China NMPA Accepts IND Application for Eftansomatropin Pivotal Trial in Pediatric Patients with Growth Hormone Deficiency

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SHANGHAI and GAITHERSBERG, Md., Aug. 4, 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 National Medical Products Administration (NMPA) has accepted its 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 recombinant human growth hormone (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. Additionally, preliminary research and trials have proved that as a natural protein based rhGH, eftansomatropin has not shown safety concerns typically associated with conventional pegylated rhGH drugs on the market, while maintaining comparable efficacy.

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. About 165 subjects will be enrolled and treated in the study.

"The China NMPA's acceptance of this pivotal IND for eftansomatropin represents an important step towards bringing this innovative product to the Chinese market as planned," said Dr. Joan Shen, CEO of I-Mab. "With eftansomatropin, we will be able to potentially address a substantial unmet medical need with a safer, highly differentiated, and convenient therapy for pediatric patients suffering from the growth hormone deficiency."

The Company owns the rights of eftansomatropin from Genexine Inc. (KOSDAQ: 095700) for development, manufacturing and commercialization in China. Genexine has previously completed three clinical trials with eftansomatropin in Europe and Asia, including one Phase 1 trial in healthy adult volunteers, one Phase 1b/2 multi-regional trial in adults with growth hormone deficiency (NCT02946606), and one Phase 2 multi-regional trial in PGHD (NCT03309891). Overall, eftansomatropin was shown to be well-tolerated, and has met clinical efficacy endpoints by weekly or twice-monthly administration.

According to Frost & Sullivan, PGHD affected approximately 3.4 million patients in Greater China, but only 3.7% of all PGHD patients were receiving growth hormone replacement therapy, which primarily consists 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 growth hormone deficiency. 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 developing biologics of novel or highly differentiated in the therapeutic areas of immuno-oncology and autoimmune diseases. The 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

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) Phase III trial of pediatric growth hormone deficiency, 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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