TRACON Pharmaceuticals Announces Successful Type B Meeting with FDA for Pivotal Study of Envafolimab in Sarcoma

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Company Reaches Agreement with Regulatory Agency on Key Elements of ENVASARC Trial

Pivotal Trial Expected to Begin in Second Half of 2020

SAN DIEGO, May 11, 2020 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted cancer therapeutics and utilizing a cost efficient, CRO-independent product development platform to partner with ex-U.S. companies to develop and commercialize innovative products in the U.S., today announced the successful completion of a Type B pre-IND meeting with the U.S. Food and Drug Administration (FDA). The FDA agreed with TRACON's proposals regarding key elements of the pivotal ENVASARC trial for envafolimab in the soft tissue sarcoma subtypes of undifferentiated pleomorphic sarcoma (UPS) and myxofibrosarcoma (MFS). TRACON expects to initiate enrollment in the ENVASARC trial in the second half of 2020.

"We appreciate the valuable discussions and guidance from our Type B meeting discussion with the FDA and concurrence on the design for the pivotal trials of envafolimab in sarcoma," said Charles Theuer, M.D., Ph.D., President and CEO. "Following the successful completion of the regulatory meeting**,** we are focused on advancing envafolimab as a single agent and in combination with Yervoy (ipilimumab) for the treatment of the sarcoma subtypes of UPS and MFS, both of which have been shown to be responsive to immune checkpoint inhibition treatment. We look forward to initiating ENVASARC later this year."

Type B Meeting and ENVASARC Study Design

The FDA determined the acceptability of the following key aspects of the proposed pivotal trial:

- Multi-center, open-label, randomized, non-comparative, parallel cohort study.
- Planned total enrollment of 160 patients, with 80 patients enrolled into cohort A of treatment with single agent envafolimab and 80 patients enrolled in cohort B with envafolimab and Yervoy.
- Primary endpoint of objective response rate (ORR) with duration of response a key secondary endpoint.
- Open-label format with blinded independent central review of endpoint data.
- Eligible patients will have received one prior cancer therapy, but no prior checkpoint inhibitor therapy.

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 dosing in Phase 1 trials in the U.S. and Japan and is being studied in China in a Phase 2 registration trial as a single agent in MSI-H tumor patients, and in a Phase 3 registration trial in combination with gemcitabine and oxaliplatin in biliary tract cancer. Subject to positive data from the MSI-H registrational trial, 3D Medicines, TRACON's corporate partner for this program, plans to file a BLA in China for envafolimab in 2020 based on ORR in MSI-H patients. The filing would be based on the principle that the response rate required for approval in China is similar to the response rate seen with Keytruda and Opdivo in MSI-H patients from separate clinical trials per their U.S. product package inserts.

About TRACON

TRACON develops targeted therapies for cancer utilizing a capital efficient, CRO independent, 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 with the goal of starting a registrational trial in the U.S. in the second half of 2020; TRC253, a small molecule drug candidate for the treatment of prostate cancer; TRC102, a small molecule drug candidate being developed for the treatment of lung cancer; and TJ004309, a CD73 antibody in Phase 1 development for the treatment of advanced solid tumors. TRACON is actively seeking additional corporate partnerships whereby it leads U.S. 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 pipeline, 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 product candidates, expectations regarding the timing and scope of clinical trials and availability of clinical data, expected

development and regulatory milestones and timing thereof, and TRACON's business development strategy and goals to enter into additional collaborations. 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, including due to risks associated with the COVID-19 pandemic or other pandemics; 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 or initiates additional trials of TRACON's 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.

Company Contact:
Mark Wiggins
Chief Business Officer
(858) 251-3492
mwiggins@traconpharma.com

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

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