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I-Mab Announces First Patient Dosed in China Phase 2 Combination Trial of Lenzoparlimab with Azacitidine in Patients with Acute Myeloid Leukemia or Myelodysplastic Syndrome

May 18, 2021

- *The phase 2 combination trial could potentially lead to a registrational study in China in 2022*
- *Accelerated development plan for lenzoparlimab aiming for NDA approval in China for treatment of hematologic malignancies*
- *Two U.S. cohort expansion studies in non-Hodgkin lymphoma and advanced solid tumors on track to deliver preliminary topline results by end 2021 or early 2022*

SHANGHAI and GAITHERSBURG, Md., May 18, 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 an abbreviated combination clinical study ([NCT04202003](#)) of lenzoparlimab (also known as TJC4) with azacitidine (AZA) in patients with newly diagnosed Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS) in China.



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Lenzoparlimab is a differentiated anti-CD47 monoclonal antibody designed to minimize inherent binding to normal red blood cells while preserving its strong anti-tumor activity. AZA is a chemotherapeutic drug that may synergize with lenzoparlimab to treat hematologic malignancies.

This phase 2 combination cohort expansion study builds on the dose escalation monotherapy trial in China and will evaluate the safety, tolerability and efficacy of lenzoparlimab in combination with AZA in patients with newly diagnosed AML who are intolerant to intensive chemotherapy or treatment-naïve patients with intermediate and high-risk myelodysplastic syndrome. Patient enrollment is expected to be completed by Q4 2021.

"Lenzoparlimab has already shown promising and differentiated features as a novel therapy in phase 1 studies. We look forward to advancing lenzoparlimab as a combination treatment in patients with AML and MDS to further validate its safety and clinical efficacy. A pivotal trial towards registration is anticipated immediately after this," said Dr. Joan Shen, CEO of I-Mab.

The Company is on track with its accelerated clinical development plan for lenzoparlimab with the ambition for NDA approval as the first CD47 antibody drug for the treatment of hematologic malignancies in China while advancing two ongoing clinical trials of lenzoparlimab in combination with Rituxan® in patients with NHL and Keytruda® in advanced solid tumors in the U.S. The NHL combination study also included clinical sites in China as an international multi-center trial (IMCT) to potentially bridge to a registrational clinical trial in China if approved by the NMPA. Patient enrollment of both the NHL and solid tumor trials will be completed by Q4 2021 with the preliminary topline data expected thereafter.

About CD47 and Lenzoparlimab

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, making it a potentially promising cancer drug. 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. In a scientific breakthrough, scientists at I-Mab have discovered a unique CD47 antibody, lenzoparlimab, that works efficiently to target tumor cells while exerting a minimal untoward effect on red blood cells to avoid severe anemia.

Lenzoparlimab's hematologic safety advantage and superb anti-tumor activities have been demonstrated previously in a series of robust pre-clinical studies. The results of phase 1 clinical trial have provided further clinical validation of this differentiation in patients with cancer. I-Mab continues to advance a combination study of lenzoparlimab 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 leمزoparlimab, including to design and conduct further clinical trials to evaluate leمزoparlimab in multiple cancers globally and in China.

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](#).

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 leمزoparlimab (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 leمزoparlimab (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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