TRACON Announces May 8 Date for Type B Teleconference Meeting with FDA to Discuss Trial Design for ENVASARC: A Potential Pivotal Study of Envafolimab in Sarcoma

April 6, 2020

SAN DIEGO, April 06, 2020 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer and utilizing a product development platform to partner with ex-U.S. companies to develop and commercialize innovative products in the U.S., announced today that the U.S. Food and Drug Administration (FDA) has granted TRACON a Type B Teleconference to take place on May 8, 2020 to discuss the trial design for a potential pivotal study of envafolimab in sarcoma (ENVASARC).

Expected Envafolimab Milestones Over the Next 6 Months

- Type B teleconference meeting with the FDA on May 8 to discuss the potential pivotal trial design of ENVASARC for envafolimab in sarcoma
- Apply for orphan drug designation for envafolimab in soft tissue sarcoma
- File IND for envafolimab to conduct the planned ENVASARC study
- Submission of marketing application for envafolimab in China by our corporate partners, 3D Medicine and Alphamab Oncology
- Presentation of envafolimab clinical data at ASCO by our corporate partners 3D Medicine and Alphamab Oncology
- Enroll the first patient in ENVASARC, a potential pivotal trial of envafolimab in the U.S.

About Envafolimab

Envafolimab is a novel, single-domain antibody against PD-L1 that is administered by subcutaneous injection without the need for an adjuvant. Envafolimab is currently being dosed in Phase 1 trials in the U.S., China and Japan, a Phase 2 registration trial as a single agent in MSI-H tumor patients in China, and in a Phase 3 registration trial in biliary tract cancer in combination with gemcitabine and oxaliplatin in China. Subject to positive data from the MSI-H registrational trial, 3D Medicines has stated that it plans to file a BLA in China for envafolimab in 2020 based on overall response rate in MSI-H patients. The filing is predicated on the principle that the response rate required for approval in China is similar to the response rate for Keytruda and Opdivo in MSI-H patients from separate clinical trials per the product package inserts.

About TRACON

TRACON develops targeted therapies for cancer utilizing a capital efficient product development platform. The Company's clinical-stage pipeline includes: Envafolimab, a subcutaneous PD-L1 single-domain antibody being developed for the treatment of sarcoma; TRC102, a small molecule drug being developed for the treatment of lung cancer; 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 leads U.S. commercialization. In these partnerships TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the U.S. 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 plans to further develop envafolimab, expectations regarding the timing and scope of clinical trials, including ENVASARC, and availability and announcement of clinical data, expected development and regulatory milestones and timing thereof, anticipated meetings with the FDA and results therefrom, potential utility of product candidates, and TRACON’s business development strategy and goals. 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 expected timelines, if at all; potential guidance from the FDA regarding ENVASARC that is inconsistent with TRACON’s expectations; 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 has limited control over whether or when third party collaborators complete on-going trials, initiate additional trials or seek regulatory approval of product candidates; the fact that TRACON’s collaboration agreements are subject to early termination; whether TRACON will be able to enter into additional collaboration agreements on favorable terms or at all; 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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