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I-Mab Reports Phase 1 Clinical Trial Data of Highly Differentiated Anti-CD47 Monoclonal Antibody Lemzoparlimab at the 2020 SITC Annual Meeting

11月 9, 2020

- Initial monotherapy results demonstrate differentiated safety and PK profile and efficacy signal of lemzoparlimab for the treatment of relapsed/refractory malignancy

- I-Mab to host call for investors on November 9 at 8:30am ET

SHANGHAI and GAITHERSBURG, Md., Nov. 9, 2020 /PRNewswire/ -- I-Mab (the "Company") (Nasdaq: IMAB), a clinical stage biopharmaceutical company committed to the discovery, development and commercialization of novel biologics, today announced initial results from its U.S. phase 1 clinical trial (NCT03934814) evaluating lemzoparlimab (also known as TJC4) for the treatment of relapsed or refractory solid tumors and lymphoma. The results were released in a poster entitled "*A first-in-patient study of lemzoparlimab, a differentiated anti-CD47 antibody, in subjects with relapsed/refractory malignancy: initial monotherapy results*" at the 2020 Society for Immunotherapy of Cancer (SITC) Annual Meeting, on November 9, 2020 (Abstract #385).

Lemzoparlimab is a unique CD47 antibody that exerts strong anti-tumor activity while exhibiting a minimal binding to red blood cells. It is designed to avoid severe anemia -- a common toxicity of CD47 antibodies of the same class.

"Lemzoparlimab was originally discovered and developed by I-Mab as a globally competitive CD47 antibody and has been uniquely designed to overcome the toxicity associated with this drug target," said Jingwu Zang, M.D., Ph.D., Founder, Honorary Chairman and Director of I-Mab. "The initial clinical results are consistent with the key differentiation of lemzoparlimab in terms of drug safety and the PK profile. These clinical advantages put lemzoparlimab in a highly competitive position among CD47 antibodies of the same class."

The phase 1 study is an open-label, multi-center, multiple dose study conducted in two parts. The first part is comprised of a single agent dose escalation followed by two separate combination regimens in an escalating dose range (Part 1b with pembrolizumab; Part 1c with rituximab). The second part is a dose expansion study in the combination therapies.

The data to be presented at SITC include the initial results from the single agent therapy (N=20), which is designed to determine the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and anti-tumor activity of lemzoparlimab. The key findings include:

- Lemzoparlimab was well tolerated up to 30 mg/kg on a weekly basis without priming dosing strategy. No dose-limiting toxicity and no clinical or laboratory evidence of hemolytic anemia were observed throughout.
- Lemzoparlimab PK appears to be linear at mid to high dose levels following a single dose with no significant "sink effect".
- One confirmed Partial Response (PR) was observed in the 30 mg/kg monotherapy cohort (N=3). The patient had failed prior treatments with checkpoint inhibitors.

"We are very encouraged by the safety and tolerability data that have emerged from the phase 1 trial," said Jordan Berlin, M.D. from Vanderbilt University, the principal investigator of the trial. "It shows the promise of lemzoparlimab as a differentiated CD47 antibody for multiple cancers, and we look forward to advancing the development of lemzoparlimab for patients with advanced solid tumors and hematologic malignancies." Dr. Berlin will present the data during the virtual poster sessions on November 11, 2020 5:15-5:45 p.m. EST and November 13, 2020 4:40-5:10 p.m. EST.

Recruitment of patients for the dose escalation study of lemzoparlimab in combination with pembrolizumab or rituximab is ongoing. Additional information on the clinical trial (NCT03934814) is available on www.clinicaltrials.gov.

In September 2020, I-Mab and AbbVie entered into a global strategic partnership to develop and commercialize lemzoparlimab. Subject to pre-closing conditions, both companies will be collaborating to further advance the clinical development of lemzoparlimab for the treatment of multiple cancers globally and in China.

I-Mab Conference Call and Webcast Information

Investors and analysts are invited to join the conference call today at 8:30 a.m. ET using the following dial-in information:

United States: +1-888-346-8982
International: +1-412-902-4272
Mainland China: 400-120-1203
Hong Kong: 800-905-945
Conference ID: 10149942

A live webcast and an archived replay of the conference call can be accessed on the Company's investor relations website at <http://ir.i-mabbiopharma.com>.

A telephone replay will be available approximately two hours after the conclusion of the call by dialing +1-877-344-7529 (U.S.), 1-412-317-0088 (International). The conference ID number for the replay is 10149942. The replay will be available through November 16, 2020.

About CD47 and Lemzoparlimab

CD47 is a cell surface protein over-expressed in a wide variety of cancers and can act to protect tumors by delivering a "don't eat me" signal to otherwise tumor-engulfing macrophages. CD47 antibody blocks this signal and enables macrophages to attack tumor cells, making it a potentially promising cancer drug. However, development of CD47 antibody as a cancer therapy is hampered by its hematologic side effects, such as severe anemia, caused by natural binding of CD47 antibody to red blood cells. In a scientific breakthrough, scientists at I-Mab have discovered a unique CD47 antibody, lemzoparlimab, that works efficiently to target tumor cells while exerting minimal untoward effect on red blood cells, thus avoiding severe anemia.

Lemzoparlimab's hematologic safety advantage and superb anti-tumor activities have been demonstrated previously in a series of robust pre-clinical studies. The results of the phase 1 clinical trial have provided further, clinical validation of this differentiation in patients with cancer. I-Mab continues to advance a combination study of lemzoparlimab with Keytruda® for the treatment of solid tumors and with Rituxan® for the treatment of patients with lymphoma in the U.S., in addition to an ongoing clinical trial with patients with AML/MDS in China.

In September 2020, I-Mab and AbbVie entered into a global strategic partnership to develop and commercialize lemzoparlimab, including to design and conduct further clinical trials to evaluate lemzoparlimab in multiple cancers globally and in China. The collaboration is subject to certain pre-closing conditions.

About I-Mab

I-Mab (Nasdaq: IMAB) is a dynamic, global biotech company exclusively focused on discovery, development and soon 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-PoC (Proof-of-Concept) and Fast-to-Market development strategies through internal R&D and global partnerships. The Company is on track to transitioning from a clinical stage biotech company toward a fully integrated global biopharmaceutical company with cutting-edge R&D capabilities, world-class GMP manufacturing facility and commercial capability. I-Mab has offices in Beijing, Shanghai, Hangzhou, Hong Kong and Maryland, United States. For more information, please visit <http://ir.i-mabbiopharma.com> and follow I-Mab on [LinkedIn](#), [Twitter](#) and [WeChat](#).

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 lemzoparlimab (TJC4) phase 1 trial, the potential implications of clinical data for patients, and I-Mab's advancement of, and anticipated clinical development, regulatory milestones and commercialization of lemzoparlimab (TJC4). 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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