TRACON Pharmaceuticals Highlights Updated Envafolimab Results in MSI-H/dMMR Colorectal Cancer and Results from Clinical Trial of Opdivo and Yervoy Combination Therapy in Undifferentiated Pleomorphic Sarcoma Conducted by Alliance for Clinical Trials in Onc

May 29, 2020

Undifferentiated Pleomorphic Sarcoma is the Major Sarcoma Subtype to be Enrolled in TRACON's Pivotal ENVASARC Trial of Envafolimab as a Single Agent and in Combination with Yervoy

Pivotal ENVASARC Trial to Start in the Second Half of 2020

SAN DIEGO, May 29, 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 highlighted data from poster #11511 at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program, entitled, "Multicenter phase II study of nivolumab +/- ipilimumab for patients with metastatic sarcoma (Alliance A091401): Results of expansion cohorts." Investigators from the Alliance for Clinical Trials in Oncology (Alliance), a broad community of scientists and clinicians who are committed to the prevention and treatment of cancer, reported an impressive 29% confirmed objective response rate (ORR) in patients (n=14) with highly refractory Undifferentiated Pleomorphic Sarcoma (UPS) who received Opdivo in combination with Yervoy in a non-comparative randomized trial.

TRACON recently reported on the results of poster #3021 at ASCO 2020, entitled "Envafolimab (KN035) in Advanced Tumors with Mismatch-Repair Deficiency," which was presented by the Company's corporate partners, 3D Medicines and Alphamab Oncology, and showed that single agent envafolimab demonstrated a 30.0% confirmed ORR in 50 patients with MSI-H/dMMR colorectal cancer (CRC) who failed a fluoropyrimidine, oxaliplatin and irinotecan (n=39) or those with advanced gastric cancer who failed at least one prior systemic treatment (n=11), who had at least two on-study tumor assessments. The confirmed ORR in MSI-H/dMMR CRC patients treated with envafolimab who failed a fluoropyrimidine, oxaliplatin and irinotecan was 28.2%, which was nearly identical to the 28% confirmed ORR reported in the Opdivo package insert in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin and irinotecan.

"The previously reported non-comparative randomized Alliance clinical data indicated that Opdivo combined with Yervoy tripled the ORR in high grade sarcomas compared to single agent Opdivo (ORR of 16% versus 5%). These new data from expansion cohorts indicate that the combination of Opdivo and Yervoy demonstrated a higher ORR than Opdivo alone in UPS, of 29% in highly refractory disease. It has been shown that UPS is one of the sarcoma subtypes with the highest responses to checkpoint inhibitors to date and, given these encouraging combination therapy data, the upcoming ENVASARC pivotal trial is a potentially promising study for patients," said Sandra D'Angelo, M.D., Associated Attending at Memorial Sloan Kettering Cancer Center and lead investigator for the Alliance clinical trial.

"We believe these data bode well for the ENVASARC trial, which will assess the potential of envafolimab as a single agent and in combination with Yervoy in UPS that has progressed following one or two prior lines of treatment," said James Freddo, M.D., TRACON Chief Medical Officer. "Given the ASCO 2020 data indicating that envafolimab's activity is similar to that of Opdivo in MSI-H/dMMR cancer, but without infusion related reactions, we believe our trial's objective of targeting a 15% ORR in ENVASARC is achievable. Moreover, given the 4% ORR of Votrient, the only approved therapy for refractory UPS and myxofibrosarcoma (MFS), a sarcoma subtype genetically related to UPS that will also be included in ENVASARC, we believe envafolimab combined with Yervoy could provide a transformative new standard of care for sarcoma patients."

The complete envafolimab clinical trial poster is available at: https://meetinglibrary.asco.org/record/189156/poster

The complete Alliance clinical trial poster is available at: https://meetinglibrary.asco.org/record/186749/poster

About Envafolimab

Envafolimab is a novel, single-domain antibody against PD-L1 that is administered by subcutaneous injection without the need for an adjuvant. Envafolimab is currently dosing in Phase 1 trials in the U.S. and Japan and is being studied in China in a Phase 2 registration trial as a single agent in patients with MSI-H/dMMR cancer, and in combination with gemcitabine and oxaliplatin in a Phase 3 registration trial in biliary tract cancer. 3D Medicines and Alphamab Oncology plans to submit a BLA in China for envafolimab in 2020 based on overall response rate and duration of response in MSI-H/dMMR patients. The submission would be based on the data from the ongoing pivotal phase 2 trial of envafolimab in MSI-H/dMMR cancer.

About TRACON

TRACON develops targeted therapies for cancer utilizing a capital efficient 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 with the goal of starting a registrational trial in the U.S. in the second half of 2020; TRC253, a small molecule drug candidate being developed of the treatment of prostate

cancer; TRC102, a small molecule drug candidate being developed for the treatment of lung cancer; and TJ004309, a CD73 antibody in Phase 1 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 plans to further develop product candidates, expectations regarding the timing and scope of clinical trials, availability of clinical data and regulatory activities, expected development milestones and timing thereof, potential utility of product candidates, potential events, payments and actions under collaboration and license agreements, and TRACON’s business development strategy and goals to enter into additional collaborations. 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; 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 or initiate additional trials 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.

Company Contact:
Mark Wiggins
Chief Business Officer
(858) 251-3492
mwiggins@traconpharma.com

Investor Contact:
Andrew McDonald
LifeSci Advisors LLC
646-597-6987
Andrew@lifesciadvisors.com

Source: TRACON Pharmaceuticals, Inc.