# 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 September 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)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-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): $\Box$			
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):			

On September 2, 2021, Connect Biopharma Holdings Limited issued the press release attached hereto as Exhibit 99.1, which is incorporated herein by reference.

# **Exhibit Index**

Exhibit No.
Exhibit 99.1

<u>Description</u>

<u>Press release dated September 2, 2021: Connect Biopharma Announces First Patient Dosed in Standalone China Pivotal Trial</u> Evaluating CBP-201 in Adults with Moderate-to-Severe Atopic Dermatitis

### **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: September 2, 2021

# CONNECT BIOPHARMA HOLDINGS LIMITED

By \_\_/s/ Eric Hall

Name: Eric Hall

Title: Interim Chief Financial Officer

# Connect Biopharma Announces First Patient Dosed in China Pivotal Trial Evaluating CBP-201 in Adults with Moderate-to-Severe Atopic Dermatitis

SAN DIEGO, CA and TAICANG, SUZHOU, China – September 2<sup>nd</sup> 2021 – 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 the first patient has been dosed in a China specific pivotal trial evaluating CBP-201 in adults with moderate-to-severe atopic dermatitis.

This multicenter, randomized, double-blind, parallel group, placebo-controlled trial was designed to assess the efficacy and safety of up to two doses of CBP-201 administered subcutaneously (SC) to eligible patients with moderate to severe atopic dermatitis. The trial is expected to enroll approximately 255 patients across 55 clinical sites in China and is divided into an initial treatment period of 16 weeks, a further maintenance period of 36 weeks and a follow-up period of 8 weeks (NCT05017480).

"Atopic dermatitis is a chronic inflammatory skin disease that significantly impacts patients' quality of life, and its prevalence in China is increasing, leading to a growing burden for patients," said Dr. Jianzhong Zhang, MD, Principal Investigator and Director of the Dermatology Disease Department at Peking University People's Hospital. "Despite the recent approval of a new biologic treatment in China, many patients do not achieve a return to clear and normal skin. It is hoped that CBP-201, which is capable of blocking both IL-4 and IL-13 that drive the inflammation associated with atopic dermatitis may bring additional benefit to patients, particularly in measures of efficacy and possibly in lowering the burden of treatment through a need for fewer injections."

"The commencement of this China specific clinical trial of CBP-201 in moderate-to-severe atopic dermatitis is a significant step for Connect Biopharma as we look to advance the development pathway for CBP-201," said Dr. Pauline Li, MD, Head of Clinical Development, Asia for Connect Biopharma. "While we are advancing CBP-201 across multiple indications in global trials, this trial, if successful, could accelerate the availability of CBP-201 to patients in China."

#### **About Atopic Dermatitis**

Atopic dermatitis (AD), which has an estimated lifetime prevalence of up to 20% and is increasing globally, is the most commonly diagnosed chronic inflammatory skin disorder. It is characterized by skin barrier disruption and immune dysregulation. Estimates of prevalence of AD in China show this increasing over time and recent longitudinal studies have reported a dermatologist diagnosed prevalence of 7.8% in Chinese outpatients visiting tertiary hospitals. In the United States, it is estimated that 26.1 million people have AD, of which 6.6 million have moderate-to-severe disease. Further, over 58% of adults with moderate-to-severe AD have disease which physicians consider to be inadequately controlled by approved therapeutic modalities, including topical anti-inflammatory agents and systemic agents.

#### **About CBP-201**

CBP-201, discovered using Connect Biopharma's proprietary Immune Modulation Technology Platform, is an antibody designed to target interleukin-4 receptor alpha (IL-4R $\alpha$ ), which is a validated target for the treatment of several inflammatory diseases including atopic dermatitis (AD). CBP-201 has shown a favorable safety and efficacy profile in a Phase 1b clinical trial in adult patients with moderate-to-severe atopic dermatitis, suggesting a potential for a differentiated efficacy profile compared with data from clinical trials of the current biologic standard of care therapy. CBP-201 is currently being evaluated in several Phase 2b clinical trials: in adult patients with moderate-to-severe atopic dermatitis (NCT04444752), in adult patients with moderate-to-severe persistent asthma (NCT04773678), and in adult patients for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) (NCT04783389).

### **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, is an antibody designed to target interleukin-4 receptor alpha (IL-4R $\alpha$ ) and is currently being evaluated in clinical trials for the treatment of atopic dermatitis (AD), asthma and chronic rhinosinusitis with nasal polyps (CRSwNP). Our second lead product candidate is CBP-307, a modulator of a T cell receptor known as sphingosine 1-phosphate receptor 1 (S1P1) that is in development for the treatment of ulcerative colitis (UC) and Crohn's disease (CD). Furthermore, we are developing CBP-174, a peripherally restricted antagonist of histamine receptor 3, for the treatment of pruritus associated with skin inflammation.

With current 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-201 to achieve a differentiated profile to address the unmet needs of patients with AD and the size, the duration, and the results of the Company's China only pivotal trial and phase 2 clinical trials of CBP-201. 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 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"). 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.

#### **IR/PR Contacts:**

Lazar FINN Partners
David Carey (IR)
T: +1-(212) 867-1768

 $\underline{david.carey@finnpartners.com}$ 

Erich Sandoval (Media) T: +1-(917)-497-2867

 $\underline{erich.sandoval@finnpartners.com}$ 

Corporate Contacts: <a href="mailto:info@connectpharm.com">info@connectpharm.com</a>