



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

July 2, 2025

Data show confirmed ORR of 83% (10/12) at doses selected for ongoing expansion study

Median follow-up of 9.0 months as of the updated data cutoff

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

Company to host investor event on Tuesday, July 8th

ROCKVILLE, Md., July 02, 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 the presentation of positive Phase 1b combination data for givastomig, in combination with nivolumab and mFOLFOX6, at the *European Society for Medical Oncology Gastrointestinal Cancers Congress 2025 (ESMO GI 2025)* in Barcelona (abstract #388MO). Givastomig is a bispecific antibody targeting Claudin 18.2 and 4-1BB. I-Mab plans to host a virtual investor event on Tuesday, July 8th (register [here](#)) to review these data.

The Phase 1b data (NCT04900818) show a confirmed objective response rate (ORR) of 71% across all doses (12/17), and 83% (10/12) at doses selected for the ongoing dose expansion study (8 mg/kg and 12 mg/kg). Responses occurred in tumors with low levels of PD-L1 expression and/or Claudin 18.2 (CLDN18.2) expression, with favorable overall tolerability. There were no Grade 3 or greater events for nausea and vomiting, and only one Grade 3 TRAE for increased liver enzymes. The data are based on the results of the dose escalation part of a Phase 1b study evaluating the givastomig combination as first line therapy (1L) in patients with Claudin 18.2-positive gastric cancers ($\geq 1+$ IHC staining intensity in $\geq 1\%$ of tumor cells). The primary endpoint is safety. The study enrolled only patients in the U.S.

"The positive Phase 1b combination data presented at ESMO GI bolster our confidence in givastomig's potential to be a best-in-class Claudin 18.2 directed therapy. Givastomig has been well tolerated when combined with immuno-oncology and chemotherapy, has shown a high objective response rate, with rapid onset and durable responses that have deepened over time, supported by consistent pharmacokinetic data and soluble 4-1BB induction," said **Phillip Dennis, MD, PhD, Chief Medical Officer of I-Mab**. "In addition, we are optimistic about the results from the 8 mg/kg and 12 mg/kg doses. These doses showed an ORR of 83%, with consistent responses across PD-L1 and Claudin 18.2 expression levels, and a favorable overall safety profile. These data further our conviction in the ongoing Phase 1b dose expansion study. We believe givastomig has broad potential in a number of gastric cancer settings and look forward to continued advancement of the program."

"I am encouraged by the response rates, as well as the deepening of responses over time, demonstrated by the givastomig combination regimen in the Phase 1b dose escalation study that we presented today at ESMO GI. Despite approved therapies, targeted treatment options for gastric cancers continue to be limited. While the data are early, givastomig combination therapy demonstrates a high response rate across Claudin 18.2 and PD-L1 expression levels," said **Samuel J Klempner, MD, Associate Professor of Medicine at Massachusetts General Hospital**. "In addition, I have been pleased to observe that givastomig has a favorable overall tolerability profile with a low level of gastrointestinal side effects -- especially important for patients with gastric cancer. I look forward to participating in the ongoing givastomig clinical development program, and hope we may be able to expand the population of patients who may benefit from Claudin 18.2 directed agents."

Virtual Investor Event:

Register ([here](#)) for the Post-ESMO GI 2025 Investor Event to be held on Tuesday, July 8th at 2:00 PM EDT. A replay of the webinar will be accessible on the Events page of the I-Mab website for 90 days.

Fireside Chat Event with Lucid Capital Markets to Recap the Presentation:

Tune in ([here](#)) for a fireside chat sponsored by Christopher Liu, PharmD, Managing Director at Lucid Capital Markets that will be accessible today at 2:00pm EDT on the Events page of the I-Mab website. A replay of the fireside chat will be available for 90 days.

ESMO GI Presentation Details:

A full copy of the ESMO GI presentation is available on the Publications and Presentations page of the I-Mab website [here](#).

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 May 15, 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 $\geq 1+$ IHC staining intensity in $\geq 1\%$ of tumor cells), regardless of PD-L1 expression levels
- All patients were enrolled at sites within the United States

Efficacy Results:

- Confirmed 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)
 - 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 pharmacokinetics (PK) were 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)

ORR: % (n)	PD-L1 ≥ 5	PD-L1 < 5
CLDN18.2 ≥ 75	80 (8/10)	0 (0/2)
CLDN18.2 < 75	100 (1/1)	75 (3/4)

Durability:

- 8 of 17 patients remained on study treatment and the longest treatment duration was 13.3 months as of the data cutoff
- Median follow-up was 9.0 months across all dose levels as of the data cutoff

Safety:

- Treatment-related adverse events (TRAEs) leading to discontinuation of any treatment were 12% (two patients), five patients had progressive disease, two patients withdrew from the study for social reasons
- No dose limiting toxicities (DLT) were observed and a maximum tolerated dose (MTD) was not reached
- Common TRAEs ($\geq 10\%$ 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
- Four cases of Grade 3 and two cases of Grade 4 treatment-related neutropenia were observed driven by an early

restriction on prophylaxis use of G-CSF, which has been subsequently lifted. The neutropenia cases were primarily attributed to mFOLFOX6 in the 8 mg/kg cohorts

- No Grade 5 TRAEs were reported

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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