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I-Mab Reports Latest Phase 2 Clinical Data of its Differentiated CD73 Antibody Uliledlimab

May 26, 2022

- *Uliledlimab appears safe and well-tolerated as a monotherapy and a combination therapy with toripalimab with no dose limiting toxicity*
- *Encouraging efficacy signals were observed in a non-small cell lung cancer (NSCLC) patient cohort*
- *Results indicate CD73 expression correlates with clinical response as a potential predictive biomarker*
- *Company aims to initiate Phase 3 study in NSCLC in 2023*
- *The Company will host investors call on Friday, May 27 at 8 a.m. ET*

SHANGHAI and GAITHERSBURG, MD., May 26, 2022 /PRNewswire/ -- I-Mab (the "Company") (Nasdaq" IMAB), a clinical-stage biopharmaceutical company committed to the discovery, development and commercialization of novel biologics, today announced preliminary data of its ongoing Phase 2 clinical trial ([NCT04322006](#)) with uliledlimab (also known as TJD5, or TJ004309), a differentiated CD73 antibody, and its global clinical development plan.



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At the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, preliminary results through December 2021 from an ongoing Phase 2 clinical study of uliledlimab in combination with toripalimab (TJOYI®) in patients with non-small cell lung cancer (NSCLC) were released.^[1] These results were largely consistent with those observed in Phase 1 clinical trial in relation to favorable drug safety and pharmacokinetics (PK) and pharmacodynamic (PD) profile of uliledlimab. Uliledlimab appears safe and well-tolerated up to the highest doses tested at 30 mg/kg Q3W, as a monotherapy and a combination therapy with toripalimab with no dose limiting toxicity (DLT). Uliledlimab exhibited a linear PK profile at doses ≥5mg/kg and a dose-dependent receptor occupancy with no "hook effect", where the antibody loses its effectiveness at high concentrations.

The most updated Phase 2 data are summarized as follows with the new data cutoff of March 29, 2022. Among three NSCLC patient cohorts who were under different treatment settings, clinical response varied. The highest response rates were observed in the patient cohort with advanced NSCLC (mostly stage 4 disease) who were previously ineligible for standard of care, while the other two cohorts with advanced NSCLC who were heavily treated showed a lower clinical response. Among 19 efficacy evaluable patients from this cohort, 5 partial responses (5 PR, overall response rate [ORR]=26%) and 9 stable disease (9 SD, disease control rate [DCR] =73.7%) were observed. Approximately 80% patients in this cohort showed low PD-L1 expression in baseline tumor samples (tumor proportion score [TPS] 1-49% or TPS<1%) who were considered less responsive to a checkpoint inhibitor therapy as demonstrated in KEYNOTE-042 (ORR=16.9% for patient with PD-L1 TPS 1-49%)^[2]. Noticeably, the clinical response observed in this patient cohort displayed a correlation with CD73 expression in tumors. High CD73 expression (≥35% expression level in tumor cells or immune cells) was found in 4/5 PRs with a mean value of 53.4%, 4/9 SDs with a mean value of 30.5% and none in the 5 remaining patients with a mean value of 19.2% who progressed on the treatment. The clinical data continue to mature.

"The data represent a step forward for advanced non-small-cell lung cancer patients. To date, uliledlimab has shown a favorable safety profile and positive anti-tumor activity in lung cancer patients, particularly in those patients with a higher baseline CD73 expression," 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. "While the study is ongoing and we are analyzing the data as they mature, we are extremely encouraged by these results and the clinical benefits that uliledlimab may offer to cancer patients."

This Phase 2 clinical trial is still ongoing with patients on-study for continued treatment and follow-up evaluation. The Company plans to expand the study with the aim to focus on the selected NSCLC patient cohort for further evaluation of treatment efficacy as well as the role of CD73 as a potential predictive biomarker. The future clinical development plan of uliledlimab includes a Phase 3 registrational clinical trial in patients with NSCLC to be expected next year if approved by the China National Medical Products Administration and another clinical trial in the United States in other selected

cancer types and beyond combination with PD-1/PD-L1 therapy in the next 12 months.

"The latest data readout, although preliminary, gives hope to those lung cancer patients who often do not benefit from the currently available treatments," said Dr. Andrew Zhu, President of I-Mab. "We are excited by uliledlimab's potential as a best-in-class CD73 antibody and the clinical results obtained so far have given us the confidence for further clinical development towards registration. We look forward to accelerating our clinical development plan in China and the U.S. with the goal to initiate a registrational clinical study soon."

Uliledlimab is a differentiated CD73 antibody that is designed to avoid a "hook effect" seen in other clinical stage CD73 antibodies. This differentiated property is enabled through uliledlimab's novel C-terminus epitope and its associated intra-dimer binding mode, leading to a favorable PK and PD relationship as confirmed in both Phase 1 and the ongoing Phase 2 clinical trials.

In a Phase 1 clinical trial of uliledlimab in combination with atezolizumab (Tecentriq®), uliledlimab was well tolerated with encouraging efficacy signals in heavily treated cancer patients (ORR=23%, DCR=46%) as presented at ASCO 2021^[3]. Recommended Phase 2 dose (RP2D) was determined at 20 mg/kg, Q3W and there was a potential correlation between high tumoral expression of CD73 and the observed clinical response.

The Company will host an investor conference call to provide an in-depth clinical data analysis at 8 a.m. Eastern Time on May 27, 2022. Details for the conference call are as follows:

Meeting URL: <https://i-mabbiopharma.zoom.us/j/84961586624?pwd=TVQ0SUtyMUU6d2dZbHgybGVScGwvUT09>

Meeting ID: 849 6158 6624

Password: 160619

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 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 an innovative global specialty 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://www.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 uliledlimab (TJD5) clinical trials, the potential implications of clinical data for patients, and I-Mab's advancement of, and anticipated clinical development, regulatory milestones and commercialization of uliledlimab (TJD5). 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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[1] [Safety, efficacy, pharmacokinetics of uliledlimab alone or combined with toripalimab in advanced solid tumor: Initial results of a Phase I/II study](#)

[2] Mok TS, Wu YL, Kudaba I, et al. Pembrolizumab versus chemotherapy for previously untreated, PD-L1-expressing, locally advanced or metastatic non-small-cell lung cancer (KEYNOTE-042): a randomised, open-label, controlled, Phase 3 trial. LANCET 2019.

[3] [Preliminary safety, pharmacokinetics \(PK\), pharmacodynamics \(PD\) and clinical efficacy of uliledlimab \(TJ004309\), a differentiated CD73 antibody, in combination with atezolizumab in patients with advanced cancer.](#)

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