I-Mab Completes Enrollment in Planned Phase 1b Dose Expansion Study for Givastomig in Combination with Immunochemotherapy in Patients with 1L Gastric Cancers

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- *Enrollment in the planned second dose expansion cohort completed ahead of expectations*
- *Topline results expected in Q1 2026*
- *Positive Phase 1b dose escalation data presented at ESMO GI on July 2nd*

ROCKVILLE, Md., Aug. 11, 2025 (GLOBE NEWSWIRE) -- I-Mab (NASDAQ: IMAB) (the Company), a U.S.-based, global biotech company, focused on the development of precision immuno-oncology agents for the treatment of cancer, **today announced that enrollment in the planned Phase 1b dose expansion cohorts evaluating givastomig, a bispecific Claudin 18.2 x 4-1BB antibody, in combination with nivolumab and mFOLFOX6, has been completed ahead of expectations.**

The Phase 1b study (NCT04900818) is evaluating the safety, efficacy, pharmacokinetics (PK), and pharmacodynamics (PD) of givastomig, a potential best-in-class, Claudin 18.2 (CLDN18.2) x 4-1BB bispecific antibody, used in combination with nivolumab and mFOLFOX6, as first line therapy (1L) in patients with CLDN18.2-positive gastric cancers (≥1+ intensity in ≥1% of cells). The primary endpoint is safety. The study enrolled only patients in the U.S. The dose expansion cohorts of the study enrolled a total of 40 patients across two doses (8 mg/kg and 12 mg/kg).

"Our optimism in givastomig has been bolstered by the accelerated pace of enrollment in the Phase 1b trial and the ongoing enthusiasm of the study's investigators. These observations highlight the unmet need for improved gastric cancer therapy, the oncology community's growing interest in Claudin 18.2-directed therapies and its awareness of the givastomig clinical program. I am encouraged by the Phase 1b dose escalation data, and hopeful that givastomig can become a new treatment option for patients with Claudin 18.2-positive gastric cancers," said **Phillip Dennis, MD, PhD, Chief Medical Officer of I-Mab**. "I especially want to thank the patients, their families, investigators and study sites for their continued support for this program."

Data from the dose escalation cohorts of the study were presented on July 2, 2025 in a Mini Oral presentation at the European Society for Medical Oncology Gastrointestinal Cancers Congress (ESMO GI) 2025 in Barcelona, Spain, accessible here. The data showed that givastomig in combination with immunochemotherapy achieved an 83% (10/12) objective response rate (ORR) at the doses (8 mg/kg and 12 mg/kg) selected for dose expansion. Response onset was rapid, durable and deepened over time, with favorable overall safety. I-Mab hosted a virtual investor event on July 8, 2025 reviewing the Phase 1b dose escalation data (accessible for viewing here).

About Givastomig

Givastomig (TJ033721 / ABL111) is a bispecific antibody targeting Claudin 18.2 (CLDN18.2)-positive tumor cells. It conditionally activates T cells through the 4-1BB signaling pathway in the tumor microenvironment where CLDN18.2 is expressed. Givastomig is being developed for first line (1L) metastatic gastric cancers, with further potential in other solid tumors. In Phase 1 trials, givastomig has shown promising anti-tumor activity attributable to a potential synergistic effect of proximal interaction between CLDN18.2 on tumor cells and 4-1BB on T cells in the tumor microenvironment, while minimizing toxicities commonly seen with other 4-1BB agents.

An ongoing Phase 1b study is evaluating givastomig for the treatment of gastric cancer in the 1L setting in combination with standard of care, nivolumab (an anti-PD-1 checkpoint inhibitor) plus chemotherapy, in dose escalation (n=17) and dose expansion (n=40) cohorts. The study builds on positive Phase 1 monotherapy data.

Givastomig is being jointly developed through a global partnership with ABL Bio, in which I-Mab is the lead party and shares worldwide rights, excluding Greater China and South Korea, equally with ABL Bio.

About I-Mab

I-Mab (NASDAQ: IMAB) is a U.S.-based, global biotech company, focused on the development of precision immuno-oncology agents for the treatment of cancer. The Company's differentiated pipeline is led by givastomig, a potential best-in-class, bispecific antibody (Claudin 18.2 x 4-1BB) designed to treat Claudin 18.2-positive gastric cancers. Givastomig conditionally activates T cells via the 4-1BB signaling pathway in the tumor microenvironment where Claudin 18.2 is expressed. Givastomig is being developed for first-line metastatic gastric cancers, with additional potential in other solid tumors. In Phase 1 trials, givastomig was observed to

maintain strong tumor-binding and anti-tumor activity, attributable to a potential synergistic effect of proximal interaction with Claudin 18.2 and 4-1BB, while minimizing toxicities commonly seen with other 4-1BB agents.

For more information, please visit 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", "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 timing of topline results from the Phase 1b expansion study of givastomig, and the potential benefits of givastomig, including its ability to become a new treatment option for patients with gastric cancers. 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; I-Mab's limited operating history; 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 annual report on Form 20-F filed with the SEC on April 3, 2025, as well as the 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.

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