



**I-MAB**  
BIOPHARMA

## **I-Mab Announces First Patient Dosed in Phase 2 Clinical Trial of TJ107 in Glioblastoma Multiforme in China**

February 4, 2021

SHANGHAI and GAITHERSBURG, Md., Feb. 4, 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 first patient has been dosed in a phase 2 clinical trial ([NCT04600817](#)) of TJ107 (efineptakin alpha), a novel long-acting recombinant human interleukin-7 (rhIL-7), in patients with glioblastoma multiforme (GBM) in China.

The phase 2 trial is a randomized, single-blind, placebo-controlled study to evaluate the efficacy and safety of TJ107 in lymphopenic patients with newly diagnosed GBM who have been treated with standard concurrent chemoradiotherapy. The study's goal is to determine the proportion of patients with an increase in the absolute lymphocyte counts and associated clinical response after the administration of the first TJ107 dose.

There is increasing evidence that lymphopenia induced by radiotherapy and chemotherapy is associated with poor survival in cancer patients. In case of GBM, standard treatments induce long-lasting lymphopenia in most patients, and currently there are no definitive therapies for it. A phase 1b study conducted by Genexine Inc. (KOSDAQ: 095700) demonstrated that TJ107 rapidly increased absolute lymphocyte counts and restored T cell counts especially in the naïve and memory subsets but not the regulatory T cells in terminally ill patients with solid tumors. TJ107 was well tolerated with no dose-limiting toxicity or cytokine release syndrome observed.

"Despite advances in standard therapy, GBM is associated with poor clinical outcomes and survival rates," said Professor Wenbin Li, Director of Department of Neuro-Oncology at Beijing Tiantan Hospital of Capital Medical University and the leading principal investigator of the clinical trial. "Based on its preclinical and clinical data, TJ107 promises to improve tolerance to the standard therapy, quality of life and prognosis in patients with GBM, and we look forward to making this drug accessible to our patients."

"TJ107 is the first and only long-acting rhIL-7 in the clinical stage globally and early studies have shown its potential to treat patients with GBM whose prognosis is still poor," said Dr. Joan Shen, Chief Executive Officer of I-Mab. "The initiation of the phase 2 trial brings us one step closer to delivering a highly innovative therapy to treat patients with one of the most life-threatening forms of cancer."

GBM is the most aggressive type of glial cancer which can arise in the brain *de novo* or evolve from existing tumors. GBM accounts for 17% of new brain and nervous system cancers in China, according to data from the World Health Organization in 2018.<sup>[1]</sup>

[1] 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/GX-I7**

TJ107/GX-I7 (efineptakin alpha) 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/GX-I7 in Greater China. TJ107/GX-I7 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/ GX-I7 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 biotech company focusing on discovery, development and soon commercialization of novel and highly differentiated biologics in immuno-oncology therapeutic area. The Company's mission is to bring transformational medicines to patients around the world through drug innovation. I-Mab's globally competitive pipeline of more than 15 clinical and pre-clinical stage drug candidates is driven by its internal R&D capability and global licensing partnerships, based on the Company's unique Fast-to-Proof-of-Concept and Fast-to-Market pipeline development strategies. The Company is now rapidly progressing from a clinical stage biotech company to a fully integrated global biopharmaceutical company with cutting-edge global R&D capabilities, a world-class GMP manufacturing facility and commercialization capability. I-Mab has established its global footprint in Shanghai (headquarters), Beijing, Hangzhou 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 TJ107/GX-I7 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 TJ107/ GX-I7. 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.

**For more information, please contact:**

**I-Mab**

Jielun Zhu, Chief Financial Officer  
E-mail: [jielun.zhu@i-mabbiopharma.com](mailto:jielun.zhu@i-mabbiopharma.com)  
Office line: +86 21 6057 8000

Gigi Feng, Chief Communications Officer  
E-mail: [gigi.feng@i-mabbiopharma.com](mailto:gigi.feng@i-mabbiopharma.com)  
Office line: +86 21 6057 5785

**Investor Inquiries:**

*The Piacente Group, Inc.*  
Emilie Wu  
E-mail: [emilie@thepiacentegroup.com](mailto:emilie@thepiacentegroup.com)  
Office line: + 86 21 6039 8363

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