TRACON Pharmaceuticals Announces Appointment of Brenda Marczi, PharmD, as Senior Vice President, Regulatory Affairs, and Granting of Inducement Award

July 20, 2021

SAN DIEGO, July 20, 2021 (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., announced today the appointment of Brenda Marczi, PharmD, as Senior Vice President, Regulatory Affairs, and the granting of an inducement equity award to Dr. Marczi.

"We are very pleased to welcome Brenda to the senior management team at TRACON," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "Her vast regulatory affairs experience working with the FDA will be instrumental to TRACON as we execute on our plan to complete the ENVASARC trial."

Dr. Marczi brings more than three decades of regulatory affairs experience to TRACON. Dr. Marczi's past roles include Vice President, Regulatory Affairs at Ferring Pharmaceuticals where she was responsible for all U.S. regulatory activities, including the launch and commercialization activities for the breakthrough designation gene therapy product for non-muscle invasive bladder cancer. Dr. Marczi also held senior roles at Eagle Pharmaceuticals and Berlex (now Bayer AG), where she oversaw the filing of multiple successful New Drug Applications.

"I am thrilled to join the impressive team at TRACON during such a pivotal time in the Company's development of envafolimab. I look forward to helping the Company achieve its goal of commercializing novel oncology therapies," said Dr. Marczi.

In connection with the appointment of Dr. Marczi as Sr. Vice President, Regulatory Affairs, Dr. Marczi was issued an inducement award consisting of an option to purchase an aggregate of 60,000 shares of the Company's common stock. The option was granted in accordance with Nasdaq Listing Rule 5635(c)(4) under the TRACON Pharmaceuticals, Inc. Amended and Restated 2015 Equity Incentive Plan (the "2015 Plan") and was approved by TRACON's Compensation Committee. The option has an exercise price per share equal to $4.90, which was the closing price of TRACON's common stock on the Nasdaq Capital Market on the date of grant. The option vests over four years, with 25% of the option shares vesting on the first anniversary of the date of grant and the remaining 75% of the option shares vesting in monthly installments over the three years thereafter. The option has a 10-year term, and is subject to the terms and conditions of the 2015 Plan and applicable stock option agreement.

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 pivotal trials. Envafolimab is currently being studied in the ENVASARC Phase 2 pivotal trial in the U.S. sponsored by TRACON, has been studied in a completed Phase 2 pivotal trial as a single agent in MSI-H/dMMR advanced solid tumor patients in China and is being studied in an ongoing Phase 3 pivotal trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China, with both Chinese trials 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 that was accepted for review in December 2020 and granted priority review in January 2021.

About ENVASARC (NCT04480502)

The ENVASARC pivotal trial is a multi-center, 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 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 cohort A of treatment with single agent envafolimab and 80 patients enrolled in cohort B of treatment with envafolimab and Yervoy. The primary endpoint is ORR by blinded independent 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; 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 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 and seek regulatory approval for product candidates, expected development and regulatory milestones, 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 clinical results may not be consistent with preliminary results or results from prior studies; 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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Source: TRACON Pharmaceuticals, Inc.