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I-Mab Announces First Two Patients Dosed in U.S. Phase 2 Combination Trial of Uliledlimab with Atezolizumab in Patients with Selected Advanced Solid Tumors

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SHANGHAI and GAITHERSBURG, Md., Dec. 3, 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 two patients have been dosed in the U.S. phase 2 dose expansion clinical study of its proprietary CD73 antibody uliledlimab (also known as TJD5) in combination with atezolizumab (Tecentriq®) in patients with ovarian cancer and other selected advanced or metastatic solid tumors.



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Uliledlimab is a novel, humanized CD73 antibody that binds to a unique epitope and completely inhibits CD73, reversing the adenosine-mediated immunosuppression in the tumor microenvironment and inhibiting tumor growth. CD73 has been implicated in immune escape by cancer cells and may contribute to tumor resistance to checkpoint immunotherapies, such as PD-(L)1 inhibitors. Uliledlimab has the unique property of not exhibiting the "hook effect," which potentially increases the therapeutic window and improves clinical efficacy compared to other CD73 antibodies. The phase 1 clinical data has demonstrated favorable safety and promising clinical activity for the combination of uliledlimab and atezolizumab in patients with advanced cancers.

This U.S. phase 2 dose expansion study is a multi-center, open-label trial that will explore the clinical activities of uliledlimab in combination with atezolizumab and potential biomarkers in patients with selected advanced or metastatic solid tumors. This clinical study will include a dose expansion cohort of patients with ovarian cancer resistant to platinum therapy, and a biomarker-driven "basket" cohort of patients with head and neck squamous cell carcinoma (HNSCC), non-small cell lung cancer (NSCLC), gastrointestinal cancer, triple-negative breast cancer (TNBC), or ovarian cancer with PD-L1 expression $\geq 1\%$. Uliledlimab is undergoing clinical development in China and the U.S. in parallel with different focus of targeted patient populations. The clinical data from both geographies will be leveraged to accelerate global development towards pivotal clinical study in patients with selected solid tumor types.

"Uliledlimab has unique pharmacological properties which position it as the next-generation immuno-oncology agent," said Dr. Joan Shen, CEO of I-Mab. "We hope the data from this study will accelerate the clinical development towards registration and to address the needs of patients with immune checkpoint resistance."

Based on the results of the phase 1 study, the Company was able to determine the Recommended Phase 2 Dose (RP2D) which it is using for this phase 2 study. Upon completion of the phase 1 study earlier this year, I-Mab decided to conduct subsequent studies in the U.S under its own management.

I-Mab is also conducting a China phase 2 cohort expansion study of uliledlimab in combination with toripalimab (TUOYI®), a PD-1 inhibitor, in patients with advanced or metastatic cancers who are refractory to or intolerant of all available therapies.

About Uliledlimab (TJD5)

Uliledlimab (TJD5) is a differentiated, humanized antibody against CD73, an ecto-enzyme expressed on stromal cells and tumors that converts extracellular adenosine monophosphate (AMP) to adenosine. Adenosine in turn binds to adenosine receptors on relevant immune cells and inhibits anti-tumor immune responses in tumor microenvironment. Uliledlimab is expected to offer clinical benefit by suppressing tumor growth in concert with checkpoint therapies such as PD-(L)1 antibodies. Uliledlimab is effective in anti-tumor activities through a unique intra-dimer binding, leading to differentiated and favorable functional properties as evident in preclinical studies.

About I-Mab

I-Mab (Nasdaq: IMAB) is an innovation-driven global biopharma company focused on the discovery, development and commercialization of novel and highly differentiated biologics for immuno-oncology and autoimmune diseases. The Company's mission is to bring transformational medicines to patients around the world through innovation. I-Mab's globally competitive pipeline of more than 20 clinical and preclinical-stage drug candidates is driven by its internal discovery and global partnerships for in-licensing, based on the Company's Fast-to-Proof-of-Concept and Fast-to-Market development strategies. The Company is progressing from a clinical-stage biotech company into a fully integrated global biopharmaceutical company with cutting-edge R&D capabilities, a world-class GMP manufacturing facility, and commercial 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](#).

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 uliledlimab 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 uliledlimab. 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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