I-Mab Accelerates Clinical Development of Anti-CD47 Monoclonal Antibody Lemzoparlimab in the US and China

December 4, 2020

SHANGHAI and GAITHERSBURG, Md., Dec. 4, 2020 /PRNewswire/ -- I-Mab (the "Company") (Nasdaq: IMAB), a clinical stage biopharmaceutical company committed to the discovery, development and commercialization of novel or highly differentiated biologics, today announced the advancement of clinical development of the highly differentiated anti-CD47 monoclonal antibody lemzoparlimab (also known as TJC4) in the US and China, achieving milestones as planned. The Company is progressing its US combination trial (NCT03934814), studying lemzoparlimab in combination with Rituxan® and Keytruda® in dose expansion cohorts in non-Hodgkin lymphoma (NHL) and advanced solid tumors, respectively. The combination study with Rituxan® will enroll NHL patients from both the US and China. Topline results from this study are expected next year.

"The results from early investigational studies support the notion that lemzoparlimab is a differentiated CD47 antibody therapy for cancers that remains among the most common causes of death around the world," said Jordan Berlin, M.D. from Vanderbilt University, the principal investigator of the trial in the US. "As preclinical studies have suggested potential therapeutic effect when combined with other immuno-oncology drugs, we believe this warrants further study of the compound as a combination therapy."

I-Mab is also poised to advance lemzoparlimab into late-stage clinical development in China. It will soon complete its ongoing phase 1/2a dose escalation trial (NCT04202003) to assess lemzoparlimab as monotherapy for patients with relapsed/refractory acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) in China. The clinical results from this monotherapy dose escalation study will be presented at an appropriate scientific conference early next year.

Further, last week, China CDE accepted I-Mab's IND application to advance to a combination trial with azacitidine (AZA) in untreated AML or MDS. The open-label, multi-center combination trial will evaluate the safety, efficacy and tolerability of lemzoparlimab in combination with AZA in patients with newly diagnosed AML who are ineligible for intensive chemotherapy, or in patients with higher-risk MDS. The planned study builds upon the ongoing phase 1/2a monotherapy dose escalation trial and will potentially lead to a registrational study in China.

"It has been reported and demonstrated that AZA can lead to significant increase of the 'eat me' signals on cancer cells. The combination of lemzoparlimab, which blocks the CD47 'don't eat me' signals on tumor cells, with AZA can greatly enhance macrophage activity to offer a strong therapeutic effect in patients," said Prof. Jianxiang Wang, principal investigator in China and Director at the Institute of Hematology, China Academy of Medical Services. "There are limited treatments available currently for those patients suffering from AML and MDS."

I-Mab's global collaboration with AbbVie will facilitate global development of lemzoparlimab. In September, I-Mab and AbbVie entered into the partnership, subject to certain pre-closing conditions, to develop and commercialize lemzoparlimab, including design and conduct further clinical trials to evaluate lemzoparlimab globally including China. Both companies have jointly developed plans for the treatment of multiple cancers.

"Based on the strength of our data to-date, we have been able to rapidly advance the clinical development of lemzoparlimab. The progress we have made for our China and US trials, as well as our global partnership with AbbVie, has well positioned I-Mab to accelerate the clinical development towards a registrational trial and to be one step closer in benefiting cancer patients globally,"said Jingwu Zang, M.D., Ph.D., Founder, Honorary Chairman and Director of I-Mab.

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 a minimal untoward effect on red blood cells to avoid 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 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 solid tumors and with Rituxan® for lymphoma in the U.S., in addition to an on-going clinical trial in patients with AML 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 Acute Myeloid Leukemia (AML)

Acute Myeloid Leukaemia (AML) is a type of blood cancer that occurs due to the excessive production of myeloblasts, a specific type of white blood cell, in the bone marrow. Overall, AML is considered one of the most difficult-to-treat cancers, with poor survival rates (Oran, B., & Weisdorf, D. J., 2012). The five-year survival rate for patients diagnosed with AML remains approximately 29% (Institute, National Cancer, 2018).

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 1/2 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.

For more information, please contact:

I-Mab

Jielun Zhu, Chief Financial Officer
E-mail: jielun.zhu@i-mabbiopharma.com
Office line: +86 21 6057 8000

Gigi Feng, Chief Communications Officer
E-mail: gigi.feng@i-mabbiopharma.com
Office line: +86 21 6057 5785

Investor Inquiries:

Burns McClellan, Inc. (Americas and Europe)
Steve Klass
E-mail: sklass@burnsmc.com
Office line: +1 212 213 0006

The Piacente Group, Inc. (Asia)
Emilie Wu
E-mail: emilie@thepiacentegroup.com
Office line: + 86 21 6039 8363

View original content to download multimedia:http://www.prnewswire.com/news-releases/i-mab-accelerates-clinical-development-of-anti-cd47-monoclonal-antibody-lemzoparlimab-in-the-us-and-china-301186473.html

SOURCE I-Mab