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I-Mab Advances Late-stage Development of Its Differentiated CD38 Antibody Felzartamab (TJ202) in China

October 13, 2021

- *Completed patient enrollment in phase 3 registrational trial of felzartamab in combination with lenalidomide for second-line treatment of multiple myeloma (MM)*
- *Felzartamab for MM third-line treatment is on track for BLA submission in Q4 2021*
- *New IND application for combination of felzartamab with another I-Mab clinical asset as a potential first-line treatment for MM is planned in Q4 2021*

SHANGHAI and GAITHERSBURG, Md., Oct. 13, 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 it has completed the patient enrollment of the phase 3 clinical trial of human CD38 antibody felzartamab (also known as TJ202) in combination with lenalidomide as a second-line therapy in patients with multiple myeloma (MM).



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The phase 3 trial (NCT03952091) is a randomized, open-label, parallel-controlled, multi-center study to evaluate the efficacy and safety of the combination of felzartamab, lenalidomide (LEN) and dexamethasone (DEX) versus the combination of LEN and DEX in patients with relapsed or refractory MM who received at least one prior line of treatment. The primary endpoint of the study is to evaluate the progression-free survival (PFS) comparing the efficacy of felzartamab plus LEN/DEX versus LEN/DEX. Data from this study are expected to be the major package supporting Biologics License Application (BLA) submission for second-line treatment of MM in China.

"We are delighted to have completed the patient enrollment as planned under very challenging circumstances. The results will further support the clinical program towards registration to treat patients with multiple myeloma in China," said Dr. Joan Shen, CEO of I-Mab.

I-Mab has completed the single-arm registrational trial with felzartamab and DEX as a third-line therapy for MM patients in Greater China (NCT03860038). Topline data from the study has met the primary and secondary endpoints and confirmed its clinical advantages as estimated. BLA submission is on track in Q4 2021. Further, a new IND application is planned in Q4 2021 to initiate a clinical trial for combination of felzartamab with another I-Mab clinical asset as a potential first-line treatment for MM.

About Felzartamab

Felzartamab (TJ202/MOR202) is an investigational human monoclonal antibody derived from MorphoSys' HuCAL® antibody technology. The antibody is directed against CD38 on the surface of multiple myeloma cells, which has been characterized as one of the most strongly and uniformly expressed antigens on the surface of malignant plasma cells. According to its suggested mode of action, the antibody recruits cells of the body's immune system to kill the tumor through antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP). The antibody does not involve complement dependent cytotoxicity, or CDC, an additional immune mechanism involved in tumor cell killing. Scientific research suggests that an anti-CD38 antibody may have therapeutic potential also in other cancers as well as autoimmune diseases. Based on a licensing agreement between MorphoSys and I-Mab signed in November 2017, I-Mab owns the exclusive rights for development and commercialization of TJ202/MOR202 in mainland China, Taiwan, Hong Kong and Macao.

HuCAL® is a registered trademark of MorphoSys AG.

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, Guangzhou, Lishui 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](#).

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 felzartamab 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 felzartamab. 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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