TRACON Pharmaceuticals Announces FDA Clearance of ENVASARC Pivotal Trial

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Dosing in Pivotal Trial Expected to Begin in Fourth Quarter of 2020 in the U.S.

SAN DIEGO, Aug. 17, 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 the clearance of the pivotal ENVASARC protocol after filing the protocol with the U.S. Food and Drug Administration (FDA) as part of an Investigational New Drug (IND) application on July 15. The application cross referenced the open envafolimab IND maintained by TRACON's corporate partners 3D Medicines and Alphamab Oncology. TRACON expects to initiate enrollment in the ENVASARC trial at 25 sites in the U.S. in the fourth quarter of 2020.

"We are pleased to receive clearance from the FDA to initiate the pivotal ENVASARC trial of envafolimab in sarcoma and look forward to dosing the first patient in the fourth quarter of this year," said James Freddo, M.D., Chief Medical Officer of TRACON. "Immunotherapy has radically changed the treatment paradigm for a number of cancers and our hope is envafolimab will do the same for sarcoma patients who have few treatment options."

ENVASARC Study Design

Key elements for the ENVASARC pivotal 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 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 registrational trials. Envafolimab is currently dosing 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. 3D Medicines and Alphamab Oncology, TRACON's corporate partners for this program, plan to submit a BLA to NMPA in China for envafolimab in 2020 based on the ORR in MSI-H/dMMR advanced solid tumor patients. The confirmed ORR in MSI-H/dMMR colorectal cancer patients treated with envafolimab who failed a fluoropyrimidine, oxaliplatin and irinotecan reported at ASCO 2020 was 28.2%, which was nearly identical to the 28% confirmed ORR reported in the Opdivo package insert in MSI-H/dMMR colorectal cancer patients who failed a fluoropyrimidine, oxaliplatin, and irinotecan and the 27.9% 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 for the treatment of sarcoma with the goal of initiating a registrational trial in the U.S. in the fourth quarter of 2020; TRC253, a Phase 3 ready small molecule drug candidate for the treatment of prostate cancer; TRC102, a Phase 2 small molecule drug candidate in development for the treatment of lung cancer; and TJ004309, a Phase 1 CD73 antibody in 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, 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.

Company Contact:
Mark Wiggins
Chief Business Officer
(858) 251-3492
mwiggins@traconpharma.com

Investor Contact:
Andrew McDonald
LifeSci Advisors LLC
646-597-6987
Andrew@lifesciadvisors.com

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