



**I-MAB**  
BIOPHARMA

## I-Mab Announces Publication of Claudin18.2 x 4-1BB Bispecific Antibody Givastomig in JITC

July 5, 2023

GAITHERSBURG, Md. and SHANGHAI, July 5, 2023 /PRNewswire/ -- I-Mab (the "Company") (Nasdaq: IMAB), a clinical-stage biopharmaceutical company committed to the discovery, development, and commercialization of pioneering immunotherapies, today announced the publication of a manuscript entitled "CLDN18.2 and 4-1BB bispecific antibody givastomig exerts antitumor activity through CLDN18.2-expressing tumor-directed T-cell activation" in the latest [issue](#) of *The Journal for Immuno-Therapy of Cancer* (JITC).



### CLDN18.2 and 4-1BB bispecific antibody givastomig exerts antitumor activity through CLDN18.2-expressing tumor-directed T-cell activation

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Givastomig is engineered to bind to CLDN18.2-expressing cancer cells and co-stimulatory receptor 4-1BB on adjacent T cells, with the aim of activating T cells specifically within CLDN18.2-expressing tumors and triggering a potent tumor-killing effect. This innovative approach offers the potential for effective and targeted immuno-therapy in gastric cancer, a disease characterized by a poor prognosis and limited treatment options.

Results from this study demonstrated that 4-1BB<sup>+</sup> T cells co-exist in close proximity to CLDN18.2<sup>+</sup> gastric cancer cells in patients. Moreover, givastomig bound to tumor cells across a wide range of CLDN18.2 expression levels and induced 4-1BB activation only in the context of CLDN18.2 binding, indicating the targeted effect of 4-1BB activation in the presence of CLDN18.2<sup>+</sup> cells. In the *in vivo* CLDN18.2-expressing tumor model, givastomig induces localized immune activation in tumors, increasing the ratio of CD8<sup>+</sup>/Treg cells, resulting in superior anti-tumor activity and long-lasting memory response against tumor rechallenge.

"The findings from our research demonstrate the significant potential of givastomig in treating gastric cancer patients with varying levels of CLDN18.2 expression," said Dr. Lin Shen, Professor of Clinical Oncology at the Beijing Cancer Hospital of Peking University, and Director of SIP LifeLink Oncology Research Institute. "By activating 4-1BB signaling in a CLDN18.2 engagement-dependent manner, givastomig can avoid the risk of liver toxicity and systemic immune response commonly observed with other 4-1BB stimulating agents in previous clinical trials."

"We are excited to see this manuscript published in JITC, as it showcases the innovative design and remarkable anti-tumor activity in preclinical models of givastomig," said Dr. Andrew Zhu, President of I-Mab. "This molecule has demonstrated promising results in this study by effectively activating T cells and triggering a localized immune response within the tumor microenvironment. With ongoing clinical studies, we aim to build upon these findings and ultimately make this innovative therapy accessible to patients with gastric cancer."

Givastomig is currently undergoing Phase 1 clinical studies both in the U.S. and in China. Encouragingly, the Phase 1 study has shown favorable safety profile and promising efficacy signals thus far. The Company intends to report additional clinical data from the study at a major medical conference in the second half of the year.

#### About Givastomig

Givastomig, also known as TJ-CD4B/ABL111, is a Claudin 18.2 and 4-1BB bispecific antibody capable of binding to tumor cells expressing Claudin 18.2, i.e., gastric cancer and pancreatic cancer cells, and stimulating intra-tumoral T cells by the 4-1BB arm designed to be activated only upon tumor engagement while silent elsewhere. Givastomig effectively maintains a strong tumor binding property and anti-tumor activity attributable to a synergistic effect of both Claudin 18.2 antibody and 4-1BB antibody while avoiding or minimizing liver toxicity and systemic immunotoxicity commonly seen with 4-1BB antibodies as a drug class. Being developed under collaboration between I-Mab and ABL Bio, a clinical-stage biotechnology company in South Korea, givastomig is currently being investigated in a phase 1 clinical study in the U.S. and China. 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 gastroesophageal junction.

#### About I-Mab

I-Mab (Nasdaq: IMAB) is a dynamic, global biotech company focused on discovery, development, and commercialization of novel or highly differentiated biologics in the therapeutic areas of immuno-oncology and autoimmune diseases. The Company's mission is to bring transformational

medicines to patients around the world through innovation. I-Mab's innovative pipeline of more than 10 clinical and pre-clinical stage drug candidates is driven by the Company's Fast-to-Proof-of-Concept and Fast-to-Market development strategies through internal R&D and global partnerships and commercial partnerships. I-Mab has established its global footprint in Shanghai, Beijing, Hangzhou, Lishui and Hong Kong in China, and Maryland and San Diego in the United States. For more information, please visit <http://www.i-mabbiopharma.com> and follow I-Mab on [LinkedIn](#), [Twitter](#), and [WeChat](#).

### **I-Mab Forward Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding data from clinical studies of givastomig, the potential implications of clinical data for patients, and I-Mab's advancement of, and anticipated clinical development, regulatory milestones, and commercialization of givastomig. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including but not limited to I-Mab's ability to demonstrate the safety and efficacy of its drug candidates; the clinical results for its drug candidates, which may not support further development or 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 the impact of the COVID-19 pandemic on the Company's clinical development, commercial and other operations, 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 US Securities and Exchange Commission. All forward-looking statements are based on information currently available to I-Mab, and 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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