I-Mab Presents Updated Phase 1 Givastomig Data at ESMO 2024

September 16, 2024

- *Expanded Phase 1 monotherapy study of givastomig, a Claudin 18.2 X 4-1BB bispecific antibody immunostimulant, shows promising single-agent activity in heavily pre-treated patients with gastric cancers expressing Claudin 18.2 at low and high levels*
- *The recommended Phase 2 dose for givastomig was determined to be 8-12 mg/kg; givastomig was well tolerated up to the highest study doses*
- *A Phase 1b study, evaluating givastomig in combination with standard-of-care treatment (nivolumab + chemotherapy (FOLFOX)) in front-line gastric cancer patients, is ongoing*

ROCKVILLE, Md., Sept. 16, 2024 /PRNewswire/ -- I-Mab (NASDAQ: IMAB) (the "Company"), a U.S.-based, global biotech company exclusively focused on the development of highly differentiated immunotherapies for the treatment of cancer, today announced a poster presentation highlighting encouraging top-line results from its ongoing Phase 1 clinical study (NCT04900818) of givastomig, a novel first-in-class/ Claudin18.2 (CLDN18.2) and 4-1BB bispecific antibody immunostimulant, in patients with advanced cancers, especially gastric cancers (including gastroesophageal carcinoma, or GEC) at the European Society for Medical Oncology (ESMO) Congress 2024, taking place in Barcelona, Spain.

Givastomig (TJ033721 / ABL111) is a bispecific antibody targeting Claudin 18.2-positive tumor cells that conditionally activates T cells via the 4-1BB pathway in the tumor microenvironment, where Claudin 18.2 is expressed. Givastomig stands out among other Claudin 18.2-targeted therapies based on its nonclinical findings of localized, conditional activation, even in tumors with low levels of CLDN18.2 expression, and has exhibited a favorable safety profile in clinical trial participants to date.

"We believe givastomig has the potential to be a front-line treatment option for patients with gastric cancers. Data presented at ESMO 2024 show that givastomig demonstrated continued monotherapy efficacy signals in heavily pre-treated patients, especially gastric cancers with a range of Claudin 18.2 expression levels and a strong overall safety profile. Together, this profile supports our view that givastomig has the potential to be a differentiated, class-leading therapy," said **Dr. Phillip Dennis, MD, PhD,** Chief Medical Officer of I-Mab. "The first evaluation of givastomig as a front-line therapy for gastric cancers is underway. The Phase 1b dose expansion study will evaluate givastomig in combination with standard-of-care, nivolumab plus chemotherapy. We continue to be enthusiastic about the program, and we look forward to sharing the results from this study in the second half of 2025."

Poster Title: Updated Safety and Efficacy from the Phase I Study of Givastomig, a Novel Claudin 18.2/4-1BB Bispecific Antibody Immunostimulant, in Claudin 18.2 Positive Advanced Gastroesophageal Carcinoma (GEC), Poster 1017

Data are based on the ongoing Phase 1 study that includes results from the Phase 1a dose escalation segment presented at ESMO 2023 and additional data from the Phase 1b dose expansion segment. The Phase 1b segment will evaluate the safety, efficacy, pharmacokinetics (PK), and pharmacodynamics (PD) of givastomig.

The poster presents data on 43 patients with advanced gastroesophageal carcinoma (GEC) who were enrolled in the dose expansion study. Participants were required to have GEC tumors centrally confirmed to be CLDN18.2-positive (CLDN18.2+), defined as ≥1% of tumor cells with ≥1+ intensity by immunohistochemistry (IHC).

Key observations include:

Of the 43 patients with CLDN18.2+ GEC who received givastomig monotherapy at doses ranging from 5 to 18 mg/kg, **partial responses were observed in seven patients** (one at 5 mg/kg, one at 8 mg/kg, four at 12 mg/kg, and one at 18 mg/kg) with an **objective response rate (ORR) of 16.3% (7/43 patients)** for single agent givastomig. Five of the seven patients who had achieved a partial response **(71%) had previously received a checkpoint inhibitor**. **Stable disease (SD) was reported in 14 patients**, which resulted in a disease control rate ("DCR") of 48.8% (21/43 patients).

- No dose-limiting toxicity was reported up to 15 mg/kg Q2W and 18 mg/kg Q3W, and a maximum tolerated dose (MTD) was not identified.
- The most common treatment-related adverse events (TRAEs) were mainly grade 1 or 2.
- Givastomig exhibited a linear PK at doses ≥5 mg/kg and showed a dose-dependent increase in soluble 4-1BB levels, reaching a plateau at doses 8 mg/kg to 18 mg/kg.
- CLDN18.2 expression in responders ranged from 11% to 100%. Five responders had received prior treatment of PD-(L)1

inhibitors.

A full copy of the poster is available on the I-Mab website under the "Innovation – Publications & Presentations" tab.

About Givastomig

Givastomig (TJ033721 / ABL111) is a bispecific antibody targeting Claudin 18.2-positive tumor cells. It conditionally activates T cells in the tumor microenvironment where Claudin 18.2 is expressed using 4-1BB. Givastomig appears to maintain a strong tumor binding property and anti-tumor activity, attributable to a synergistic effect of proximal interaction with CLDN18.2 and 4-1BB, while avoiding or minimizing liver toxicity and systemic immunotoxicity commonly seen with other emerging 4-1BB product candidates. In March 2022, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation for givastomig for the treatment of gastric cancer, including cancer of the gastroesophageal junction. A Phase 1b study is ongoing evaluating combination therapy with standard-of-care, nivolumab plus chemotherapy, in patients with front-line gastric cancers, including gastroesophageal cancer (NCT04900818).

The 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.

About I-Mab

I-Mab (NASDAQ: IMAB) is a U.S.-based, global biotech company exclusively focused on the development of highly differentiated immunotherapies for the treatment of cancer. I-Mab has established operations in Rockville, Maryland. For more information, please visit https://www.i-mabbiopharma.com and follow us on LinkedIn and X.

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 statements regarding: the potential benefits of givastomig; 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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