CANbridge Pharmaceuticals Inc.

北海康成製藥有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 1228)

INSIDE INFORMATION

This announcement is made pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited and Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

CANbridge Pharmaceuticals Inc. (the "**Company**", together with its subsidiaries, the "**Group**") hereby informs the shareholders and potential investors of the Company of the attached press release that the Group has reported positive top-line CAN106 Phase 1 data and received approval to treat patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) in Phase 1b/2 Trial in China.

The Group cannot guarantee that CAN106 will ultimately be successfully developed and marketed. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By Order of the Board of Directors
CANbridge Pharmaceuticals Inc.
Dr. James Qun Xue
Chairman

Beijing, 7 February 2022

As at the date of this announcement, the board of directors of the Company comprises Dr. James Qun Xue as executive director; Dr. Kan Chen, Dr. Derek Paul Di Rocco and Mr. Xiao Le as non-executive directors; and Mr. James Arthur Geraghty, Dr. Richard James Gregory and Mr. Peng Kuan Chan as independent non-executive directors.

CANbridge Reports Positive Top-Line CAN106 Phase 1 Data

Receives Approval to Treat Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) in Phase 1b/2 Trial in China

Results Suggest Complete Blockade of Complement Function

CAN106 Safe and Well-Tolerated

Beijing, China; Cambridge, Mass., February 7, 2022 – CANbridge Pharmaceuticals, Inc. ("CANbridge," stock code 1228.HK), a China-based global biopharmaceutical company committed to the research, development and commercialization of transformative rare disease and rare oncology therapies, announced top-line results from a Phase 1 single ascending dose (SAD) study of CAN106, a novel, long-acting, anti-C5 complement recombinant human monoclonal antibody that is under development for the treatment of complement-mediated diseases, in 31 healthy volunteers in Singapore. This placebo-controlled study sequentially enrolled six dose cohorts (0.25, 0.75, 2, 4, 8, and 12 mg/kg CAN106) that were followed for at least 112 days. CAN106 was shown to be safe and well-tolerated with mostly mild or moderate adverse events and no drug-related serious adverse events (SAEs).

CAN106 showed dose-dependent and linear pharmacokinetic exposure with low inter-subject variability and a terminal elimination half-life of approximately 32 days. Within 24 hours of dosing, CAN106 led to dose-dependent reduction in free C5, a key complement protein required for activation of the terminal complement pathway, as well as inhibition of CH50, an ex vivo assay of serum hemolytic activity that measures the activity of the classical and terminal complement pathways. All subjects in the highest two dose cohorts (8 and 12 mg/kg) showed >99% reduction in free C5. Subjects in these two cohorts also had a >90% inhibition of CH50, which was sustained for 2 to 4 weeks, with the majority reaching the lower limit of CH50 activity quantification. The threshold of CH50 >90% inhibition has been used to indicate complete blockade of the classical and terminal complement pathways (Peffault de Latour R et al., Blood. 2015; 775-783). The complement system is part of the innate immune system, which when dysregulated, is implicated in the pathophysiology of multiple rare diseases. C5 is a clinically validated target for several of complement-mediated diseases.

CANbridge has received an Investigational New Drug (IND) approval in China to commence a Phase 1b/2 study of CAN106 in patients with paroxysmal nocturnal hemoglobinuria (PNH), a rare, acquired, and life-threatening disease in which the complement system destroys red blood cells (hemolysis). Market access to anti-C5 therapies is limited in many parts of the world. In China, there are currently no approved long-acting treatments for PNH. CAN106 was co-developed with WuXi Biologics under a rare disease strategic partnership. CANbridge holds the exclusive global development and commercialization rights and plans to develop CAN106 globally for PNH, as well as for other complement-mediated diseases which involve the activation of the C5 protein.

"We are extremely encouraged by this strong data showing that CAN106 was safe, well-tolerated and reduced free C5 levels in healthy volunteers by more than 99%, while also inhibiting CH50 by more than 90%," said James Xue, Ph.D., Founder, Chairman and CEO, CANbridge Pharmaceuticals Inc. "These results suggest complete functional blockade of terminal complement activity, and importantly, provide the first human data validating CAN106 as a potential treatment for complement-mediated diseases. We look forward to advancing CAN106 in PNH as a first-in-class treatment in China, and as a best-in-class treatment in many markets, where PNH treatment options are few, and to expand CAN106 clinical development globally for other complement-mediated disease indications as either a first-in-class or best-in-class therapy."

"The results of this Phase 1 compare well with other anti-C5 therapies and support the further clinical development of CAN106 in patients with PNH," said Gerry Cox, M.D., Ph.D., Chief Development Strategist and Acting Chief Medical Officer at CANbridge. "CAN106 appears to have a favorable safety profile, high potency, and a long half-life supporting a potential extended dosing interval in PNH patients. CAN106 could provide a meaningful treatment option for PNH patients in China, where the standard of care is primarily steroid therapy, and in rare cases, bone marrow transplantation. There are no long-acting anti-C5 therapies approved in China, and market access is limited in many other countries as well."

About the Study

The study,"Safety, Tolerability, Pharmacokinetics (PK) and Pharmacodynamics (PD) of a Single Ascending Dose (SAD) of CAN106 Administered Intravenously (IV) in Healthy Subjects," was a randomized, double-blind, placebo-controlled, single dose escalation study of CAN106 in 31 healthy subjects (23 received CAN106 and 8 received placebo) conducted at a single site in Singapore. The objectives were to assess the safety and tolerability of single escalating doses of CAN106, to characterize the PK and PD profile of CAN106, and to evaluate the immunogenicity of CAN106. The dose range was 0.25 mg/kg – 12 mg/kg, and follow-up was between 112 and 196 days.

About CAN106

CAN106 is a novel, long-acting recombinant human monoclonal antibody that binds to and neutralizes C5, a key component of the complement system. By preventing the cleavage of C5 into C5a and C5b, CAN106 is intended to prevent the C5b-dependent formation and activation of the membrane attack complex (MAC) on susceptible cell surfaces, with resulting cell lysis (destruction), which in the case of paroxysmal nocturnal hemoglobinuria (PNH), is red blood cells. CAN106 acts downstream of C3 in the complement pathway, preserving the generation of C3a and C3b, which are important for innate immunity.

CAN106 has demonstrated a favorable PK/PD profile, safety, and tolerability, indicating that CAN106 has the potential to effectively inhibit C5 in patients with certain complement-mediated diseases.

About Paroxysmal Nocturnal Hemoglobinuria (PNH)

Paroxysmal nocturnal hemoglobinuria (PNH) belongs to a group of fatal and rare disorders that occur when the complement system, a part of the immune system that helps clear microbes and damaged cells by attacking their cell membranes, is dysregulated. In patients with PNH, the proteins that normally protect their red blood cells are not present, leaving these denuded cells susceptible to complement attack, which results in their destruction (hemolysis). This leads to severe anemia, thromboembolism, gastrointestinal pain and dysfunction, fatigue, cardiac failure, pulmonary hypertension, renal impairment, and eventually, death. Treatment options include steroids, allogeneic bone marrow transplantation, the anti-C5 monoclonal antibodies eculizumab and ravulizumab, and the C3 inhibitor, pegcetacoplan. PHN is an acquired genetic condition that can occur at any age across genders and race, but most commonly presents in adults in their 30s to 40s and continues for the life of the patient.

The incidence of PNH in Western countries is estimated to be 1-to-2 per million people per year. In Asia, the rate is approximately 10 per million people per year, according to the 2019 China Rare Diseases Diagnosis and Treatment Guide. There is only one approved C5-targeting monoclonal therapy approved in China, where cost is also a prohibiting factor.

About CANbridge Pharmaceuticals Inc.

CANbridge Pharmaceuticals Inc. ("CANbridge," stock code 1228.HK) is a China-based global biopharmaceutical company committed to the research, development and commercialization of transformative therapies for rare disease and rare oncology.

CANbridge has a comprehensive and differentiated pipeline of 13 drug assets with significant market potential, targeting some of the most prevalent rare diseases and rare oncology. These include Hunter syndrome (MPS II) and other lysosomal storage disorders (LSDs), complement mediated disorders, hemophilia A, metabolic disorders, rare cholestatic liver diseases and neuromuscular diseases, as well as glioblastoma multiforme (GBM).

CANbridge strategically combines global collaborations and internal research to build and diversify its drug portfolio and invest in next-generation gene therapy technologies for rare disease treatments. CANbridge global partners include, but are not limited to, Apogenix, GC Pharma, Mirum, Wuxi Biologics, Privus, the University of Massachusetts Medical School (UMass) and LogicBio.

For more on CANbridge Pharmaceuticals Inc., please go to: www.canbridgepharma.com.

The forward-looking statements made in this article relate only to the events or information as of the date on which the statements are made in this article. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the data on which the statements are made or to reflect the occurrence of unanticipated events. You should read this article completely and with the understanding that our actual future results or performance may be materially different from what we expect. In this article, statements of, or references to, our intentions or those of any of our Directors or our Company are made as of the date of this article. Any of these intentions may alter in light of future development.

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