I-Mab Announces China NMPA Clearance for Phase 1 Clinical Trial of Lemzoparlimab in Relapsed or Refractory Advanced Lymphoma

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- First international multi-center clinical trial (IMCT) of lemzoparlimab in China

- Second IND approval from China NMPA for lemzoparlimab

SHANGHAI and GAITHERSBURG, Md., Sept. 21, 2020 /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 lemzoparlimab (also known as TJC4) to initiate a phase 1 clinical trial in patients with relapsed or refractory advanced lymphoma (CXSL2000206) as part of an ongoing IMCT being conducted also in the U.S. Additionally, a phase 1/2a clinical trial in patients with relapsed or refractory acute myeloid leukemia (r/r AML) in China (CXSL1900039; NCT04202003;) is currently underway with clinical results expected in early 2021.

Lemzoparlimab is a highly differentiated anti-CD47 monoclonal antibody originally discovered and developed by I-Mab. It is designed to minimize inherent binding to normal red blood cells while preserving its strong anti-tumor activity, a critical attribute in potentially differentiating lemzoparlimab from other antibodies of the same class currently in development.

The preliminary results of the recent phase 1 clinical trial in the U.S. have shown differentiation of lemzoparlimab in terms of safety and pharmacokinetics profiles in cancer patients. Lemzoparlimab was well tolerated as a single agent at a dose up to 30 mg/kg/week without introducing any priming dose strategy. In all DLT-evaluable patients, no dose-limiting toxicities or severe hematologic adverse events were observed. Full data will be presented at an appropriate scientific conference later this year. At the same time, combination therapy of lemzoparlimab with pembrolizumab in patients with solid tumors and classical Hodgkin's lymphoma are also ongoing in the U.S.

"We strongly believe that lemzoparlimab has the potential to make a significant difference in the treatment of multiple cancers, particularly hematologic malignancies in China," said Dr. Joan Shen, CEO of I-Mab. "We look forward to accelerating this program through close collaboration between the U.S. and China teams and delivering a potentially life-changing medicine to patients in need."

Earlier this month, I-Mab entered into a global strategic partnership with AbbVie to develop and commercialize lemzoparlimab. Both companies will collaborate to design and conduct further global clinical trials to evaluate lemzoparlimab in multiple cancers. I-Mab retains all rights to develop and commercialize lemzoparlimab in mainland China, Macau and Hong Kong. The collaboration also allows for potential collaboration on future CD47-related therapeutic agents.

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, making it a potentially promising cancer drug. However, development of CD47 antibody as a cancer therapy is hampered by its hematologic side effects, such as severe anemia, caused by natural binding of CD47 antibody to red blood cells. In a scientific breakthrough, scientists at I-Mab have discovered a unique CD47 antibody, lemzoparlimab, that works efficiently to target tumor cells while exerting a minimal untoward effect on red blood cells to avoid severe anemia.

Lemzoparlimab's hematologic safety advantage and superb anti-tumor activities have been demonstrated previously in a series of robust pre-clinical studies. The results of phase 1 clinical trial have provided further clinical validation of this differentiation in patients with cancer. I-Mab continues to advance a combination study of lemzoparlimab with Keytruda® for solid tumor and with Rituxan® for lymphoma in the U.S., in addition to an on-going clinical trial in patients with AML in China.

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 immuno-oncology. 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-PoC (Proof-of-Concept) and Fast-to-Market development strategies through internal R&D and global partnerships. The Company is on track to transitioning from a clinical stage biotech company toward a fully integrated global biopharmaceutical company with cutting-edge R&D capabilities, world-class GMP manufacturing facility and commercial capability. I-Mab has offices in Beijing, Shanghai, Hong Kong and Maryland, United States. For more information, please visit http://ir.i-mabbiopharma.com

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 lemzoparlimab (TJC4) Phase 1 trial, the potential implications of clinical data for patients, and I-Mab's advancement of, and anticipated clinical development, regulatory milestones and commercialization of lemzoparlimab (TJC4). 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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