I-Mab Highlights Positive Givastomig Phase 1b Dose Escalation Data in Combination with Immunochemotherapy in Patients with 1L Gastric Cancers at ESMO GI 2025

June 26, 2025

71% objective response rate (ORR) (12/17) per RECIST v1.1, with a favorable safety profile

83% ORR (10/12) in patients across doses selected for ongoing dose expansion study

Responses observed in patients with low PD-L1 and/or CLDN18.2 expression

Updated results to be presented at ESMO GI on July 2nd

Company to host investor event on July 8th

ROCKVILLE, Md., June 26, 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 publication of *ESMO Gastrointestinal Cancers Congress 2025 (ESMO GI 2025)* abstract #388MO related to positive data from a Phase 1b study evaluating givastomig in combination with nivolumab and mFOLFOX6 chemotherapy for metastatic gastric cancers. An objective response rate (ORR) of 71% (12/17) was observed across all dose levels with an ORR of 83% (10/12) observed at dose levels selected for the ongoing dose expansion study (8 and 12 mg/kg). Responses were rapid and deepened over time, and were observed in tumors with low levels of PD-L1 expression and/or low levels of Claudin 18.2 (CLDN18.2) expression. There was a favorable safety profile, with low incidence of GI and liver toxicities. I-Mab intends to host a virtual investor event on Tuesday, July 8th (register here) to recap the data being presented at ESMO GI.

The abstract is based on the results of the dose escalation part of a Phase 1b study (NCT04900818) evaluating the safety, efficacy, pharmacokinetics (PK), and pharmacodynamics (PD) of givastomig used in combination with nivolumab and mFOLFOX6 as first line therapy (1L) in patients with Claudin 18.2-positive gastric cancers (≥1+ intensity in ≥1% of cells). The primary endpoint is safety. The study only enrolled patients in the U.S.

"We are excited to share positive initial data from the Phase 1b dose escalation study of givastomig in gastric cancers at ESMO GI 2025. Givastomig shows promising activity in the first line setting, with responses that are both rapid onset and durable, deepening over time. This is the first study to evaluate givastomig in combination with immunochemotherapy and we are very pleased by the overall tolerability, consistent pharmacokinetic data and soluble 4-1BB induction. We look forward to sharing the data with the oncology and investment communities at ESMO GI 2025 on July 2nd," **said Phillip Dennis, MD, PhD, Chief Medical Officer of I-Mab.**

"Givastomig's strong response data and favorable safety profile are encouraging. I look forward to presenting the data for this novel Claudin 18.2 targeted therapy next week at ESMO GI and discussing with colleagues," **said Samuel J Klempner, MD, Associate Professor of Medicine at Massachusetts General Hospital.** "Gastroesophageal cancers continue to be a significant unmet medical need, and novel combination approaches are critical. On behalf of the study team, I am enthusiastic to continue to support the givastomig clinical program."

ESMO GI Presentation Details:

Title: Preliminary Safety and Efficacy of Givastomig, a Novel Claudin 18.2/4-1BB Bispecific Antibody, in Combination with Nivolumab and mFOLFOX in Metastatic Gastroesophageal Carcinoma (mGEC)
Speaker: Samuel J. Klempner, MD, Associate Professor of Medicine, Massachusetts General Hospital
Presentation Number: 388MO
Date and Time: Wednesday, July 2nd at 16:50 CEST (10:50am EST)

Givastomig Phase 1b Dose Escalation Data Summary in 1L Gastric Cancers

- 17 advanced metastatic gastric cancer patients were treated with givastomig across the 5 mg/kg (n=5), 8 mg/kg (n=6), and 12 mg/kg (n=6) dose levels as of the February 28, 2025, data cutoff. All patients were efficacy evaluable

Patient Characteristics:

- The 17 patients enrolled in the study were treatment naïve metastatic gastric, esophageal or gastroesophageal adenocarcinomas
- Patients were HER2-negative, Claudin 18.2-positive (defined as >1+ intensity in >1% of tumor cells) regardless of PD-L1 expression levels
- All patients were enrolled at sites within the United States

Efficacy Results:

- Objective Response Rates (ORRs):
  - 71% of patients (12/17) achieved a partial response (PR) per RECIST v1.1
    - 5 mg/kg (2/5)
    - 8 mg/kg (5/6)
    - 12 mg/kg (5/6), with one unconfirmed response as of the data cutoff
  - At the doses selected for dose expansion (8 and 12 mg/kg), 83% (10/12) of patients achieved PRs
  - 80% of patients (4/5) with CLDN18.2 expression below 75% (CLDN-Low) achieved a PR. The CLDN-Low response rate increased to 100% of patients (3/3) in the doses selected for expansion (8 and 12 mg/kg)
- The disease control rate (DCR) was 100% across the three dose levels
- Dose-dependent PK was observed, similar to monotherapy PK.
- Patients also experienced a dose dependent induction of soluble 4-1BB, a positive indicator of T cell activation and engagement

ORR: % (n)	**All (n=17)**	**Cohorts Chosen for expansion (8 and 12 mg/kg) (n=12)**
PD-L1		
Any	71 (12/17)	83 (10/12)
≥5	82 (9/11)	89 (8/9)
<5	50 (3/6)	67 (2/3)
≥1	73 (11/15)	82 (9/11)
<1	50 (1/2)	100 (1/1)
CLDN18.2		
≥75	67 (8/12)	78 (7/9)
<75	80 (4/5)	100 (3/3)

Durability:

- 8 of 17 patients remained on study treatment and the longest treatment duration was 11.3 months as of the data cutoff

Safety:

- No dose limiting toxicities (DLT) were observed and a maximum tolerated dose (MTD) was not reached
- Common treatment related adverse events (TRAEs, ≥10% of patients) were generally Grade 1 or Grade 2 including nausea, vomiting, infusion related reaction, fatigue, decreased appetite, diarrhea, abdominal pain, chills, dyspepsia and gastritis
- Grade 3 TRAEs attributed to givastomig were rare, with single cases of abdominal pain, ALT/AST increases, gastritis, and infusion related reaction
- No Grade 4 or Grade 5 TRAEs were reported

Virtual Investor Event:

Register for the Post-ESMO GI 2025 Investor Event here. A replay of the webinar will be accessible on the News & Events page of the I-Mab website for 90 days.

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 and dose expansion cohorts. Dose escalation is complete, and enrollment in the first dose expansion cohort (n=20) finished ahead of schedule. Enrollment continues to progress ahead of schedule in the second dose expansion cohort (n=20). 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 Company's pipeline and clinical development of I-Mab's drug candidates, including givastomig; the projected advancement of the Company's portfolio and anticipated milestones and related timing; the Company's expectations regarding the impact of data from ongoing and future clinical trials; the timing and progress of studies and trials (including with respect to patient enrollment); the potential benefits of givastomig; 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 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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