I-Mab Announces Encouraging Phase 1 Clinical Data of PD-L1x4-1BB Bispecific Antibody Ragistomig at ASCO 2024

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- *Encouraging objective responses were observed in heavily pre-treated patients, including 1 complete response (CR) and 6 partial responses (PR), mainly in patients previously treated with checkpoint inhibitors*
- *Phase 1 dose-escalation data demonstrated that ragistomig monotherapy can be safely administered through the highest planned doses*
- *Data will be presented at the 2024 Annual Meeting of the American Society of Clinical Oncology (ASCO2024) in a poster session scheduled for June 1, 2024 at 9:00 am CDT*

ROCKVILLE, Md., May 23, 2024 (GLOBE NEWSWIRE) -- I-Mab (the "Company") (NASDAQ: IMAB) a U.S.-based, global biotech company, exclusively focused on the development and potential commercialization of highly differentiated immunotherapies for the treatment of cancer, today announced that Gerald Falchook, MD, and the team at I-Mab's partner for ragistomig (or "ABL503"), ABL Bio (KOSDAQ: 298380), will present a poster related to Phase 1 data for ragistomig at the 2024 American Society for Clinical Oncology Annual Meeting ("ASCO 2024"), taking place from May 31st to June 4th at the McCormick Place Convention Center in Chicago, IL.

Ragistomig was designed as a bispecific antibody to provide anti-PD-L1 activity and 4-1BB-driven T-cell activation in one molecule. The combination of an Fc-silent and conditional 4-1BB engagement was intended to optimize the compound for safety, including the potential for lower hepatotoxicity compared to traditional 4-1BB agonists.

The first-in-human Phase 1 study was designed to define the dose-limiting toxicity and safety profile of ragistomig monotherapy (primary endpoints) as well as to observe the objective response rate (ORR), pharmacokinetic (PK) and immunogenicity profiles (secondary endpoints). The study is being conducted in patients with advanced or relapsed/refractory solid tumors and the majority of patients (56.6%) received prior anti-PD(L)-1 immunotherapy. The main observations from the study include:

- A manageable safety profile;
- Definition of an optimal dose of 5 mg/kg, with dose proportional pharmacokinetics (PK);
- Overall response rate of 25% at 5 mg/kg, based on 3 partial responses (PR) out of 12 patients with median progression free survival (PFS) of 15.6 weeks;
- Clinical benefit rate of 75% at 5 mg/kg, based on 3 PRs and 6 stable disease (SD);
- 71.4% of responders had received prior anti-PD-(L1) inhibitors and were all relapsed or refractory to anti-PD-(L1) inhibitors; and
- A complete response (CR) was seen in one heavily pretreated patient (7 prior lines of therapy, ovarian cancer) at 3 mg/kg.

"We are pleased to present the Phase 1 data to date for ragistomig at ASCO 2024. While immune checkpoint inhibitors have made a significant contribution to the treatment of solid tumor cancers, many tumors do not respond or become refractory to these agents. Ragistomig was designed to provide a new treatment option for patients who are resistant to immune checkpoint inhibitors," said Raj Kannan, Chief Executive Officer at I-Mab. "Topline data indicate that the study met its objectives, enabling the definition of an optimal dose, and provided several early efficacy observations in patients relapsed or refractory to prior checkpoint inhibitor treatment. These data support further development of ragistomig as both a monotherapy and in combination with other compounds. We look forward to advancing the clinical program in collaboration with our partner, ABL Bio."

Louie Naumovski, MD, PhD, Interim Chief Medical Officer for I-Mab commented, "We are pleased by ragistomig's manageable safety, T-cell activation profile and dose proportional pharmacokinetics. Observation of responses is also encouraging, including a 25% ORR and a 75% clinical benefit rate (CBR), at the optimal dose of 5 mg/kg. Notably, the majority of patients were heavily pretreated, with three or more lines of therapy, including a prior PD-(L)1 inhibitor, and the majority of responders (71.4%) had received prior anti-PD-(L)1 therapy. Together, these data provide sound support to continue the development of ragistomig, with ongoing follow-up of this initial Phase 1 study."

The data will be reported in a poster entitled "*Phase 1 trial Safety and Efficacy of Ragistomig, a Bispecific Antibody Targeting PD-L1 and 4-1BB in Advanced Solid Tumors*" (Abstract #2529, Poster Board 8), at ASCO 2024 on June 1, 2024 from 9:00 a.m. – 12:00 p.m. C.D.T. in the Developmental Therapeutics – Immunotherapy session by Dr. Gerald Falchook, MD, Director of the Sarah Cannon Research Institute at HealthONE, a clinical trials program in Denver, Colorado, for patients with advanced cancer.

About Ragistomig

Being developed jointly with ABL Bio, ragistomig (also known as ABL503) is a differentiated PD-L1-based bispecific antibody that fuses an Fc-silent anti-PD-L1 arm, as the tumor-dependent T-cell activator, with a single chain variable fragment of an anti-4-1BB engaging antibody, as the conditional T-cell activator, upon tumor engagement. Using ABL Bio's "Grabody-T" bispecific antibody platform technology, ragistomig/ABL503 stimulates 4-1BB activation only in the presence of PD-L1 expressing tumor cells to minimize the risk of off-tumor toxicity and overcome resistance to PD-(L)1 inhibition. Preclinical studies have demonstrated that the bispecific antibody shows better anti-tumor activity than equimolar doses of single agents alone or in combination. A Phase 1 dose escalation and dose expansion study (NCT04762641) is currently being conducted in the U.S. and South Korea. The study was designed to define the dose-limiting toxicity and adverse event profile of ragistomig (primary endpoints) as well as to observe the objective response rate, pharmacokinetic and immunogenicity profiles (secondary endpoints).

About I-Mab

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

I-Mab 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", "anticipates", "future", "intends", "plans", "believes", "estimates", "confident", "design", "encourage", "forward", "continue", "ongoing", and similar terms or the negative of such terms. Statements that are not historical facts, including statements about I-Mab's beliefs and expectations, are forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the following: the anticipated reporting of Phase 1 data for ragistomig/ABL503 at ASCO 2024; the intended design, composition, use, and benefits of ragistomig/ABL503 (including to optimize the compound for safety, including the potential for lower hepatotoxicity compared to traditional 4-1BB agonists, and to provide a new treatment option for patients who are resistant to immune checkpoint inhibitors); the intended design of the Phase 1 study; the potential implications of the observations of the first in-human Phase 1 study; I-Mab's intent to advance the clinical program in collaboration with ABL Bio; and the intent to continue the development of ragistomig/ABL503, with ongoing follow-up of the initial Phase 1 study. These forward-looking statements involve inherent risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such forward-looking statements. These risks and uncertainties include, but are 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 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; as well as the discussions of potential risks, uncertainties, and other important factors in I-Mab's most recent annual report on Form 20-F and I-Mab's subsequent filings with the SEC. 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. 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.

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