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

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SHANGHAI and GAITHERSBURG, Md., Oct. 18, 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 the China National Medical Products Administration (NMPA) has approved the IND submission for the initiation of phase 2 clinical trial of efineptakin alfa (also known as TJ107/GX-I7/NT-I7) in combination with PD-1 antibody in patients with advanced solid tumors, including triple-negative breast cancer (TNBC) as well as head and neck cancers.



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Efineptakin alfa is the world's first and only long-acting recombinant human interleukin-7 (rhIL-7) developed as a T lymphocyte-booster for cancer-related immunotherapy. Efineptakin alfa is expected to show 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. Treatment with efineptakin alfa has distinct advantages over other cytokines such as human IL-2 that have a narrow therapeutic window and cause serious adverse effects.

Efineptakin alfa has been tested as monotherapy and in combination with checkpoint inhibitors to treat advanced solid tumors in the U.S., South Korea and China. According to the data from the NIT-110 dose-escalation study presented at ASCO 2021, the combination of efineptakin alfa and pembrolizumab is safe and well-tolerated in patients with advanced solid tumors. It significantly increased T cell numbers in both the tumor microenvironment and the peripheral blood. At the SITC 2020, data from the phase 1b/2 Keynote-899 study (NCT03752723) have shown that simultaneous treatment of efineptakin alfa at 1200µg/kg with pembrolizumab (Keytruda®) induced 27.8% ORR in patients with metastatic TNBC. In addition, interim results from the phase 1 trial (NCT03687957) in high-grade gliomas unresponsive to chemoradiotherapy showed a 1.3 – 4.1 fold increase in the absolute lymphocyte count (ALC) with a one-year survival rate of 83.3%. [1] Further, a China phase 1b trial (NCT04001075) in patients with advanced solid tumors will soon complete to facilitate further development of efineptakin alfa.

"Efineptakin alfa is the first rhIL-7 for cancer treatment and underscores I-Mab's commitment to innovation. Oriented by patients' needs, we look forward to initiating this important trial to accelerate the clinical development and deliver a potentially transformative solution to patients," said Dr. Joan Shen, CEO of I-Mab.

Efineptakin alfa is also being studied in another phase 2 clinical trial (NCT04600817) to evaluate its efficacy and safety in lymphopenic patients with newly diagnosed glioblastoma multiforme (GBM) who have been treated with standard concurrent chemoradiotherapy. The study is currently advancing rapidly with the first patient dosed in February 2021.

[1] Data can be viewed in NeoImmuneTech's poster presentation at 2021 ASCO Annual Meeting at the following link: http://neoimmunetech.com/_download.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, Guangzhou, Lishui, 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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