



Connect Biopharma's Exclusive Licensee in China, Simcere Pharmaceutical, Announced Submission of its New Drug Application for Rademikibart for the Treatment of Atopic Dermatitis in China

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SAN DIEGO, July 09, 2025 (GLOBE NEWSWIRE) -- Connect Biopharma Holdings Limited (Nasdaq: CNTB) ("Connect Biopharma", "Connect", or the "Company"), a clinical-stage biopharmaceutical company focused on transforming care for the treatment of inflammatory diseases, today announced that the Company's collaborator and exclusive licensee in China, Simcere Pharmaceutical Co., Ltd. ("Simcere"), has submitted its New Drug Application for rademikibart to the National Medical Products Administration of China ("NMPA") for the treatment of atopic dermatitis ("AD") in adults and adolescents.

"Simcere continues to make strong progress in advancing rademikibart in China, our potentially best in class next generation IL-4R α antibody," said Barry Quart, Pharm.D., CEO and Director of Connect Biopharma. "Atopic dermatitis remains a large and growing market in China, and rademikibart has the potential to significantly improve the condition for millions of patients. Together, we remain committed to advancing rademikibart for the treatment of a range of inflammatory diseases including AD, asthma, and chronic obstructive pulmonary disease."

In 2023, Connect and Simcere entered into an exclusive license and collaboration agreement for rademikibart in China. Under the agreement, Simcere was granted exclusive rights to develop, manufacture, and commercialize rademikibart for all indications in Greater China, including mainland China, Hong Kong, Macau, and Taiwan, while Connect retains rights in all other markets.

As part of the agreement, Connect is eligible to receive milestone payments up to an aggregate remaining amount of approximately \$110 million upon the achievement of certain development, regulatory and commercial milestones. Connect is also eligible to receive royalties at tiered percentage rates up to low double-digit percentages on net sales in Greater China. The AD market in China represents considerable opportunity, with an estimated 70 million patients with AD.

About Rademikibart

Rademikibart is a fully human monoclonal antibody targeting interleukin-4 receptor alpha (IL-4R α), a common subunit of interleukin-4 receptor (IL-4) and interleukin-13 receptor (IL-13). By binding with IL-4R α , rademikibart can block the functions of IL-4 and IL-13 effectively, thereby blocking the T helper 2 (Th2) inflammatory pathway, thus achieving the goal of treating Th2 related inflammatory diseases such as atopic dermatitis and asthma.

About Simcere

Simcere Pharmaceutical Co., Ltd. is an innovation and R&D-driven pharmaceutical company and focuses on the therapeutic areas including neuroscience, anti-oncology, autoimmune and anti-infection. The company develops innovative therapies in disease areas that may have significant clinical needs in the future, aiming to achieve the mission of "for patients, for life". Driven by its in-house R&D efforts and synergistic innovation, Simcere has established strategic cooperation partnerships with many innovative companies and research institutes.

About Connect Biopharma

Connect Biopharma is a global, clinical-stage biopharmaceutical company dedicated to developing innovative therapies and transforming care for the treatment of inflammatory diseases. The Company's lead product candidate, rademikibart (formerly known as CBP-201), is an antibody designed to target IL-4R α and has demonstrated activity in both atopic dermatitis and asthma. The Company is currently conducting global studies of rademikibart for the treatment of acute exacerbations of asthma and COPD, areas with significant unmet need.

For more information visit www.connectbiopharm.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended (the "Act"). Forward-looking statements are statements that are not of historical fact and include, without limitation, statements regarding future events, our future financial condition, results of operations, business strategy and plans, prospective products (as well as their potential to achieve a differentiated, competitive, or favorable benefit or profile or trend, including on safety, tolerability, improvement, maintenance, clinical response, dosing, efficacy and/or convenience), planned or expected product approval applications or approvals, anticipated milestones, expected data readouts and enrollments, research and development plans and costs, potential future partnerships, expectations about existing partnerships, timing and likelihood of success, objectives of management for future operations, future results of anticipated product development efforts, adequacy of existing cash and potential partnership funding to fund operations and capital expenditure requirements, anticipated patient populations or market opportunities for our prospective products, if approved, as well as statements regarding industry trends. These statements are based on management's current expectations of future events only as of the date of this press release and are inherently subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond our control, including, among other things: the ability of our clinical trials to demonstrate safety and efficacy of our product candidates and other positive results; whether we will need expanded or additional trials in order to obtain regulatory approval for our product candidates; our ability to obtain and maintain regulatory approval of our product candidates; existing regulations and regulatory developments in the U.S., the PRC, Europe and other jurisdictions; the ability of our current cash and investments position to support planned operations; our plans and ability to obtain, maintain, protect and enforce our intellectual property rights and our proprietary technologies, including extensions of existing patent terms where available; our continued reliance on third parties to conduct additional clinical trials of

our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials; and the degree of market acceptance of our product candidates, if approved, by physicians, patients, healthcare payors and others in the medical community.

Words such as “aim,” “anticipate,” “believe,” “could,” “expect,” “feel,” “goal,” “intend,” “look forward to,” “may,” “optimistic,” “plan,” “potential,” “promising,” “will,” and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. The inclusion of forward-looking statements should not be regarded as a representation by Connect Biopharma that any of its expectations, projections or plans will be achieved. Actual results may differ materially due to the risks and uncertainties inherent in our business and other risks described in our filings with the U.S. Securities and Exchange Commission (the “SEC”). Further information regarding these and other risks is included under the heading “Risk Factors” in our annual and periodic reports filed with the SEC. These forward-looking statements should not be taken as forecasts or promises nor should they be taken as implying any indication, assurance or guarantee that the assumptions on which such forward-looking statements have been made are correct or exhaustive or, in the case of the assumptions, fully stated in this presentation. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You are cautioned not to place undue reliance on the scientific data presented or any forward-looking statements, which speak only as of the date of such presentation(s) or such statements. Except as required by law, Connect Biopharma undertakes no obligation to publicly update any forward-looking statements, whether because of new information, future events or otherwise. Connect Biopharma claims the protection of the safe harbor for forward-looking statements contained in the Act for all forward-looking statements.

This press release discusses our product candidate, rademikibart, which is under clinical investigation and has not yet been approved for marketing by the U.S. Food and Drug Administration, the NMPA, or by any other regulatory agency. No representation is made as to the safety or effectiveness of rademikibart for the uses for which it is being studied. The trademarks included herein are the property of the owners thereof and are used for reference purposes only.

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