



**I-MAB**  
BIOPHARMA

## I-Mab Announces Acceleration of Givastomig Investment and Leadership Appointments

September 8, 2025

- Expands investment in givastomig in 1L metastatic gastric cancers, with plans to initiate a global randomized Phase 2 study in combination with immunotherapy, in Q1 2026, with additional Phase 1b cohorts to follow
- Reiterates expectations to report topline givastomig Phase 1b dose expansion data in Q1 2026
- Plans to broaden the 1L development strategy into locally advanced gastric cancer as well as other Claudin 18.2-positive tumor types, including biliary tract cancer (BTC) and pancreatic ductal adenocarcinoma (PDAC)
- Mr. Wei Fu, I-Mab's Chairman of the Board of Directors, appointed as Executive Chairman, supported by further executive additions

ROCKVILLE, Md., Sept. 08, 2025 (GLOBE NEWSWIRE) -- [I-Mab](#) (NASDAQ: IMAB) (I-Mab or 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 accelerated investment in its lead program, givastomig, an investigational Claudin 18.2 (CLDN18.2)-directed bispecific antibody (CLDN18.2 x 4-1BB), including plans to initiate a global randomized Phase 2 study and additional Phase 1b cohorts. The Company also reiterated its expectations to report Phase 1b dose expansion data in Q1 2026. In addition, I-Mab announced leadership additions, including the appointment of Mr. Wei Fu as Executive Chairman, and the appointment of Dr. Sean Cao as Chief Business Development Officer (CBO).

"2025 has been a year of significant progress for I-Mab. Compelling Phase 1b combination data and positive investigator engagement have accelerated the givastomig program and reinforced our confidence in its potential to be a best-in-class Claudin 18.2-directed therapy for metastatic gastric cancers in the 1L setting," said **Sean Fu, PhD, Chief Executive Officer of I-Mab**. "Based on these accomplishments, we are expanding our investment in givastomig, with plans to initiate a randomized Phase 2 study in Q1 2026."

"This is an exciting time for I-Mab, marked by clinical progress and organizational development," said **Mr. Wei Fu, Executive Chairman of I-Mab**. "I am very excited to work side-by-side with Sean Fu and the executive team as we embark on the next stage of the Company's growth. With each step forward, I-Mab maintains an unwavering focus on value creation, supported by a strong cash balance and dedication to advancing our mission to improve the lives of patients globally."

### ***Givastomig Clinical Program Overview:***

#### **1L Gastric Cancer (GC) Studies:**

- **Phase 1b dose expansion data expected in Q1 2026:** Phase 1b dose expansion cohorts evaluating givastomig at two dose levels (8mg/kg and 12mg/kg) in combination with nivolumab and chemotherapy (n=40) as a first-line (1L) treatment for patients with metastatic gastric cancers.
- **Initiation of a global randomized Phase 2 study in 1L metastatic gastric cancers:** The Company intends to initiate a randomized Phase 2 study in 1L metastatic gastric cancers evaluating givastomig in combination with nivolumab and chemotherapy versus nivolumab and chemotherapy alone. Progression free survival (PFS) data are expected in 2027.
- **Initiation of a 1L metastatic GC cohort for patients who do not qualify for checkpoint inhibitors or the existing approved CLDN18.2 1L GC therapy (Double-Low):** The Company intends to initiate an additional Phase 1b cohort evaluating givastomig in combination with chemotherapy (n=20) as a 1L treatment for patients with metastatic gastric cancers whose tumors express Claudin 18.2 in <75% of cells (CLDN-Low) and CPS scores <1 (PD-L1 Low), known as (Double-Low) patients. This population represents a significant unmet medical need since these patients are not eligible to receive the existing approved CLDN18.2-directed therapy or immunotherapies. The current standard of care is chemotherapy alone in this patient population.

#### **Expansion of Givastomig into Gastrointestinal Malignancies Characterized by CLDN18.2 Expression:**

- **1L Pancreatic Ductal Adenocarcinoma (PDAC):** The Company intends to initiate an additional Phase 1b cohort in 1L, CLDN18.2-positive PDAC evaluating givastomig in combination with chemotherapy.
- **1L Biliary Tract Cancer (BTC):** The Company intends to initiate an additional Phase 1b cohort in 1L, CLDN18.2-positive BTC evaluating givastomig in combination with a checkpoint inhibitor and chemotherapy.

#### **Investigator Initiated Trials (IITs) Broaden Evaluation into Other Tumor Types in a Neoadjuvant Setting:**

- **Dr. Kohei Shitara, National Cancer Center Hospital East, Japan:** A single arm study evaluating givastomig in combination with a checkpoint inhibitor and chemotherapy as a 1L neoadjuvant therapy for locally advanced, CLDN18.2-positive, resectable gastric cancers.
- **Dr. Jeremy Kratz, University of Wisconsin, sponsored by the Department of Veterans Affairs:** A single arm study evaluating givastomig in combination with chemotherapy as a 1L neoadjuvant therapy for CLDN18.2-positive, resectable pancreatic cancer.

#### **Governance and Leadership Updates:**

Mr. Wei Fu, the current Chairman of the Board of Directors (the Board) has been appointed to the role of Executive Chairman by the Board. Additionally, the Board has appointed Dr. Sean Cao to the newly created role of Chief Business Development Officer (CBO). Dr. Cao will devote approximately half of his professional time to I-Mab to further support I-Mab's growth. Dr. Cao joins I-Mab from CBC Group and affiliates, bringing expertise in business development.

#### **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 exploratory studies in other CLDN18.2-positive gastrointestinal 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.

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 and other Claudin 18.2-positive gastrointestinal tumors. Additionally, I-Mab is collaborating with its partner, ABL Bio, for the development of ragistomig, a bispecific antibody integrating PD-L1 as a tumor engager and 4-1BB as a conditional T cell activator, in solid tumors.

For more information, please visit <https://www.i-mabbiopharma.com> and follow us on [LinkedIn](#).

#### **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. 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 potential benefits of I-Mab's drug candidates, including givastomig; anticipated clinical milestones and results, including the timing of initiating clinical studies and reporting data from clinical trials; and the expected impact of the new leadership appointments. 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 and I-Mab's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; and 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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