



I-MAB
BIOPHARMA

I-Mab Receives China CDE Approval to Initiate Phase 3 Clinical Trial of Eftansomatropin in Pediatric Patients with Growth Hormone Deficiency

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- Eftansomatropin, a long acting recombinant human growth hormone (rhGH) ready for Phase 3 Clinical Trial in China

SHANGHAI and GAITHERSBURG, Md., Sept. 30, 2020 /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 China Center for Drug Evaluation (CDE) has approved the pivotal trial application for eftansomatropin (also known as TJ101) as a weekly treatment for growth hormone deficiency in pediatric patients (PGHD).

Eftansomatropin is an innovative long-acting rhGH with a novel molecular format utilizing Genexine's patented half-life extension hyFc® fusion technology, which stimulates the production of insulin-like growth factor 1 (IGF-1) in the liver, alongside growth-stimulating effects on a variety of tissues, including osteoblast and chondrocyte activities that stimulate bone growth. Because of its unique features, eftansomatropin may have some long term safety advantages over the conventional pegylated rhGH drugs. In phase 1 and 2 clinical studies, eftansomatropin was shown to be well-tolerated, and clinical efficacy of weekly or biweekly regimens was comparable to the daily injected rhGH (genotropin).

"The planned initiation of our phase 3 study for eftansomatropin marks a critical milestone not just for I-Mab, but for pediatric patients with growth hormone deficiency broadly," said Dr. Joan Shen, CEO of I-Mab. "We hope to bring an innovative therapy, such as eftansomatropin, that is safe, efficacious and convenient for pediatric patients once proven."

The phase 3 trial is a multi-center, randomized, open-label, active-controlled clinical study designed to assess the safety, efficacy and pharmacokinetics of eftansomatropin in PGHD. The primary objective is to demonstrate non-inferiority of eftansomatropin administered in subcutaneous injection, compared to the active control Norditropin® (somatropin), a daily rhGH marketed in China.

I-Mab owns the rights of eftansomatropin from Genexine Inc. (KOSDAQ: 095700) for development, manufacturing and commercialization in China. According to Frost & Sullivan, only 3.7% of 3.4 million pediatric patients in Greater China with growth hormone deficiency receive growth hormone therapies, which primarily consist of daily injections of rhGH. Recombinant human growth hormone therapy has been included in the National Reimbursement Drug List in China.

About eftansomatropin

Eftansomatropin is a potential highly differentiated long-acting recombinant human growth hormone being developed as a more convenient and effective therapy for GHD. Like endogenous growth hormone, eftansomatropin stimulates the production of insulin-like growth factor 1 in the liver, which has growth-stimulating effects on a variety of tissues, including osteoblast and chondrocyte activities that stimulate bone growth. IGF-1 is a reliable pharmacodynamic marker and the key mediator of growth-promoting activity of eftansomatropin. Eftansomatropin is based on Genexine's patented hyFc® technology. The hyFc part consists of a portion of human immunoglobulin D ("IgD") and G4 ("IgG4"). The former contains a flexible hinge, and the latter is responsible for half-life extension through neonatal Fc receptor ("FcRn")-mediated recycling.

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 transitioning from a clinical stage biotech company toward a fully integrated global biopharmaceutical company with cutting-edge R&D capabilities, world-class GMP manufacturing facility and commercial capability. I-Mab has offices in Beijing, Shanghai, Hong Kong and Maryland, United States. For more information, please visit <http://ir.i-mabbiopharma.com>

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 eftansomatropin (TJ101) clinical trials, the potential implications of clinical data for patients, and I-Mab's advancement of, and anticipated clinical development, regulatory milestones and commercialization of eftansomatropin (TJ101). 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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