TRACON Announces Publication in Cancer Cell of Clinical Data that Provides Molecular Insight into the Mechanism of Action of TRC102 and Patient Populations Most Likely to Respond to Treatment

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SAN DIEGO, Nov. 23, 2020 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted cancer therapeutics and utilizing a cost efficient, CRO-independent product development platform to partner with ex-U.S. companies to develop and commercialize innovative products in the U.S., today announced the publication of clinical data that provides molecular insight into TRC102's mechanism of action and patient populations most likely to respond to treatment. The article, entitled, *"Molecular Features of Cancers Exhibiting Exceptional Responses to Treatment,"* highlights the clinical features and tumor biology of an exceptional responder patient treated with TRC102 at the National Cancer Institute (NCI): https://www.traconpharma.com/wp-content/uploads/2020/11/Can_Cell_2020_Nov_Mol_Analysis_ER.pdf

The patient was diagnosed with metastatic and highly refractory colorectal cancer and received temozolomide (Temodar®) and TRC102. Following treatment, the patient was considered an exceptional responder through the achievement of a near compete response lasting 45 months at the most recent follow-up. Detailed molecular analyses of the patient's tumor showed silencing of DNA repair pathways that may have resulted in sensitivity to the inhibition of DNA base excision repair pathway by TRC102. Specifically, MGMT expression was silenced by promoter methylation, and RAD50, a mediator of DNA double strand break repair, was silenced by genetic mutation and loss of heterozygosity. The publication authors hypothesized that the combination of Temodar and TRC102 was effective because all necessary DNA repair pathways were compromised genetically or through the activity of TRC102. MGMT expression was also assessed in biopsies from 11 colorectal patients who subsequently enrolled in an expansion cohort, one of which demonstrated a partial response. The tumor associated with the partial response did not express MGMT, whereas each of the 10 tumors that did not respond to therapy expressed this enzyme robustly.

TRC102 is being studied in multiple Phase 1 and Phase 2 clinical trials sponsored by the NCI through a Cooperative Research and Development Agreement. TRC102 was also evaluated in a Phase 2 trial in combination with Temodar chemotherapy in 19 patients with progressive or recurrent glioblastoma who progressed following Temodar and external beam radiotherapy. Extended survival was observed in two patients for more than two years, both of whom demonstrated activation of the DNA base excision repair pathway and showed hyperactivation of DNA damage response genes prior to treatment with TRC102.

"The *Cancer Cell* publication supports our belief that patients whose cancers are dependent on the DNA base excision repair pathway to repair DNA damage from chemotherapy may be particularly sensitive to the pharmacologic effects of TRC102," said James Freddo, M.D., Chief Medical Officer of TRACON. "The NCI data are also consistent with the results from the Phase 2 trial of Temodar and TRC102 in refractory glioblastoma. We remain committed to developing TRC102 in collaboration with the NCI and believe that the data generated to date provide strong rationale for studying TRC102 in combination with Temodar and radiotherapy in newly diagnosed patients with malignant glioma."

About TRC102

TRC102 (methoxyamine) is a novel, clinical-stage small molecule inhibitor of the DNA base excision repair pathway, which is a pathway that causes resistance to alkylating and antimetabolite chemotherapeutics. TRC102 is currently being studied in multiple Phase 1 and Phase 2 clinical trials sponsored by the National Cancer Institute through a Cooperative Research and Development Agreement (CRADA). TRC102 was granted orphan drug designation by the US FDA for the treatment of malignant glioma in 2020. For more information about the clinical trials, please visit TRACON's website at www.traconpharma.com/clinical-trials.

About Malignant Glioma and GBM

GBM (also called glioblastoma) is a fast-growing malignant glioma that develops from star-shaped glial cells (astrocytes and oligodendrocytes) that support the health of the nerve cells within the brain. GBM is the most invasive type of glial tumors, rapidly growing and commonly spreading into nearby brain tissue. The National Cancer Institute estimates that approximately 22,850 adults (12,630 men and 10,280 women) are diagnosed with brain and other nervous system cancer annually in the U.S. and approximately 15,320 of these diagnoses will result in death. GBM has an incidence of two to three per 100,000 adults per year in the U.S., and accounts for 52 percent of all primary brain tumors.

About TRACON

TRACON develops targeted therapies for cancer utilizing a capital efficient, CRO independent, product development platform. The Company's clinical-stage pipeline includes: Envafolimab, a subcutaneous PD-L1 single-domain antibody being developed for the treatment of sarcoma in a registrational trial in the U.S.; TRC253, a Phase 3 ready small molecule drug candidate for the treatment of prostate cancer; TRC102, a Phase 2 small molecule drug candidate in development for the treatment of lung cancer and glioblastoma; and TJ004309, a Phase 1 CD73 antibody in development for the treatment of advanced solid tumors. TRACON is actively seeking additional corporate partnerships whereby it leads U.S. regulatory and clinical development and shares in the cost and risk of clinical development and leads U.S. commercialization. In these partnerships TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the U.S. To learn more about TRACON and its product pipeline, visit

TRACON's website at 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 and the National Cancer Institute’s plans to further develop product candidates, expectations regarding clinical trials, development and regulatory plans, the potential benefits of TRC102, and TRACON’s business development strategy and goals. 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, including due to risks associated with the COVID-19 pandemic or other pandemics; the fact that future preclinical studies and clinical trials may not be successful or otherwise consistent with results from prior studies; the fact that TRACON has limited control over whether or when third party collaborators complete on-going trials, initiate additional trials or seek regulatory approval of TRACON’s product candidates; the fact that TRACON’s collaboration agreements are subject to early termination; whether TRACON will be able to enter into additional collaboration agreements on favorable terms or at all; 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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