I-Mab Receives IND Approval for Phase 1 Clinical Trial of Bispecific Antibody TJ-CD4B in Solid Tumors in China

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SHANGHAI and GAITHERSBURG, Md., Dec. 15, 2021 /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 Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) has approved the IND submission for the initiation of a phase 1 clinical study of the bispecific antibody TJ-CD4B (also known as ABL111) in patients with solid tumors, including gastric cancer, gastroesophageal junction carcinoma, esophageal adenocarcinoma, and pancreatic ductal carcinoma in China.

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 immune cells to elicit a localized and combined immune response against solid tumors. It has potential application in a wide range of malignancies, particularly in gastric and pancreatic cancer. Preclinical studies have demonstrated superior CLDN18.2-dependent immune activation with TJ-CD4B as compared to 4-1BB monoclonal antibodies. In the preclinical data presented at the 2021 SITC Annual meeting, TJ-CD4B was well-tolerated with no evidence of systemic toxicity.

"The approval of IND marks a significant milestone for the Company, as TJ-CD4B will be the first CLDN18.2 x 4-1BB bispecific antibody of its kind to enter the clinical stage in China," said Dr. Joan Shen, CEO of I-Mab. "TJ-CD4B has shown encouraging results in preclinical studies and the first-in-human dose escalation trial is ongoing in the U.S. smoothly. With the initiation of clinical study in China, we expect to advance TJ-CD4B rapidly and deliver a promising solution to aggressive cancer types that have a poor prognosis."

The phase 1 clinical study in China will be conducted as the dose-expansion portion of an ongoing trial (NCT04900818) initiated in June this year in patients with advanced solid tumors in the U.S., which will accelerate the overall clinical development of TJ-CD4B.

About TJ-CD4B

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, TJ-CD4B/ABL111 is currently being investigated in a phase 1 clinical study in the U.S.

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.

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 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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