I-Mab Announces Completion of Patient Enrollment in Phase III Clinical Trial of Eftansomatropin alfa for Treatment of Pediatric Growth Hormone Deficiency

May 31, 2022

SHANGHAI and GAITHERSBURG, Md., May 31, 2022 /PRNewswire/ -- I-Mab (the "Company") (Nasdaq: IMAB), a clinical-stage biopharmaceutical company committed to the discovery, development and commercialization of novel biologics, today announced the completion of patient enrollment in a Phase 3 clinical trial (TALLER) of highly differentiated long-acting recombinant human growth hormone eftansomatropin alfa (also known as TJ101), which is being investigated as a weekly treatment for pediatric growth hormone deficiency (PGHD) in China. The primary endpoint is annual height velocity.

"In China, only a small percentage of children with growth hormone deficiency are receiving treatment, which presents a significant unmet medical need. It is a remarkable accomplishment by I-Mab for successfully completing the patient enrollment on schedule amid the covid pandemic," commented Professor Xiaoping Luo, a national thought leader in PGHD, principal investigator of the TALLER study and chairman of the Department of Pediatrics at Wuhan Tongji Hospital.

TALLER is a multi-center, randomized, open-label, active-controlled phase 3 clinical study (NCT04633057) that has enrolled 168 patients in China. The study aims to evaluate the efficacy, safety, and pharmacokinetics (PK) of eftansomatropin alfa in PGHD, as compared to Norditropin®, a daily rhGH marketed in China.

The safety, tolerability and efficacy of eftansomatropin alfa have been well demonstrated in multiple completed early clinical studies. In November 2021, I-Mab announced a strategic collaboration with Jumpcan Pharmaceutical Group to accelerate the development, manufacturing and commercialization of eftansomatropin alfa in mainland China.

"We are excited by having achieved this important milestone as we are now so close to offering this differentiated therapy to patients," said Dr. Andrew Zhu, President of I-Mab. "Eftansomatropin alfa provides a convenient weekly treatment option in the current growth hormone market that is dominated by daily injectables. We look forward to advancing this study at full speed towards registration."

"We are so pleased to see that the patient enrollment has been successfully completed as planned," said Dr. Jun Liu, General Manager of Jumpcan. "Under the strategic collaboration between the two companies, we will support I-Mab to expedite the Phase 3 study to bring this novel therapy quickly to market and meet the clinical demand."

Following the completion of the enrollment, final data from the TALLER study is anticipated in 2023 followed by a Biologics License Application (BLA) submission.

About Eftansomatropin alfa (TJ101)

Eftansomatropin alfa (TJ101) is a potential highly differentiated long-acting recombinant human growth hormone being developed as a more convenient and effective therapy for growth hormone deficiency (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.

Eftansomatropin alfa is currently in Phase 3 clinical study. Because of its unique molecular features, eftansomatropin alfa may have advantages over

the conventional pegylated rhGH drugs and daily injections. In the previous clinical trials, including a Phase 2 study in Europe, eftansomatropin alfa demonstrated its safety and clinical efficacy of weekly or biweekly regimens as compared to that of the daily injected rhGH (Genotropin).

In November 2021, I-Mab and Jumpcan Pharmaceutical Group entered into a strategic collaboration to accelerate the development, manufacturing and commercialization of eftansomatropin alfa in mainland China. I-Mab will be the marketing authorization holder (MAH) of the product and supply the product at agreed cost to Jumpcan. Jumpcan will be responsible for commercializing the product and developing new indications in collaboration with I-Mab in mainland China. I-Mab will provide clinical, manufacturing and academic support.

About I-Mab

I-Mab (Nasdaq: IMAB) is an innovation-driven global biopharma company focused on the discovery, development and commercialization of novel and highly differentiated biologics for immuno-oncology diseases. The Company's mission is to bring transformational medicines to patients around the world through innovation. I-Mab's globally competitive pipeline of more than 20 clinical and preclinical-stage drug candidates is driven by its internal discovery and global partnerships for in-licensing, based on the Company's Fast-to-Proof-of-Concept and Fast-to-Market development strategies. The Company is progressing from a clinical-stage biotech company into an innovative global specialty biopharmaceutical company with cutting-edge R&D capabilities, a world-class GMP manufacturing facility, and commercial capability. I-Mab has established its global footprint in Shanghai (headquarters), Beijing, Hangzhou, Guangzhou, Lishui and Hong Kong in China, and Maryland and San Diego in the United States. For more information, please visit http://www.i-mabbiopharma.com and follow I-Mab on LinkedIn, Twitter, and WeChat.

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.

I-Mab Contacts

Richard Yeh
Chief Operating Officer
IR@i-mabbiopharma.com

Gigi Feng
Chief Communications Officer
PR@i-mabbiopharma.com

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:https://www.prnewswire.com/news-releases/i-mab-announces-completion-of-patient-enrollment-in-phase-iii-clinical-trial-of-eftansomatropin-alfa-for-treatment-of-pediatric-growth-hormone-deficiency-301557652.html

SOURCE I-Mab