I-Mab Announces IND Acceptance for Phase 2 Clinical Trial of Efineptakin Alfa in Combination with PD-1 Therapy in China

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- *Efineptakin alfa in combination with pembrolizumab induced 27.8% ORR in metastatic TNBC patients in a phase 1b/2 trial in South Korea*
- *Efineptakin alfa in patients with GBM showed a 83.3% survival ratio over one year in a phase 1 trial in the U.S.*

SHANGHAI and GAITHERSBURG, Md., July 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 an IND application for the initiation of a phase 2 clinical trial of efineptakin alfa (also known as TJ107/GX-I7/NT-I7) in combination with anti-PD-1 antibody in patients with advanced solid tumors, including triple-negative breast cancer (TNBC) and head and neck cancers (HNC), has been accepted by the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA).

Efineptakin alfa is the world's first and only long-acting recombinant human interleukin-7 ("rhIL-7") being developed as a T lymphocyte-booster for cancer-related immunotherapy. Efineptakin alfa is expected to show a therapeutic effect as a combination therapy with immune checkpoint inhibitors due to its inherent properties to increase T-cells that are critical for tumor suppression. Its T-cell properties comes with unique selectivity that only stimulates tumor-fighting lymphocytes and spares tumor-protecting Treg cells, differentiating it from other cytokines such as human IL-2.

The IND submission leverages accumulative clinical data from multiple previous studies of efineptakin alfa as monotherapy and in combination with checkpoint inhibitors in the treatment of advanced solid tumors, conducted by I-Mab in China and Genexine and NeoImmuneTech in South Korea and the U.S., respectively. Data from the phase 1b/2 Keynote-899 study, presented at SITC 2020, have shown that simultaneuous treatment of efineptakin alfa at 1200μg/kg with pembrolizumab (Keytruda®) induced 27.8% ORR in patients with metastatic TNBC. According to the data from NIT-110 dose escalation presented at ASCO 2021, the combination treatment was safe and well-tolerated in the study. In addition, interim results from the phase 1 trial (NCT03687957) in newly diagnosed patients with high-grade gliomas that have undergone chemoradiotherapy showed that absolute lymphocyte count (ALC) increased by 1.3 – 4.1 fold at week 4 in a dose-dependent manner and lasted up to 12 weeks after injection, with a one-year survival rate of 83.3% being observed so far.[1] Furthermore, a phase 1b trial (NCT04001075) in China is about to complete to facilitate the further development of efineptakin alfa.

"Current clinical data suggest that efineptakin alfa has the great potential to revolutionize the treatment in particularly difficult-to-treat cancers," said Dr. Joan Shen, CEO of I-Mab. "We have already initiated a phase 2 trial in lymphopenic patients with newly-diagnosed glioblastoma multiforme earlier this year. With these additional studies, we hope to fast-track the clinical development of efineptakin alfa in China and bring this potentially very valuable treatment to a large population of cancer patients."

[1] Data can be viewed in NeoImmuneTech's poster presentation at 2021 ASCO Annual Meeting at the following link: http://neoimmunetech.com/_down.html?upload=%2Fupload_rb&fname=AX_7356756659.pdf&orifname=nit_ir%20presentation_asco2021_e.pdf

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 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-PoC (Proof-of-Concept) and Fast-to-Market development strategies through internal R&D and global partnerships. The Company is on track to transition from a clinical stage biotech company toward a fully integrated global biopharmaceutical company with cutting-edge R&D capabilities, world-class GMP manufacturing facilities and commercial capability. I-Mab has offices in Beijing, Shanghai, Hangzhou, Hong Kong and Maryland, 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 phase 1/2 trial, 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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