



Connect Biopharma Completes Enrollment of CBP-307 Global Phase 2 Clinical Trial in Moderate-to-Severe Ulcerative Colitis

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SAN DIEGO, CA and TAICANG, SUZHOU, China, Nov. 19, 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-307 in adult patients with moderate-to-severe Ulcerative Colitis (UC).

This global, randomized, double-blind, placebo-controlled phase 2 clinical trial is being conducted at multiple sites, including in the U.S., to evaluate the efficacy and safety of CBP-307 in 134 subjects, where CBP-307 or placebo is expected to be administered to eligible adult subjects with moderate-to-severe UC for 12 weeks (induction phase). Following this 12-week induction phase, responders to treatment (as defined by change in the adapted Mayo score from baseline) are expected to be treated for a further 36 weeks in a double-blind manner, with non-responders expected to enter an open-label arm and be treated for an additional 36 weeks (maintenance phase). All enrolled patients are expected to participate in a follow-up phase of 4 weeks following the end of the maintenance phase ([NCT04700449](#)).

"We are pleased to complete the enrollment of the CBP-307 global phase 2 trial in patients with moderate-to-severe UC, our lead clinical program for our oral S1P1 modulator," said Zheng Wei, PhD, Co-Founder and CEO of Connect Biopharma. "Despite the recent approval of oral therapies for the treatment of UC, there remains the need for additional safe and effective therapies, and we believe that CBP-307 has the potential to address this unmet need. We look forward to announcing topline results of the 12-week induction phase of this trial by the end of the first quarter of 2022."

About Ulcerative Colitis

Ulcerative colitis (UC) is a common form of inflammatory bowel disease (IBD) that causes chronic inflammation of the large intestine. It is estimated that in 2015 there were 3.1 million U.S. adults with a diagnosis of IBD.¹ As of 2016, UC was slightly more prevalent than CD in North America.²

Current treatment options include 5-aminosalicylic acid preparations, systemic corticosteroids and immunosuppressants, injectable biologics and surgery.³ While these treatments provide benefit, significant unmet need remains. We believe that CBP-307 has the potential to improve care outcomes for patients with UC by providing improved safety, efficacy and ease of administration compared with currently available therapies.

About CBP-307

CBP-307 is an orally available, next generation small molecule modulator of the sphingosine-1-phosphate 1 receptor (S1P1), a G-protein coupled receptor (GPCR) that plays a central role in regulating T cell movement out of lymph nodes and into the periphery and is a validated therapeutic target. CBP-307 has been shown to be a highly potent and selective modulator of S1P1 in in vitro preclinical studies and has shown selectivity of over 80,000-fold in S1P1 versus S1P3. In two completed Phase 1 randomized, double blind, placebo-controlled studies, CBP-307 exhibited an excellent safety profile and potent T cell modulation activity as well as a pharmacokinetic and pharmacodynamic profile consistent with once daily dosing.

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-4R α), 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-307 to address the unmet needs of patients with UC and/or the execution, size, duration, and/or results of the phase 2 clinical trial evaluating 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"). 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-307 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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