Connect Biopharma Announces Positive Type C Meeting with the FDA for Rademikibart

April 1, 2025

– FDA aligned on plan to initiate parallel Phase 2 trials of rademikibart in patients with moderate-to-severe asthma or COPD experiencing an acute exacerbation –

– Expect to initiate both trials in Q2 2025 –

SAN DIEGO, April 01, 2025 (GLOBE NEWSWIRE) -- Connect Biopharma Holdings Limited (Nasdaq: CNTB) (Connect or Connect Biopharma), a clinical-stage biopharmaceutical company focused on transforming acute and chronic care of asthma and chronic obstructive pulmonary disease (COPD), today announced positive feedback from its Type C meeting with the U.S. Food and Drug Administration (FDA), Division of Pulmonology, Allergy, and Critical Care, in the Office of Immunology and Inflammation.

"We are pleased to have the FDA's alignment on our two parallel Phase 2 trials evaluating rademikibart in patients experiencing an acute exacerbation of asthma or COPD, an area where no biologic therapies have been approved or systematically studied," said Barry Quart, Pharm.D., CEO and Director of Connect Biopharma. "During our Type C meeting, the FDA acknowledged the unmet need for reducing recurrent exacerbations during the vulnerable 28-day period following an acute exacerbation of asthma or COPD. In our previously completed Phase 2 study for the maintenance treatment of asthma, a 600 mg subcutaneous (SC) loading dose of rademikibart was well-tolerated and delivered robust improvement in pulmonary function in less than 24 hours. This promising data suggests that rademikibart could provide meaningful and rapid benefit to the millions of patients who experience exacerbations of asthma or COPD and are seen in emergency departments or are hospitalized each year."

Based on the advice from the FDA at the meeting, Connect plans to begin enrolling patients in these trials during the second quarter of this year.

The two parallel Phase 2 randomized, double-blind, placebo-controlled trials are expected to each enroll approximately 160 patients and include patients with uncontrolled, moderate-to-severe asthma or COPD with eosinophils ≥300 cells/μL who are experiencing an acute exacerbation. The trials are designed to evaluate the benefits of a single 600 mg SC dose of rademikibart in patients over 28 days following an acute exacerbation. Based on the results of a recently published trial of a similar design, approximately 45% of patients receiving the current standard of care experienced treatment failure in the 28 days following an acute exacerbation, demonstrating the continued unmet need for better treatments for these patients[1]. Connect expects to report data from both rademikibart Phase 2 trials in the first half of 2026 with a cash runway into 2027.

"Asthma and COPD patients face a heightened risk of further exacerbations within the first 28 days following an initial episode. While biologics have demonstrated significant success in maintenance therapy, none have been approved to address airway symptoms immediately after an acute exacerbation," said Mario Castro, MD, MPH, Professor and Chief of Pulmonary, Critical Care and Sleep Medicine at the University of Kansas School of Medicine. "The pulmonology community is encouraged by the plan to evaluate the potential benefits of a single 600 mg SC dose of rademikibart following an acute exacerbation in these Phase 2 trials in patients with asthma and COPD."

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—an area with significant unmet need—rademikibart has the potential to also drive chronic utilization in asthma and COPD amongst the approximately 1 million asthma patients and 1.3 million COPD patients in the U.S. who experience acute exacerbations annually. In a Phase 2 trial for 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 periodic reports filed with the SEC, including in our annual report on Form 10-K for the year ended December 31, 2024, and any subsequent filings 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 product candidates that are under clinical study, and which have 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 these product candidates for the use for which such product candidates are being studied. The trademarks included herein are the property of the owners thereof and are used for reference purposes only.

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1. Ramakrishnan S, et.al. Treating eosinophilic exacerbations of asthma and COPD with benralizumab (ABRA): a double-blind, double-dummy, active placebo-controlled randomised trial. Lancet 2025; 13(1): 59-68.