I-Mab Receives FDA Orphan Drug Designation for its Novel Claudin 18.2 x 4-1BB Bispecific Antibody TJ-CD4B for the Treatment of Gastric Cancer

3月 3, 2022

SHANGHAI and GAITHERSBURG, Md., March 3, 2022 /PRNewswire/ -- I-Mab (the "Company") (Nasdaq: IMAB), a clinical-stage biopharmaceutical company committed to the discovery, development, and commercialization of novel biologics, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for TJ-CD4B, a novel Claudin 18.2 x 4-1BB bispecific antibody, for the treatment of gastric cancer including cancer of gastroesophageal junction.

"The Orphan Drug Designation underscores the FDA's recognition of TJ-CD4B's potential promise as a novel therapy for gastric cancer and other related cancers," said Dr. Andrew Zhu, President of I-Mab. "TJ-CD4B is designed to work through a novel mechanism of action and is being tested in cancer patients. With the Orphan Drug Designation, we expect to expedite its global clinical development and potentially offer a novel treatment option for such an aggressive group of cancers that have very poor prognosis."

TJ-CD4B is the first clinical-stage bispecific antibody that binds to Claudin 18.2 (CLDN18.2)-expressing cancer cells and co-stimulatory molecule 4-1BB on T cells to exert a tumor-killing effect. Unlike other therapies involving CLDN18.2, TJ-CD4B has a broader anti-tumor effect covering cancers expressing low levels of CLDN18.2. Preclinical studies have suggested that TJ-CD4B is superior to current CLDN18.2 antibodies and 4-1BB agonistic antibodies due to its stronger anti-tumor activity and a minimal 4-1BB related systemic toxicity.

TJ-CD4B is part of I-Mab's highly innovative bispecific antibody pipeline. It is currently undergoing phase 1 clinical trials (NCT04900818) both in the U.S. and China in patients with advanced solid tumors, including gastric cancer, gastroesophageal junction carcinoma, esophageal adenocarcinoma, and pancreatic ductal carcinoma. I-Mab has made significant progress in the global clinical development of TJ-CD4B. In the ongoing dose-escalation study, TJ-CD4B was safe and well-tolerated at dose up to 3 mg/kg weekly. The Company plans to advance the study in biomarker-selected population subsequently.

Gastric cancer is the fifth most common cancer and third most common cause of death due to cancers globally. As the condition is asymptomatic in the early stages, it is generally diagnosed in advanced stages and carries a poor prognosis. Existing therapies for advanced refractory gastric cancer offer only modest clinical outcomes. In the U.S., gastric cancer is found in about 26,000 persons every year and accounts for about 1.5% of all new cancers diagnosed.[1] In China, gastric cancer is the second most frequently diagnosed cancer and the second leading cause of cancer–related deaths[2].

The FDA grants Orphan Drug Designation to investigational drugs and biologics that are intended for the treatment of rare diseases that affect fewer than 200,000 people in the U.S. Orphan Drug Designation provides drug developers with various benefits designed to support the development of novel drugs and biologics, including market exclusivity for seven years upon FDA approval, tax credits for qualified clinical trials, and exemption from FDA application fees.

[1] American Cancer Society. Key Statistics about stomach cancer. Available at: https://www.cancer.org/cancer/stomach-cancer/about/key-statistics.html#:~:text=How%20common%20is%20stomach%20cancer,6%2C740%20men%20and%204%2C440%20women)

[2] Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2018;68(6):394–424.

About TJ-CD4B/ABL111

TJ-CD4B, also known as ABL111, is a Claudin 18.2 and 4-1BB bispecific antibody capable of binding to tumor cells expressing Claudin 18.2, i.e., gastric cancer and pancreatic cancer cells, and stimulating intra-tumoral T cells by the 4-1BB arm designed to be activated only upon tumor engagement while silent elsewhere. TJ-CD4B/ABL111 effectively maintains a strong tumor binding property and anti-tumor activity attributable to a synergistic effect of both Claudin 18.2 antibody and 4-1BB antibody while avoiding or minimizing liver toxicity and systemic immunotoxicity commonly seen with 4-1BB antibodies as a drug class. Being developed under collaboration between I-Mab and ABL Bio, a clinical-stage biotechnology company in South Korea, TJ-CD4B/ABL111 is currently being investigated in a phase 1 clinical study in the U.S. and China.

About I-Mab

I-Mab (Nasdaq: IMAB) is an innovation-driven global biopharma company focused on the discovery, development and commercialization of novel and highly differentiated biologics for immuno-oncology and autoimmune diseases. The Company's mission is to bring transformational medicines to patients around the world through innovation. I-Mab's globally competitive pipeline of more than 20 clinical and preclinical-stage drug candidates is driven by its internal discovery and global partnerships for in-licensing, based on the Company's Fast-to-Proof-of-Concept and Fast-to-Market development strategies. The Company is progressing from a clinical-stage biotech company into a fully integrated global biopharmaceutical company with cutting-edge R&D capabilities, a world-class GMP manufacturing facility, and commercial capability. I-Mab has established its global footprint in Shanghai (headquarters), Beijing, Hangzhou, Guangzhou, Lishui and Hong Kong in China, and Maryland and San Diego in the United States. For

more information, please visit http://ir.i-mabbiopharma.com and follow I-Mab on LinkedIn, Twitter, and WeChat.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding data from the TJ-CD4B preclinical and clinical studies, the potential implications of clinical data for patients, and I-Mab's advancement of, and anticipated clinical development, regulatory milestones, and commercialization of TJ-CD4B. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including but not limited to I-Mab's ability to demonstrate the safety and efficacy of its drug candidates; the clinical results for its drug candidates, which may not support further development or NDA/BLA approval; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of I-Mab's drug candidates; I-Mab's ability to achieve commercial success for its drug candidates, if approved; I-Mab's ability to obtain and maintain protection of intellectual property for its technology and drugs; I-Mab's reliance on third parties to conduct drug development, manufacturing and other services; I-Mab's limited operating history and I-Mab's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; and the impact of the COVID-19 pandemic on the Company's clinical development, commercial and other operations, as well as those risks more fully discussed in the "Risk Factors" section in I-Mab's most recent annual report on Form 20-F, as well as discussions of potential risks, uncertainties, and other important factors in I-Mab's subsequent filings with the US Securities and Exchange Commission. All forward-looking statements are based on information currently available to I-Mab, and I-Mab undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

I-Mab Contacts
John Long
Chief Financial Officer
IR@i-mabbiopharma.com

Gigi Feng
Chief Communications Officer
PR@i-mabbiopharma.com

Investor Inquiries
The Piacente Group, Inc.
Emilie Wu
E-mail: emilie@thepiacentegroup.com
Office line: +86 21 6039 8363