Connect Biopharma Announces Positive Long-Term Data from the Maintenance Period Through Week 48 of CN002 Phase 2 Icanbelimod Trial in Patients with Moderate-to-Severe Ulcerative Colitis

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- Icanbelimod demonstrated sustained clinical remission, a regulatory relevant efficacy endpoint, through Week 48 in 80% of patients who achieved clinical remission at Week 12 of the induction period.
- Icanbelimod continued to be well-tolerated, consistent with observed induction period safety data.

SAN DIEGO, CA and TAICANG, China, June 01, 2023 (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 positive data at Week 48 from Phase 2 trial (CN002) for icanbelimod (formerly known as CBP-307), a once-daily, orally administered, selective sphingosine 1-phosphate receptor 1 (S1P1) modulator in development for the treatment of ulcerative colitis (UC).

Trial Design (Maintenance Period)
The maintenance period of CN002 was a 36-week treatment period that followed the 12-week induction period (N=145) where icanbelimod 0.2 mg, administered orally once daily (PO QD), showed statistically significant improvements in clinical remission and clinical response compared to placebo, and a numerical improvement in change from baseline in adapted Mayo score.

The maintenance period included patients who achieved clinical response at the end of the induction period of the trial and continued treatment on icanbelimod 0.2 mg (n=21), 0.1 mg (n=12) or placebo (n=13) PO QD, and an icanbelimod 0.2 mg PO QD open-label arm for all non-responders (n=40) from the induction period.

Icanbelimod 0.2 mg PO QD Efficacy Data Highlights from Maintenance Period

- 86% (18/21) of patients who received icanbelimod completed the maintenance period.
- 67% (12/18) of patients who completed the study through Week 48 achieved clinical remission.
- 80% (8/10) of patients who achieved clinical remission at the end of the induction period sustained it through Week 48.
- Overall, 57% (12/21) of patients with clinical response at the end of the induction period achieved clinical remission at the end of the maintenance period.

Safety Data Highlights from Maintenance Period

- Icanbelimod was well-tolerated and long-term safety data through Week 48 remained consistent with safety findings observed in the induction period.
- Frequencies of treatment emergent adverse events were similar between icanbelimod and placebo groups, and most were mild to moderate in severity with no new safety signals noted.

"Current treatment options for UC have not demonstrated break-through efficacy based on clinical remission, highlighting the need for new and more effective therapies. Based on the icanbelimod 0.2 mg data, the clinical remission efficacy, safety data and absolute lymphocyte count reduction are compelling," said Brian Feagan, M.D., Professor in the Departments of Medicine, Epidemiology and Biostatistics at the Shulich School of Medicine & Dentistry, University of Western Ontario. "Additionally, because icanbelimod has rapid recovery of lymphocytes upon discontinuation and high potency, there is an opportunity to optimize the dosing strategy in future trials to further enhance the already encouraging efficacy data," added Dr. Feagan.

"These promising data from the maintenance period of CN002 further support the potential of icanbelimod to be not only a best-in-class S1P1 modulator, but also an important new treatment option among current standard of care therapies, offering patients with UC a much-needed sustainable control of inflammation," said Zheng Wei, Ph.D., Co-Founder and CEO of Connect Biopharma. "We are actively exploring strategic partnerships to advance icanbelimod into a registrational program to realize its therapeutic potential. In addition, we plan to submit the full data from the study to a medical congress later this year."

About CN002 Trial

CBP-307CN002 is a Phase 2 study evaluating the efficacy and safety of icanbelimod 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 (icanbelimod 0.1 mg (n=39); icanbelimod 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" exists, meaning that treatment options remain limited and clinical remission is still not achieved in 70–80% patients.

About Icanbelimod (formerly known as CBP-307)

Discovered internally using Connect Biopharma's proprietary Immune Modulation Technology, icanbelimod 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. Icanbelimod was observed to be generally well tolerated and showed evidence of clinical activity in both the 12-week induction and 36-week maintenance periods of the 48-week 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.

About Connect Biopharma Holdings Limited

Connect Biopharma is a global, clinical-stage biopharmaceutical company applying its expertise in T cell biology and deep knowledge of the drug discovery industry to develop innovative therapies to treat chronic inflammatory diseases with the goal of improving the lives of millions of those affected around the world. 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 (AD) and asthma. The Company's second product candidate, icanbelimod, 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 or reporting data or whether such milestones or data will be achieved or generated, the potential of such product candidates, including to achieve any benefit, improvement, differentiation or profile or any product approval or be effective, and the Company's ability to identify and enter into a strategic partnership. 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 data 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 April 11, 2023, 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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