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I-Mab Announces Encouraging Phase 1b/2 Study Results of Patients with Advanced NSCLC Receiving Uliledlimab and Toripalimab Combination Therapy at ASCO 2023

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- *Uliledlimab is a differentiated monoclonal antibody designed to target CD73 and promote stronger activation of patients' immune system against cancer cells.*

- *In newly diagnosed patients who were not eligible for or declined chemotherapy treatment, 63% of the patients with CD73^{High} and PD-L1 TPS \geq 1% responded to the combination therapy while the response rate was 31% in all patients regardless of CD73 or PD-L1 expression.*

- *A strong correlation is observed between high CD73 expression in tumors and better clinical response, particularly in patients with PD-L1 TPS \geq 1%, demonstrating the potential role of CD73 as a predictive biomarker.*

- *A biomarker-guided pivotal trial is being planned.*

- *Results from uliledlimab Phase 1b/2 clinical trial will be reported in a poster presentation on June 3 at ASCO 2023.*

GAITHERSBURG, Md. and SHANGHAI, May 25, 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 encouraging results from the Phase 1b/2 study ([ClinicalTrial.gov](https://clinicaltrials.gov/ct2/show/study/NCT04322006) Identifier: [NCT04322006](https://clinicaltrials.gov/ct2/show/study/NCT04322006)) evaluating uliledlimab, the Company's proprietary and highly differentiated CD73 antibody, in combination with toripalimab (TUOYI®), a PD-1 antibody, in patients with treatment-naïve advanced non-small cell lung cancer (NSCLC), and exploring the potential value of CD73 expression as a predictive biomarker. The results will be reported in a poster presentation on June 3 at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting.

The study is a dose expansion portion of a Phase 1b/2 trial evaluating the safety and efficacy of the combination therapy and investigating the potential correlation between tumor CD73 expression and clinical response for patients with treatment-naïve advanced NSCLC.

As of April 14, 2023, a total of 70 patients were enrolled in the study. Uliledlimab demonstrated a favorable safety profile up to 30mg/kg Q3W in combination with toripalimab with most treatment-related adverse events (TRAEs) being Grade 1 or Grade 2 in severity. In the efficacy evaluable population (n=67), the objective response rate (ORR) was 31.3% regardless of PD-L1 and CD73 expression. CD73^{High} was established as >40% of tumor or immune cells with \geq 1+ staining intensity identified by immunohistochemistry (IHC). The cutoff was determined through receiver operating characteristic (ROC) analysis.

Notably, patients with CD73^{High} exhibited a higher ORR compared with those with CD73^{Low} (53% vs. 18%). The ORR further increased to 63% in patients with both CD73^{High} and PD-L1 tumor proportion score (TPS) \geq 1%, whereas patients with CD73^{Low} had an ORR of 20%. At the time of data cutoff, with a median follow-up of 10.4 months, 18 out of 21 responders remained on treatment, and the median duration of response (DOR) was not reached. Progression-free survival (PFS) and overall survival (OS) data will be analyzed when the data are fully mature.

"These results hold promise for the treatment of NSCLC patients, as demonstrated by the favorable safety and efficacy outcomes," said Professor Yi-Long Wu, Principal Investigator of the study and Professor of Guangdong Provincial People's Hospital, Guangdong Academy of Medical Sciences and Guangdong Lung Cancer Institute. "We are particularly excited about the potential of CD73 expression as a predictive biomarker, which is consistent with findings in our previous studies. The results may transform how we personalize NSCLC treatment through stratification by a predictive biomarker."

"The new results are compelling for uliledlimab as a new treatment for NSCLC and its potential to make a meaningful impact on patients' lives. We're particularly excited by the strong correlation between high CD73 expression and clinical response. With this finding, we are in a unique position to apply CD73 as a predictive biomarker to raise the probability of treatment success for NSCLC," said Dr. Andrew Zhu, President and Acting CEO of I-Mab. "Building on encouraging results from this study, we intend to commence a biomarker-guided pivotal trial with the aim of providing these promising new treatment options to patients as quickly as we can."

These data will be reported in a poster presentation, entitled *Uliledlimab and Toripalimab Combination Therapy in Treatment Naïve Advanced NSCLC: Phase 1b/2 Clinical Trial Results Using CD73 as a Potential Predictive Biomarker* (Abstract #2570), at ASCO on June 3, 2023, from 8:00 a.m. – 11:00 a.m. C.T. by Dr. Qing Zhou, Professor of Guangdong Provincial People's Hospital.

About Uliledlimab

Uliledlimab (also known as 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 the tumor microenvironment. Uliledlimab is expected to offer clinical benefits 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 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 uliledlimab, 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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