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I-Mab Reports Multiple Positive Clinical Updates of Differentiated CD47 Antibody Lemzoparlimab

September 30, 2021

- *The preliminary efficacy and safety data from the phase 2 U.S. trial in NHL has been submitted for presentation at ASH 2021. The current U.S. NHL clinical trial has now expanded to include clinical sites in China as an international multi-center clinical trial, which will potentially lead to a registrational trial in China upon approval by the NMPA.*
- *The on-going clinical trial of lemzoparlimab in combination with AZA for AML/MDS is on track for completion of patient enrollment by Q4 2021, which will potentially lead to a registrational trial in China upon approval by the NMPA.*
- *NMPA has recently approved the IND application for a phase 2 clinical trial of lemzoparlimab in combination with toripalimab in patients with advanced solid tumors.*

SHANGHAI and GAITHERSBURG, Md., Sept. 30, 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 multiple clinical advancements of its anti-CD47 monoclonal antibody lemzoparlimab (also known as TJC4).



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I-Mab has initiated a phase 2 expansion trial ([NCT03934814](https://clinicaltrials.gov/ct2/show/study/NCT03934814)) of lemzoparlimab in combination with rituximab (Rituxan®) in non-Hodgkin's lymphoma (NHL) patients in China. The expanded trial is part of the ongoing international multi-center trial (IMCT) that is being conducted in the U.S. and now also in China. The study is designed to evaluate the safety, pharmacokinetics (PK), pharmacodynamic (PD) and determine the recommended phase 2 dose (RP2D) of lemzoparlimab in combination with rituximab in patients with lymphomas. On September 28, 2021, the first patient in the expanded trial was dosed. Patient enrollment for the trial is expected to be completed in a few months.

Progress in clinical trials of lemzoparlimab in NHL and AML/MDS:

- In the U.S. clinical trial of lemzoparlimab in combination with rituximab for NHL patients, the preliminary efficacy and safety data have been summarized and submitted for presentation at the 2021 American Society of Hematology (ASH) Annual Meeting. The expanded clinical trial is on track and expected, pending approval by the NMPA, to lead to a registrational trial in patients with NHL in 2022 in China.
- In the China clinical trial of lemzoparlimab in combination with azacitidine (AZA) in patients with myelodysplastic syndrome (MDS), preliminary clinical response data is being evaluated, and patient enrollment is on track for completion in Q4 2021, the complete data set will be analyzed and reported at a later time. The Company plans to initiate another registrational trial in patients with MDS in 2022 in China based on the efficacy and safety data from this study, pending approval by the NMPA.

Progress in clinical trials of lemzoparlimab in patients with solid tumors:

I-Mab is currently investigating lemzoparlimab in combination with pembrolizumab (Keytruda®) in advanced solid tumors in U.S. Data readout is expected in early 2022. Further, on September 16, the Center for Drug Evaluation (CDE) of China National Medical Products Administration (NMPA) approved the Company's IND application to advance to a phase 2 clinical trial of lemzoparlimab in combination with toripalimab (TUOYI®) in patients with advanced solid tumors. The combined clinical results will potentially support a registrational trial later in China.

In all clinical trials conducted so far by the Company, including NHL, AML/MDS and solid tumors, lemzoparlimab have been evaluated without the need of a priming dose.

"Accumulative data from the ongoing lemezoparlimab clinical trials further increase our understanding of its safety, PK and efficacy profile," said Dr. Joan Shen, CEO of I-Mab. "We are encouraged by the clinical data of lemezoparlimab obtained so far and are rapidly advancing the clinical development of lemezoparlimab towards multiple registrational trials, with the goal of becoming the first CD47 antibody drug in China."

About CD47 and Lemzoparlimab

CD47 is a cell surface protein over-expressed in a wide variety of cancers and can act to protect tumors by delivering a "don't eat me" signal to otherwise tumor-engulfing macrophages. CD47 antibody blocks this signal and enables macrophages to attack tumor cells. However, development of CD47 antibody as a cancer therapy is hampered by its hematologic side effects, such as severe anemia, caused by natural binding of CD47 antibody to red blood cells. Scientists at I-Mab have discovered a novel CD47 antibody, lemezoparlimab, that is designed to target tumor cells while exerting a minimal untoward effect on red blood cells.

I-Mab continues to advance a combination study of lemezoparlimab with Keytruda® for solid tumors in the U.S. and with Rituxan® for lymphoma in the U.S. and China, in addition to an on-going clinical trial in patients with AML in China.

In September 2020, I-Mab and AbbVie entered into a global strategic collaboration to develop and commercialize lemezoparlimab, including to design and conduct further clinical trials to evaluate lemezoparlimab in multiple cancers globally and in China. AbbVie has assumed sponsorship of the U.S. study as of April 2021.

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 lemezoparlimab (TJC4) phase 1/2 trial, the potential implications of clinical data for patients, and I-Mab's advancement of, and anticipated clinical development, regulatory milestones and commercialization of lemezoparlimab (TJC4). 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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