



TRACON's TRC105 Receives FDA Fast Track Designation

San Diego, CA – May 14, 2015 – TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, age-related macular degeneration and fibrotic diseases, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the development of TRC105 in patients with advanced renal cell carcinoma (RCC) that have progressed following treatment with one inhibitor of the VEGF pathway in combination with standard dose Inlyta® (axitinib).

“We are pleased to receive fast track designation for TRC105 for the treatment of patients with advanced renal cell carcinoma,” said Charles P. Theuer, MD, PhD, President and CEO of TRACON. “Angiogenesis drives tumor growth in renal cell carcinoma and despite multiple products approved to treat the disease, resistance to treatments remains a serious challenge. We remain encouraged by data presented at GU ASCO indicating the combination of TRC105 with Inlyta was well tolerated and demonstrated signs of activity in patients who progressed on prior VEGF inhibitors, including Sutent® (sunitinib) and Votrient® (pazopanib), as well as immune checkpoint inhibitor treatment.”

The FDA created the Fast Track designation process to facilitate the development and expedite the review of drugs to treat serious diseases and address unmet medical needs. Fast Track designation confers important benefits, including the potential eligibility for Priority Review of a New Drug Application, if relevant criteria are met.

TRACON is sponsoring a multicenter, open-label, randomized clinical trial of **TRC105** in combination with **AXitinib** in patients with **Advanced or metastatic RCC (TRAXAR)**. The primary endpoint of the Phase 2b study is progression-free survival. Approximately 150 patients with clear cell RCC who have failed one prior VEGF inhibitor are expected to enroll in the study. Patients may have also failed one prior mTOR inhibitor and one prior immunotherapy. For additional information on this clinical trial, please visit www.clinicaltrials.gov, identifier NCT01806064.

About Advanced Renal Cell Carcinoma

The American Cancer Society's 2015 statistics cite kidney cancer as among the top ten most commonly diagnosed forms of cancer among both men and women in the United States.¹ Clear cell RCC is the most common type of kidney cancer in adults.² If detected in its early stages, the five-year survival rate for RCC is high; however, the five-year survival rate for patients with advanced or late-stage metastatic RCC is under 10 percent, with no identified cure for the disease.³

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 clinical trials sponsored by both TRACON and the National Cancer Institute for the treatment of multiple solid tumor types in combination with VEGF inhibitors. TRC105 is also being



developed in combination with VEGF inhibitor treatments in age-related macular degeneration. For more information about the clinical trials, please visit TRACON's website at http://www.traconpharma.com/clinical_trials.php.

About TRACON

TRACON develops targeted therapies for cancer, age-related macular degeneration and fibrotic diseases. TRACON's current pipeline includes two clinical stage product candidates: TRC105, an anti-endoglin antibody that is being developed for the treatment of renal cell carcinoma, soft tissue sarcoma, hepatocellular carcinoma, glioblastoma and choriocarcinoma, 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.

¹Cancer Facts & Figures 2015. American Cancer Society. Available at <http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-044552.pdf>

²American Cancer Society, 2014. Available at <http://www.cancer.org/acs/groups/cid/documents/webcontent/003107-pdf.pdf>

³<http://www.cancer.org/cancer/kidneycancer/detailedguide/kidney-cancer-adult-survival-rates>

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