



TRACON Pharmaceuticals Announces Results of Second Independent Data Monitoring Committee Review of Safety Data from ENVASARC Pivotal Trial

August 9, 2021

- Trial to Continue as Planned

SAN DIEGO, Aug. 09, 2021 (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 that the Independent Data Monitoring Committee for the ENVASARC pivotal trial has recommended that the trial proceed as planned following the review of 12 week safety data from more than 20 patients enrolled into the trial as of May 2021. The safety data reviewed included data from more than 10 patients enrolled into cohort A of treatment with single agent envafolelimab and more than 10 patients enrolled into cohort B of treatment with envafolelimab and Yervoy (ipilimumab).

"Envafolelimab continues to be well tolerated as a single agent and when combined with Yervoy in refractory sarcoma patients who are enrolled in the ENVASARC trial. We remain on track for the Independent Data Monitoring Committee to review interim efficacy data in the fourth quarter of this year," said James Freddo, M.D., TRACON's Chief Medical Officer.

About Envafolelimab

Envafolelimab (KN035), a novel, single-domain antibody against PD-L1, is the first subcutaneously injected PD-(L)1 inhibitor to be studied in pivotal trials. Envafolelimab is currently being studied in the ENVASARC Phase 2 pivotal trial in the U.S. sponsored by TRACON, has been studied in a completed Phase 2 pivotal trial as a single agent in MSI-H/dMMR advanced solid tumor patients in China and is being studied in an ongoing Phase 3 pivotal trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China, with both Chinese trials sponsored by 3D Medicines. TRACON's partners Alphamab Oncology and 3D Medicines submitted an NDA to the NMPA in China for envafolelimab in MSI-H/dMMR cancer that was accepted for review in December 2020 and granted priority review in January 2021. In the Phase 2 MSI-H/dMMR advanced solid tumor trial, the confirmed objective response rate (ORR) by blinded independent central review in MSI-H/dMMR colorectal cancer (CRC) patients treated with envafolelimab who failed a fluoropyrimidine, oxaliplatin and irinotecan was 32%, which was similar to the 28% confirmed ORR reported in the Opdivo package insert in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin, and irinotecan and the 33% confirmed ORR reported for Keytruda in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin and irinotecan in cohort A of the KEYNOTE-164 clinical trial.

About ENVASARC (NCT04480502)

The ENVASARC pivotal trial is a multicenter, open label, randomized, non-comparative, parallel cohort study at approximately 25 top cancer centers in the United States that began dosing in December 2020. TRACON expects the trial to enroll 160 patients with UPS or MFS who have progressed following one or two lines of prior treatment and have not received an immune checkpoint inhibitor, with 80 patients enrolled into cohort A of treatment with single agent envafolelimab and 80 patients enrolled into cohort B of treatment with envafolelimab and Yervoy. The primary endpoint is ORR by blinded independent central review with duration of response a key secondary endpoint.

About TRACON

TRACON develops targeted therapies for cancer utilizing a capital efficient, CRO independent, product development platform. The Company's clinical-stage pipeline includes: Envafolelimab, a PD-L1 single-domain antibody given by rapid subcutaneous injection that is being studied in the pivotal ENVASARC trial for sarcoma; TRC102, a Phase 2 small molecule drug candidate 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, availability of clinical data and future reviews of data by the Independent Data Monitoring Committee, expected development and regulatory milestones and timing thereof, the potential benefits of product candidates, 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 clinical results may not be consistent with preliminary results or 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 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:

Brian Ritchie

LifeSci Advisors LLC

(212) 915-2578

britchie@lifesciadvisors.com



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