I-Mab Announces Acceptance of IND Application from China NMPA for Phase 2 Clinical Trial of Enoblituzumab in Combination with Pembrolizumab in Solid Tumors

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SHANGHAI and GAITHERSBURG, Md., Sept. 28, 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 National Medical Products Administration (NMPA) has accepted the Company's IND application to initiate a phase 2 trial for enoblituzumab (also known as TJ271) in combination with pembrolizumab (Keytruda®) in patients with selected solid tumors in China. I-Mab has in-licensed the rights to exclusively develop and commercialize enoblituzumab in Greater China from MacroGenics (Nasdaq: MGNX).

Enoblituzumab is a highly differentiated humanized monoclonal antibody directed against B7-H3, a member of the B7 family of T-cell checkpoint regulators. B7-H3 plays a key role in regulating immune response against cancers and is widely expressed in multiple cancers. Its presence on tumors is associated with poor clinical prognosis. Enoblituzumab is engineered with an optimized Fc domain that enables a dual anti-tumor mechanism by antibody-dependent cell-mediated killing of cancer cells and enhanced T-cell immune response. There are increasing preclinical data generated by I-Mab and preliminary clinical evidence from MacroGenics supporting increased efficacy for the combination of enoblituzumab and PD-1 antibody against cancers.

Enoblituzumab has become one of the Company's core clinical assets. The phase 2 clinical trial in China will evaluate the efficacy of the combination of enoblituzumab and pembrolizumab. It is designed as a "basket" clinical trial involving non-small cell lung cancer (NSCLC), urothelial carcinoma, and other selected cancer types based on treatment signals observed in previous studies conducted by MacroGenics.

MacroGenics conducted multiple clinical studies of enoblituzumab for the treatment of cancers including squamous cell carcinoma of head and neck (SCCHN) and NSCLC, demonstrating enoblituzumab is well tolerated with observed efficacy signals. For example, data from a phase 1 cohort expansion study, presented at SITC 2018, have reported that enoblizutumab in combination with PD-1 antibody achieved an objective response rate (ORR) of 33.3% in SCCHN patients and of 35.7% in NSCLC patients with PD-L1 expression <1%. Currently, MacroGenics is conducting a phase 2 study of enoblituzumab in combination with retifanlimab (PD-1 antibody) or tebotelimab (PD-1 & LAG-3 bispecific DART® molecule) for first-line treatment of patients with recurrent or metastatic SCCHN.

"With the initiation of the phase 2 clinical trial we hope to accelerate the clinical development of enoblituzumab in Greater China," said Dr. Joan Shen, CEO of I-Mab. "We will be leveraging the data from clinical trials conducted by MacroGenics to advance the clinical development of enoblituzumab for approval in Greater China."

About Enoblituzumab

Enoblituzumab is an investigational Fc-optimized monoclonal antibody that targets B7-H3, a member of the B7 family of immune regulator proteins. B7-H3 is widely expressed by many different tumor types and may play a key role in regulating the immune response to various types of cancer. Enoblituzumab has been or is currently being evaluated in clinical trials as a monotherapy or in combination with anti-PD-1-based therapies in patients with B7-H3-expressing cancers. I-Mab Biopharma acquired the development and commercial rights from MacroGenics for Greater China.

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, 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 enoblituzumab 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 enoblituzumab. 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 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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