I-Mab Announces Multiple Presentations at the 2022 American Association for Cancer Research (AACR) Annual Meeting

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SHANGHAI and GAITHERSBURG, Md., March 9, 2022 /PRNewswire/ -- I-Mab (the "Company") (Nasdaq: IMAB), a clinical-stage biopharmaceutical company committed to the discovery, development, and commercialization of novel biologics, today announced that two poster presentations featuring translational research data of enoblituzumab (also known as TJ271) and preclinical data of TJ-C64B will be presented at the American Association for Cancer Research (AACR) 2022 Annual Meeting, to be held April 8-13, 2022.

"We continue to make significant progress in advancing our innovative pipeline to generate the next wave of novel cancer therapeutics for patients around the world," said Dr. Andrew Zhu, President of I-Mab. "The translational research data of enoblituzumab provide compelling rationale to further investigate combination therapy for increased clinical efficacy against multiple cancer types. In addition, the preclinical data of TJ-C64B provide the underlying mechanism of action for further clinical development of this novel bispecific antibody."

Enoblituzumab is a highly differentiated humanized monoclonal antibody directed against the immune regulator B7-H3, which has been associated with poor prognosis and is widely expressed in multiple cancers. Enoblituzumab mediates the antibody-dependent killing of cancer cells and has demonstrated strong anti-tumor activity in preclinical studies. Currently, I-Mab is conducting a phase 2 trial in China for enoblituzumab in combination with pembrolizumab (Keytruda®) in patients with solid tumors, including non-small cell lung cancer (NSCLC), urothelial carcinoma (UC), and other selected cancers.

TJ-C64B is the third bispecific antibody with a conditional T cell engager based on 4-1BB-activation platform. It binds simultaneously to Claudin 6 (CLDN6)-expressing cancer cells and the costimulatory molecule 4-1BB. CLDN6 is a tight junction transmembrane protein hardly detected in adult normal tissues, but aberrantly expressed in a variety of tumors, including ovarian cancer, testicular cancer, hepatocellular and lung adenocarcinoma. TJ-C64B is designed to conditionally activate T cells through 4-1BB stimulation upon CLDN6 engagement, positioning it as a potential novel immunotherapy for ovarian cancer and other CLDN6 positive tumors.

Details for the 2022 AACR presentations are as follows:

Abstract Title: **Inhibition of B7-H3 by Enoblituzumab Elicits Anti-Tumor Immune Modulation in Both Innate and Adaptive Immunity**
Abstract #: 4228
Presenting author: Xuejun Liu, PhD
Date and Time: Wednesday, Apr 13, 2022
9:00 AM – 12:30PM (EST)

Summary:

- The function of B7-H3 and enoblituzumab in regulating immune response was investigated in human PBMCs using the Nanostring nCounter platform for gene expression and CyTOF mass cytometry for immunophenotyping.
- Data confirmed the immunosuppressive function of B7-H3 and demonstrated the immunoregulatory function of enoblituzumab as evidenced by the activation of cytolytic T cell and NK cells, reinvigoration of exhausted cells, and suppression of M2-like myeloid cells.
- Enoblituzumab exhibited tumor killing activity against ES-2, a B7-H3-expressing ovarian cancer cell line *in vitro*. Consistent with the enoblituzumab-associated increased 4-1BB expression in T and NK cells, activation of 4-1BB by urelumab, a 4-1BB agonist, further enhanced enoblituzumab-mediated tumor killing activity.
- These findings provide rationale for combination therapy with blockade of B7-H3 by enoblituzumab with other immunotherapies to achieve increased clinical efficacy against multiple cancer types.

Abstract Title: **Discovery of a Novel Claudin 6 x 4-1BB Bispecific Antibody with Potent Anti-Tumor Activity through Conditional 4-1BB Activation**
Abstract #: 5558
Presenting author: Jian Li, PhD
Date and Time: Friday, Apr 8, 2022
1:00 PM (EST)

Summary:

- Data have confirmed the novel CLDN6-targeted 4-1BB bispecific antibody TJ-C64B to induce potent 4-1BB stimulation and anti-tumor activity in a CLDN6-dependent manner while minimizing the risk of liver toxicity.
- In humanized 4-1BB syngeneic mouse model, TJ-C64B exhibited significant tumor growth inhibition, associated with elevation in tumor infiltrating CD45 and CD8 cells as well as CD8/Treg ratio.
- From the safety perspective, there were no significant changes in liver enzymes following repeated TJ-C64B administration, suggesting a minimal risk for liver toxicity commonly induced by other 4-1BB agonist antibodies.
- Taken together, these data support further development of TJ-C64B towards clinical development subsequently.

About Enoblituzumab

Enoblituzumab is an investigational Fc-optimized monoclonal antibody that targets B7-H3, a member of the B7 family of immune regulator proteins. B7-H3 is widely expressed by many different tumor types and may play a key role in regulating the immune response to various types of cancer. Enoblituzumab has been or is currently being evaluated in clinical trials as a monotherapy or in combination with anti-PD-1-based therapies in patients with B7-H3-expressing cancers. I-Mab licensed the development and commercial rights from MacroGenics for Greater China.

About TJ-C64B

TJ-C64B is a bispecific antibody simultaneously targeting tumor associated antigen Claudin 6 (CLDN6) and costimulatory molecule 4-1BB for CLDN6+ tumor treatment. TJ-C64B is specifically designed to conditionally activate T cells through 4-1BB stimulation upon CLDN6 engagement, providing a more localized activation of the immune system with good efficacy and reduced systemic toxicity. TJ-C64B is currently under preclinical development.

About I-Mab

I-Mab (Nasdaq: IMAB) is an innovation-driven global biopharma company focused on the discovery, development, and commercialization of novel and highly differentiated biologics for immuno-oncology and autoimmune diseases. The Company's mission is to bring transformational medicines to patients around the world through innovation. I-Mab's globally competitive pipeline of more than 20 clinical and preclinical-stage drug candidates is driven by its internal discovery and global partnerships for in-licensing, based on the Company's Fast-to-Proof-of-Concept and Fast-to-Market development strategies. The Company is progressing from a clinical-stage biotech company into a fully integrated global biopharmaceutical company with cutting-edge R&D capabilities, a world-class GMP manufacturing facility, and commercial capability. I-Mab has established its global footprint in Shanghai (headquarters), Beijing, Hangzhou, Guangzhou, Lishui and Hong Kong in China, and Maryland and San Diego in the United States. For more information, please visit http://ir.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 the enoblituzumab and TJ-C64B preclinical studies, the potential implications of clinical data for patients, and I-Mab's advancement of and anticipated clinical development, regulatory milestones, and commercialization of enoblituzumab and TJ-C64B. 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 U.S. 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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