I-Mab Presents Interim Clinical Data of Lemzoparlimab in Combination with Rituximab in Relapsed and Refractory Non-Hodgkin Lymphoma at ASH 2021

12月 14, 2021

- Positive clinical activity was observed in heavily pretreated patients who had progressed on prior Anti-CD20 therapies

SHANGHAI and GAITHERSBURG, Md., Dec. 14, 2021 /PRNewswire/ -- I-Mab (the "Company") (Nasdaq: IMAB), a clinical stage biopharmaceutical company committed to the discovery, development and commercialization of novel biologics, today reported interim data from an ongoing clinical trial (NCT03934814) of lemzoparlimab in combination with rituximab (Rituxan®) in heavily treated patients with relapsed or refractory non-Hodgkin's lymphoma (NHL), at the 63rd American Society of Hematology (ASH) Annual Meeting.

Lemzoparlimab is a novel CD47 antibody that blocks CD47 and SIRPα interaction through a epitope designed to confer red blood cell (RBC) sparing properties. In all clinical trials conducted so far, lemzoparlimab is administered without a priming dose.

"Lemzoparlimab's initial results show it appears to be safe and well-tolerated in combination with rituximab without the need of a priming dose," said Amitkumar Mehta, MD, Associate Professor and Director of the Lymphoma Program at the University of Alabama at Birmingham and O'Neal Comprehensive Cancer Center at UAB. "This data support further evaluation of lemzoparlimab in combination with rituximab, which is currently ongoing in study in patients with r/r DLBCL and indolent lymphoma."

The preliminary data was generated from nine patients with relapsed and refractory NHL who received at least two prior lines of therapies, with a median of four lines. Lemzoparlimab was safe and well-tolerated at doses of 20 mg/kg and 30 mg/kg weekly, without a priming dose. The maximum tolerated dose (MTD) was not reached. Most treatment-related adverse events (TRAE) were manageable infusion-related reactions (n=4). Among seven efficacy-evaluable patients, four achieved complete response (CR) [1 transformed FL-DLBCL +3 FL], one partial response (PR) of FL were observed (ORR=71%); two reported stable disease (SD); and the disease control rate (DCR) is 100%. Tumor shrinkage was observed in all evaluable patients. The median time to response was 50 days and response lasted from 61 to 236 days. A high level (80% and 90%) of intra-tumoral distribution measured by IHC of tumor biopsy was reached at 20 mg/kg and 30mg/kg weekly.

"We're encouraged by the interim results reported today. The clinical data of lemzoparlimab further builds our confidence for an innovative therapy that utilizes macrophages against tumors, said Dr. Joan Shen, Chief Executive Officer of I-Mab. "It is very exciting that lemzoparlimab is bringing new hopes to our patients, and we are accelerating its clinical development through international multi-center trials in the U.S. and China."

The ongoing study with 30 mg/kg lemzoparlimab weekly combined with rituximab is being expanded to enroll more patients with relapsed and refractory diffuse large B-cell lymphoma (DLBCL) or indolent lymphoma.

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. However, development of CD47 antibody as a cancer therapy has been hampered by its hematologic side effects, such as severe anemia, caused by natural binding of CD47 antibody to red blood cells. Scientists at I-Mab have discovered a novel CD47 antibody, lemzoparlimab, that is designed to target tumor cells while exerting a minimal untoward effect on red blood cells.

Multiple clinical studies are ongoing in both the U.S. and China to explore indications in treating both hematologic maliglencies and solid tumors. Lemzoparlimab is being studied in patients with myelodysplastic syndrome (MDS), acute myelocytic leukemia (AML), and advanced solid tumors in combination with chemotherapy and immune checkpoint inhibitors in the U.S. and China. Combined clinical results from these studies will potentially support registrational trials later in China.

In September 2020, I-Mab and AbbVie entered into a global strategic collaboration to develop and commercialize lemzoparlimab. This includes the design and conduct of further clinical trials to evaluate lemzoparlimab in multiple cancers through global and China-specific trials. AbbVie has assumed sponsorship of the U.S. study as of April 2021.

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 lemzoparlimab clinical studies, the potential implications of clinical data for patients, and I-Mab's advancement of, and anticipated clinical development, regulatory milestones, and commercialization of lemzoparlimab. 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

John Long, Chief Financial Officer
E-mail: john.long@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 5709

Investor Inquiries:

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

View original content to download multimedia:https://www.prnewswire.com/news-releases/i-mab-presents-interim-clinical-data-of-lemzoparlimab-in-combination-with-rituximab-in-relapsed-and-refractory-non-hodgkin-lymphoma-at-ash-2021-301443905.html

SOURCE I-Mab