



**I-MAB**  
BIOPHARMA

## **I-Mab Announces China NMPA Approval for Phase 1b Trial of Felzartamab in Systemic Lupus Erythematosus**

June 25, 2021

SHANGHAI and GAITHERSBURG, Md., June 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 Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has approved the Investigational New Drug (IND) application to initiate a phase 1b trial of felzartamab, a CD38 antibody, in patients with systemic lupus erythematosus (SLE).

The phase 1b trial of felzartamab, also known as TJ202/MOR202, is a multi-center study to evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) in patients with SLE in China. Felzartamab is a fully human and differentiated monoclonal antibody that targets dysregulated CD38-positive B cells responsible for the pathogenic inflammatory processes underlying SLE inducing immune-mediated tissue damage. As it selectively targets the pathogenic B cells involved in SLE, felzartamab is supposed to have a distinct advantage over conventional B-cell targeting therapies. Preclinical studies suggest that felzartamab has disease-modifying potential in the treatment of SLE.

"SLE is a chronic and incurable auto-immune disease, which can cause multiple organ damages. The current treatment options are very limited," said Dr. Joan Shen, CEO of I-Mab. "Felzartamab has the potential to modify the underlying pathophysiology of this disease and may offer a unique treatment option in long-term clinical management of SLE if approved."

I-Mab is also currently conducting two parallel registrational trials with felzartamab to aim for registration for the treatment of multiple myeloma in Greater China. Felzartamab originally derived from MorphoSys' HuCAL® antibody technology and MorphoSys is currently evaluating the safety and efficacy of felzartamab in patients with anti-PLA2R antibody-positive membranous nephropathy.

### **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 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 felzartamab preclinical studies, 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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