage with the FDA as soon as feasible regarding a Phase 3 registrational development program for rademikibart as add-on treatment for COPD."

"Acute exacerbations continue to be a major driver of morbidity in COPD, and there remains a need for therapies that can improve outcomes following these events," said Surya Bhatt, MD, Director of the University of Alabama at Birmingham, UAB Center for Lung Analytics and Imaging Research (CLAIR) in Birmingham, Alabama. "The reduction in COPD exacerbations is compelling, and the clinically meaningful increase in pulmonary function provides a very important improvement over standard-of-care and supports the potential for rademikibart to improve outcomes for COPD patients following an acute exacerbation and for chronic maintenance."

Mario Castro MD, MPH, Professor of Medicine and Chief of the Division of Pulmonary, Critical Care and Sleep Medicine at the University of Kansas School of Medicine added, "One of the greatest challenges in COPD management is helping patients recover from an acute exacerbation and remain stable once they leave the hospital. The reductions in hospitalizations seen with rademikibart address a critical period when patients are at particularly high risk for worsening disease. By helping stabilize patients during the vulnerable post-exacerbation period, rademikibart has the potential to provide benefit in both acute and long-term disease management and meaningfully improve patient care."

The Phase 2 Seabreeze STAT COPD study (CBP-201-207) is a randomized, double-blind, placebo-controlled study evaluating 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 study enrolled 159 participants globally with an eosinophil count of ≥ 300 cells/ μ L who have experienced an acute COPD exacerbation. Participants were randomized 1:1 to receive either a single dose of rademikibart or placebo, 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 COPD, emergency department (ED) (re)visit or unscheduled medical visit for worsening of COPD symptoms, or the necessity to intensify pharmacologic treatment within 28 days after randomization. Secondary endpoints included post-bronchodilator (post-BD) FEV₁ at Week 1 (key secondary), rate and time to new moderate and severe COPD exacerbations, change-from-baseline in clinical respiratory symptoms of COPD, post-BD FEV₁ at other timepoints, and incidence of adverse events for 8 weeks after dosing. For more information, please visit clinicaltrials.gov (identifier NCT06940154).

Key topline results include:

- Rademikibart significantly reduced the rate of treatment failure by 81% through Week 4 compared to placebo ($p=0.0122$)
- Rademikibart significantly reduced the rate of new moderate to severe COPD exacerbations by 85% through Week 4 compared to placebo ($p=0.030$)
- Rademikibart significantly reduced new visits to emergency departments and hospital admissions for new exacerbations by 100% through Week 4 compared to placebo ($p=0.0137$)
- Rademikibart significantly reduced the use of rescue inhalers from Week 2 through Week 7 and significantly improved COPD symptoms at Week 2 compared to placebo (Total Score, $p=0.0197$)

- Clinically meaningful 70 mL greater improvement in FEV₁ at Week 4 with rademikibart compared to placebo (p=0.1607)
- 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 lower incidence of adverse events and serious adverse events reported in the rademikibart arm compared to the placebo arm.

Company-Hosted Conference Call and Webcast

Connect will host a conference call and webcast today, September 30, 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 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 National Medical Products 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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