Connect Biopharma Announces Positive Rademikibart Global Phase 2b Topline Results in Adult Patients with Moderate-to-Severe Persistent Asthma

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- The global trial met its primary endpoint showing both doses of rademikibart treatment significantly improved lung function at Week 12
- The significant improvement in lung function was observed as early as Week 1 and was sustained through Week 24 with both doses of rademikibart
- Significant improvement in asthma control occurred early and was sustained through Week 24 for both doses of rademikibart
- Safety results suggest rademikibart was generally well tolerated
- A conference call and webcast presentation to discuss the data will be held today at 8:30 a.m. ET, details below

SAN DIEGO, CA and TAICANG, China, Dec. 12, 2023 (GLOBE NEWSWIRE) -- Connect Biopharma Holdings Limited (Nasdaq: CNTB) ("Connect Biopharma" or the "Company"), a global clinical-stage biopharmaceutical company dedicated to improving the lives of patients with chronic inflammatory diseases through the development of therapies derived from T cell-driven research, announced today positive topline results from the global Phase 2b trial evaluating rademikibart efficacy and safety in adult patients with moderate-to-severe persistent asthma.

This Phase 2b trial was a global, multicenter, randomized, double-blind, placebo-controlled study conducted in 79 sites in the United States, Poland, Hungary, China and South Korea with 322 patients randomized 1:1:1 to rademikibart 150 mg every two weeks (Q2W) with a loading dose of 600 mg (n=106), rademikibart 300 mg Q2W with a loading dose of 600 mg (n=108) and placebo (n=108). Two-thirds of the randomized patients were treated in the United States.

The trial met its primary endpoint of absolute change from baseline in pre-bronchodilator (BD) forced expiratory volume over one second (FEV_1) showing that at Week 12, lung function significantly improved over placebo with both rademikibart doses (see table below). The significant improvements seen compared to placebo with both rademikibart 150 mg and 300 mg started as early as Week 1 ($p < 0.001$ for both) and were sustained through 24 weeks of treatment ($p = 0.001$ and $p < 0.001$, respectively). A predefined exploratory analysis showed further improvement in lung function was achieved in patients with eosinophil levels of ≥ 300 cells/µl (see table below).

	Full Analysis Set (primary endpoint)			***Patients with baseline Eosinophils ≥ 300 cells/µL (exploratory endpoint)***		
		Rademikibart Q2W			**Rademikibart Q2W**	
	Placebo (n=96)	**150 mg (n=96)**	**300 mg (n=86)**	**Placebo (n=37)**	**150 mg (n=33)**	**300 mg (n=41)**
LS Mean Change from Baseline in pre-BD FEV_1 at Week 12	95 mL	235 mL	283 mL	-8 mL	235 mL	320 mL
Difference in LS Means		140 mL ($p = 0.005$)	189 mL ($p < 0.001$)		243 mL ($p < 0.001$)	328 mL ($p < 0.001$)

Strong and significant improvement in asthma control was also observed. The absolute placebo-adjusted changes from baseline in the Asthma Control Questionnaire (ACQ) score at Week 24 were -0.44 ($p < 0.001$) in the rademikibart 150 mg group and -0.33 ($p < 0.01$) in the rademikibart 300 mg group. Improvement was evident as early as Week 1 and statistically significant starting at Week 2 through Week 24 for both doses of rademikibart.

Although the study was not powered to detect differences in exacerbations, treatment with rademikibart showed strong trends toward reduced exacerbations with more than half of all exacerbations during the 24-week study occurring in the placebo group (25 exacerbations vs. 11 and 13 in patients receiving rademikibart 150 mg and 300 mg, respectively). Additionally, there were strong trends toward prolonging the time to first exacerbation in both rademikibart groups compared to placebo.

"We are thrilled with the results of our global Phase 2b study in asthma showing clinically meaningful and sustained improvement in lung function with both high and low doses of rademikibart showing improvement as early as Week 1," commented Zheng Wei, Ph.D., Co-Founder and CEO of Connect Biopharma. "These global results, along with the recently announced positive results in the China pivotal trial in patients with atopic dermatitis, further support the potential of rademikibart as a best-in-class next generation anti-IL-4Rα antibody in Th2-mediated diseases."

Treatment with 150 mg and 300 mg Q2W of rademikibart was generally well tolerated. Treatment emergent adverse events (TEAEs) (≥ 5% of subjects) were relatively similar across groups, with the most common TEAEs being COVID-19, cough, dyspnea, and wheezing. Of note, this trial was started during the worldwide COVID-19 pandemic and COVID-19 adverse events were noted across all treatment groups. No new safety signals were observed.

"In the Phase 2b global asthma trial, strong efficacy data was seen in the rademikibart groups, with improvements in airflow and daily asthma

symptoms observed rapidly within the first week of treatment. Patients treated with rademikibart further showed a trend towards meaningful, up to 50%, reductions in severe asthma exacerbations over the 24-week trial even without powering for this endpoint," said Edward Kerwin, M.D., Medical Director, Clinical Research Institute, Allergy and Asthma Center of Southern Oregon. "Rademikibart looks like a potential transformational therapy that could benefit a substantial group of uncontrolled asthmatic patients who struggle globally for asthma control and freedom from exacerbations."

The Company plans to schedule an End of Phase 2 (EoP2) meeting with the U.S. Food and Drug Administration to discuss rademikibart's Phase 3 regulatory path. Additionally, the Company plans to submit detailed results from this study for presentation at a future medical congress.

Conference Call and Webcast Presentation

Connect Biopharma management will host a conference call and webcast presentation today at 8:30 a.m. ET to review the trial results. Edward Kerwin, M.D., Medical Director, Clinical Research Institute, Allergy and Asthma Center of Southern Oregon and participant in over 250 clinical trials of new allergy, asthma, and internal medicine medications will be present to answer clinical questions during the live Q&A session. To participate in the conference call, please dial 1-877-407-0784 (U.S.) or 1-201-689-8560 (international) and use conference ID 13743026. To access the webcast presentation, please click here.

A replay of the webcast and accompanying presentation will be available following the event through the Presentations, Events and News page of the Investors section of the Connect Biopharma website.

About Connect Biopharma Holdings Limited

Connect Biopharma is a global, clinical-stage biopharmaceutical company applying its expertise in T cell biology and deep knowledge of the drug discovery industry to develop innovative therapies to treat chronic inflammatory diseases with the goal of improving the lives of millions of those affected around the world. The Company is building a rich pipeline of proprietary small molecules and antibodies, using functional T cell assays, to screen and discover potent product candidates against validated immune targets. The Company's lead product candidate, rademikibart (formerly known as CBP-201), is an antibody designed to target interleukin-4 receptor alpha (IL-4Rα) in development for the treatment of atopic dermatitis (AD) and asthma. The Company's second product candidate, icanbelimod (formerly known as CBP-307), is a modulator of S1P1 T cell receptors and is in development for the treatment of ulcerative colitis (UC). The Company's third product candidate, CBP-174, is an investigational antagonist of histamine receptor 3 designed to act peripherally, in development for the treatment of pruritus associated with AD. For more information, please visit: https://www.connectbiopharm.com/

Forward-Looking Statements

Connect Biopharma cautions that statements included in this release that are not a description of historical facts are forward-looking statements. Words such as "may," "could," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "look forward," "potential," "continue" or "project" or the negative of these terms or other comparable terminology are intended to identify forward-looking statements. These statements include the Company's plans to advance the development of its product candidates, the timing of achieving any development or regulatory milestones or reporting data or whether such milestones or data will be achieved or generated, including whether any new drug application will be submitted or accepted and the timing thereof, and the potential of such product candidates, including to achieve any benefit, improvement, differentiation, trend or profile or any product approval or be effective. The inclusion of forward-looking statements should not be regarded as a representation by Connect Biopharma that any of its plans will be achieved. Actual data may differ materially from those set forth in this release due to the risks and uncertainties inherent in the Company's business and other risks described in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 20-F filed with the SEC on April 11, 2023, and its other reports. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Connect Biopharma undertakes no obligation to revise or update this release to reflect events or circumstances after the date hereof. Further information regarding these and other risks is included in Connect Biopharma's filings with the SEC which are available from the SEC's website (www.sec.gov) and on Connect Biopharma's website (www.connectbiopharm.com) under the heading "Investors." All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

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