I-Mab Announces First Patient Dosed in Phase 3 Registrational Study of CD47 Antibody Lemzoparlimab in MDS in China

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GAITHERSBURG, Md. and SHANGHAI, April 24, 2023 /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 in a Phase 3 registrational trial (ClinicalTrials.gov Identifier: NCT05709093) in China for patients with higher-risk myelodysplastic syndrome (MDS) has been treated with lemzoparlimab, a novel CD47 antibody, in combination with azacitidine (AZA).

The Phase 3 trial is a randomized, controlled, open-label, multi-center study to evaluate the efficacy and safety of lemzoparlimab in combination with AZA versus AZA monotherapy as first-line therapy in subjects with higher-risk MDS. This is the first approved Phase 3 trial for anti-CD47 therapies in mainland China.

"We are excited to have dosed the first patient in the Phase 3 study for lemzoparlimab in higher-risk MDS, a disease with very limited treatment options. This milestone represents a significant step towards addressing the unmet medical needs of MDS patients and underscores our commitment to developing innovative therapies that could make a meaningful difference in their lives," said Dr. Andrew Zhu, President and Acting CEO of I-Mab. "We are hopeful that lemzoparlimab could become the first-to-market CD47-targeting therapy in China, providing a potentially new, safer, and effective treatment option for patients in need."

MDS is a type of hematologic malignancy that mainly affects older adults, causing dysplastic hematopoiesis, cytopenia(s), and risk of acute myeloid leukemia (AML) transformation. The incidence rate of MDS increases with age, especially among those aged 70 and above.

Hypomethylating agents (HMAs) and allogenic stem cell transplant (allo-HSCT) are the current standard of care for higher-risk MDS, but allo-HSCT can be limited by its associated morbidity. HMAs such as AZA and decitabine have been the primary therapies available for higher-risk MDS in mainland China in the past 15 years, but many patients experience leukemic transformation and long-term survival expectations remain discouraging.

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 antibodies block this signal and enable macrophages to attack tumor cells. However, development of CD47 antibodies as a cancer therapy has been hampered by its hematologic side effects, such as severe anemia, caused by natural binding of the 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 including 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 Myelodysplastic Syndrome

Myelodysplastic syndrome (MDS) is typically a hematologic malignancy of older adults characterized by dysplastic hematopoiesis, cytopenia(s), and risk of acute myeloid leukemia (AML) transformation. In the general population, the incidence rate of MDS in the U.S. and Europe is approximately 4-5 cases per 100,000 people per year. However, among individuals between 70 and 79 years, the incidence rate increases to 26.9 per 100,000 people, and further to 55.4 per 100,000 people among those aged 80 years and older. MDS in Asian population tends to occur at an earlier age and more often have hypocellular bone marrows.

The treatment approach to MDS depends largely on risk stratification of an individual's disease, most commonly using the Revised International Prognostic Scoring System (IPSS-R), which takes into account peripheral blood cytopenias and bone marrow blast percentage and cytogenetics. The IPSS-R separates MDS into 5 risk categories (very low, low, intermediate, high, very high) with median survival and risk of developing AML worsening from very low-risk to very high-risk disease.

About I-Mab

I-Mab (Nasdaq: IMAB) is a dynamic, global biotech company 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, Beijing, Hangzhou, 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 clinical studies of lemzoparlimab, 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.

I-Mab Contacts

Richard Yeh	Gigi Feng
Chief Operating Officer, interim Chief Financial Officer	Chief Communications Officer
IR@i-mabbiopharma.com	PR@i-mabbiopharma.com

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