Connect Biopharma Announces Week 12 Top-Line Results from Phase 2 CBP-307 Trial in Patients with Moderate-to-Severe Ulcerative Colitis

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- *Primary endpoint of change from baseline on adapted Mayo Score for CBP-307 0.2 mg once-daily, orally administered dose showed a numerical improvement, but did not achieve statistical significance*
- *Clinical Remission on adapted Mayo Score and other secondary endpoints achieved statistical significance with strong evidence of pharmacodynamic activity as measured by reduction in lymphocyte counts, and CBP-307 was observed to be generally well tolerated*
- *Company intends to engage in partnership discussions for future development of CBP-307 to focus on lead program CBP-201 (IL4R antagonist)*

SAN DIEGO, CA and TAICANG, China, May 03, 2022 (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 top-line results at 12 weeks from its Phase 2 trial for CBP-307 (CBP-307CN002), a once-daily, orally administered, selective sphingosine 1-phosphate (S1P) receptor modulator in development for the treatment of ulcerative colitis (UC).

Administration of CBP-307 0.2 mg demonstrated a numerical reduction for the primary endpoint of least squares (LS) mean change from baseline in adapted Mayo Score at Week 12 that did not meet statistical significance. A significantly higher proportion of patients who received CBP-307 0.2 mg dose achieved Clinical Remission based on both the complete and adapted Mayo Scores, which has been accepted by the FDA as the primary endpoint in clinical trials that have supported prior approvals for treatments of UC. Additionally, reductions in lymphocyte counts amongst individuals receiving CBP-307 0.2 mg confirmed pharmacodynamic activity of CBP-307 in patients with active UC.

"Ulcerative colitis is a serious chronic condition with continued unmet need. The overall 12-week results for CBP-307 demonstrate the therapeutic potential to induce a significant treatment response consistent with clinical data of other S1P modulators in patients with UC," said David T. Rubin, MD, Professor of Medicine and Chief of the Section of Gastroenterology, Hepatology, and Nutrition at The University of Chicago Medicine.

The primary endpoint of LS mean change from baseline in adapted Mayo Score (stool frequency, rectal bleeding, and endoscopy scores) at Week 12 for CBP-307 0.2 mg and placebo were -2.65 and -2.01, respectively (p=0.103). Secondary endpoints that were met for CBP-307 0.2 mg included a significantly higher proportion of patients reaching Clinical Remission compared to placebo as measured by both adapted (28.3% vs 9.6%, difference=18.7; p=0.016) and complete Mayo Scores (18.9% vs 5.8%, difference=13.1; p=0.044), respectively. For patients receiving CBP-307 0.2 mg, significant improvements were also noted for change in complete Mayo Score (adapted Mayo Score with physician's global assessment) from baseline to Week 12 (LS Mean Change from Baseline for CBP-307 vs. placebo: -3.67 vs -2.74, p=0.05) and in Clinical Response as measured by complete Mayo Score (52.8% vs 30.8%, p=0.023). Analysis of exploratory pharmacodynamic endpoints showed that patients receiving CBP-307 0.2 mg demonstrated a mean percent lymphocyte count reduction from baseline of 51.2% with mean absolute lymphocyte counts reduced to approximately 0.8 (10^9/L) at week 12.

Across the CBP-307 0.2 mg and placebo groups, the occurrence of drug-related treatment emergent adverse events (TEAEs) was 66.0% and 38.5%, respectively. In addition, CBP-307 0.2 mg and placebo groups were similar in the occurrence of Grade 3 or higher TEAEs (7.5% vs 7.7%, respectively) and Serious TEAEs (3.8% vs 5.8%, respectively). There were no cases of progressive multifocal leukoencephalopathy and no deaths. The overall safety results in this study showed CBP-307 to be generally well tolerated in patients with moderate-to-severe UC. Given the safety findings along with the efficacy results of this study, the Company believes that CBP-307 warrants further clinical development in UC.

"These top-line, induction phase data demonstrate the potential for CBP-307 to provide benefit to patients living with moderate-to-severe UC," said Zheng Wei, Ph.D., Co-Founder and CEO of Connect Biopharma. "Together, with recent positive results from our Phase 2 study of CBP-201 in atopic dermatitis, they support our approach to T cell-driven research in immunological pathways. To focus our resources to advance CBP-201, our lead product candidate, in a global Phase 3 clinical program and the ongoing pivotal China trial for atopic dermatitis, we plan to explore strategic partnerships to progress CBP-307 into future trials."

An accompanying deck of today's CBP-307 data is available in the Events and Presentations section of Connect Biopharma's Investor Relations site at https://investors.connectbiopharm.com/presentations-events/events.

About CBP-307CN002 Trial

CBP-307CN002 is an active Phase 2 study evaluating the efficacy and safety of CBP-307 as an induction and maintenance therapy in adult patients with moderate-to-severe UC. The randomized, double-blind, placebo-controlled, multi-center study enrolled a total of 145 patients in two active dose arms (CBP-307 0.1 mg [n=39]; CBP-307 0.2 mg [n=53]) and a placebo arm (n=53) from over 60 sites in 4 countries.

About Ulcerative Colitis

Ulcerative Colitis (UC) is an idiopathic inflammatory condition of the mucosal and submucosal colon that has a globally increasing prevalence thought to be driven by societal changes. There are approximately 600,000 to 900,000 people in the United States living with ulcerative colitis. When insufficiently controlled, UC leads to progressive organ damage that presents as functional impairment and anatomical changes such as dysplasia,

which may ultimately progress to cancer. Despite the availability of new treatments that have advanced the standard of care, a “therapeutic ceiling” means that treatment options remain limited and clinical remission is still not achieved in 70–80% patients.

About CBP-307

Discovered internally using Connect Biopharma's proprietary Immune Modulation Technology, CBP-307 is an orally administered small molecule designed to modulate sphingosine 1-phosphate receptor 1 (S1P1), which is a validated target for the treatment of several inflammatory diseases, including UC. CBP-307 was observed to be generally well tolerated and showed evidence of clinical activity in the induction period of a Phase 2 clinical trial in adults with moderate-to-severe UC, suggesting a potential for a differentiated risk–benefit profile compared with data from clinical trials of current orally administered therapies. CBP-307 is also the subject of an ongoing maintenance phase and safety follow-up in the Phase 2 UC trial and two completed and two ongoing Phase 1 trials in healthy volunteers.

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 atopic dermatitis (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 UC. 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 additional information, please visit www.connectbiopharm.com.

FORWARD-LOOKING STATEMENTS (UPDATED)

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," “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 potential of such product candidates, including to achieve any benefit or profile, and trends within the ulcerative colitis population, and partnerships for the future development of CBP-307. 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”), 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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