I-Mab Announces Approval from China CDE to Initiate Phase 3 Registrational Study of Lemzoparlimab in Combination with Azacitidine in Higher-Risk Myelodysplastic Syndrome

September 13, 2022

GAITHERSBURG, Md. and SHANGHAI, Sept, 13, 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 it has successfully completed an End-of-Phase 2 (EoP2) meeting with the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA), and has obtained approval from the CDE to initiate a Phase 3 registrational trial evaluating lemzoparlimab, a novel CD47 antibody, in combination with azacitidine (AZA) for the first-line treatment of patients with newly diagnosed higher-risk myelodysplastic syndrome (HR-MDS). The outcome of the EoP2 meeting supports the advancement of lemzoparlimab into Phase 3 study for a potential biologic license application (BLA) submission. The Company is on track to initiate the study as planned.

The EoP2 meeting was supported by encouraging results from the Phase 2 clinical trial evaluating lemzoparlimab in combination with AZA in patients with newly diagnosed HR-MDS (NCT04202003). The top-line efficacy data demonstrated that lemzoparlimab combined with AZA showed encouraging clinical response in HR-MDS patients. Results also showed that lemzoparlimab combined with AZA can be safely administered without the need of a priming dose. The full results were reported in a proffered paper presentation at the European Society for Medical Oncology (ESMO) Congress 2022 on September 10, 2022.

"We are pleased by the constructive feedback from the CDE, which has given us the greenlight to initiate the Phase 3 trial with lemzoparlimab for HR-MDS, a difficult-to-treat disease with high unmet medical need in this patient population with few treatment options," said Dr. Andrew Zhu, President of I-Mab. "We look forward to initiating our Phase 3 study to support a planned BLA submission in China for lemzoparlimab with the goal of providing a novel therapeutic option for patients suffering from this disease."

About CD47 and Lemzoparlimab

CD47 is a cell surface protein over-expressed in a wide variety of cancers and can act to protect tumors by delivering a "don't eat me" signal to otherwise tumor-engulfing macrophages. CD47 antibody blocks this signal and enables macrophages to attack tumor cells. However, development of CD47 antibody as a cancer therapy has been hampered by its hematologic side effects, such as severe anemia, caused by natural binding of CD47 antibody to red blood cells. Scientists at I-Mab discovered a novel CD47 antibody, lemzoparlimab, that is designed to target tumor cells while exerting a minimal untoward effect on red blood cells.

Multiple clinical studies of lemzoparlimab are ongoing to explore indications in treating patients with myelodysplastic syndrome (MDS), acute myelocytic leukemia (AML), non-Hodgkin's lymphoma (NHL), and advanced solid tumors in combination with chemotherapy and immune checkpoint inhibitors.

About I-Mab

I-Mab (Nasdaq: IMAB) is a dynamic, global biotech company exclusively focused on discovery, development and soon, commercialization of novel or highly differentiated biologics in the therapeutic areas of immuno-oncology and autoimmune diseases. The Company's mission is to bring transformational medicines to patients around the world through innovation. I-Mab's innovative pipeline of more than 10 clinical and pre-clinical stage drug candidates is driven by the Company's Fast-to-Proof-of-Concept and Fast-to-Market development strategies through internal R&D and global partnerships and commercial partnerships. 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 the therapeutic and commercial potential of the lemzoparlimab, data from the lemzoparlimab clinical studies, the potential implications of clinical data for patients, and I-Mab's advancement of, and anticipated clinical development, regulatory milestones and approvals, and commercialization of lemzoparlimab. Among other risks, there can be no guarantee that the lemzoparlimab, alone or in combination with azacitidine will enter or complete the Phase 3 clinical trial or receive regulatory approval. 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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