TRACON Pharmaceuticals Announces FDA Approval of Amended ENVASARC Protocol

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Patient dosing underway, interim efficacy data on track for second half 2022

SAN DIEGO, March 10, 2022 (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 United States, today announced that the first patient has been dosed following the approval of the amended ENVASARC protocol by the U.S. Food and Drug Administration ("FDA").

In December 2021, based on the highly tolerable safety profile and the significantly higher objective response rate (ORR) observed in lower weight patients in ENVASARC, the IDMC recommended increasing the dose of envafolimab to 600 mg every three weeks (Q3W), which is double the original envafolimab dose of 300 mg Q3W. Given the robust activity demonstrated by higher doses of envafolimab in previously completed studies, including in the pivotal trial in MSI-H/dMMR cancer that was the basis for approval of envafolimab in China, TRACON submitted the amended ENVASARC protocol in January that was cleared by the FDA in February. Patient dosing is now underway at this 600 mg Q3W dose.

"We are pleased to have initiated envafolimab dosing at 600 mg following FDA approval of the amended ENVASARC protocol," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "Given the ENVASARC data to date, particularly the highly tolerable safety profile and response rate in lower weight patients, we believe a doubling of the dose will be well tolerated and result in higher envafolimab exposures, thereby optimizing envafolimab's efficacy for the largest number of sarcoma patients. The new envafolimab dose is higher than the dose that produced the 45% ORR in MSI-H/dMMR cancer that was the basis for approval in China. We look forward to the interim ENVASARC efficacy data review by the IDMC which we expect will occur in the second half of 2022."

About Envafolimab

Envafolimab (KN035), a single-domain antibody against PD-L1 invented by Alphamab Oncology, is the first subcutaneously injected PD-(L)1 inhibitor 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 approximately 25 top cancer centers in the United States 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 overall response rate by 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: 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 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 United States. 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 doubling of the dose of envafolimab to be administered and the resulting envafolimab exposures; timely receipt of the efficacy data review by the IDMC; TRACON's and its collaboration partners' plans to further develop product candidates; expectations regarding the timing and scope of clinical trials and availability of clinical data; expected development, regulatory and commercial milestones and timing thereof; potential utility 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 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; 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 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.

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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