# TRACON Pharmaceuticals Presents Positive Top-line Clinical Data from Dose Escalation Portion of Phase 1 Trial of TRC105 and Opdivo® for Treatment of Non-Small Cell Lung Cancer

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SAN DIEGO, Dec. 26, 2018 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration and fibrotic diseases, today announced positive top-line clinical results from a Phase 1 study of TRC105 and Opdivo® (nivolumab) for the treatment of non-small cell lung cancer.

In this Phase 1b trial, patients with refractory metastatic non-small cell lung cancer were enrolled regardless of baseline PD-L1 tumor expression. Patients were treated with 8 mg/kg or 10 mg/kg of TRC105 weekly for four doses and then 15 mg/kg every two weeks, in combination with the approved dose of Opdivo of 240 mg every two weeks. Best response was assessed by immune RECIST 1.1.

The combination of TRC105 and Opdivo was well-tolerated without the development of dose limiting toxicity in six patients who were treated as part of dose escalation. One of these six patients, whose archival tumor did not express PD-L1 and who had not received prior PD-1/PD-L1 checkpoint inhibition treatment, developed a partial response and remains on study after 10 months. Two of the other five patients, one of whom who progressed following prior Opdivo treatment, remain on trial with stable disease. Patients are currently enrolling into two parallel 12 patient expansion cohorts, one that includes patients who have relapsed following prior PD-1/PD-L1 checkpoint inhibition treatment and one that consists of patients who have not received prior PD-1/PD-L1 checkpoint inhibition treatment.

“We initiated this Phase 1 trial based on the potentiation of PD-1 checkpoint inhibition observed with TRC105 in pre-clinical models. We are pleased that TRC105 was well-tolerated with Opdivo, and with the early evidence of activity seen in the study,” said Charles Theuer, M.D. Ph.D., President and CEO of TRACON. “We expect to present data from the expansion cohorts in mid-2019.”

Further details of the dose escalation portion of the study will be presented at the International Association for the Study of Lung Cancer (IASLC) annual meeting in February 2019 in Santa Monica, CA, by Dr. Francisco Robert of the University of Alabama, Birmingham.

**About Carotuximab (TRC105)**

TRC105 is a novel, clinical stage antibody to endoglin, a protein overexpressed on proliferating endothelial cells that is essential for angiogenesis, the process of new blood vessel formation. TRC105 is currently being studied in a pivotal Phase 3 trial in angiosarcoma and multiple Phase 2 clinical trials, in combination with VEGF inhibitors, as well as in a Phase 1 trial with Opdivo. TRC105 has received orphan designation for the treatment of soft tissue sarcoma in both the U.S. and EU. The ophthalmic formulation of TRC105, DE-122, is currently in a randomized Phase 2 trial for patients with wet AMD. For more information about the clinical trials, please visit TRACON’s website at www.traconpharma.com/clinical_trials.php.

**About TRACON**

TRACON develops targeted therapies for cancer and ophthalmic diseases. The Company’s clinical-stage pipeline includes: TRC105, an endoglin antibody that is being developed for the treatment of multiple cancers; DE-122, the ophthalmic formulation of TRC105 that is being developed in wet AMD through a collaboration with Santen Pharmaceutical Company Ltd.; TRC102, a small molecule being developed for the treatment of lung cancer and glioblastoma; and TRC253, a small molecule being developed for the treatment of prostate cancer. TRACON is actively seeking additional corporate partnerships whereby it leads regulatory and clinical development and shares in the cost and risk of clinical development and commercialization of new product candidates. In these partnerships TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the United States. To learn more about TRACON and its product candidates, 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 its product candidates, expectations regarding the timing and scope of clinical trials and availability of clinical data, expected development milestones, and potential utility of TRACON’s product candidates. 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; 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; 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; the possibility of unexpected expenses or other uses of TRACON's cash resources; 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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