I-Mab Announces First Patient Dosed in China Phase 3 Study of Eftansomatropin Alfa in Pediatric Patients with Growth Hormone Deficiency

February 25, 2021

SHANGHAI and GAITHERSBURG, Md., Feb. 25, 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 the phase 3 pivotal trial (TALLER) for eftansomatropin alfa (also known as TJ101) as a weekly treatment for pediatric growth hormone deficiency (PGHD) in China.

Eftansomatropin alfa 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. Most rhGHs have to be injected daily, which often hampers patient compliance and can adversely affect the clinical outcomes. Because of its unique features, eftansomatropin alfa may have long-term safety advantages over the conventional pegylated rhGH drugs, and its longer-acting regimen may offer advantages over daily injections. In the previous clinical trials, including a phase 2 study in Europe, eftansomatropin alfa was demonstrated to be safe and well-tolerated, and the clinical efficacy of weekly or biweekly regimens was comparable to that of the daily injected rhGH (genotropin).

"We look forward to the start of this pivotal trial. A successful result would have significant implications in the quality of life of the patients," said Professor Xiaoping Luo, a national thought leader in PGHD, principal investigator of the study and chairman of the Department of Pediatrics at Wuhan Tongji Hospital.

"In China where there are more than 3.4 million children with growth hormone deficiency and only a small percentage of them receiving treatment. I-Mab is well positioned to address this significant unmet need," said Dr. Joan Shen, CEO of I-Mab. "With the initiation of this pivotal trial, we hope to bring a highly differentiated growth hormone replacement therapy to our children."

About TALLER

TALLER is a multi-center, randomized, open-label, active-controlled phase 3 clinical study (NCT04633057) designed to assess the safety, efficacy, and pharmacokinetics (PK) of eftansomatropin alfa in pediatric growth hormone deficiency. The trial will enroll 165 patients between 3 years and 10 years of age across multiple centers in China. Patients will be randomized to receive either eftansomatropin alfa 1.2 mg/kg weekly or the active comparator drug Norditropin® (somatropin) 0.035 mg/kg daily subcutaneous injections for 52 weeks. The primary objective is to demonstrate non-inferiority of eftansomatropin alfa to the active control Norditropin®, a daily rhGH marketed in China.

About Eftansomatropin alfa

Eftansomatropin alfa 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 alfa stimulates the production of insulin-like growth factor 1 (IGF-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 alfa. Eftansomatropin alfa 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 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 eftansomatropin alfa (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 alfa (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.

For more information, please contact:

I-Mab

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

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

Investor Inquiries:

The Piacente Group, Inc.
Emilie Wu
E-mail: emilie@thepiacentegroup.com
Office line: +86 21 6039 8363

View original content to download multimedia:http://www.prnewswire.com/news-releases/i-mab-announces-first-patient-dosed-in-china-phase-3-study-of-eftansomatropin-alfa-in-pediatric-patients-with-growth-hormone-deficiency-301235443.html

SOURCE I-Mab