



## **I-Mab and Genexine Announce China NMPA Clearance for Phase 2 Clinical Trial of TJ107/HyLeukin-7™ in Glioblastoma Multiforme**

May 21, 2020

- I-Mab to initiate Phase 2 clinical trial in glioblastoma multiforme (GBM) in China**
- I-Mab and Genexine expand collaboration for development of TJ107/HyLeukin-7™**

SHANGHAI, GAITHERSBURG, Md. and SEOUL, South Korea, May 21, 2020 /PRNewswire/ -- I-Mab (NASDAQ: IMAB), a clinical-stage biopharmaceutical company committed to the discovery, development and commercialization of novel or highly differentiated biologics to treat diseases with significant unmet medical needs, particularly cancers and autoimmune disorders, and Genexine Inc. (KOSDAQ: 095700), a clinical-stage biotechnology company focused on developing innovative immunotherapeutics and novel long-acting biologics, today announced that the China National Medical Products Administration (NMPA) has cleared the initiation of a Phase 2 clinical trial of TJ107/HyLeukin-7™ (Efineptakin alfa), the novel long-acting recombinant human interleukin-7 (rhIL-7), in lymphopenic patients with newly-diagnosed glioblastoma multiforme (GBM). In addition, the two companies expanded their collaboration beyond the initial agreement to include development of TJ107/HyLeukin-7™ for this indication.

The affirmation was provided by NMPA in response to a pre-IND request to support the clinical development plans for TJ107/HyLeukin-7™ as a potential treatment for GBM. Per the clearance, I-Mab and Genexine are able to initiate a phase 2 clinical study in China without additional IND application submission required.

"There's a critical need to bring innovative therapies for patients suffering from GBM, an aggressive brain cancer with a particularly grim prognosis. I-Mab and Genexine appreciate the NMPA's accelerated assessment and giving the greenlight to initiate a Phase 2 clinical trial of TJ107/HyLeukin-7 for GBM," said Dr. Joan Shen, CEO of I-Mab. "I-Mab's expanded collaboration with Genexine speaks volume of our productive partnership and excellent progress made to date, which bring us a step closer to deliver on our promise to help patients in need."

Under the terms of the expanded collaboration, I-Mab will be mainly responsible for conducting the Phase 2 GBM clinical trial in China, and Genexine will share the development strategies, data and costs for success of this clinical trial. Financial terms are not disclosed.

"Standard of care in treating GBM induces long-lasting lymphopenia in most patients. As a potential treatment for patients suffering from this devastating cancer, TJ107/HyLeukin-7™ has demonstrated to effectively induce T cells, especially naïve and memory T cells, and correct lymphopenia in patients with late stage solid tumors," said Dr. Jung Won Woo, Executive Vice President, CDO, Genexine. "We are delighted to deepen our partnership with I-Mab to develop a potential novel therapy."

The restoring ability of T cell deficiency of TJ107/HyLeukin-7™ in a Phase 1b study (NCT03478995) by Genexine was presented at the Society for Immunotherapy of Cancer's 34th Annual Meeting in 2019. The study was on 21 terminal patients with solid tumor, and showed that TJ107/HyLeukin-7™ was well tolerated without dose limiting toxicity and cytokine release syndrome. Dose-dependent increase of absolute lymphocyte counts and T cell subsets (not Treg) were also observed. The findings suggested that TJ107/HyLeukin-7™ can be an excellent combination partner for chemo-radiation, cancer vaccines and immune checkpoint inhibitors such as anti-PD-1/PD-L1 antibodies, by increasing T lymphocytes and thereby contributing to enhanced anti-tumor effects.

By leveraging the results of Genexine's ongoing clinical trials in South Korea, I-Mab is currently conducting a Phase 1b trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and determine recommended Phase 2 dose (RP2D) of TJ107/HyLeukin-7™ in Chinese subjects with advanced solid tumors (NCT04001075).

According to the data released by GLOBOCAN 2018 by International Agency for Research on Cancer, WHO, new cases of brain and nervous system cancers reached 76,494 in China, approximately 17% of which was GBM<sup>[1]</sup>. The annual incidence rate of GBM in China is 5 to 8 per 100,000 person-year.

<sup>[1]</sup> Ostrom Q T, Gittleman H, Liao P, et al. *CBTRUS statistical report: primary brain and other central nervous system tumors diagnosed in the United States in 2010–2014*[J]. *Neuro-oncology*, 2017, 19(suppl\_5): v1-v88.

### **About TJ107/HyLeukin-7™**

TJ107/HyLeukin-7™ (Efineptakin alfa) 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 discovering of long-acting biologics. I-Mab has acquired exclusive rights from Genexine to develop and commercialize TJ107/HyLeukin™ in Greater China. TJ107/HyLeukin-7™ 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. TJ107/HyLeukin-7™ 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 developing biologics of novel or highly differentiated in the therapeutic areas of immuno-oncology and autoimmune diseases. Company's mission is to bring transformational medicines to patients 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 become a fully integrated end-to-end global biopharmaceutical company with cutting-edge discovery platforms, proven preclinical and clinical development expertise, and world-class GMP manufacturing capabilities. I-Mab has offices in Beijing, Shanghai, Hong Kong and Maryland, United States. For more information, please visit <http://ir.i-mabbiopharma.com>

## About Genexine, Inc.

Genexine, Inc., listed on KOSDAQ (095700) since 2009, is a leading biotherapeutics company focused on immuno-oncology and orphan disease. Genexine's goal is to bring out innovative biotherapeutics to save the lives of patients with serious diseases. Genexine has a robust pipeline of products in the clinical stage, e.g. Hyleukin-7™(GX-I7), HyTropin (GX-H9), Papitrol (GX-188E), etc. based on long-acting Fc fusion technology and DNA vaccine technology. Hyleukin-7™ is under Phase 1b or Phase 2 trials in several cancer types for monotherapy or combination therapy. Papitrol, a therapeutic DNA vaccine for HPV-associated diseases is under Phase 2 trial in combination with Keytruda (Merck) for advanced recurrent cervical cancer. Genexine has completed multinational phase 2 trials of HyTropin (long-acting human growth hormone, hGH-hyFc) in PGHD and AGHD. Founded in 1999, Genexine has over 160 employees, and half of them are scientists with MSc, or Ph.D. Genexine is located in Pangyo Techno Valley near Seoul, Korea. For more information, please visit <http://www.genexine.com>.

## I-Mab forward looking statements

This press release includes certain disclosures which contain "forward-looking statements." You can identify forward-looking statements because they contain words such as "anticipate" and "expected." Forward-looking statements are based on I-Mab's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in filings with the U.S. Securities and Exchange Commission. 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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