I-Mab Announces Positive Phase 2 Data of Lemzoparlimab in Combination with Azacitidine (AZA) in Patients with Higher Risk Myelodysplastic Syndrome at ESMO 2022

September 10, 2022

- *Lemzoparlimab combined with AZA showed encouraging clinical response in higher-risk MDS patients*
- *For patients received initial dose over 3 months, the ORR is 80.6% and for patients received initial dose over 6 months the ORR is 86.7%, CR rate 40%*
- *Lemzoparlimab does not require priming dosing with no unexpected safety signals in combination therapy with AZA*
- *For subjects achieving CR, remaining gene mutation frequency such as TP53, TET2 and RUNX1 were significantly decreased*
- *A randomized Phase 3 trial in higher-risk MDS is planned*

GAITHERSBURG, Md. and SHANGHAI, Sept. 10, 2022 /PRNewswire/ -- I-Mab (the "Company") (Nasdaq: IMAB), a clinical-stage biopharmaceutical company committed to the discovery, development, and commercialization of novel biologics, today announces encouraging data from its Phase 2 clinical trial (NCT04202003) of lemzoparlimab (also known as TJC4) in combination with azacitidine (AZA) in patients with newly diagnosed higher risk myelodysplastic syndrome (HR-MDS), presented in an oral presentation on September 10 at the European Society for Medical Oncology (ESMO) Congress 2022.

The open-labeled Phase 2 clinical trial is designed to investigate the efficacy and safety of lemzoparlimab in combination with AZA in patients with newly diagnosed HR-MDS. A total of 53 patients were enrolled as of March 31, 2022, receiving lemzoparlimab at a weekly dose of 30 mg/kg intravenously (IV) and AZA at 75 mg/m2 subcutaneously (SC) on Days 1–7 in a 28-day cycle.

Top-line data showed that for patients who began treatments 6 months or longer prior to the analysis (n=15), the overall response rate (ORR) and complete response rate (CRR) was 86.7% and 40% respectively. For patients who began treatment 4 months or longer prior to the analysis (n=29), the ORR and CRR was 86.2% and 31% respectively. While the study enrolled more patients with worse baseline conditions due to underlying disease (74% of patients had grade ≥3 anemia and 51% of patients had grade ≥3 thrombocytopenia), the results showed that lemzoparlimab combined with AZA was well-tolerated and the safety profile was consistent with AZA monotherapy.

Decreased red blood cells, measured as hemoglobin, and decreased platelets are major causes of morbidity for patients with HR-MDS and the median hemoglobin and platelet levels for patients on study increased in response to treatment. Of the 29 patients who were dependent upon blood transfusions at baseline, 9 patients (31%) became transfusion independent at the time of analysis. Furthermore, the majority of CR patients showed reduction in variant allele frequency (VAF) of MDS-related gene mutation including *TP53*, *TET2* and *RUNX1*, with 56% achieving minimal residual disease negativity ($\leq 10^{-4}$) by flow cytometry. These data are consistent with the anti-leukemic activities and expected drug safety of lemzoparlimab.

"Without the need of priming dose, the latest Phase 2 data show clinically meaningful efficacy of lemzoparlimab treatment in combination with AZA among patients with newly diagnosed HR-MDS," said Prof. Zhijian Xiao, Professor at Institute of Hematology and Blood Disease Hospital, Chinese Academy of Medical Sciences, and leading principal investigator of the study. "The results are encouraging and provide further clinical validation to the promise of lemzoparlimab as a potential best-in-class CD47 antibody, especially for patients with HR-MDS or who are unfit for intensive therapy."

"The clinical activity seen with lemzoparlimab in combination with AZA thus far, in addition to the favorable safety profile, continues to show promise in this difficult-to-treat patient population," said Prof. Chunkang Chang, Director of Hematology Department of Shanghai Sixth People's Hospital, and leading principal investigator of the study. "Lemzoparlimab represents a potentially important novel treatment option for patients with HR-MDS as well as many other hematological malignancies. We're very enthusiastic about the results to date and look forward to advancing the trial and broadening its

application into other malignancies."

"We are excited about the topline data of lemzoparlimab in HR-MDS selected for proffered oral presentation at ESMO Congress 2022," said Dr. Andrew Zhu, President of I-Mab. "The Phase 2 clinical data demonstrated a good safety profile, along with promising efficacy, and underscored I-Mab's commitment to bring transformational therapies to patients in need. These results warrant our focused efforts to advance lemzoparlimab towards initiation of a Phase 3 registrational trial."

The Company is on track to initiate a Phase 3 clinical trial in patients with MDS 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 has been 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 discovered a novel CD47 antibody, lemzoparlimab, that is designed to target tumor cells while exerting a minimal untoward effect on red blood cells.

Multiple clinical studies of lemzoparlimab are ongoing to explore indications in treating patients with myelodysplastic syndrome (MDS), acute myelocytic leukemia (AML), non-Hodgkin's lymphoma (NHL), and advanced solid tumors in combination with chemotherapy and immune checkpoint inhibitors.

About I-Mab

I-Mab (Nasdaq: IMAB) is a dynamic, global biotech company exclusively focused on discovery, development and soon, commercialization of novel or highly differentiated biologics in the therapeutic areas of immuno-oncology and autoimmune diseases. The Company's mission is to bring transformational medicines to patients around the world through innovation. I-Mab's innovative pipeline of more than 10 clinical and pre-clinical stage drug candidates is driven by the Company's Fast-to-Proof-of-Concept and Fast-to-Market development strategies through internal R&D and global partnerships and commercial partnerships. 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.

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 lemzoparlimab clinical studies, the potential implications of clinical data for patients, and I-Mab's advancement of, and anticipated clinical development, regulatory milestones, and commercialization of lemzoparlimab. 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 US 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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