I-Mab and ABL Bio Receive US FDA Approval to Initiate Phase 1 Trial of Bispecific Antibody TJ-CD4B/ABL111 in Patients with Advanced or Metastatic Solid Tumors

3月 30, 2021

SHANGHAI, China and GAITHERSBURG, Md., March 30, 2021 (GLOBE NEWSWIRE) -- I-Mab (the “Company”) (Nasdaq: IMAB), a clinical-stage biopharmaceutical company committed to the development of novel biologics, and ABL Bio, Inc. (Kosdaq:298380, hereafter “ABL”), a South Korean biotech specializing in bispecific antibody technology, jointly announced that the U.S. Food and Drug Administration (FDA) has approved the Investigational New Drug (IND) application for initiating phase 1 trial for bispecific antibody TJ-CD4B/ABL111. The phase 1 clinical trial will evaluate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of TJ-CD4B/ABL111 in advanced or metastatic solid tumors.

TJ-CD4B/ABL111 is a novel bispecific antibody that works through binding to a tumor antigen Claudin 18.2 (CLDN18.2) which is selectively expressed in several cancers and to 4-1BB, a co-stimulatory molecule expressed on T cells, to activate immune response within tumor for better anti-tumor activity. Preclinical studies demonstrate that TJ-CD4B/ABL111 has superior anti-tumor property as compared to the two monoclonal antibodies when acting alone or in combination. This superior anti-tumor activity is achieved locally on tumor site, thus minimizing the risk of liver and systemic side effects commonly associated with 4-1BB antibody when used alone.

"With its high specificity and novel properties, TJ-CD4B/ABL111 could have significant advantages over other 4-1BB monoclonal antibodies in terms of the efficacy and toxicities. It could become a key player against various advanced cancers. We are very excited about the initiation of the clinical study and hope to bring this highly valuable compound to the cancer patients with the critical unmet needs," said Dr. Taylor Guo, chief scientific officer of I-Mab.

"With the FDA approval of the IND application to initiate a phase 1 clinical trial of TJ-CD4B/ABL111, we expect to progress rapidly with the clinical development of TJ-CD4B/ABL111," said Dr. Sang Hoon Lee, Founder and CEO of ABL. "In partnership with I-Mab, we look forward to providing a superior therapeutic option for patients with advanced and metastatic solid cancers."

The phase 1 clinical study will be a multi-center, dose escalation study in the U.S. I-Mab also plans to conduct dose expansion studies for TJ-CD4B/ABL111 in patients with gastric cancers, gastro-esophageal junction adenocarcinoma, esophageal adenocarcinoma and pancreatic ductal adenocarcinoma in China later this year.

About TJ-CD4B/ABL111
TJ-CD4B, also known as 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 whilst silent elsewhere. TJ-CD4B 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 it avoids or minimizes liver toxicity and systemic immunotoxicity commonly seen with 4-1BB antibodies as a drug class. TJ-CD4B is being developed under collaboration between I-Mab and ABL.

About I-Mab

I-Mab (Nasdaq: IMAB) is an innovation-driven global biotech company focusing on discovery, development and soon commercialization of novel and highly differentiated biologics in immuno-oncology therapeutic area. The Company's mission is to bring transformational medicines to patients around the world through drug innovation. I-Mab's globally competitive pipeline of more than 15 clinical and pre-clinical stage drug candidates is driven by its internal R&D capability and global licensing partnerships, based on the Company's unique Fast-to-Proof-of-Concept and Fast-to-Market pipeline development strategies. The Company is now rapidly progressing from a clinical stage biotech company to a fully integrated global biopharmaceutical company with cutting-edge global R&D capabilities, a world-class GMP manufacturing facility and commercialization capability. I-Mab has established its global footprint in Shanghai (headquarters), Beijing, Hangzhou 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.

About ABL Bio

ABL Bio, Inc. (Kosdaq: 298380) is a South Korean biotechnology company developing antibody therapeutics for immuno-oncology and neurodegenerative diseases. With internal R&D and global partnerships, ABL has developed multiple BsAb platforms, such as ‘Grabody-T,’ ‘Grabody-I’ and ‘Grabody-B’ and built an innovative pipeline of multiple clinical and pre-clinical stage drug candidates. In the oncology area, we have developed Grabody-T, a modular 4-1BB engaging platform that has demonstrated superior efficacy and safety. In the neurodegenerative disorder space, we have developed Grabody-B platform, which is designed to maximize blood-brain barrier (BBB) penetration. Grabody-B is applicable to various CNS targets across a plethora of neurological disorders, potentially providing a breakthrough to address the high unmet medical needs in neurodegeneration. For more information, please visit www.ablbio.com

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 TJ-CD4B clinical trials, the potential implications of clinical data for patients, and the advancement by I-Mab and ABL, and anticipated clinical development, regulatory milestones and commercialization of TJ-CD4B. 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 the ability of I-Mab and ABL to demonstrate the safety and efficacy of TJ-CD4B; the clinical results for the drug candidate, 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 the drug candidate; the ability to achieve commercial success for the drug candidate, 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.

ABL Forward Looking Statements

Statements in this press release contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform act of 1995. Words such as "will," "could," "hope," "expect," "plan" and similar expressions that are based on ABL's current expectations and assumptions are subject to risks and uncertainties that are difficult to predict. The risks and uncertainties include but are not limited to, potential delays in clinical trial recruitment and participation; ABL and I-Mab's ability to demonstrate the safety and efficacy of ABL111; adverse results in the clinical development process; changes in expected or existing competition; changes in the biopharmaceutical landscape; ABL's ability to obtain and maintain protection of intellectual property for its technology and drugs; ABL's reliance on third parties to conduct drug development; the company's financial position; future decisions by the FDA or other regulatory authorities; volatile global economic conditions; and the impact of the global COVID-19 pandemic. The reader is cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements are based on information currently available to ABL and the company assumes no obligation to provide public updates to these forward-looking statements that are only as of the date of this press release, even if new information is available in the future.

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:

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

ABL Contacts
Jaecheon Jerry Lee
Chief Financial Officer
business.development@ablbio.com
+82 31 8018 9802

Investor Inquiries:

Hyunjun Kim
investor.relations@ablbio.com
+82 31 8018 9845