Connect Biopharma Reports First Half 2023 Financial Results and Provides Business Update

September 12, 2023

- Key data readouts with Company's lead drug candidate rademikibart expected in the fourth quarter of 2023
  - Topline results from Stage 2 of the China pivotal trial in atopic dermatitis
  - Topline results from Global Phase 2 trial in asthma
- Cash balance of $131.6 million expected to support planned operations into at least 2026

SAN DIEGO and TAICANG, China, Sept. 12, 2023 (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 reported financial results for the six months ended June 30, 2023 and provided a business update.

"We continued to focus on advancing our lead asset rademikibart in our China pivotal trial in atopic dermatitis and Global Phase 2 trial in asthma. Based on current progress of both trials, we believe we are on-track for data readouts in the fourth quarter this year." said Zheng Wei, Ph.D., Co-Founder and Chief Executive Officer of Connect Biopharma. "We also reported positive long-term data from the Phase 2 maintenance period in ulcerative colitis with our other late-stage asset – icanbelimod. Our team continues to progress our robust pipeline, and we look forward to the rademikibart data readouts expected by end of 2023."

First Half 2023 and Recent Highlights

- Reported in June 2023 positive long-term data from the maintenance period through Week 48 of icanbelimod Phase 2 trial in patients with moderate-to-severe ulcerative colitis (UC). Icanbelimod demonstrated sustained clinical remission, an endpoint that the FDA has previously considered relevant from a regulatory perspective, through Week 48 in 80% of patients who achieved clinical remission at Week 12 of the induction period. There were no new safety signals and icanbelimod continued to be well-tolerated, consistent with observed induction period safety data.
- The Company's research engine has contributed three additional assets in the discovery/pre-clinical phase for type 2 inflammatory diseases: CBP-233 – an anti IL-33 monoclonal antibody (mAb), CBP-246 – an anti-IL-1 receptor accessory protein (IL-1RAcP) mAb, and CBP-403 – a bispecific mAb targeting Th2 cytokines.
- Published in July 2023 the pre-clinical data characterizing rademikibart in Nature's Scientific Reports. The publication titled "Preclinical immunological characterization of rademikibart (CBP-201), a next-generation human monoclonal antibody targeting IL-4Rα, for the treatment of Th2 inflammatory diseases" is available online and on the Company's website.
- Presented four posters at the 2023 World Congress of Dermatology in July 2023 from the initial 16-week treatment period with rademikibart of the China pivotal trial in patients with moderate-to-severe atopic dermatitis (AD), which is the largest readout in AD in China to date. 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.
- Received positive pre-New Drug Application (NDA) feedback from China's Center of Drug Evaluation (CDE) on the China pivotal study with 330 patients evaluating rademikibart in patients with moderate-to-severe AD.
- Completed full targeted enrollment of 306 patients in February 2023 in more than 100 sites in 5 countries for the rademikibart Global Phase 2 trial in patients with moderate-to-severe asthma with Type 2 inflammation. The primary endpoint of the study is a change from baseline in forced expiratory volume (FEV1) at Week 12. Secondary endpoints include change from baseline in lung function at other timepoints, exacerbation of asthma, patient reported outcomes, pharmacodynamic markers and use of rescue medication.
- Presented two oral presentations on rademikibart clinical development program in patients with moderate-to-severe AD at the American Academy of Dermatology (AAD) Annual Meeting in March 2023. Specifically, data from post-hoc analyses of the rademikibart Global Phase 2b trial showed rapid and sustained improvements across all body regions. Also, the data for the primary population from the ongoing rademikibart China pivotal trial showed rapid and sustained improvement with no efficacy plateau at Week 16.

Anticipated Upcoming Milestones

- Rademikibart AD China pivotal trial: The ongoing 36-week Stage 2 maintenance period, through Week 52, readout is expected in Q4'23. The Company is on track with an NDA submission to the CDE by the end of Q1'24, and a potential approval for AD in China could happen as early as 2025.

- Rademikibart Asthma Global Phase 2 trial: The Company is on track to complete the trial, with last patient last visit expected in October 2023 and a topline readout expected in Q4'23.

Financial Results for the First Half 2023

- Cash, cash equivalents, and short-term investments were RMB 950.7 million (USD 131.6 million) as of June 30, 2023, compared to RMB 1,127.3 million as of December 31, 2022. The decrease was mainly due to ongoing research and development (R&D) costs associated with the Company's clinical drug programs and administrative costs to support the business operations. The Company believes that based on its current operating plans it has sufficient cash and investments to support planned operations into at least 2026, including funding of all clinical and regulatory milestones discussed above.
- R&D expenses decreased to RMB 185.3 million (USD 25.6 million) for the six months ended June 30, 2023, from RMB 340.8 million for the six months ended June 30, 2022. This decrease was driven primarily by completion of the icanbelimod Global Phase 2 UC trial in early 2023, termination of the rademikibart Global Phase 2 trial for patients with chronic rhinosinusitis with nasal polyps in 2022, and higher product manufacturing costs incurred last year to enable drug product availability of rademikibart for clinical trials.
- Administrative costs decreased to RMB 56.2 million (USD 7.8 million) for the six months ended June 30, 2023, compared with RMB 71.8 million for the six months ended June 30, 2022. The decrease was primarily due to lower professional fees including accounting, legal, and consulting costs, lower insurance costs and lower share-based compensation expenses.
- Net loss totaled RMB 212.0 million (USD 29.3 million) for the six months ended June 30, 2023, compared with a net loss of RMB 401.3 million for the six months ended June 30, 2022.

income statement

	For Six Months Ended June 30,		
	2022	**2023**	**2023**
	RMB'000	**RMB'000**	**USD'000 (1)**
Research and development expenses	(340,775)	(185,283)	(25,642)
Administrative expenses	(71,830)	(56,222)	(7,781)
Other income	1,584	10,061	1,392
Other gains - net	9,241	8,168	1,130
Operating loss	**(401,780)**	**(223,276)**	**(30,901)**
Finance income	1,294	11,837	1,638
Finance cost	(58)	(72)	(10)
Finance income - net	1,236	11,765	1,628
Net loss before income tax	**(400,544)**	**(211,511)**	**(29,273)**
Income tax expense	(737)	(449)	(62)
Net loss	**(401,281)**	**(211,960)**	**(29,335)**
Net loss attributable to:			
Owners of the Company	**(401,281)**	**(211,960)**	**(29,335)**
	RMB	**RMB**	**USD**
Net loss per share			
Basic and diluted	**(7.3)**	**(3.9)**	**(0.5)**

balance sheet

	December 31,	June 30,	June 30,
	2022	**2023**	**2023**
	RMB'000	**RMB'000**	**USD'000 (1)**
Cash, cash equivalents, short-term and long-term investments	1,127,268	950,668	131,566
Total assets	1,211,930	1,041,095	144,080
Total liabilities	115,060	111,381	15,415
Accumulated losses	(3,175,220)	(3,387,180)	(468,762)
Total shareholders' equity	1,096,870	929,714	128,665

(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 six months ended June 30, 2023, are soley for the convenience of the readers and calculated at the reate of USD 1.00 = RMB 7.2258, representing the exchange rate as of June 30, 2023, 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 any other rate, on June 30, 2023, or any other date.

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). 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 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 or regulatory milestones or reporting data or whether such milestones or data 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, and the Company's ability to identify and enter into a strategic partnership. 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 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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