I-Mab Presents Positive Uliledlimab Pharmacokinetics Data at 2024 World Conference on Lung Cancer

September 10, 2024

- Pharmacokinetic/pharmacodynamic (PK/PD) modeling data from three Phase 1 studies providing dosing support for upcoming clinical trials
- Exposure-Response (E-R) Analysis showed a positive correlation between uliledlimab concentration and ORR probability in mNSCLC patients
- Randomized Phase 2 study of uliledlimab in combination with pembrolizumab plus chemotherapy expected to begin in 1H 2025

ROCKVILLE, Md., Sept. 10, 2024 /PRNewswire/ -- I-Mab (NASDAQ: IMAB) (the "Company"), a U.S.-based, global biotech company exclusively focused on the development of highly differentiated immunotherapies for the treatment of cancer, today announced a poster presentation of PK/PD modeling data for uliledlimab at the International Association for the Study of Lung Disease (IASLD)'s 2024 World Conference on Lung Cancer (WCLC 2024) held September 7-10, 2024 in San Diego, CA.

Uliledlimab (TJ004309) is an antibody designed to target CD73, the rate-limiting enzyme critical for adenosine-driven immunosuppression in the tumor microenvironment. Blocking CD73 allows anti-tumor immunity to proceed without the presence of an adenosine-induced "immunological fog". The WCLC 2024 presentation includes data from uliledlimab PK/PD analyses from three Phase 1 studies including patients with treatment naïve metastatic non-small cell lung cancer (mNSCLC).

"The PK/PD analysis presented at WCLC underscores our view that uliledlimab has the potential to be a differentiated, best-in-class, CD73 inhibitor. The data support our dose selection work and upcoming combination studies, with a study of uliledlimab plus pembrolizumab plus chemotherapy expected to begin in the first half of 2025," said **Phillip Dennis, MD, PhD**, Chief Medical Officer of I-Mab. "We are particularly encouraged by the E-R analysis, which showed a positive relationship between uliledlimab exposure and the probability of an overall response in patients with NSCLC, as well as positive target engagement data and dose proportional PK results. These data, plus a previously presented favorable safety profile and clinical efficacy, fortify our view that uliledlimab has the potential to meaningfully improve the care of patients with mNSCLC."

Poster Title: Integrated PK/PD Modeling for Uliledlimab, an Anti-CD73 Monoclonal Antibody, in Non-Small Cell Lung Cancer Patients (Poster #2979)

Data are based on analysis of three Phase 1 studies conducted in China evaluating uliledlimab, as a monotherapy and in combination studies with the checkpoint inhibitors, toripalimab or atezolizumab, in patients with advanced cancers, including mNSCLC.

Key Findings Include:

- Most of the simulated population (95%) could achieve the target threshold with 30 mg/kg of uliledlimab
- Integrated PK/PD modeling and pharmacometrics analyses indicate there is a positive relationship between the probability of overall response and uliledlimab trough concentration in NSCLC patients
- CD73 receptor occupancy (RO) in peripheral B cells achieved 90% or above and maintained at high levels until the end of treatment
- The 30 mg/kg dose with a single boost dose on C1D8 provided uliledlimab concentrations that achieved the target concentration of 80 μg/mL immediately after the first dose and maintained this threshold afterward
- A C_{trough} target threshold of 80 μg/mL may be clinically meaningful, associated with PFS benefit and is achievable by a 30 mg/kg initial dose followed by a booster dose on Cycle 1, Day 8 (C1D8)

A full copy of the poster is available on the I-Mab website, on the "Innovation, Publications & Presentations" tab.

About I-Mab

I-Mab (NASDAQ: IMAB) is a U.S.-based, global biotech company exclusively focused on the development of highly differentiated immunotherapies for the treatment of cancer. I-Mab has established operations in Rockville, Maryland. For more information, please visit https://www.i-mabbiopharma.com and follow us on LinkedIn and X.

Forward Looking Statements

This announcement contains forward-looking statements. These statements are made under the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements can be identified by terminology such as "will", "expects", "believes", "designed to",

"anticipates", "future", "intends", "plans", "potential", "estimates", "confident", and similar terms or the negative thereof. I-Mab may also make written or oral forward-looking statements in its periodic reports to the U.S. Securities and Exchange Commission (the "SEC"), in its annual report to shareholders, in press releases and other written materials and in oral statements made by its officers, directors or employees to third parties. Statements that are not historical facts, including statements about I-Mab's beliefs and expectations, are forward-looking statements. Forward-looking statements in this press release include, without limitation, statements regarding: the Company's pipeline and capital strategy, including the Company's stock repurchase program; the projected advancement of the Company's portfolio and anticipated milestones and related timing; the market opportunity and I-Mab's potential next steps (including the potential expansion, differentiation, or commercialization) for uliledlimab, givastomig and ragistomig; the Company's expectations regarding the impact of data from ongoing and future clinical trials; the Company's financial condition and results of operations and anticipated changes in the Company's revenues or expenses; the Company's expectations regarding its cash runway; timing and progress of studies and trials (including with respect to patient enrollment); and the availability of data and information from ongoing studies and trials. Forward-looking statements involve inherent risks and uncertainties that may cause actual results to differ materially from those contained in these forward-looking statements, including but not limited to the following: I-Mab's ability to demonstrate the safety and efficacy of its drug candidates; the clinical results for its drug candidates, which may or may not support further development or New Drug Application/Biologics License Application (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; and 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, 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 SEC. All forward-looking statements are based on information currently available to I-Mab. 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

Investors & Media
Tyler Ehler
Senior Director, Investor Relations
IR@imabbio.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/i-mab-presents-positive-uliledlimab-pharmacokinetics-data-at-2024-world-conference-on-lung-cancer-302242691.html

SOURCE I-Mab Biopharma