Connect Moves Forward CBP-201 Top-Line Results Timeline for Pivotal China Atopic Dermatitis Trial to Second Half 2022

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—Connect to Evaluate Efficacy and Safety Data on 255 Patients Already Enrolled —

—Expected Timing for Potential NDA Approval in China Remains Unchanged and is Targeted for 2025 —

SAN DIEGO and TAICANG, SUZHOU, China, July 11, 2022 (GLOBE NEWSWIRE) -- Connect Biopharma Holdings Limited (Nasdaq: CNTB) ("Connect Biopharma" or the "Company") today announced it has been informed by the Center for Drug Evaluation of the National Medical Products Administration (CDE), that it can conduct primary analysis of its ongoing pivotal trial for its lead product candidate CBP-201 to treat adult patients with moderate-to-severe atopic dermatitis (AD) based on the 255 patients already enrolled. As a result, Connect Biopharma plans to report this trial's top-line results by year-end, earlier than originally planned.

"Based on this latest feedback from the CDE, we expect to report top-line primary analysis data from the Stage 1 16-week treatment period of CBP-201 in the second half of 2022," said Dr. Zheng Wei, Ph.D., Co-Founder and CEO of Connect Biopharma. "We plan to use the results from this PRC-specific trial, if positive, to initiate pre-NDA discussions with the CDE. Pending positive outcome of those discussions, we would be on track to file a New Drug Application (NDA) in 2024 after completion and analysis of the Stage 2 36-week treatment period, with a potential NDA approval in China as soon as 2025."

"We remain confident that we can deliver a differentiated new drug to treat this debilitating disease and that there is potential for our clinical results to show a greater clinical response and more convenient dosing regimen compared to currently available treatments," concluded Dr. Zheng Wei.

In addition, the projected timeline of the Company's global Phase 3 program in moderate-to-severe AD remains unchanged including to enroll the first patient by the end of 2022.

About CBP-201 for AD
CBP-201 is an antibody designed to target interleukin-4 receptor alpha (IL-4Rα), which is a validated target for the treatment of several inflammatory diseases, including AD. CBP-201 was well tolerated and showed evidence of clinical activity in a Phase 2b clinical trial (NCT04444752) in adult patients with moderate-to-severe AD, suggesting a potential for a differentiated efficacy profile compared with data from clinical trials of the current biologic standard of care therapy. CBP-201 is also being evaluated in a China-specific pivotal trial in adults with moderate-to-severe AD (NCT05017480).

The China-specific pivotal trial is designed to evaluate the safety and efficacy of CBP-201 with the primary endpoint of IGA 0,1 response rate (e.g., the proportion of patients whose IGA score is 0-1 with a decrease of IGA score by ≥2 points from baseline) at week 16 vs. placebo.

Key secondary endpoints include EASI-75 response rate, EASI-90 response rate, and weekly average PP-NRS change at week 16 from baseline. The CDE has recommended that the Company analyze IGA and EASI response rates as co-primary endpoints, and the Company is evaluating this recommendation.

The enrollment of 255 adult patients with moderate-to-severe AD for the PRC-specific trial was completed in the first half of 2022, with patients randomized in a 2-to-1 ratio to receive either CBP-201 or placebo control.

Through the first 16 weeks (Stage 1 of the treatment period), patients in the CBP-201 cohort received a loading dose of 600 mg of CBP-201 to be followed by 300 mg every two weeks (Q2W). The patients in the placebo control cohort initially received a matching placebo loading dose to be followed by a matching placebo dose Q2W. From week 16 through week 52 (Stage 2 of the treatment period), patients who achieve EASI-50 response in Stage 1 will be equally randomized at week 16 to receive either CBP-201 300 mg Q2W or CBP-201 300 mg every four weeks (Q4W). Patients who have not achieved EASI-50 in Stage 1 of the treatment period will be assigned to receive CBP-201 300 mg Q2W in the Stage 2 treatment period.

About Atopic Dermatitis
Atopic dermatitis (AD), which has an estimated lifetime prevalence of up to 20% and is increasing globally, is the most commonly diagnosed chronic inflammatory skin disorder. It is characterized by skin barrier disruption and immune dysregulation. Estimates of prevalence of AD in China show an increase over time and recent longitudinal studies have reported a dermatologist-diagnosed prevalence of 7.8% in Chinese outpatients visiting tertiary hospitals. In the United States, it is estimated that 26.1 million people have AD, of which 6.6 million have moderate-to-severe disease. Further, over 58% of adults with moderate-to-severe AD have disease that physicians consider to be inadequately controlled by approved therapeutic modalities, including topical anti-inflammatory agents and systemic agents.

About Connect Biopharma Holdings Limited
Connect Biopharma is a global, clinical-stage biopharmaceutical company dedicated to improving the lives of patients with inflammatory diseases through the development of therapies derived from T cell-driven research. It is building a rich pipeline of internally designed, wholly owned, small molecules and antibodies using functional cellular assays with T cells to screen and discover potent product candidates against validated immune targets. Its lead product candidate, CBP-201, is an antibody designed to target interleukin-4 receptor alpha (IL-4Rα) in development for the treatment of AD and asthma. The Company's second most advanced product candidate, CBP-307, is a modulator of a T cell receptor known as S1P1 in development for the treatment of ulcerative colitis. Clinical development has begun for its third product candidate, CBP-174, a peripherally acting antagonist of histamine receptor 3, for the treatment of pruritus associated with AD.

With operations in the United States and China, Connect Biopharma is building a rich global pipeline of molecules and antibodies targeting several aspects of T cell biology. For more information, please visit www.connectbiopharm.com.

Forward-Looking Statements

The Company cautions that statements included in this report 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, and the potential of such product candidates, including to achieve any benefit or profile or any product approval. The inclusion of forward-looking statements shall not be regarded as a representation by Connect Biopharma that any of its plans will be achieved. Actual results may differ from those set forth in this report due to the risks and uncertainties inherent in the Connect Biopharma business and other risks described in the Company's filings with the SEC, including the Company’s Annual Report on Form 20-F filed with the SEC on March 31, 2022, 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 the Company undertakes no obligation to revise or update this report 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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