



## **TRACON Pharmaceuticals Presents New Circulating Tumor Cell Data from Ongoing Pivotal Phase 3 TAPPAS Trial of TRC105 and Votrient® in Patients with Angiosarcoma**

November 15, 2018

### **Changes in Endoglin Expressing Circulating Tumor Cells (CTC) Detected in Phase 3 TAPPAS Trial**

#### **Changes in CTC count may be useful as a prognostic biomarker and baseline CTC may be useful as a predictive biomarker**

SAN DIEGO, Nov. 15, 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 presented new data from the Company's ongoing Phase 3 TAPPAS study of TRC105 and Votrient® (pazopanib) in patients with angiosarcoma at the Connective Tissue Oncology Society (CTOS) annual meeting, taking place in Rome, Italy.

In a poster presentation entitled, "Detection of Endoglin-Expressing Circulating Tumor Cells in Patients Enrolled in An Adaptive Enrichment Phase 3 Trial of TRC105 And Pazopanib versus Pazopanib alone in Patients with Advanced AngioSarcoma (TAPPAS)," circulating tumor cell data were presented from patients enrolled into the TAPPAS Phase 3 trial. Endoglin expressing nucleated CTCs were detected using ApoStream technology (ApoCell, a Precision Medicine company).

Paired patient plasma samples taken at baseline and six weeks following treatment with either TRC105 and Votrient or single agent Votrient were analyzed in a blinded manner, without knowledge of treatment assignment. Endoglin+ CTCs decreased overall after 6 weeks of study treatment (baseline mean = 66/ml; median = 1.38/ml; range 0 – 1172/ml versus 6 week mean = 1.30/ml; median = 1.38/ml; range 0 - 185/ml). Three key findings emerged in the blinded analysis:

- 18 of 51 patients (35%) had a greater than two-fold reduction in endoglin+ CTCs, including 13/51 patients (25%) with a greater than 10-fold reduction.
- 19 of 51 patients (37%) had a greater than two-fold increase in endoglin+ CTCs, including 13/51 patients (25%) with a greater than 10-fold increase.
- 14 of 51 patients (27%) had no significant change in endoglin+ CTCs, all but one of whom had fewer than four endoglin+ CTCs per mL detected at baseline.

"The CTC analysis done as part of the TAPPAS Phase 3 trial has been robust and we have seen differences in CTC count following treatment which will be unblinded and correlated with treatment arm in the final analysis. Change in CTC count on study may be useful as a prognostic biomarker, and baseline CTC count may be useful as a predictive biomarker," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "In the meantime, we look forward to the Phase 3 TAPPAS trial interim analysis expected in the first quarter of 2019."

The poster is available on TRACON's website at [www.traconpharma.com](http://www.traconpharma.com)

#### **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](http://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 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](http://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 and of CTC counts as a biomarker. 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; whether any potential biomarker measurements will ultimately correlate to clinical efficacy; 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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Source: TRACON Pharmaceuticals, Inc.