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I-Mab Announces First Patient Dosed in Phase 1 Clinical Trial of Claudin 18.2 and 4-1BB Bispecific Antibody TJ-CD4B in Solid Tumors in China

July 22, 2022

GAITHERSBURG, Md. and SHANGHAI, July 22, 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 first patient in China has been treated with TJ-CD4B (also known as ABL111), a novel Claudin 18.2 x 4-1BB bispecific antibody, in a Phase 1 international multi-center clinical trial (IMCT) for patients with solid tumors, including gastric cancer, gastroesophageal junction carcinoma, esophageal adenocarcinoma, and pancreatic ductal carcinoma ([NCT04900818](#)).



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TJ-CD4B is the first clinical-stage bispecific antibody of its drug class. It binds to Claudin 18.2-expressing cancer cells and co-stimulatory molecule 4-1BB on T cells to exert a tumor-killing effect. In March 2022, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation for TJ-CD4B for the treatment of gastric cancer including cancer of gastroesophageal junction.

"Patients with gastric, esophageal and pancreatic cancers carry a poor prognosis with limited treatment options. TJ-CD4B has demonstrated its potential to become an effective treatment option in preclinical studies. In particular, TJ-CD4B is superior to other therapies targeting Claudin 18.2 and has a broader anti-tumor effect covering cancers expressing low levels of Claudin 18.2," said Professor Lin Shen, Vice President of Clinical Oncology at the Beijing Cancer Hospital of Peking University, and leading principal investigator of the study. "The ongoing clinical testing of TJ-CD4B in cancer patients will help determine its treatment potential for a wide range of malignancies that currently lack effective therapies."

"TJ-CD4B, powered by 4-1BB-activation platform, is a promising asset of the Company's highly innovative bispecific antibody pipeline and represents the new generation of I-Mab's continued innovation. This asset has the potential to treat highly challenging cancers, such as gastric cancer, one of the most prevalent cancer types in China and an illness that often suffers from poor prognosis," said Dr. Andrew Zhu, President of I-Mab. "TJ-CD4B is being developed both in the U.S. and China. This is another important milestone in global clinical development of TJ-CD4B. We look forward to rapidly advancing the study to evaluate the key drug properties of TJ-CD4B for further development."

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. In March 2022, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation for TJ-CD4B/ABL111 for the treatment of gastric cancer, including cancer of gastroesophageal junction.

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 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 an innovative global specialty 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://www.i-mabbiopharma.com> and follow I-Mab on [LinkedIn](#), [Twitter](#), and [WeChat](#).

I-Mab 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.

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