TRACON Pharmaceuticals Announces Dosing of First Patient in ENVASARC Pivotal Trial

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Company Expects Interim Data in Mid-2021

SAN DIEGO, Dec. 10, 2020 (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 dosing of the first patient in the ENVASARC registration trial.

“We are pleased to initiate dosing in the ENVASARC registration trial of envafolimab in sarcoma,” said Sant Chawla, M.D., Director of the Sarcoma Oncology Center, Santa Monica. “Immunotherapy has radically changed the treatment paradigm for a number of cancers, and we believe envafolimab has the potential to do the same for sarcoma patients who have few treatment options.”

“Dosing the first patient in the ENVASARC registration trial within one year of executing the license to envafolimab fulfills our 2020 expectations for what has been a productive year of clinical development and regulatory interactions for our lead product candidate,” said Charles Theuer, M.D., Ph.D., President and Chief Executive Officer of TRACON. “We look forward to the availability of interim top-line data from this important study, which we expect in mid-2021.”

About ENVASARC (NCT 04480502)

Key elements of the ENVASARC registration trial include:

- Multi-center, open-label, randomized, non-comparative, parallel cohort study at approximately 25 top cancer centers in the United States.
- Eligible patients will have undifferentiated pleomorphic sarcoma (UPS) or myxofibrosarcoma (MFS) and received one or two prior cancer therapies, but no prior immune checkpoint inhibitor therapy.
- Planned total enrollment of 160 patients, with 80 patients enrolled into cohort A of treatment with single agent envafolimab and 80 patients enrolled in cohort B of treatment with envafolimab and Yervoy®.
- Primary endpoint of objective response rate (ORR) with duration of response a key secondary endpoint.
- Open-label format with blinded independent central review of efficacy endpoint data.

About Envafolimab

Envafolimab (KN035), a novel, single-domain antibody against PD-L1, is the first subcutaneously injected PD-(L)1 inhibitor to be studied in registration trials. Envafolimab is currently being studied in the ENVASARC Phase 2 registration trial in the U.S. sponsored by TRACON, as well as in a Phase 2 registration trial as a single agent in MSI-H/dMMR advanced solid tumor patients and a Phase 3 registration 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. Alphamab Oncology and 3D Medicines submitted an NDA to the NMPA in China for envafolimab in MSI-H/dMMR cancer in November 2020. In the Phase 2 registration trial, the confirmed objective response rate (ORR) by blinded independent central review in MSI-H/dMMR colorectal cancer (CRC) patients treated with envafolimab 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 KEYNOTE-164.

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 subcutaneous PD-L1 single-domain antibody being developed in a registration trial for the treatment of certain sarcomas; TRC253, a small molecule drug candidate for the treatment of prostate cancer; TRC102, a Phase 2 small molecule drug candidate being developed for the treatment of lung cancer and glioblastoma; 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 and availability of clinical data, 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 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, 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.

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