Connect Biopharma Announces Positive Long-Term Data from the China Pivotal Trial of Rademikibart in Patients with Moderate-to-Severe Atopic Dermatitis

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- Clinical response (IGA 0/1 and EASI-75) achieved at Week 16 with rademikibart treatment was maintained through Week 52 with both every two weeks (Q2W) and every four weeks (Q4W) dosing regimens
  - Approximately 90% of patients on Q4W dose maintained both IGA 0/1 and EASI-75 through Week 52
- Over 36 weeks of treatment in Stage 2 of the study, the percentage of patients achieving IGA 0/1 and EASI-75 continued to increase
- Rademikibart continued to be well tolerated over 52 weeks of treatment
- A conference call and webcast presentation to discuss the data will be held today at 8:30 a.m. ET, details below

SAN DIEGO, CA and TAICANG, China, Nov. 21, 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, announced today positive topline results from the Stage 2 (maintenance period) of its China pivotal trial evaluating rademikibart's (formerly known as CBP-201) efficacy and safety in patients with moderate-to-severe atopic dermatitis (AD). These results follow the previously reported Stage 1 results of the trial, which met all primary and key secondary endpoints.

"We are very pleased with the Stage 2 results of our pivotal China trial, showing that the strong improvements observed in patients at Week 16 in Stage 1 were maintained with both every two weeks and every four weeks dosing regimens," said Zheng Wei, Ph.D., Co-Founder and CEO of Connect Biopharma. "This study demonstrated that rademikibart has a best-in-class potential, and if approved as a Q4W treatment, we believe could offer patients with AD a highly efficacious treatment with less frequent dosing than current approved treatments. I'd like to thank the patients, their families, the clinical and manufacturing teams, and all of our vendors that were an integral part of this trial. In addition, as announced today, we are excited to partner with Simcere Pharmaceutical to advance rademikibart as a potential new treatment option for patients with AD and potentially other disease indications in Greater China."

Positive Stage 2 results at Week 52 show the potential of rademikibart as a Q4W treatment for AD

In Stage 2, patients that achieved EASI-50 (responders) regardless of initial treatment in the 16-week Stage 1 were randomized to either Q2W rademikibart (n=113) or Q4W rademikibart (n=112) arms. Patients that did not achieve EASI-50 (non-responders) were assigned to an open label Q2W rademikibart arm (n=86).

An efficacy analysis in patients that achieved IGA 0/1 or EASI-75 at Week 16 showed that with both Q2W at Q4W dosing regimens, 76%-87% of them maintained their IGA 0/1 and 92% of patients maintained their EASI-75 at Week 52, respectively.

	Rademikibart Week 52 Results *In patients that achieved IGA 0/1 or EASI-75 at Week 16*	
	Rademikibart 300 mg Q4W	Rademikibart 300 mg Q2W
IGA 0/1 with ≥2-point reduction	87.2% (n=40)	76.0% (n=34)
EASI-75	91.9% (n=79)	91.7% (n=76)

Evaluation of all patients that achieved EASI-50 at Week 16 with rademikibart (active drug responders) showed continued improvement from Week 16 to Week 52. 21%-28% more patients achieved IGA 0/1, and 11%-16% more patients achieved EASI-75 at Week 52.

	Rademikibart Week 52 Results *In patients that achieved EASI-50 at Week 16*			
	Rademikibart 300 mg Q4W (n=91)		Rademikibart 300 mg Q2W (n=91)	
	Week 16	Week 52	Week 16	Week 52
IGA 0/1 with ≥2-point reduction	41.8%	62.6%	30.9%	59.1%
EASI-75	73.6%	84.6%	68.5%	84.8%

Additionally, of the patients who achieved a clinically meaningful ≥4-point reduction in peak pruritus numerical rating scale (PP-NRS), 95.2% were able to maintain that level with Q4W dosing and 81.6% with Q2W dosing at the end of the study. With respect to quality of life, a ≥5-point reduction on the

dermatology life quality index (DLQI) is considered clinically important and 93.4% (Q2W) and 90.0% (Q4W) were able to maintain this level at the end of the 52-week study.

Treatment with 300 mg Q2W and Q4W of rademikibart was generally well tolerated, and there were no new safety signals. There was only one patient discontinuation due to an adverse event (pregnancy) in the rademikibart Q2W open label arm.

"The maintenance data of rademikibart out to Week 52 from the China pivotal trial are very compelling. They build upon the strong results shown in the first 16 weeks of treatment, showing additional gains in efficacy with continued treatment with rademikibart, as well as very high rates of maintained efficacy with Q4W dosing of rademikibart," commented Jonathan Silverberg, M.D., Ph.D., M.P.H., a Professor of Dermatology at The George Washington University School of Medicine and Health Sciences in Washington, DC. "Moderate-severe AD is a chronic disease with high patient-burden. Multiple unmet needs remain with current treatment options. Having a therapy with more sustained efficacy and convenient dosing may improve clinical outcomes and is a welcome addition to our treatment armamentarium."

The Company separately announced today that it granted the development and commercial rights of rademikibart in Greater China to Simcere Pharmaceutical, a large pharmaceutical company in China with an extensive partnership track record and proven capabilities in regulatory affairs, manufacturing, clinical operations and commercialization. Simcere will be responsible for rademikibart's new drug application in China, which is still on track for submission by the end of Q1 2024. Additionally, Connect Biopharma remains on track for the topline readout next month from its global Phase 2 trial of rademikibart in patients with moderate-to-severe asthma.

Conference Call and Webcast Presentation

Connect Biopharma management team will host a conference call and webcast presentation today at 8:30 a.m. ET to review the trial results. Jonathan Silverberg, M.D. will be present to answer clinical questions during the live Q&A session. To participate in the conference call, please dial 1-877-407-0784 (U.S.) or 1-201-689-8560 (international) and use conference ID 13742753. To access the webcast presentation, please click here.

A replay of the webcast and accompanying presentation will be available following the event through the Presentations, Events and News page of the Investors section of the Connect Biopharma website.

About Rademikibart China Pivotal Trial (CN002)

The China pivotal trial comprised of two stages. The 16-week Stage 1 included patients randomized to Q2W rademikibart (n=219) and placebo arms (n=111). A primary analysis of 255 patients from Stage 1 (induction stage) showed that all primary and key secondary endpoints were met, showing statistically significant improvements in IGA 0/1 and EASI-75. Following communications with China's Center for Drug Evaluation, the trial was expanded to include an additional 75 patients towards the end of Stage 1. Consistent with the initial analysis, all primary and key secondary endpoints were met in the expanded trial population. In Stage 2 (maintenance stage), patients that achieved EASI-50 (responders) regardless of initial treatment in Stage 1 were randomized to either Q2W rademikibart (n=113) or Q4W rademikibart (n=112) arms. Patients who did not achieve EASI-50 (non-responders) were assigned to an open label Q2W rademikibart arm (n=86). Patients were treated with 300 mg Q2W or Q4W for an additional 36-week period (through Week 52).

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 an investigational antagonist of histamine receptor 3 designed to act peripherally, 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, 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 or profile or any product approval or be effective, and whether the Company's Greater China partnership will meet expectations. 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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