TRACON Pharmaceuticals Announces Appointment of Dongliang Zhuang, Ph.D. as Vice President of Statistics and Biometrics

May 3, 2021

SAN DIEGO, May 03, 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 Dongliang Zhuang, Ph.D. as Vice President of Statistics and Biometrics.

“We are very pleased to welcome Dongliang to the TRACON senior management team,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “His strong experience at the U.S. FDA and on BLA submissions at biopharmaceutical companies will be invaluable to TRACON as we execute on our plan to complete the ENVASARC trial and begin activities expected to culminate in a BLA for envafolimab based on ENVASARC data.”

Dr. Zhuang brings more than two decades of broad statistical experience to TRACON. Following his time at the U.S. FDA, he served as the Head of Biostatistics and Programming at multiple biopharmaceutical companies. At Amylin, he was the project statistician for the development of the company’s leading diabetic product Bydureon including the pivotal trial that was the basis for FDA approval, and lead statistician for Byetta where he oversaw studies that supported the successful Byetta New Drug Application.

“TRACON has a first-class management team, the efficient Product Development Platform of CRO-independent research to conduct global clinical trials, and a promising drug candidate with near-term commercial potential in envafolimab,” said Dr. Zhuang. “I am thrilled to support TRACON’s mission and oversee statistics and biometrics within its broad oncology pipeline, which has the potential to address significant unmet needs across multiple tumor types.”

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 3D Medicines. TRACON’s partners 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. In the Phase 2 MSI-H/dMMR advanced solid tumor 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 the KEYNOTE-164 clinical trial.

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; TRC253, a Phase 3 ready small molecule drug candidate for the treatment of prostate cancer; 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 product candidates, expectations regarding the timing and scope of clinical trials, expected development and regulatory milestones and timing thereof, potential utility of product candidates, and TRACON's business development and commercialization strategy and goals. 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 expected timelines, if at all; potential guidance from the FDA regarding clinical development plans that is inconsistent with TRACON's expectations; 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's collaboration agreements are subject to early termination; whether or when envafolimab receives regulatory approval in the United States or is successfully commercialized; 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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Source: TRACON Pharmaceuticals, Inc.