Connect BioPharma Successfully Completes CBP-174 Phase 1 Single Ascending Dose Study

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– CBP-174 in development for pruritus associated with allergic and inflammatory skin diseases, including atopic dermatitis, was observed to be safe and well-tolerated –

SAN DIEGO and TAICANG, SUZHOU, China, Aug. 30, 2022 (GLOBE NEWSWIRE) -- 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 it successfully completed its first-in-human Phase 1 study of CBP-174 designed to evaluate safety, tolerability, and pharmacokinetics (PK) in healthy adults. CBP-174, a highly selective, peripherally acting H3 receptor (H3R) antagonist drug candidate is in development to treat pruritus (itch) associated with allergic and inflammatory skin diseases, including atopic dermatitis (AD).

CBP-174 administered orally, was observed to be safe and well-tolerated across eight dose escalation cohorts evaluated up to a maximum dose of 16 mg or placebo in this randomized, double-blind, placebo-controlled, single ascending dose (SAD) study. There were no serious adverse events, and reported adverse events were predominantly mild in severity and no dose-limiting toxicities were identified. Other safety parameters, including vital signs, ECGs, and laboratory results showed no clinically notable safety findings. PK of CBP-174 exhibited rapid absorption with dose proportional increases in exposure followed by linear elimination.

“This promising first human data demonstrates good progress for CBP-174 as a novel treatment for pruritus associated with allergic and inflammatory skin conditions, such as atopic dermatitis, which afflicts millions of individuals worldwide,” said Dr. Zheng Wei, Ph.D., Co-Founder and CEO of Connect Biopharma. “This is our first clinical trial for our third clinical-stage drug candidate, and we look forward to continuing the evaluation of CBP-174 as we work toward improving the quality-of-life outcomes for patients with debilitating dermatologic diseases.”

About CBP-174
Connect Biopharma is developing CBP-174, a highly selective, peripherally acting H3R antagonist for oral administration, to treat chronic pruritus associated with allergic and inflammatory skin conditions, including AD. Pre-clinical models have indicated that CBP-174 led to reductions in scratching in mice within the first 30 minutes of dosing, which could potentially translate to rapid reduction in pruritus in humans.

About the CBP-174 Phase 1 Trial
The Phase 1 trial sought to assess safety, tolerability, and PK of CBP-174 in healthy adults. The CBP-174 Phase 1 trial was a randomized, double-blind, placebo-controlled, SAD study. The study was conducted in Australia and included eight dose escalation cohorts and one extension cohort with administration of a single oral dose of CBP-174 or placebo. A total of 72 subjects were dosed with 8 subjects included in each cohort, whereby 54 and 18 subjects received CBP-174 and placebo, respectively.

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-4Rα) 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, for the treatment of pruritus associated with AD. For more information, please visit: https://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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