TRACON Pharmaceuticals Announces Submission of IND Application for TJ4309 (CD73 Antibody TJD5) for Treatment of Advanced Solid Tumors

December 26, 2018

SAN DIEGO, Dec. 26, 2018 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, today announced that TRACON has submitted an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for the initiation of a Phase 1 clinical study of TJ4309 in patients with advanced solid tumors.

TJ4309, also known as TJD5, is a CD73 antibody from I-Mab's proprietary discovery pipeline that is being co-developed through an agreement between TRACON and I-Mab that was signed on November 28, 2018. The agreement between the two companies is part of a broad strategic partnership to develop multiple immuno-oncology programs with first-in-class and best-in-class potential from I-Mab's immuno-oncology portfolio, including several proprietary bispecific antibodies under development by I-Mab.

"The IND filing for TJ4309 within four weeks of signing the strategic partnership agreement with I-Mab is an important milestone for TRACON in two ways," commented Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "We have both expanded our pipeline into immuno-oncology and further demonstrated the efficiency of our product development platform designed to reduce the cost and time of clinical development for our partners. We look forward to initiating this Phase 1 clinical trial in early 2019."

About TJ4309

TJ4309, also known as TJD5, is a novel, humanized antibody against CD73, highly expressed on various cancer cells that converts extracellular adenosine monophosphate (AMP) to adenosine, leading to the formation of immunosuppressive tumor microenvironment. TJD5 is expected to start a phase I clinical trial in the US in early 2019 to assess the tolerability and preliminary efficacy as a single agent and in combination with a PD-1/PD-L1 checkpoint inhibitor in patients with advanced solid tumors. The antibody is also expected to be studied in clinical trials in China sponsored by I-Mab.

About TRACON

TRACON develops targeted therapies for cancer and ophthalmic diseases. The Company's clinical-stage pipeline includes: TRC105, an endoglin antibody that is being developed for the treatment of multiple cancers; DE-122, the ophthalmic formulation of TRC105 that is being developed in wet AMD through a collaboration with Santen Pharmaceutical Company Ltd.; TRC102, a small molecule being developed for the treatment of lung cancer and glioblastoma; and TRC253, a small molecule being developed for the treatment of prostate cancer. 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 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 United States. 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, potential benefits of the collaborations between TRACON and I-Mab, 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; risks that the FDA does not allow the IND for TJ4309; 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 United States 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.

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