Connect Biopharma Announces Publication of Positive Data from Global Phase 2 Trial of Rademikibart in Patients with Moderate-to-Severe Uncontrolled Asthma

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– Rademikibart demonstrated rapid onset of action with significant improvements in lung function observed at one week and maintained through 24 weeks –

– In patients with eosinophilic-driven asthma (≥300 eosinophils/μL) receiving rademikibart for 24 weeks, the mean difference from placebo in forced expiratory volume was +420 mL, amongst the largest increases reported for a biologic –

SAN DIEGO, March 31, 2025 (GLOBE NEWSWIRE) -- Connect Biopharma Holdings Limited (Nasdaq: CNTB) (Connect Biopharma), a clinical-stage biopharmaceutical company focused on transforming acute and chronic care of asthma and Chronic Obstructive Pulmonary Disease (COPD), today announced the online publication of positive results from the global Phase 2 trial of rademikibart in patients with moderate-to-severe uncontrolled asthma in the *American Journal of Respiratory and Critical Care Medicine* (AJRCCM). These data highlight rademikibart's potential as a novel biologic treatment option for patients with asthma and Type 2 inflammation, demonstrating rapid onset of action, sustained improvement in forced expiratory volume in one second (FEV_1), and clinically important reductions in annual exacerbation rates.

In the global Phase 2 trial (CBP-201-WW002), 322 adult patients with moderate-to-severe, persistent, uncontrolled asthma were randomized 1:1:1 to two rademikibart groups (150 mg or 300 mg every 2 weeks, following a 600 mg loading dose) or placebo, administered subcutaneously, for 24 weeks. Two-thirds of the randomized patients were treated in the United States. Improvement in lung function based on the primary endpoint of prebronchodilator FEV_1 was clinically meaningful and highly statistically significant, beginning at week one following the 600 mg loading dose and sustained through 24 weeks of treatment:

- Significant increases in FEV_1 were observed in both rademikibart dose groups for all high eosinophil count subgroups of patients (i.e., subgroups ≥150 cells/μL at baseline, the initial protocol-specified lower limit entry criterion).
- At Week 24, in patients with ≥300 eosinophils/μL at baseline receiving rademikibart 300 mg (N=40), the mean difference from placebo in FEV_1 was +420 mL; the Week 1 FEV_1 improvement in these patients was +312 mL[1].
- Consistent with the improved airway function, patients receiving rademikibart had substantially fewer acute exacerbations (24 events in 214 patients) than those receiving placebo (26 events in 108 patients).
- Asthma control, as measured by the five-question Asthma Control Questionnaire (ACQ-5), improved rapidly reaching statistical significance for both rademikibart doses compared with placebo at Week 2, and continued to improve through Week 24 in the overall population.
- Rademikibart was generally well-tolerated with most treatment-emergent adverse events (TEAEs) being mild or moderate in intensity and no serious TEAEs were related to treatment with rademikibart.
- No eosinophilia-related TEAEs were reported for rademikibart in the study and no patient in the subgroup of patients receiving rademikibart who had baseline eosinophils over 500 cells/μL exhibited a peak eosinophil level of >3000 cells/μL. This compares very favorably to almost 13% reported in clinical trials of dupilumab in this subgroup of patients[2].

Based on the data from this trial, Connect Biopharma previously received agreement from the U.S. Food and Drug Administration in an end-of-Phase 2 meeting with the Division of Pulmonology, Allergy, and Critical Care, in the Office of Immunology and Inflammation, to advance rademikibart into Phase 3 trials for the maintenance treatment of asthma.

"It is notable that rademikibart, particularly in patients with true eosinophilic driven asthma, was associated with numerically larger placebo-adjusted improvements in FEV_1 than those previously reported for other biologics," said Michael E. Wechsler, MD, MMSc, Professor of Medicine and Director, NJH Cohen Family Asthma Institute at National Jewish Health in Denver, Colorado. "These numerically larger improvements in efficacy were obtained with no incidents of hypereosinophilia, suggesting that increases in eosinophil levels previously observed are not an IL-4Rα class effect."

"Publication in AJRCCM of the results from the Phase 2 study of rademikibart in patients with chronic moderate-to-severe asthma and Type 2 inflammation underscores the potentially significant impact of rademikibart for these patient populations. Given the substantial increases in FEV_1, clinically meaningful decreases in exacerbations, and the favorable safety profile observed in the Phase 2 trial, rademikibart has the potential to benefit patients with chronic asthma and patients with other respiratory diseases with Type 2 inflammation such as COPD," said Barry Quart, Pharm.D., CEO and Board Director of Connect Biopharma. "Based on these data and post hoc analyses soon to be presented at the upcoming American Thoracic Society meeting, we believe there is a significant opportunity to study rademikibart during the four weeks following an acute exacerbation of asthma or COPD, a vulnerable period when approximately half of patients who receive current standard of care will experience another exacerbation and where no biologic therapies have been approved or systematically studied. We believe the unique clinical profile of rademikibart may provide significant benefit during this critical period and look forward to sharing the outcomes from our upcoming Phase 2 trials in

acute asthma and COPD."

The full publication can be accessed here.

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, 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, 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.

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1. Data on file

2. Wechsler ME, Klion AD, et.al. Effect of Dupilumab on Blood Eosinophil Counts in Patients With Asthma, Chronic Rhinosinusitis With Nasal Polyps, Atopic Dermatitis, or Eosinophilic Esophagitis. J Allergy Clin Immunol Pract 2022; 10: 2695-2709.