I-Mab Announces China NMPA Clearance for Phase 1 Study of TJ210/MOR210 in Patients with Advanced Solid Tumors

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SHANGHAI and GAITHERSBURG, Md., Feb. 10, 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 the China National Medical Products Administration (NMPA) has cleared the Investigational New Drug (IND) application for TJ210/MOR210 to initiate a phase 1 clinical trial to evaluate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of TJ210/MOR210 monotherapy in patients with advanced solid tumors.

TJ210/MOR210 is a monoclonal antibody developed by MorphoSys that is directed against complement factor C5a receptor 1 (C5aR1). Produced in the tumoral microenvironment, its ligand C5a acts as a chemoattractant to recruit tumor-promoting cells such as myeloid-derived suppressor cells, M2 macrophages and neutrophils. TJ210/MOR210 is designed to induce anti-tumor properties by blocking the activation and migration of C5aR1-expressing myeloid cells.

Preclinical studies have shown that targeting the C5aR-C5a axis exerts anti-tumor activity with immune checkpoint inhibitors. Furthermore, *in vitro* activity was observed for blocking the C5a/C5aR pathway also at very high C5a concentrations, leading to a long duration of action. TJ210/MOR210 demonstrated a good safety profile with no observed adverse effects up to the highest dose tested in non-clinical safety studies.

The phase 1 clinical trial is an open-label dose escalation study with multiple doses to evaluate the safety, tolerability, and PK/PD and preliminary efficacy of TJ210/MOR210 in subjects with relapsed or refractory advanced solid tumors. I-Mab is also conducting a phase 1 dose escalation clinical trial in patients with r/r advanced solid tumors in the U.S. The first patient in the U.S. study was dosed in January 2021.

"We are pleased to obtain the IND clearance for TJ210/MOR210 into clinical trials in China. Now with clinical trials both in the U.S. and China, we expect to accelerate this investigational drug development. The clinical data generated will enable us to further explore TJ210/MOR210's potentials in treating patients with cancers, especially those who failed with or relapsed from the existing therapies," said Dr. Joan Shen, CEO of I-Mab.

About TJ210/MOR210

TJ210/MOR210 is a novel human antibody directed against C5aR1 derived from MorphoSys's HuCAL Platinum® technology. C5aR1, the receptor of the complement factor C5a, is investigated as a potential new drug target in the field of immuno-oncology and autoimmune diseases. Tumors have been shown to produce high amounts of C5a, which, by recruiting and activating myeloid-derived suppressor cells (MDSCs), M2 macrophages and neutrophils, is assumed to contribute to an immune-suppressive pro-tumorigenic microenvironment. TJ210/MOR210 is intended to block the interaction between C5a and its receptor, thereby potentially neutralizing the immune suppressive function of C5a and enabling immune cells to attack the tumor.

HuCAL Platinum® is a registered trademark of MorphoSys AG.

About I-Mab

I-Mab (Nasdaq: IMAB) is an innovation-driven global biotech company focusing on discovery, development and soon commercialization of novel and highly differentiated biologics in immuno-oncology therapeutic area. The Company's mission is to bring transformational medicines to patients around the world through drug innovation. I-Mab's globally competitive pipeline of more than 15 clinical and pre-clinical stage drug candidates is driven by its internal R&D capability and global licensing partnerships, based on the Company's unique Fast-to-Proof-of-Concept and Fast-to-Market pipeline development strategies. The Company is now rapidly progressing from a clinical stage biotech company to a fully integrated global biopharmaceutical company with cutting-edge global R&D capabilities, a world-class GMP manufacturing facility and commercialization capability. I-Mab has established its global footprint in Shanghai (headquarters), Beijing, Hangzhou 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 TJ210/MOR210 phase 1 studies, the potential implications of clinical data for patients, and I-Mab's advancement of, and anticipated clinical development, regulatory milestones and commercialization of TJ210/MOR210. 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 dru g 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 U.S. 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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