TRACON Pharmaceuticals Announces Initiation of Randomized Phase 2 Trial of TRC102 in Lung Cancer Sponsored by the National Cancer Institute

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SAN DIEGO, Feb. 02, 2022 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (NASDAQ: TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted cancer therapeutics today announced that the National Cancer Institute (NCI) has initiated a randomized Phase 2 trial of TRC102 in combination with chemoradiation in patients with stage III non-squamous non-small cell lung cancer (NCT05198830: https://clinicaltrials.gov/ct2/show/NCT05198830?term=TRC102&draw=2&rank=3).

The open-label two arm trial will enroll 78 patients and assess the benefit of adding TRC102 to current standard of care treatment of pemetrexed, cisplatin, and radiation therapy followed by consolidative durvalumab. The primary endpoint of the trial is progression free survival (PFS) and the trial is designed to detect an improvement in PFS at one year from 56% to 75%. Enrollment is expected to begin in June 2022 and results are expected in 2024.

“We are pleased by the continued support of the National Cancer Institute for the development of TRC102 through our Cooperative Research and Development Agreement (CRADA), including sponsorship of the initial randomized trial of TRC102,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "The initiation of a randomized clinical trial of TRC102 marks an important milestone for the program.”

The randomized trial builds upon positive data from a Phase 1 trial of TRC102 in combination with chemoradiation presented at ASCO 2020 that demonstrated a 100% response rate in 15 patients with Stage IIIA or Stage IV non-squamous non-small cell lung cancer, including three patients who had a complete response to treatment. These data compared favorably to historical data of the same combination of chemoradiation without TRC102 in advanced lung cancer from the PROCLAIM and the PACIFIC clinical trials.

About TRC102

TRC102 (methoxyamine) is a novel, small molecule inhibitor of the DNA base excision repair pathway, which is a pathway that causes resistance to alkylating and antimetabolite chemotherapeutics. TRC102 is currently being studied in multiple Phase 1 and Phase 2 clinical trials sponsored by the National Cancer Institute through a Cooperative Research and Development Agreement (CRADA) and has orphan drug designation from the U.S. FDA in malignant glioma, including glioblastoma.

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 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 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 products; 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; 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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