TRACON Pharmaceuticals Announces Presentation of Positive Clinical Data for Envafolimab in MSI-H/dMMR Cancer at ASCO 2020 Virtual Scientific Program by its Corporate Partners 3D Medicines and Alphamab

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Envafolimab Demonstrated a 30% Confirmed Objective Response Rate (ORR) by RECIST by Independent Central Review in Patients with Advanced Refractory MSI-H/dMMR Colorectal and Gastric Cancer

ORR and Other Data will be Updated at ASCO

TRACON Expects to Initiate its Pivotal ENVASARC Trial of Envafolimab in Sarcoma in Second Half of 2020

SAN DIEGO, May 14, 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 that positive data from envafolimab in a pivotal trial in China for the treatment of MSI-H/dMMR cancer will be presented by the Company's corporate partners, 3D Medicines and Alphamab, at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program.

ASCO abstract #3021 entitled "Envafolimab (KN035) in Advanced Tumors with Mismatch-Repair Deficiency" reviewed data available on December 17, 2019 from the ongoing pivotal Phase 2 trial of envafolimab given by subcutaneous injection without an adjuvant in MSI-H/dMMR cancer. The trial enrolled 103 patients with MSI-H colorectal (CRC) or gastric cancer (GC) or with dMMR in other advanced solid tumors, in an open label format with efficacy endpoints, including the primary endpoint of confirmed objective response rate (ORR) determined by independent central review. MSI-H/dMMR status was assessed centrally for CRC and GC and locally for other tumors.

Key highlights included:

- The confirmed ORR in 50 patients with CRC who failed a fluoropyrimidine, oxaliplatin **and** irinotecan (n=39) plus those with advanced GC who failed at least one prior systemic treatment (n=11), with at least two on-study tumor assessments, was 30% (95% CI: 18%, 45%), of whom 80% were responding with median follow-up of 7.5 months at the time of the data cutoff.
- The confirmed ORR in the overall population (n=103) was 34% (95% CI: 25%, 44%), of whom 86% were responding with median follow-up of 6.7 months at the time of the data cutoff.
- The confirmed ORR in 24 patients with CRC who failed a fluoropyrimidine and oxaliplatin **or** irinotecan (n=24) was 54% (95% CI: 33%, 74%) of whom 85% were responding at the time of the data cutoff.
- Envafolimab was well tolerated with a safety profile similar to that of approved PD-(L)1 checkpoint inhibitors but without infusion related reactions.

"We are impressed by the confirmed ORR of envafolimab from its pivotal trial in Chinese patients with MSI-H/dMMR cancer, which is a genetically defined tumor type," said Charles Theuer, M.D., Ph.D., President and CEO. "We believe these data are important in assessing the potential of this novel subcutaneously administered product candidate in TRACON's initial indications in the U.S. of undifferentiated pleomorphic sarcoma (UPS) and myxofibrosarcoma (MFS), two soft tissue sarcoma subtypes which have responded to treatment with other checkpoint inhibitors. Moreover, these data indicate that envafolimab's activity in MSI-H cancer is similar to other checkpoint inhibitors, such as Keytruda or Opdivo but without infusion related reactions. We look forward to initiating our pivotal ENVASARC trial for envafolimab in UPS and MFS in the second half of 2020, for which we recently reached agreement on the key elements with the U.S. FDA."

The complete abstract is available at: https://meetinglibrary.asco.org/record/189156/abstract

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 MSI-H/dMMR tumor patients, and in combination with gemcitabine and oxaliplatin in a Phase 3 registration trial in biliary tract cancer. 3D Medicines plans to file a BLA in China for envafolimab in 2020 based on overall response rate and duration of response in MSI-H/dMMR patients. The filing would be based on the the ongoing pivotal phase 2 trial data 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.

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