TRACON Pharmaceuticals Provides Positive Update on Ongoing ENVASARC Pivotal Phase 2 Trial

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Objective Response Rate by investigator review increased to 15% since interim analysis in September

Full ENVASARC enrollment expected in 1Q 2024 and final data anticipated during 3Q 2024

SAN DIEGO, Dec. 20, 2023 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (NASDAQ: TCON), a clinical stage biopharmaceutical company utilizing a cost-efficient, CRO-independent product development platform to advance its pipeline of novel targeted cancer therapeutics and to partner with other life science companies, today announced that the ongoing pivotal Phase 2 ENVASARC trial has enrolled more than 70 of the 80 planned patients in Cohort C of single agent envafolimab treatment at a dose of 600 mg subQ every three weeks.

Additional safety and efficacy data were reviewed for 46 patients enrolled into cohort C who were the subject of the September independent data monitoring committee (IDMC) review. At that time, patients had completed a minimum of 12 weeks of efficacy evaluations and the objective response rate (ORR) was 13% by investigator review and 8.7% by blinded independent central review (BICR). Since then, an additional patient has achieved an objective response by investigator review, which increased the ORR by investigator review to 15%. The most recent objective response has not yet been confirmed by BICR and the patient remains on treatment. Median duration of response by BICR remains greater than six months. In addition, envafolimab remains well tolerated and grade $\geq$ 3 related toxicity has not been reported to date.

"We continue to believe that these data position envafolimab to become a potentially compelling treatment option for patients with the refractory sarcoma subtypes of UPS and MFS based on the ORR and tolerability data to date," said Charles Theuer, M.D., Ph.D., TRACON's Chief Executive Officer. "ENVASARC enrollment continues to be brisk, reflecting the high unmet need that exists for these patients."

Updated safety and efficacy data are expected in 1Q 2024, including in the more than 20 patients enrolled following the September IDMC review who will have had a minimum of 12 weeks of efficacy evaluations (two CT scans) at that time.

The primary endpoint of the ENVASARC study is achievement of an ORR in nine of 80 patients (11.25%) treated with envafolimab by BICR and median duration of response of greater than six months is a key secondary endpoint.

About Envafolimab

Envafolimab (KN035), a single-domain antibody against PD-L1 invented by Alphamab Oncology and licensed by TRACON, is the first approved subcutaneously injected PD-(L)1 inhibitor. Envafolimab was approved by the Chinese NMPA in November 2021 in adult patients with MSI-H/dMMR advanced solid tumors who failed systemic treatment and have no satisfactory alternative treatment options. In December 2019, Alphamab Oncology, 3D Medicines and TRACON entered into a collaboration whereby TRACON has the right to develop and commercialize envafolimab in soft tissue sarcoma in North America. Envafolimab is currently being studied in the ENVASARC Phase 2 pivotal trial in the United States sponsored by TRACON and a Phase 3 pivotal trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China sponsored by TRACON's corporate partners, Alphamab Oncology and 3D Medicines. TRACON has received orphan drug designation from the U.S. Food and Drug Administration (FDA) for envafolimab for patients with soft tissue sarcoma and fast track designation from the FDA for envafolimab for patients with locally advanced, unresectable or metastatic undifferentiated pleomorphic sarcoma (UPS) and myxofibrosarcoma (MFS) who have progressed on one or two prior lines of chemotherapy.

About ENVASARC (NCT04480502)

The ENVASARC Phase 2 pivotal trial is a multicenter, open label, randomized, non-comparative, parallel cohort study at 30 top cancer centers in the United States and the United Kingdom that began dosing in December 2020. ENVASARC is enrolling patients with UPS or MFS who have progressed following one or two lines of prior treatment and have not received an immune checkpoint inhibitor. In Cohort C, a total of 80 patients will receive treatment with single agent envafolimab at 600 mg every three weeks. The primary endpoint is objective response rate by central review with duration of response a key secondary endpoint.

About TRACON

TRACON is a clinical-stage biopharmaceutical company utilizing a cost-efficient, CRO-independent, product development platform to advance its pipeline of novel targeted cancer therapeutics and to partner with other life science companies. The Company's clinical-stage pipeline includes: Envafolimab, a PD-L1 single-domain antibody given by rapid subcutaneous injection that is being studied in the pivotal ENVASARC trial for sarcoma; YH001, a potential best-in-class CTLA-4 antibody in Phase 1 development; and TRC102, a Phase 2 small molecule drug candidate for the treatment of lung cancer. TRACON is actively seeking additional corporate partnerships through a profit-share or revenue-share partnership, or through franchising TRACON's product development platform. TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the United States or who wish to become CRO-independent. 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 expectations for the timing and scope of its ENVASARC Phase 2 pivotal trial as well as TRACON's expectation for achievement of expected endpoints and goals, the availability and expected results of clinical data and the timing of future reviews of data by BICR, continued timely accrual in the ENVASARC Phase 2 pivotal trial, and the potential for envafolimab to become a treatment option. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: risks associated with clinical development and regulatory approval of pharmaceutical product candidates, including that the ENVASARC Phase 2 pivotal trial may not achieve its primary and secondary endpoints; risks relating to cost

variability of clinical trials; whether other therapies are developed and compete with TRACON's product candidates; whether TRACON or others will be able to complete (including the ENVASARC Phase 2 pivotal trial) or initiate clinical trials on TRACON's expected timelines, if at all, including due to risks associated with clinical, macroeconomic and geopolitical events; 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 on favorable terms or at all; 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 except as required by law.

Company Contact:
Charles Theuer
Chief Executive Officer
(858) 550-0780
ctheuer@traconpharma.com

Investor Contact:
Brian Ritchie
LifeSci Advisors LLC
(212) 915-2578
britchie@lifesciadvisors.com