TRACON Pharmaceuticals Announces Completion of Enrollment in Randomized Phase 2b TRAXAR Study of TRC105 and Inlyta® in Renal Cell Carcinoma

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SAN DIEGO, Sept. 07, 2017 (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 that it has completed enrollment in the randomized Phase 2b TRAXAR study of TRC105 and Inlyta® (axitinib) in patients with advanced or metastatic renal cell carcinoma (RCC).

TRACON expects to report top-line progression-free survival (PFS) data from the study later this year, with the exact timing driven by the number of progression events or deaths (from any cause) that define PFS. The study is expected to yield between 80 and 110 events as confirmed by the study's independent central review committee at the time of data readout, which is expected to provide between 70% and 80% power to detect an improvement in PFS from 4.8 months with Inlyta to 7.2 months with the combination of TRC105 and Inlyta. PFS will also be assessed in patients with predefined levels of two soluble biomarkers that correlated with response in the Phase 1b portion of the trial, osteopontin and TGF-β receptor III.

"The completion of enrollment in the TRAXAR study represents an important step in the development of TRC105 and keeps us on track to deliver top-line data later this year," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "The TRAXAR study provides a strong example of the depth of the TRACON product development platform as we have efficiently conducted the study at more than 50 sites located in Europe and the United States."

About the TRAXAR Phase 2b Clinical Trial in RCC

The Phase 2b TRAXAR clinical trial is a multicenter, open-label, randomized clinical trial of TRC105 in combination with Inlyta versus Inlyta alone in patients with advanced or metastatic RCC. The primary endpoint of the Phase 2b study is progression-free survival and the trial enrolled 150 patients who failed one prior VEGF inhibitor 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(carotuximab)

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 one Phase 3 and multiple Phase 2 clinical trials sponsored by TRACON or the National Cancer Institute 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 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, 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.; TRC102, a small molecule that is being developed for the treatment of lung cancer and glioblastoma; and TRC253, a small molecule that is being developed for the treatment of prostate cancer. To learn more about TRACON and its product candidates, visit TRACON's website at www.traconpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the expected size and statistical power of, and availability of data from, the on-going Phase 2b study of TRC105 in combination with Inlyta. 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 will be consistent with results of the Phase 1b study of TRC105 in combination with Inlyta, 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.

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