



Connect Biopharma Reports CBP-201 Achieved All Primary and Key Secondary Endpoints in Pivotal Atopic Dermatitis (AD) Trial in China

- All primary and key secondary endpoints were met and highly significant at Week 16 in 255 adult patients with moderate-to-severe AD
- Safety and tolerability results for CBP-201 consistent with targeting the IL-4R α pathway
- Data support advancing the regulatory discussions with the CDE for submitting an NDA in China
- Conference call to discuss these data will be held today at 5:30am PDT/8:30am EDT

SAN DIEGO and TAICANG, SUZHOU, China – October 4, 2022 – [Connect Biopharma Holdings Limited](#) (Nasdaq: CNTB) (Connect Biopharma or the Company), a global clinical-stage biopharmaceutical company developing T cell-driven therapies to treat inflammatory diseases, today announced topline results for the primary analysis population of the pivotal trial of the Company’s lead candidate, CBP-201, in patients with moderate-to-severe atopic dermatitis (AD) in China. This multi-center, randomized, double-blind, parallel group, placebo-controlled trial is evaluating the efficacy and safety of CBP-201 as well as the potential for an extended CBP-201 dosing interval during the maintenance phase of treatment.

The primary endpoint of IGA of 0 or 1 (“clear” or “almost clear”) with at least 2 grades of reduction at Week 16 from baseline was significantly greater for the CBP-201 (300 mg every two weeks) group with 30.3% of patients showing improvement compared to 7.5% for the placebo group ($p < 0.001$). CBP-201 also met key secondary endpoints, including 83.1%, 62.9% and 35.8% of patients achieving a 50%, 75%, 90% reduction in the Eczema Area and Severity Index score (EASI-50, EASI-75, EASI-90) from baseline compared to 41.1%, 23.4% and 6.3% for the placebo group ($p < 0.001$), respectively. Significant improvement in pruritus with 35.0% of patients experiencing a reduction of 4 or greater on the Peak Pruritus-Numerical Rating Scale (PP-NRS) compared to 9.6% for placebo ($p < 0.001$). The percent change from baseline compared to placebo showed a statistically significant improvement in itch (as measured by PP-NRS) one week after the first dose.

CBP-201 was generally well tolerated, with safety results comparable to placebo, with a similar incidence of Treatment-Emergent Adverse Event (TEAEs) of 73.5% versus 72.9% for the placebo group, Serious Adverse Events (SAEs) of 0.6% versus 3.5% over the 16-week treatment period. Most TEAEs were mild to moderate in severity and did not lead to study drug discontinuation. The incidence of injection site reactions lasting longer than 24 hours (6.5% versus 0.0% in the placebo group), all of which were mild in severity, and conjunctivitis (4.7% versus

3.5% in the placebo group) were the most frequently reported treatment-emergent adverse events of special interest.

“We treat patients daily who suffer from this debilitating disease and its symptoms, which include persistent and intense itching and painful skin lesions, redness, dryness, oozing, crusting and cracking of the skin,” said Professor Jianzhong Zhang, Director of Dermatology Department at Peking University People’s Hospital, and Principal Investigator on the trial. “These impressive results from the largest primary efficacy AD dataset in Chinese patients give sufferers hope for a safe and therapeutic treatment. We look forward to the potential of adding an important treatment to our armamentarium to further address AD patients’ unmet needs.”

“We are pleased that these positive and important topline results from our pivotal China trial provide potentially NDA-supportive efficacy and safety data for CBP-201,” said Zheng Wei, PhD, Co-Founder and CEO of Connect Biopharma. “The ongoing Stage 2 of the CBP-201 pivotal trial gives us an important opportunity to further evaluate efficacy with continued dosing at every two weeks as well as at a more convenient every four-week (Q4W) dosing regimen, which also demonstrated significant improvements in skin clearance, disease severity, and itch in our global Phase 2b trial.”

The Company anticipates engaging with the Center for Drug Evaluation of the National Medical Products Administration (CDE) in the next several months to determine the potential for a New Drug Application (NDA) filing.

Conference Call and Webcast Details

To join today’s conference call or webcast at 5:30 a.m. PDT/8:30 a.m. EDT today, please choose from these options:

- For a listen-only webcast that includes the slide presentation, investors can follow this link: <https://edge.media-server.com/mmc/p/2anxatz>. The replay will be available for 12 months.
- To take part in the live telephone conference call, follow this link to register in advance: <https://register.vevent.com/register/BI56f637ba4d29429cb9b5c656dc338cea> Upon registering, you will receive a dial-in number and unique PIN to join the conference call.
- A copy of the presentation will also be available via the Company’s Investor Relations events and presentations web page at: <https://investors.connectbiopharm.com/presentations-events/events>

About the Trial

The CBP-201 pivotal trial in patients with moderate-to-severe atopic dermatitis (AD) in China is an ongoing multi-center, randomized, double-blind, parallel group, placebo-controlled, efficacy and safety trial of patients divided

into two stages. Patients in the study were randomized in a 2-to-1 ratio to receive either CBP-201 or placebo control. During Stage 1, a 16-week period, patients were randomized into two groups which received either: a single loading dose of CBP-201 600 mg, to be followed by 300 mg every two weeks, or placebo. After Stage 1, patients achieving EASI-50 or greater will be randomized to receive either CBP-201 300 mg every two weeks (Q2W) or CBP-201 300 mg every four weeks (Q4W) for the Stage 2 36-week maintenance period. Patients who did not reach at least EASI-50 during Stage 1 will receive CBP-201 300 mg Q2W during Stage 2.

The analysis was conducted based on CDE feedback on the primary analysis population of 255 adult patients who have completed Stage 1. Based on this analysis, the Company anticipates engaging with the CDE to determine whether analysis on additional adult and adolescent patients enrolled in the trial outside the primary analysis population will be required.

About Atopic Dermatitis and CBP-201

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.

CBP-201 is an antibody designed to target interleukin-4 receptor alpha (IL-4R α), a validated target for the treatment of several inflammatory diseases, including AD. CBP-201 was generally well tolerated and showed evidence of clinical activity in a global Phase 2b clinical trial in adult patients with moderate-to-severe AD.

About Connect Biopharma Holdings Limited

Connect Biopharma is a U.S. and China-based clinical-stage biopharmaceutical company dedicated to improving the lives of patients with inflammatory diseases through the development of therapies derived from T cell research. 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, CBP-201, is an antibody designed to target interleukin-4 receptor alpha (IL-4R α) in development for the treatment of atopic dermatitis and asthma. The Company's second most advanced product candidate, CBP-307, is a modulator of S1P1 T cell receptor and is in development for the treatment of ulcerative colitis (UC). The Company's third product candidate, CBP-174, is a peripherally acting antagonist of histamine receptor 3, 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 press 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,” “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 should not be regarded as a representation by Connect Biopharma that any of its plans will be achieved. Actual results 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 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 Connect Biopharma undertakes no obligation to revise or update this news 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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