



## **TRACON Pharmaceuticals Announces First Patient Dosed in Phase 3 TAPPAS Trial of TRC105 in Angiosarcoma**

*Trial Being Conducted under Special Protocol Assessment (SPA) with the FDA*

**San Diego, CA – February 16, 2017** – 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 (AMD) and fibrotic diseases, announced today that it has initiated patient dosing in its Phase 3 TAPPAS (TRC105 And Pazopanib versus Pazopanib alone in patients with advanced AngioSarcoma) trial of TRC105.

“Angiosarcoma is an aggressive cancer with limited therapeutic options, and we are excited to begin this randomized Phase 3 clinical trial of TRC105 as a potential therapy for patients with this disease,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “TRC105 has orphan drug designation for soft tissue sarcoma in the U.S. and the EU, and the first patient dosed represents the culmination of TRACON’s extensive work with regulators in both regions to design a robust Phase 3 trial. We are encouraged by the activity seen to date in the ongoing Phase 2 trial of TRC105 in combination with Votrient®, and look forward to providing further updates as the TAPPAS trial progresses.”

### **About the Phase 3 TAPPAS Study**

TRACON is conducting the Phase 3 TAPPAS trial (a randomized Phase 3 trial of TRC105 And Pazopanib versus Pazopanib alone in patients with advanced AngioSarcoma) under Special Protocol Assessment (SPA) with the FDA at sites in the U.S. and Europe. This one-to-one randomized trial of TRC105 in combination with Votrient (pazopanib) versus single agent Votrient features an adaptive enrichment design that allows for greater flexibility and efficiency to identify potential signs of clinical benefit. The trial has an initial enrollment target of 124 patients and, based on an interim analysis, allows for sample size re-estimation up to a maximum of 200 patients, as well as enrichment of potentially more responsive patients with cutaneous angiosarcoma. The primary endpoint is progression-free survival, with overall survival as a secondary endpoint.

Further details of the study are available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) under NCT02979899.

### **About 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 multiple Phase 2 clinical trials sponsored by TRACON or the National Cancer Institute (NCI) for the treatment of solid tumors in combination with VEGF inhibitors. 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 Phase 1/2 trial for patients with wet AMD. TRC205, a second generation antibody to endoglin, is undergoing preclinical testing in models of fibrosis.



## About Angiosarcoma

Angiosarcoma is an aggressive form of soft tissue sarcoma (STS) of endothelial cell origin that is associated with poor prognosis. Angiosarcoma has a 5-year survival rate of less than 12%, which highlights the aggressive nature of this tumor when compared to a 5-year survival rate of approximately 56% for all STS. Angiosarcoma can arise in any soft tissue structure. About half of patients present with a primary cutaneous lesion. Although resection with curative intent followed by adjuvant radiotherapy is the treatment of choice for localized disease amenable to surgery, approximately 50% of these patients will develop metastases and die from the disease. Furthermore, metastases are frequently present at diagnosis, and resection of metastases is rarely feasible.

Angiosarcoma is an extremely rare disease and meets the definition for an orphan disease in the U.S. and EU, the two regions in which the Phase 3 TAPPAS study is being conducted. The annual incidence of angiosarcoma in the U.S. was reported by the NCI in 2015 to be 475 cases. In the EU the incidence of angiosarcoma is 0.01 per 10,000, accounting for an estimated 508 cases annually.

## About TRACON

TRACON develops targeted therapies for cancer, ophthalmic and fibrotic 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.; and TRC102, a small molecule that is being developed for the treatment of lung cancer and glioblastoma. 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 the potential benefits that may be derived from the SPA, the design of the Phase 3 TAPPAS trial and TRC105, TRACON's plans to further develop its product candidates and expectations regarding the initiation, design and timing of future clinical trials by TRACON or third parties. 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; whether TRACON will realize expected benefits from the SPA or the design of the Phase 3 TAPPAS trial; the fact that the SPA does not guarantee regulatory approval, even if the Phase 3 trial meets the agreed-upon endpoints; the fact that future preclinical studies and clinical trials may not be successful or otherwise consistent with 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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