Connect Biopharma Reports Full Year 2022 Financial Results and Provides Business Update

April 11, 2023

CDE's Pre-NDA Feedback Confirms CBP-201 for Atopic Dermatitis on Track for NDA Submission in China by End of First Quarter 2024

SAN DIEGO and TAICANG, SUZHOU, China, April 11, 2023 (GLOBE NEWSWIRE) -- Connect Biopharma Holdings Limited (Nasdaq: CNTB) (Connect Biopharma or the Company), a global clinical-stage biopharmaceutical company developing T cell-driven therapies to treat inflammatory diseases, today announced financial results for the year ended December 31, 2022 and recent corporate highlights.

"Based on feedback from China's Center for Drug Evaluation (CDE), we are on track with our timeline and look forward to advancing our lead drug candidate CBP-201 for moderate-to-severe atopic dermatitis (AD)," said Chief Executive Officer and Co-founder of Connect Biopharma Zheng Wei, Ph.D. "We plan to submit a New Drug Application (NDA) by the end of the first quarter of 2024, which could lead to potential regulatory approval in China as early as 2025. We also remain encouraged by the CBP-201 results from our China pivotal trial and post-hoc analyses from the global Phase 2b data presented last month at the American Association of Dermatology (AAD) Annual Meeting. We remain confident in the efficacy profile of CBP-201, which showed rapid and sustained improvements and has the potential to be an effective new treatment for AD. Beyond AD, we continue to focus on treating other inflammatory-mediated diseases, including ulcerative colitis and asthma, both of which also have the potential to address large patient populations with persistent unmet medical needs."

Recent Corporate Highlights

- Presented two abstracts from CBP-201 clinical development program in patients with moderate-to-severe AD at the AAD last month. Specifically, data from post-hoc analyses of the CBP-201 global Phase 2b trial showed rapid and sustained improvements across all body regions. Also, the results for the Primary Analysis Population from the ongoing CBP-201 China pivotal trial showed rapid and sustained improvement with no efficacy plateau at week 16.
- Completed full enrollment for the CBP-201 Phase 2 global trial in patients with moderate-to-severe asthma with Type 2 inflammation.
- Announced positive topline data on Stage 1 of the ongoing CBP-201 China pivotal trial in AD on the primary analysis population of 255 patients.
- Reported results from Phase 1 single ascending dose study for CBP-174 in pruritis associated with AD. CBP-174 was observed to be well-tolerated with no serious adverse events and no dose-limiting toxicities identified.

Anticipated Upcoming Milestones

CBP-201 in AD:

- **China pivotal trial:** The Company believes it is on track to complete the 36-week stage 2 maintenance phase of the trial in patients with severe-to-moderate AD in the second half of 2023. This stage of the trial includes a once-a-month (Q4W) dosing regimen. Based on feedback received from the CDE, the Company plans to submit an NDA by the end of the first quarter of 2024 for potential approval in 2025.
- **Global Phase 3 program:** The Company is seeking strategic partnerships to advance this product candidate to the next phase of clinical development with potential global and regional partners to provide the necessary infrastructure and deliver a differentiated therapeutic program with improved efficacy and dosing convenience.

CBP-201 in Asthma:

- Anticipate reporting top-line results from the Phase 2 in the second half of 2023.

CBP-307 Phase 2 trial in moderate-to-severe Ulcerative Colitis (UC):

- Results of the Phase 2 maintenance portion of the trial are expected to be reported in the second quarter of 2023 and the Company is seeking strategic partnerships to progress CBP-307 into future trials in UC and Crohn's disease.

2022 Financial Results

- Cash, cash equivalents, and short-term and long-term investments were RMB 1,127.3 million (USD 161.9 million) as of December 31, 2022, compared with RMB 1,706.9 million (USD 267.7 million) at December 31, 2021. The decrease was mainly due to ongoing research and development (R&D) associated with the Company's clinical drug programs and administrative costs. Management believes based on current operating plans the Company has sufficient cash, cash equivalents, and investments to support planned operations into at least 2025, including funding of all remaining CBP-201 China pivotal trial studies and other clinical and regulatory milestones discussed above.

- R&D expenses for the year ended December 31, 2022 totaled RMB 652.2 million (USD 93.7 million), compared with RMB 518.0 million (USD 81.2 million) for the year ended December 31, 2021, primarily due to increased third-party clinical trial costs related to advancing the clinical development of the Company's lead product candidates. This includes clinical and manufacturing expenses related to advancing CBP-201 for AD in China, completing the global Phase 2b program for CBP-201 in AD, ongoing global Phase 2 trial costs for CBP-201 in asthma, ongoing global Phase 2 trial costs for CBP-307 in UC, as well as higher personnel costs for additional R&D headcount.

- Administrative expenses totaled RMB 139.4 million (USD 20.0 million) for the year ended December 31, 2022, compared with RMB 122.4 million (USD 19.2 million) for the year ended December 31, 2021. The increase in administrative expenses was primarily due to increases in payroll and related expenses for additional headcount, including share-based compensation expense, and other infrastructure costs needed in support of the growth of our business operations.

- Net loss totaled RMB 797.1 million (USD 114.4 million) for the year ended December 31, 2022, compared with a net loss of RMB 1,306.8 million (USD 205.0 million) for the year ended December 31, 2021. The net loss in the prior year period was higher due to the recognition of RMB 674.3 million of fair value adjustments on preferred shares, which was converted to ordinary shares during the Company's 2021 IPO.

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, CBP-307, 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 results or whether such milestones or results 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, the Company's ability to identify and enter into strategic partnerships as well as the sufficiency of the Company's cash, cash equivalents, and investments to continue to support 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 results 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, which are available from the SEC's website (www.sec.gov) and on Connect Biopharma's website (www.connectbiopharm.com) under the heading "Investors." 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. 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.

Connect Biopharma Holdings Ltd.
Condensed Consolidated Statements of Loss (Unaudited)

	Year Ended December 31,		
	2021	2022	2022
	RMB'000	RMB'000	USD'000 (1)
Research and development expenses	(518,021)	(652,211)	(93,646)
Administrative expenses	(122,445)	(139,444)	(20,022)
Net impairment losses	—	(32,805)	(4,710)
Other income	18,996	6,438	924
Other (losses)/gains—net	(9,966)	12,433	1,785
Operating loss	**(631,436)**	**(805,589)**	**(115,669)**
Finance income	622	10,715	1,538
Finance cost	(44)	(144)	(21)
Finance (cost)/income—net	578	10,571	1,517
Fair value loss of financial instruments with preferred rights	(674,269)	—	—
Net loss before income tax	**(1,305,127)**	**(795,018)**	**(114,152)**
Income tax expense	(1,697)	(2,037)	(292)
Net loss	**(1,306,824)**	**(797,055)**	**(114,444)**

Net loss attributable to:			
Owners of the Company	(1,306,824)	(797,055)	(114,444)
	RMB	**RMB**	**USD**
Net loss per share			
Basic and diluted	(25.0)	(14.5)	(2.1)

Connect Biopharma Holdings Ltd.
Selected Consolidated Balance Sheet Data (Unaudited)

	As of December 31,		
	2021	**2022**	**2022**
	RMB'000	**RMB'000**	**USD'000 (1)**
Cash, cash equivalents, short-term and long-term investments	1,706,880	1,127,268	161,857
Total assets	1,855,659	1,211,930	174,013
Total liabilities	119,828	115,060	16,521
Accumulated losses	(2,378,165)	(3,175,220)	(455,908)
Total shareholders' equity	1,735,831	1,096,870	157,492

(1) Translations of the selected consolidated balance sheet data and the condensed consolidated statement of loss from RMB into USD as of and for the year ended December 31, 2022, are solely for the convenience of the readers and calculated at the rate of USD1.00=RMB 6.9646, representing the exchange rate as of December 31, 2022, set forth in the China Foreign Exchange Trade System. No representation is made that the RMB amounts could have been, or could be, converted, realized or settled into USD at that rate, or at any other rate, on December 31, 2022, or any other date.

INVESTOR CONTACT:
Ina McGuinness
805.427.1372
imcguinness@connectpharm.com

MEDIA CONTACT:
Deanne Eagle
917.837.5866
Deanne@mcguinnessIR.com