Connect Biopharma Reports Positive Top-Line Results from the Global Phase 2 Clinical Trial of CBP-201 in Patients with Moderate-to-Severe Atopic Dermatitis

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Primary endpoint met with all three CBP-201 arms achieving significant improvements

Significant improvements also reported for key secondary endpoints including other measures of skin clearance and itch with CBP-201 300mg every two weeks (*Q2W) arm*

The Company intends to initiate a Phase 3 trial program in mid-2022

SAN DIEGO and TAICANG, SUZHOU, China , Nov. 18, 2021 (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, today reported positive topline results from the global Phase 2 clinical trial of CBP-201 administered subcutaneously (SC) to adult patients with moderate-to-severe atopic dermatitis (AD) (NCT04444752).

The data show that the trial met its primary efficacy endpoint, with statistically significant improvements in the percentage reduction in the Eczema Area and Severity Index (EASI) score from baseline to Week 16. All three CBP-201 arms (300mg Q2W, 150mg Q2W or 300mg every four weeks (Q4W)) were statistically superior to placebo at Week 16. For EASI secondary endpoints, all three CBP-201 arms showed statistically significant improvements in the proportion of patients achieving at least a 50% or 75% reduction in EASI score from baseline at Week 16, compared with placebo (EASI-50 or EASI-75, respectively).

Statistically significant improvements with CBP-201 300mg Q2W over placebo were also seen for other key secondary efficacy endpoints, including the proportion of patients achieving an Investigator Global Assessment (IGA) score of 0 or 1 (clear or almost clear) and a reduction of ≥2 points from baseline at Week 16; and change from baseline to Week 16 in weekly average Peak Pruritus Numerical Rating Scale (PP-NRS), as well as a range of other endpoints.

CBP-201 was also observed to have a favorable safety profile, with a similar incidence of Treatment-Emergent Adverse Events (TEAEs), Serious Adverse Events (SAEs) and TEAEs leading to study drug discontinuation reported for CBP-201 treatment and placebo groups. Finally, there were a low reported incidence of injection site reactions (1.8%) and conjunctivitis (3.5%) in patients receiving CBP-201.

"We are very pleased to have successfully completed this trial on schedule despite the challenges of the COVID-19 pandemic. The positive efficacy and safety data provide additional evidence that CBP-201 has the potential to be an important addition to the armamentarium for the treatment of AD, a disease which we know is heterogenous with signs and symptoms varying greatly between patients," said Zheng Wei, PhD, Co-Founder and CEO of Connect Biopharma. "Based on these results, we intend to initiate a Phase 3 trial program in mid-2022 to further evaluate the role that CBP-201 may play in addressing the unmet therapeutic need that is a barrier to optimizing outcomes for many patients living with AD. This global Phase 2 trial is also an important milestone in informing us of the potential of CBP-201 in other indications currently being studied, including moderate-to-severe persistent asthma and chronic rhinosinusitis with nasal polyps."

CBP-201 Global Phase 2 Clinical Trial Design
The global Phase 2 clinical trial, "A Randomized, Double-Blind, Placebo-Controlled Multi-Centered Study of the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of CBP-201 in Adult Subjects with Moderate to Severe Atopic Dermatitis," enrolled 226 patients (ages 18–75 years) throughout the United States, China, Australia and New Zealand. Patients were randomized to one of three CBP-201 treatment groups or the placebo group. The CBP-201 treatment groups all received a 600 mg loading dose on Day 1 and then received 300 mg Q2W, 150 mg Q2W or 300 mg Q4W. The treatment period was 16 weeks, and all patients were followed for an additional period of 8 weeks.

CBP-201 and placebo were administered via subcutaneous (SC) injection.

The primary efficacy endpoint was percentage reduction in the EASI score from baseline to Week 16 for each CBP-201 group compared with the placebo group; the key secondary endpoints were the proportion of patients with an Investigator Global Assessment (IGA) score 0 or 1 and a reduction of ≥2 points at Week 16; the proportion of patients achieving EASI-50, EASI-75 or EASI-90 from baseline at Week 16; and change from baseline to Week 16 in weekly average PP-NRS. Safety assessments included reported adverse events (AEs), vital signs (VS), physical examinations and injection site changes; laboratory and electrocardiogram (ECG) evaluations; and the number of patients displaying anti-drug antibodies (ADA).

The Company intends to hold a conference call to discuss the detailed trial results from this global Phase 2 clinical trial by the end of January 2022, following the completion of further analyses.

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 CBP-201
CBP-201, discovered internally using Connect Biopharma's proprietary Immune Modulation Technology Platform, 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 atopic dermatitis (AD). CBP-201 has shown a favorable safety and efficacy profile in a Phase 1b clinical trial in adult patients with moderate-to-severe atopic dermatitis, suggesting a potential for a differentiated efficacy profile compared with data from clinical trials of the current biologic standard of care therapy. CBP-201 has been evaluated in a global Phase 2b trial in adult patients with moderate-to-severe atopic dermatitis (NCT04444752); in a China specific pivotal trial in adults with moderate-to-severe atopic dermatitis (NCT05017480); in a Phase 2b trial in adult patients with moderate-to-severe persistent asthma (NCT04773678); and in a Phase 2b trial in adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP) (NCT04783389).

About Connect Biopharma Holdings Limited
Connect Biopharma Holdings Limited is a global clinical-stage biopharmaceutical company dedicated to improving the lives of patients living with chronic inflammatory diseases through the development of therapies derived from our T cell-driven research.

Our lead product candidate, CBP-201 — an antibody designed to target interleukin-4 receptor alpha (IL-4Rα) — has been in clinical trials for the treatment of atopic dermatitis (AD), asthma, and chronic rhinosinusitis with nasal polyps (CRSwNP). Our second lead product candidate, CBP-307 — a modulator of a T cell receptor known as sphingosine 1-phosphate receptor 1 (S1P1) — has been in clinical trials for the treatment of ulcerative colitis (UC) and Crohn's disease (CD). Furthermore, we have started the clinical development of an additional product candidate, CBP-174 — a peripherally acting antagonist of histamine receptor 3 — for the treatment of pruritus associated with AD.

With headquarters in China, additional operations in the United States and Australia, and clinical development activities in those geographies as well as Europe, Connect Biopharma is building a rich global pipeline of internally designed, wholly owned small molecules and antibodies targeting several aspects of T cell biology. For additional information about Connect Biopharma, please visit our website at 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 statements regarding the potential of CBP-201 to achieve a differentiated or favorable benefit or profile to address the unmet needs of patients, and the Company's plans to initiate a Phase 3 trial program to further evaluate CBP-201. 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 release due to the risks and uncertainties inherent in the Connect Biopharma business and other risks described in the Company's filings with the Securities and Exchange Commission ("SEC"). Among other things, there can be no guarantee that planning or ongoing studies will be initiated or completed as planned, that future study results will be consistent with the results to date, that CBP-201 will receive regulatory approvals, or be commercially successful. 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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