I-Mab Announces First Patient Dosed in China Phase 2 Clinical Trial of Efineptakin Alfa in Combination with Pembrolizumab in Advanced Solid Tumors

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SHANGHAI and GAITHERSBURG, Md., Jan. 12, 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 the first patient had been dosed in its China phase 2 study (NCT05145907) of efineptakin alfa (also known as TJ107) in combination with pembrolizumab (Keytruda®) in patients with advanced solid tumors. The study will follow a "basket" trial design to include selected tumor types, including triple-negative breast cancer (TNBC) and squamous cell cancer of the head and neck (SCCHN).

Efineptakin alfa, the world's first and only long-acting recombinant human interleukin-7 (rhIL-7) developed as a T lymphocyte-booster for cancer-related immunotherapy, has distinct advantages over other cytokines such as human IL-2. Efineptakin alfa combined with immune checkpoint inhibitors, such as PD-(L)1 therapies, has a synergistic effect as it increases the number of circulating anti-tumor T cells for tumor suppression. It has been tested as monotherapy and in combination with checkpoint inhibitors to treat advanced solid tumors in the U.S., South Korea and China, with encouraging clinical results.

"As the majority of cancer patients either do not respond or respond poorly to current PD-(L)1 therapies, there are intense attempts to identify an effective agent that can work synergistically with PD-(L)1 antibodies to increase the probability of treatment success," said Professor Ye Guo, Deputy Director of Department of Oncology at Shanghai East Hospital and the principal investigator of the study. "Studies have shown that efineptakin alfa has the potential to address this unmet need. We look forward to further validating the safety and efficacy profile of efineptakin alfa in patients with solid tumors."

"The initiation of efineptakin alfa's phase 2 study is another example that I-Mab's pipeline is not only innovative but also mature with a majority of clinical programs being in the advanced clinical development stage," said Dr. Andrew Zhu, President of I-Mab. "Efineptakin alfa is the world's first rhIL-7 designed to cater to the therapeutic needs of cancer patients, so we are mindful of the importance of this therapy and are committed to expediting the clinical development of a potentially transformative solution for patients in need."

I-Mab is also evaluating efineptakin alfa in another phase 2 clinical trial (NCT04600817) in lymphopenic patients with newly diagnosed glioblastoma multiforme (GBM) who have received standard concurrent chemoradiotherapy. By leveraging the two ongoing clinical studies, the Company aims to rapidly advance the clinical development of efineptakin alfa for approval in Greater China.

About Efineptakin alfa

Efineptakin alfa, also known as TJ107/GX-I7/NT-I7, is the world's first and only long-acting recombinant human interleukin-7 (rhIL-7), known to boost T lymphocytes by increasing their number and functions. It emerged from Genexine's proprietary hyFc® platform for the discovering of long-acting biologics. I-Mab has acquired exclusive rights from Genexine to develop and commercialize efineptakin alfa in Greater China. Efineptakin alfa may have utility in cancer treatment-related lymphopenia (low blood lymphocyte levels), a common condition that occurs in cancer patients who have received chemotherapy or radiation therapy, for which there is no approved treatment. Efineptakin alfa has also been shown to synergize with a PD-1 antibody in various tumor animal models potentially through increased T-lymphocyte activation and proliferation.

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 efineptakin alfa clinical studies, the potential implications of clinical data for patients, and I-Mab's advancement of, and anticipated clinical development, regulatory milestones, and commercialization of efineptakin alfa. 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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