TRACON Pharmaceuticals Announces Dosing of 36th Patient in ENVASARC Pivotal Trial Triggering Initial IDMC Efficacy Review Expected in the Fourth Quarter

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SAN DIEGO, July 26, 2022 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals, Inc. (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 the enrollment of the 36th patient in the ENVASARC pivotal trial at the 600 mg dose of envafolimab, which enables the initial independent data monitoring committee (IDMC) interim efficacy analysis to proceed. The interim analysis is expected to occur in the fourth quarter of this year.

The initial IDMC interim efficacy analysis proceeds after the 36th patient has been enrolled for at least three months to permit two on study scans to determine the preliminary objective response rate. One objective response is required in each of the trial's two cohorts to continue accrual in that cohort. The first cohort includes the initial 18 patients who receive single agent envafolimab and the second cohort includes 18 patients who receive envafolimab with ipilimumab. A second IDMC interim efficacy analysis is expected in 2023 following enrollment of the 92nd patient.

"We are pleased at the pace of enrollment in ENVASARC and have accrued more than 36 patients in fewer than six months since the FDA approved the amended protocol. As a result, we are currently ahead of the enrollment projection that would allow for full accrual of the 160 planned patients dosed with 600 mg of envafolimab before the end of 2023," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "We look forward to reporting the IDMC recommendations following the two interim safety analyses and interim efficacy analysis expected this year."

About Envafolimab

Envafolimab (KN035), a single-domain antibody against PD-L1 invented by Alphamab Oncology, 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 pivotal ENVASARC Phase 2 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.

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. TRACON expects the trial to enroll more than 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 a cohort of treatment with single agent envafolimab at 600 mg every three weeks and 80 patients enrolled into a cohort of treatment with envafolimab at 600 mg every three weeks with Yervoy. 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; 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 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 regarding the timing and results of the first and second IDMC interim efficacy analyses, the occurrence of TRACON's discussions with the FDA and the prerequisites to have that discussion and enrollment in the ENVASARC trial. 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 novel pharmaceutical product candidates; 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 and the ongoing conflict between Ukraine and Russia; the fact that future preclinical studies, clinical trials and their IDMC interim analyses may not yield positive results or be 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 initiate 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 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.

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