I-Mab Announces Portfolio Prioritization of Givastomig (CLDN18.2 x 4-1BB Bispecific Antibody) as Lead Clinical Program

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- Givastomig: a Claudin 18.2 ("CLDN18.2") x 4-1BB bispecific antibody, will be the lead clinical program following the Company's portfolio prioritization
- The Company has completed enrollment of a dose escalation study of givastomig in combination with nivolumab plus chemotherapy, and **data is expected in the early second half of 2025**; a 40-patient dose expansion study is now underway with data expected in early 2026
- Cash balance of $184.4 million (as of September 30, 2024), expected to support operations into 2027, complemented by a strengthened U.S.-based leadership team and streamlined operating model

ROCKVILLE, MD, Jan. 6, 2025 /PRNewswire/ -- 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 highlighted its strategic outlook for 2025 and a re-prioritization of resources, with a focus on advancing its lead program, givastomig, a CLDN18.2 x 4-1BB bispecific antibody, targeting first-line metastatic gastric cancers, with further potential in other solid tumors.

"I-Mab made excellent progress executing its corporate strategy in 2024, including the establishment of a new operating model as a U.S.-based global biotech company, completion of the divestiture of operations in China, including extinguishment of all remaining redemption obligations, appointment of U.S.-based auditors, enhanced transparency through quarterly financial reporting, and buildout of a U.S.-based leadership team," said **Sean Fu, PhD, MBA, CEO and Board Member** of I-Mab. "Building on this positive momentum, the Company has implemented a portfolio prioritization to support the accelerated development of givastomig."

Portfolio Prioritization

Givastomig (TJ033721 / ABL111) is a bispecific antibody targeting 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 metastatic gastric cancers, with additional potential in other solid tumors. In Phase 1 trials, givastomig was observed to maintain a strong tumor-binding property and anti-tumor activity, attributable to a potential synergistic effect of proximal interaction with CLDN18.2 and 4-1BB, while minimizing toxicities commonly seen with other 4-1BB agents.

- The Company will focus its resources on advancing givastomig as its lead asset.
- Topline Phase 1 monotherapy dose escalation and dose expansion data presented at the annual meeting of the European Society for Medical Oncology ("ESMO 2024") showed:
    - An overall response rate ("ORR") of 16.3% (7/43), including seven partial responses ("PR") at doses between 5 mg/kg and 18 mg/kg, with five of the seven responders (71%) having received prior checkpoint inhibitor ("CPI") therapy.
    - A favorable safety profile, with mainly grade 1 or 2 treatment-related adverse events ("TRAEs"). No dose-limiting toxicities ("DLTs") were observed, and a maximum tolerated dose ("MTD") was not identified.
- A Phase 1b dose escalation study of givastomig in combination with nivolumab plus chemotherapy has been fully enrolled (n = 17) with no MTD reached and no DLTs to date; **the Company expects to present these data in the early second half of 2025.**
- Based on encouraging early data from the dose escalation study, the Company is expanding the previously planned dose expansion cohort (n = 6-8) to include two dose cohorts, each evaluating 20 patients, for a total of 40 patients.
    - Patients are being enrolled with tumors that express CLDN18.2 as low as 1+ intensity in ≥1% of cells, regardless of PD-L1 expression
    - **The Company expects to share these data in early 2026**.
- This program is being jointly developed through a global partnership with ABL Bio, in which I-Mab is the lead party and shares worldwide rights, excluding China and South Korea, equally with ABL Bio.

According to **Phillip Dennis, MD, PhD, CMO** of I-Mab, "Data arising from this study will not only help establish the breadth of patients who might respond to this novel regimen (such as those with low levels of CLDN18.2 expression that would not qualify for approved CLDN18.2 therapies), but also help establish the recommended dose of givastomig for subsequent studies."

Ulileldimab (TJ004309) is an antibody designed to target CD73, the rate-limiting enzyme critical for adenosine-driven immunosuppression in the tumor microenvironment. I-Mab owns worldwide rights to ulileldimab outside of Greater China.

- The development of ulileldimab is being paused to allow the Company to focus resources toward advancing its lead clinical program, givastomig, and to allow data to mature from an ongoing China-only randomized study conducted by its partner TJ Biopharma evaluating ulileldimab in combination with a CPI (toripalimab) in CD73-high NSCLC patients.
- As a result, further clinical investment in ulileldimab will be put on hold.
- The Company will continue to monitor data as it becomes available.
- I-Mab is positioned to potentially resume clinical development, pending positive data.

Ragistomig (TJ-L14B / ABL503) is a bispecific, Fc-silent antibody designed to provide anti-PD-L1 activity and conditional 4-1BB-driven T-cell activation in one molecule. Ragistomig is being developed for solid tumors that are refractory or have relapsed after exposure to CPIs. The program is being jointly developed through a global partnership with ABL Bio, in which ABL Bio is the lead party and shares worldwide rights, excluding China and South Korea, equally with I-Mab.

- Data reported by ABL Bio at the annual meeting of the American Society of Clinical Oncology ("ASCO 2024") showed promising objective responses in patients with various solid tumors whose tumors progressed or recurred after prior standard treatments, including patients with prior exposure to PD-(L)1 inhibitors.
- ABL Bio is continuing the Phase 1b study to increase the therapeutic index by altering the dosing level and/or frequency, and to identify the appropriate tumor types for further development.

Financial Outlook

The Company's current cash position is expected to fund the givastomig Phase 1b study through dose expansion data readouts and further development initiatives into 2027.

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. I-Mab has established operations in the U.S. in Rockville, Maryland, and Short Hills, New Jersey. For more information, please visit us at: https://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 capital strategy; the projected advancement of the Company's portfolio and anticipated milestones and related timing; the Company's expectations regarding its cash runway; timing and progress of studies and trials; 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 most recent annual report on Form 20-F, as well as 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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