



I-Mab and ABL Bio Announce First Patient Dosed in Phase 1 Trial of Bispecific Antibody TJ-L14B/ABL503 in Patients with Advanced or Metastatic Solid Tumors

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SHANGHAI, China and GAITHERSBURG, Md. and SEONGNAM, South Korea, April 06, 2021 (GLOBE NEWSWIRE) -- I-Mab (the "Company") (Nasdaq: IMAB), a clinical-stage biopharmaceutical company committed to the discovery, development and commercialization of novel biologics, and ABL Bio, Inc. (Kosdaq:298380, hereafter "ABL"), a South Korean biotech specializing in bispecific antibody technology, jointly announced that the first patient has been dosed in a phase 1 trial for bispecific antibody TJ-L14B/ABL503. The phase 1 clinical trial is an open-label, multi-center, dose-escalation and dose-expansion study to evaluate the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD), preliminary antitumor activity, maximum tolerated dose (MTD) and/or recommended phase 2 dose (RP2D) of TJ-L14B/ABL503 in locally advanced or metastatic solid tumors (NCT04762641).

Being developed jointly with ABL, TJ-L14B/ABL503 is a differentiated PD-L1-based bispecific antibody with the PD-L1 arm as the tumor-dependent T-cell activator and the 4-1BB arm as the conditional T cell activator upon tumor engagement. Using ABL's 'Grabody-T' bispecific antibody platform technology, TJ-L14B/ABL503 stimulates 4-1BB activation only in the presence of PD-L1 expressing tumor cells to minimize the risk of off-tumor toxicity. Preclinical studies have demonstrated that the bispecific antibody shows better anti-tumor activity than equimolar doses of single agents alone or in combination.

"Immune checkpoint inhibitors, such as PD-L1, have created a new paradigm for cancer treatment; however, they have limitations in their efficacy and response rates," said Dr. Joan Shen, CEO of I-Mab. "Co-targeting of PD-L1 with a bispecific antibody molecule using this particular platform is postulated to enhance antitumor activity while ensuring the safety of the patients. It may provide an alternative therapeutic approach for patients who have not responded to existing treatments."

"We are very pleased to advance the clinical development of TJ-L14B/ABL503 as planned," said Dr. Sang Hoon Lee, CEO of ABL. "With phase 1 trial for TJ-L14B/ABL503 being the first testbed for our Grabody-T bispecific antibody platform, we look forward to validating our company's technology in the field of cancer immunotherapy."

"We are excited to be the first center to conduct this study for TJ-L14B/ABL503," said Dr. Anthony W. Tolcher, FRCPC, FACP, CEO and director of clinical research at NEXT Oncology. "TJ-L14B/ABL503 has demonstrated potential to overcome the adverse toxicity issues of anti-4-1BB antibodies. In collaboration with I-Mab and ABL, we hope for a thorough evaluation to deliver a highly promising treatment for the benefit of cancer patients." NEXT Oncology is a phase 1 center in the U.S. dedicated to providing patients with advance cancer access to the newest cancer treatments available.

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-mabbioharma.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-L14B 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-L14B. 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-L14B; 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 ABL503; 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.

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