# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM (	6-K
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REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of November 2021

Commission File Number: 001-40212

# **Connect Biopharma Holdings Limited**

(Translation of registrant's name into English)

Science and Technology Park East R&D Building, 3rd Floor 6 Beijing West Road, Taicang Jiangsu Province, China 215400 (Address of principal executive office)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.		
F	Form 20-F ⊠	Form 40-F □
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):		
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):		

#### INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On November 19, 2021, Connect Biopharma Holdings Limited (the "Company") announced that it has completed full enrollment of its phase 2 clinical trial evaluating CBP-307 in adult patients with moderate-to-severe Ulcerative Colitis.

The information in the first paragraph under "Information Contained in this Report on Form 6-K" in this Report on Form 6-K is hereby incorporated by reference into the Company's Registration Statement on Form S-8 (File No. 333-254524).

On November 19, 2021, the Company issued the press release attached hereto as Exhibit 99.1, which is incorporated herein by reference.

The furnishing of the attached press release is not an admission as to the materiality of any information therein. The information contained in the press release is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make from time to time. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing or furnishing of other reports or documents with the SEC or through other public disclosures.

# **Exhibit Index**

Exhibit No. Description

Exhibit 99.1 Press release dated November 19, 2021: Connect Biopharma Completes Enrollment of CBP-307 Global Phase 2 Clinical Trial in Moderate-to-Severe Ulcerative Colitis

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: November 19, 2021

# CONNECT BIOPHARMA HOLDINGS LIMITED

By /s/ Eric Hall

Name: Eric Hall

Title: Interim Chief Financial Officer

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

SAN DIEGO, CA and TAICANG, SUZHOU, China, Nov. 19, 2021 – <u>Connect Biopharma Holdings Limited</u> (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.<sup>3</sup> 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 $\alpha$ ), 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 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

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# References

- 1. Dahlhamer JM, Zammittie EP, Ward BW, et al. Prevalence of Inflammatory Bowel Disease Among Adults Aged≥18 Years United States, 2015. MMWR. 2016;65(42):1166-1169.
- 2. Hanauer SB. Advances in IBD. Gastroentrerology & Hepatology. 2016;12(11):704-707
- 3. Kobayahsi T, Siegmund B, Le Berre C, et al. Ulcerative Colitis. Nature Reviews: Disease Primers. 2020;6:74.