



TRACON Pharmaceuticals Announces Positive Phase 1b Results for TRC105 in Combination with Inlyta® (axitinib) at the American Society of Clinical Oncology (ASCO) 2015 Genitourinary Cancers Symposium

*Objective response rate was 29% (5 of 17) in patients with metastatic renal cell carcinoma
Additional 59% (10 of 17) of patients achieved stable disease
Randomized Phase 2b study of TRC105 is now enrolling*

San Diego, CA – February 28, 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, today reported positive results from a Phase 1b clinical trial combining TRC105 with Inlyta® (axitinib) in patients with advanced or metastatic renal cell carcinoma (RCC). Data were presented at the American Society of Clinical Oncology (ASCO) 2015 Genitourinary Cancers Symposium being held in Orlando, Florida.

In the open-label dose escalation and expansion Phase 1b study, eligible patients had received at least one prior line of therapy with a VEGF receptor tyrosine kinase inhibitor (VEGFR TKI) and most received three or more prior therapies. All patients were treated with the combination of TRC105 and axitinib. The objective response rate was 29% (5 of 17 evaluable patients) and an additional 10 patients achieved stable disease, according to RECIST 1.1. Median progression-free survival (PFS) for all patients in the study was 8.4 months, while median PFS for the subset of clear cell RCC patients was 11.3 months. For comparison, the objective response rate seen in the large subgroup of VEGFR TKI-refractory patients treated with axitinib (n=194) in the axitinib AXIS Phase 3 study in second line clear cell RCC patients (a separate trial) was 11.3% and median PFS was 4.8 months. The Phase 1b study is now complete and the randomized Phase 2b study combining TRC105 with axitinib is now enrolling patients.

“These Phase 1b data of the combination of TRC105 and axitinib are encouraging and further support targeting endoglin and VEGF simultaneously to improve outcomes in patients with metastatic renal cell carcinoma,” said Charles Theuer, M.D., Ph.D, President and CEO of TRACON. “The addition of TRC105 may provide meaningful improvement in response rate, and most importantly, progression-free survival as compared to treatment with axitinib alone. We look forward to definitive data from the Phase 2b study, which is a randomized study comparing the combination of TRC105 with axitinib to treatment with axitinib alone in patients with advanced or metastatic renal cell carcinoma.”

The following key additional data from the study were presented at the meeting:

- The recommended Phase 2 dose of TRC105 was well-tolerated with axitinib and no dose-limiting toxicities were observed. The most common adverse events were low grade epistaxis, headache, fatigue, diarrhea, nausea and gingival bleeding.
- Common adverse reactions expected with axitinib treatment as a single agent such as diarrhea, hypertension, palmar-plantar erythrodysesthesia and proteinuria did not increase in frequency or severity when combined with TRC105.



- In these previously treated advanced RCC patients, the objective response rate by RECIST 1.1 was 29% (5 of 17), the stable disease rate was 59% (10 of 17) and the overall disease control rate was 88% (15 of 17).
- Additional information for the five patients with partial responses by RECIST 1.1 is shown below:
 - One fourth line patient received previous treatment with high dose IL-2, pazopanib and an immune checkpoint inhibitor. This patient's best response to their last line of treatment was stable disease for 3.7 months. This patient received treatment with TRC105 in combination with axitinib for 14.2 months.
 - One fourth line patient received previous treatment with sunitinib and two lines of everolimus treatment. This patient's best response to their last line of treatment was stable disease for 34.5 months. This patient received treatment with TRC105 in combination with axitinib and remains on treatment for 11 months to date.
 - One fourth line patient received previous treatment with sunitinib, pazopanib and an immune checkpoint inhibitor. This patient's best response to their last line of treatment was stable disease for 7.5 months. This patient received treatment with TRC105 in combination with axitinib for 11.4 months.
 - One second line patient received previous treatment with sunitinib. This patient's best response to their last line of treatment was progressive disease after 5.8 months. This patient received treatment with TRC105 in combination with axitinib and remains on treatment for 10.1 months to date.
 - One fourth line patient received previous treatment with temsirolimus, sunitinib and pazopanib. This patient's best response to their last line of treatment was progressive disease after 3.5 months. This patient received treatment with TRC105 in combination with axitinib and remains on treatment for 9.1 months to date.

About the RCC Phase 2b Clinical Trial

The Phase 2b clinical trial is a multicenter, open-label, randomized clinical trial of TRC105 in combination with axitinib in patients with advanced or metastatic RCC. The primary endpoint of the Phase 2b study is progression-free survival. Approximately 150 patients who have failed one prior VEGF inhibitor are expected to be enrolled 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 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 multiple solid tumor types, and TRC102, a small molecule that is being developed for the treatment of lung cancer and glioblastoma. Both TRC105 and TRC102 are being developed for treatment in combination with currently available therapies. To learn more about TRACON and its product candidates, please visit TRACON's website at www.traconpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the design and expected parameters of the on-going Phase 2b study of TRC105 in combination with axitinib and the potential for TRC105 as a treatment for cancer or age-related macular degeneration. Forward-looking statements speak only as of the date of this press release and TRACON does not undertake any obligation to update or revise these statements, except as may be required by law. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and actual results may differ materially from those in these forward-looking statements as a result of various factors. These factors include, but are not limited to, risks regarding whether results of subsequent studies will be consistent with results of the Phase 1b study of TRC105 in combination with axitinib, TRACON's ability to identify and enroll patients in the on-going Phase 2b study, potential delays in completing the on-going Phase 2b study and whether TRC105 will be shown to be safe and effective in subsequent studies. For a further description of these and other risks facing TRACON, please see the risk factors described in TRACON's filings with the United States Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" in those filings. Forward-looking statements speak only as of the date of this press release and TRACON undertakes no obligation to update or revise these statements, except as may be required by law.

Contact:

Casey Logan

Chief Business Officer

(858) 550-0780 ext. 236

clogan@traconpharma.com