TRACON Pharmaceuticals Announces ENVASARC Phase 2 Pivotal Trial Exceeded Futility Threshold at Final Interim Analysis and Will Continue as Planned

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Full ENVASARC accrual expected in Q4 and final data expected in mid-2024

SAN DIEGO, Sept. 18, 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 ENVASARC Phase 2 pivotal trial more than satisfied the futility threshold of 3 responses out of 46 based on the results of the second and final mandated independent data monitoring committee (IDMC) efficacy review, and the trial will continue as planned.

The IDMC reviewed interim safety and efficacy data from 46 patients enrolled into cohort C of treatment with single agent envafolimab who completed two on-treatment scans (a minimum of 12 weeks of efficacy evaluations). The objective response rate (ORR) in the initial 46 patients treated with single agent envafolimab was 13% by investigator review and 8.7% by blinded independent central review (BICR). The ORR assessed by BICR, all of which were confirmed responses, more than satisfied the prespecified futility rule and envafolimab monotherapy was generally well tolerated. Median duration of response by BICR was greater than six months. The primary endpoint of the 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.

“Envafolimab continues to demonstrate durable single agent activity and has been generally well tolerated,” said James Freddo, M.D., TRACON’s Chief Medical Officer. “Our goal is the demonstration of nine objective responses by BICR in the 80 patient cohort of single agent envafolimab treatment.”

“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.

The trial has enrolled more than 60 of the planned 80 patients and full accrual of the ENVASARC pivotal trial is expected in the fourth quarter of this year with final data anticipated in mid-2024.

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 for envafolimab for patients with soft tissue sarcoma and fast track designation from the U.S. Food and Drug Administration for envafolimab (KN035) 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 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. 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 timely achievement of expected endpoints and goals, the availability and expected results of clinical data and the timing of future reviews of data by the IDMC and 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.

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