



## Connect Biopharma Reports Full Year 2023 Financial Results and Provides Business Update

April 16, 2024

- Reported two positive readouts for rademikibart, the Company's lead asset, from the Global Phase 2b trial in moderate-to-severe persistent asthma and from the China pivotal trial in moderate-to-severe atopic dermatitis (AD)
- Type C meeting in AD and End-of-Phase 2 (EoP2) meeting in asthma have been scheduled with the U.S. Food and Drug Administration (FDA) in Q2 2024 to discuss trial results and proposed registrational programs
- Granted Simcere the exclusive rights to develop, manufacture, and commercialize rademikibart for all indications in Greater China. Simcere is actively engaged with China's Center for Drug Evaluation (CDE) regarding the potential NDA filing for marketing approval in China for treatment with rademikibart in patients with AD
- Cash, cash equivalents and short-term investments of \$118.7 million expected to support planned operations into at least 2026

SAN DIEGO, CA and TAICANG, China, April 16, 2024 (GLOBE NEWSWIRE) -- Connect Biopharma Holdings Limited (Nasdaq: CNTB) ("Connect Biopharma," "Connect" 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 reported financial results for the year ended December 31, 2023, and provided a business update.

"2023 marked an achievement-filled year for Connect highlighted by two positive readouts with our lead asset rademikibart from the global Phase 2b trial in asthma and the pivotal trial in China in AD. The clinical data we shared from these two trials demonstrated the potential for fast onset of relief, impressive maintenance effect and strong durable efficacy, even with every 4 weeks dosing, and no significant safety concerns. Taken together, the results further underscore rademikibart's best-in-biologics potential," said Zheng Wei, Ph.D., Co-Founder and Chief Executive Officer of Connect Biopharma. "Connect is well positioned for another important year in 2024, as we look forward to the scheduled meetings with the FDA to discuss rademikibart registrational programs in AD and asthma in the second quarter of 2024."

### **Full Year 2023 and Recent Highlights**

#### *Clinical Programs Highlights*

- Rademikibart Program
  - Reported positive topline data in the Global Phase 2b trial in adult patients with moderate-to-severe asthma in December 2023. The trial met its primary endpoint showing both doses of rademikibart treatment significantly improved lung function at Week 12. Moreover, the improvement in lung function was seen as early as Week 1 and was sustained through Week 24 with both doses. Significant improvements were also observed in asthma control symptoms early and were sustained through Week 24. Rademikibart was generally well tolerated with no unexpected safety signals.
  - Announced positive long-term data from the China pivotal trial in patients with moderate-to-severe AD in November 2023. Clinical response (IGA0/1 and EASI-75) achieved at Week 16 (Stage 1) with rademikibart treatment was maintained through Week 52 (Stage 2) with both every two weeks (Q2W) and every four weeks (Q4W) dosing regimens, with about 90% of the patients on Q4W dose maintaining both IGA0/1 and EASI-75 through Week 52. Additionally, the percentage of patients achieving IGA 0/1 and EASI-75 continued to increase over the 36 weeks of Stage 2 of the study. Rademikibart continued to be well tolerated over 52 weeks of treatment.
- Icanbelimod Program
  - Reported 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 (UC) in June 2023. Icanbelimod demonstrated sustained clinical remission through Week 48 in 80% of patients who achieved clinical remission at Week 12 of the induction period. There were no new safety signals in the maintenance period and icanbelimod continued to be well-tolerated, consistent with the observed safety data in the induction period.
- Publications
  - Silverberg JI, et al. [Efficacy and safety of rademikibart \(CBP-201\), a next-generation mAb targeting IL-4R \$\alpha\$ , in adults with moderate to severe atopic dermatitis: A phase 2 randomized trial \(CBP-201-WW001\)](#). *J Allergy Clin Immunol*. 2024 Apr;153(4):1040-1049.e12.
  - Wang J, et al. [Rademikibart \(CBP-201\), a next-generation monoclonal antibody targeting human IL-4R \$\alpha\$ : Two phase I randomized trials, in healthy individuals and patients with atopic dermatitis](#). *Clin Transl Sci*. 2023 Dec;16(12):2614-2627.
  - Silverberg JI, et al. [A Mini Review of the Impact of Baseline Disease Severity on Clinical Outcomes: Should We Compare Atopic Dermatitis Clinical Trials?](#) *Dermatol Ther (Heidelb)*. 2023 Dec;13(12):3019-3029.
  - Zhang L, et al. [Preclinical immunological characterization of rademikibart \(CBP-201\), a next-generation human](#)

[monoclonal antibody targeting IL-4R \$\alpha\$ , for the treatment of Th2 inflammatory diseases](#). *Sci Rep.* 2023 Jul 31;13(1):12411.

- Presentations
  - Poster presentation at the 2023 Advances in Inflammatory Bowel Diseases Meeting in December 2023 on the Phase 2 trial of icanelimod showing that patients with UC would likely derive greater clinical benefit with higher doses than icanelimod 0.2 mg QD, the maximum administered in this Phase 2 dose-ranging trial, which will thus be investigated in the Phase 3 trial program.
  - Four posters at the 2023 World Congress of Dermatology in July 2023 on data from the initial 16-week treatment period with rademikibart of the pivotal trial in China in patients with moderate-to-severe AD. The posters provided detailed and new information on the achievement of primary and secondary endpoints, and highlighted that consistent improvements were observed in both investigator-rated outcomes and patient reported outcomes.
  - Poster presentation at the 2023 Revolutionizing Atopic Dermatitis (RAD) Annual Meeting in April 2023 on the meaningful improvements observed in patients with either moderate or severe AD with 16 weeks of rademikibart treatment at either two- or four-week dosing from the global Phase 2 trial in AD.
  - Late breaking oral presentation and an e-poster with an oral presentation on rademikibart clinical development program in patients with moderate-to-severe AD at the American Academy of Dermatology (AAD) Annual Meeting in March 2023. Data presented showed that patients treated with rademikibart were observed to demonstrate rapid and sustained improvements at Week 16 in the primary population from the China pivotal trial and show rapid and sustained improvement across all body regions in a post-hoc analyses from the Global Phase 2b trial.
- Given the highly compelling therapeutic potential observed with rademikibart in multiple therapeutic areas, the Company announced the strategic prioritization of rademikibart development program to further support near-term and long-term value drivers. To maximize resources and extend its cash runway, the Company has decided to terminate, effective May 2024, the in-license agreement for CBP-174 with Pfizer (originally licensed from Arena Pharmaceuticals) and postpone the advancement of all pre-clinical and discovery programs. The Company's overall partnership strategy remains unchanged and the Company will continue to actively seek a development and commercialization partner for rademikibart and development partner for icanelimod at a global or a regional level.

#### *Corporate Development Highlights*

- Signed an exclusive licensing and collaboration agreement with Simcere in November 2023. The agreement granted Simcere the exclusive rights to develop, manufacture, and commercialize rademikibart for all indications in Greater China, while Connect retains all the rights to develop and commercialize rademikibart in all other markets. As part of the agreement, the Company received a ¥150 million (\$21 million) upfront payment and will receive up to ¥875 million (\$120 million) upon achieving certain development and commercial milestones, in addition to royalties up to low double-digit percentages of net sales.
- Appointed James Zuie-chin Huang, M.B.A., a successful entrepreneur, investor, and key opinion leader in the healthcare sector, in February 2024 to the Company's Board of Directors.

#### **Anticipated Upcoming Milestones**

- The Company has scheduled two meetings with the FDA in Q2 2024, including a Type C meeting to discuss the potential U.S. registrational path for rademikibart in AD, followed by an EoP2 meeting to discuss a U.S. registrational program for rademikibart in asthma.
- Simcere, Connect's partner in Greater China who holds responsibility for future development, including for additional indications and NDA submission, is progressing its regulatory discussion with China's CDE ahead of a planned NDA filing for rademikibart for patients with AD. Connect expects to receive an update from Simcere as early as Q2 2024 on these next steps.

#### **2023 Financial Results**

- Cash, cash equivalents and short-term investments were \$118.7 million as of December 31, 2023, compared with \$161.9 million on December 31, 2022. The \$43.2 million decrease was mainly due to cash used to advance the Company's clinical programs and fund its operations, offset by the upfront partnership payment received from Simcere. Based on its current operating plans, management believes the Company has sufficient cash and investments to support planned operations into at least 2026.
- R&D expenses for the year ended December 31, 2023, totaled \$51.9 million, compared with \$96.6 million for the year ended December 31, 2022, a decrease of \$44.7 million primarily due to fewer clinical trials, less drug product manufacturing activity, and lower personnel costs due to fewer research and development headcount compared to prior year.
- Administrative expenses totaled \$14.5 million for the year ended December 31, 2023, compared with \$20.8 million for the year ended December 31, 2022. The decrease in administrative expenses was primarily due to lower professional fees, including accounting, insurance, legal, and other consulting costs, and lower share-based compensation expense

compared to the prior year.

- Net loss totaled \$59.5 million for the year ended December 31, 2023, compared with a net loss of \$118.1 million for the year ended December 31, 2022.

**Connect Biopharma Holdings Ltd.**  
**Condensed Consolidated Statements of Loss**

<i>(in USD thousands)</i>	For the Year Ended December 31,	
	2022	2023
Research and development expenses	\$ (96,630)	\$ (51,913)
Administrative expenses	(20,806)	(14,515)
Net impairment losses	(4,698)	-
Other income	929	1,580
Other (losses)/gains - net	1,889	2,774
<b>Operating loss</b>	<b>(119,316)</b>	<b>(62,074)</b>
Finance income	1,544	2,714
Finance cost	(21)	(23)
Finance income – net	1,523	2,691
<b>Net loss before income tax</b>	<b>(117,793)</b>	<b>(59,383)</b>
Income tax expense	(298)	(120)
<b>Net loss</b>	<b>\$ (118,091)</b>	<b>\$ (59,503)</b>
<b>Net loss attributable to:</b>		
Owners of the Company	<b>\$ (118,091)</b>	<b>\$ (59,503)</b>
Net loss per share		
Basic and diluted	<b>\$ (2.15)</b>	<b>\$ (1.08)</b>

**Connect Biopharma Holdings Ltd.**  
**Selected Consolidated Balance Sheet Data**

<i>(in USD thousands)</i>	December 31,	
	2022	2023
Cash, cash equivalents, short-term and long-term investments	\$ 161,857	\$ 118,653
Total assets	174,013	125,892
Total liabilities	16,521	24,849
Accumulated losses	(479,844)	(539,347)
Total shareholders' equity	157,492	101,043

**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, rademikibart (formerly known as 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 (formerly known as CBP-307), is a modulator of S1P1 T cell receptors and is in development for the treatment of ulcerative colitis (UC). 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", "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 timing of achieving any development, regulatory or commercial milestones or reporting data or whether such milestones or data will be achieved or generated, including whether any new drug application will be submitted or accepted and the timing thereof, and the potential of such product candidates, including to achieve any benefit, improvement, differentiation, trend or profile or any product approval or be effective, the Company's ability to identify and enter into any strategic partnership, whether the Company's Greater China partnership will meet expectations, and the sufficiency of the Company's cash and investments to support planned operations. 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](http://www.sec.gov)) and on Connect Biopharma's website ([www.connectbiopharm.com](http://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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