Connect Biopharma Completes Enrollment of CBP-201 Global Phase 2 Clinical Trial in Moderate-to-Severe Atopic Dermatitis

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SAN DIEGO and TAICANG, China, April 08, 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 announced that it has completed full enrollment of the phase 2 clinical trial evaluating CBP-201 in adult patients with moderate-to-severe Atopic Dermatitis (AD).

The global, randomized, double-blind, placebo-controlled, dose-ranging clinical trial to assess the efficacy, safety, and pharmacokinetics (PK) profile of CBP-201, was designed to enroll 220 subjects and is being conducted at 60 sites across the US, China, Australia, and New Zealand. CBP-201 or placebo was administered to eligible adult subjects with moderate-to-severe AD for 16 weeks with 8 weeks of follow up (NCT04444752).

“The completion of enrollment of the CBP-201 global phase 2 trial in patients with moderate-to-severe AD is an important step for Connect and our lead clinical program,” said Zheng Wei, PhD, Co-founder and CEO of Connect Biopharma. “A significant unmet need still exists for patients and we believe that CBP-201 has the potential to show a differentiated profile to address it. We are optimistic that the results from this study, expected in the second half of this year, will continue to support our hypothesis.”

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. It is estimated that 26.1 million people in the United States have AD, of which 6.6 million have moderate-to-severe disease. It is estimated that over 58% of adults with moderate-to-severe AD have disease which physicians consider to be inadequately controlled by approved therapeutic modalities, including topical anti-inflammatory agents and systemic agents.

About CBP-201

CBP-201 is a novel IL-4Rα monoclonal antibody that has shown a favorable safety and efficacy profile in a Phase 1b clinical trial in adult patients with moderate-to-severe AD. CBP-201 was shown to be well tolerated with no new safety signals compared to other approved IL-4Rα blockers, and no reported injection site reactions or conjunctivitis. The proportion of patients given CBP-201 150mg or 300 mg or placebo, weekly for 4 weeks, who achieved an Investigator Global Assessment score of clear or almost clear skin (IGA 0,1) was 50%, 42.9% and 12.5% respectively. Additionally, skin lesion improvements were rapid, as evidenced as early as one week after dosing and were correlated with a rapid reduction in pruritus intensity and frequency. This suggests the potential for a differentiated efficacy profile, with fast onset of action for CBP-201 compared with data from clinical trials of the current biologic standard of care therapy.

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, is an antibody designed to target interleukin-4 receptor alpha (IL-4Rα), which is a validated target for the treatment of several inflammatory diseases such as atopic dermatitis (AD) and asthma. Our second lead product candidate is CBP-307, a modulator of a T cell receptor known as sphingosine 1-phosphate receptor 1 (S1P1). Specifically, we are developing CBP-307 for two types of inflammatory bowel disease (IBD), ulcerative colitis (UC) and Crohn’s disease (CD).

With current 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 profile to address the unmet needs of patients with AD and the timing of the results of the Company's phase 2 clinical trial evaluating CBP-201 in adult patients with moderate-to-severe AD. 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 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"). 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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