



I-Mab Biopharma and TRACON Pharmaceuticals Announce Dosing of the First Patient in the U.S. Phase 1 Clinical Trial of the CD73 Antibody TJD5 in Patients with Advanced Solid Tumors

August 1, 2019

SHANGHAI, China and SAN DIEGO, Aug. 01, 2019 (GLOBE NEWSWIRE) -- I-Mab Biopharma (I-Mab), a China and U.S.-based clinical stage biopharmaceutical company exclusively focusing on the discovery and development of potential first-in-class and best-in-class biologics in immuno-oncology and autoimmune diseases, and TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, today jointly announced that TRACON has dosed the first patient in a U.S. Phase 1 first-in-human clinical trial of I-Mab's proprietary CD73 antibody TJD5, also known as TJ004309, in patients with advanced solid tumors (NCT identifier number: NCT03835949). TJD5 will be dosed in the Phase 1 trial both as a single agent and in combination with TECENTRIQ® (atezolizumab), a PD-L1 antibody marketed by Roche. I-Mab entered into a research collaboration with Roche in April 2019 where Roche agreed to supply TECENTRIQ® to I-Mab for use in clinical study in combination with TJD5.

The multicenter, open-label, dose escalation Phase 1 study will evaluate safety and tolerability of TJD5, and determine a recommended dose for further clinical studies of its efficacy and safety as a single agent and in combination with standard dose TECENTRIQ® in patients with advanced or metastatic cancer who are refractory to or intolerant of all available therapy.

TJD5, a novel, differentiated humanized antibody against CD73, is from I-Mab's proprietary discovery pipeline being co-developed through a corporate collaboration between TRACON and I-Mab signed in November 2018. The two companies have a second broader strategic partnership to develop up to five bispecific antibodies from I-Mab's immuno-oncology portfolio.

"TJD5 builds on earlier successes of I-Mab's proprietary innovative pipeline and is the third internally discovered drug candidate to enter clinical studies in the U.S. This clinical milestone is the result of our well-executed 'Fast-to-PoC (proof of concept) Global Approach' to advancing our proprietary innovative drug candidates towards clinical validation in the United States, and a testament to the productive strategic partnership with TRACON," said Joan Shen, M.D., Ph.D., Head of R&D of I-Mab. "Treatment resistance to PD-1/PD-L1 is one of the major challenges across cancer types. We hope the combination of TJD5 and TECENTRIQ® will provide a novel treatment option to address the unmet medical needs."

"Submitting the IND and dosing the initial cancer patient with TJD5 following the signing of our first partnership agreement with I-Mab is an important milestone, as we have both expanded our pipeline in immuno-oncology and further demonstrated TRACON's product development capabilities designed to reduce the cost and time of clinical development for our partners," commented Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "We will continue to work with I-Mab to optimize the clinical development of TJD5, an antibody with global best-in-class potential."

About TJD5 (TJ004309)

TJD5 is a novel, humanized antibody against CD73, an ecto-enzyme expressed on stromal cells and tumors that converts extracellular adenosine monophosphate (AMP) to adenosine, which is highly immunosuppressive. TJD5 is in a Phase 1 clinical trial in the US to assess the tolerability and preliminary efficacy as a single agent and in combination with TECENTRIQ®, a PD-L1 antibody marketed by Roche, in patients with advanced solid tumors. The antibody is also expected to be studied in clinical trials in China sponsored by I-Mab.

About I-Mab

I-Mab is a dynamic and fast-growing global biotech company focusing on developing innovative biologics drugs of first-in-class and best-in-class potential in the therapeutic areas of immuno-oncology and autoimmune diseases. I-Mab's pipeline of 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 capabilities and global partnerships. I-Mab's vision is to bring transformational medicines to patients through innovation. The company is on track to become an end-to-end fully integrated biopharma and is well-recognized by capital markets to have successfully raised approximately US\$ 330 million of cash in equity financing in the past three years. Its recent USD 220 million Series C financing represents one of the largest amounts ever raised by a biotech company in China. For more information, please visit the Company's website at www.i-mabbiopharma.com

About TRACON

TRACON develops targeted therapies for cancer and ophthalmic diseases. The Company's clinical-stage pipeline includes: DE-122, the ophthalmic formulation of carotuximab, an endoglin antibody that is being developed for patients with wet AMD through a license to Santen Pharmaceutical Company Ltd.; TRC102, a small molecule drug being developed for the treatment of lung cancer and glioblastoma; TRC253, a small molecule drug being developed for the treatment of prostate cancer; and TJ004309, a CD73 antibody being developed for the treatment of advanced solid tumors. TRACON is actively seeking additional corporate partnerships whereby it leads regulatory and clinical development and shares in the cost and risk of clinical development and U.S. commercialization of new product candidates. In these partnerships TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the US. To learn more about TRACON and its product candidates, visit TRACON's website at www.traconpharma.com.

Forward-Looking Statements

Statements made in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding TRACON's and I-Mab's plans to further develop product candidates, expectations regarding the timing of regulatory submissions and clinical trials, expected development milestones, and potential utility of product candidates. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: risks associated with clinical development; whether TRACON or others will be able to complete or initiate clinical trials on TRACON's expected timelines, if at all; the fact that future preclinical studies and clinical trials may not be successful or otherwise consistent with results from prior studies; the fact that TRACON's collaboration agreements are subject to early termination; whether additional product candidates are selected to be developed under TRACON's and I-Mab's collaboration; potential changes in regulatory requirements in the US and foreign countries; TRACON's reliance on third parties for the development of its product candidates, including the conduct of its clinical trials and manufacture of its product candidates; whether TRACON will be able to obtain additional financing; and other risks described in TRACON's filings with the Securities and Exchange Commission under the heading "Risk Factors". All forward -looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. TRACON undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

I-Mab Company Contact:

Raven Lin
VP of Corporate Development
raven.lin@i-mabbiopharma.com

I-Mab Investor Contact:

Jielun Zhu
CFO
jielun.zhu@i-mabbiopharma.com

I-Mab Media Contact:

Amanda Dai
Associate Director of Public Relations
Zhenhua.dai@i-mabbiopharma.com

TRACON Company Contact:

Mark Wiggins
Chief Business Officer
(858) 550-0780 ext. 236
mwiggins@traconpharma.com

TRACON Investor Contact:

Andrew McDonald
LifeSci Advisors LLC
646-597-6987
Andrew@lifesciadvisors.com



Source: TRACON Pharmaceuticals, Inc.