TRACON Pharmaceuticals Announces Orphan Drug Designation for Envafolimab in Soft Tissue Sarcoma

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Application Included Clinical Trial Data from Soft Tissue Sarcoma Patients Treated with Envafolimab in Phase 1 Trials

SAN DIEGO, June 29, 2021 (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 the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to envafolimab, a novel, single-domain antibody against PD-L1, for the treatment of patients with soft tissue sarcoma following submission of an amended application that included Phase 1 clinical trial data from sarcoma patients treated with single agent envafolimab. Clinical trial data were submitted in response to an FDA request to provide data using envafolimab to treat patients with soft tissue sarcoma that demonstrated a therapeutic effect.

The Orphan Drug Designation submission for envafolimab in sarcoma included clinical data demonstrating confirmed objective partial responses by RECIST with duration of response in excess of six months, in two of five patients with refractory metastatic alveolar soft part sarcoma (ASPS) who received single agent envafolimab in Phase 1 clinical trials conducted by TRACON's partners 3D Medicines and Alphamab Oncology. Patients with undifferentiated pleomorphic sarcoma (UPS) or myxofibrosarcoma (MFS) were not treated as part of Phase 1 trials.

"The receipt of Orphan Drug Designation is one of multiple milestones we expect this year for envafolimab, including interim efficacy data from the pivotal ENVASARC trial in the second half of 2021," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "The 40% response rate demonstrated by envafolimab in ASPS patients is similar to the 42% response rate reported by the National Cancer Institute in ASPS patients treated with the PD-L1 antibody Tecentriq, which is consistent with data in MSI-H colorectal cancer, suggesting that subcutaneously administered envafolimab is as active as approved intravenously administered PD-1 antibodies."

Orphan Drug Designation is granted by the FDA to drugs or biologics intended to treat a rare disease or condition, defined as one that affects fewer than 200,000 people in the United States. Programs with Orphan Drug status receive partial tax credit for clinical trial expenditures, waived user fees and eligibility for seven years of marketing exclusivity.

About Envafolimab

Envafolimab (KN035), a novel, single-domain antibody against PD-L1, is the first subcutaneously injected PD-(L)1 inhibitor to be studied in pivotal trials. Envafolimab is currently being studied in the ENVASARC Phase 2 pivotal trial in the U.S. sponsored by TRACON, has been studied in a completed Phase 2 pivotal trial as a single agent in MSI-H/dMMR advanced solid tumor patients in China and is being studied in an ongoing Phase 3 pivotal trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China, with both Chinese trials sponsored by TRACON's corporate partners, Alphamab Oncology and 3D Medicines. Alphamab Oncology and 3D Medicines submitted an NDA to the NMPA in China for envafolimab in MSI-H/dMMR cancer that was accepted for review in December 2020 and granted priority review in January 2021. In the Phase 2 MSI-H/dMMR advanced solid tumor trial, the confirmed objective response rate (ORR) by blinded independent central review in MSI-H/dMMR colorectal cancer (CRC) patients treated with envafolimab who failed a fluoropyrimidine, oxaliplatin and irinotecan was 32%, which was similar to the 28% confirmed ORR reported in the Opdivo package insert in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin, and irinotecan and the 33% confirmed ORR reported for Keytruda in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin and irinotecan in cohort A of the KEYNOTE-164 clinical trial.

About ENVASARC (NCT04480502)

The ENVASARC pivotal trial is a multi-center, open label, randomized, non-comparative, parallel cohort study at approximately 25 top cancer centers in the United States that began dosing in December 2020. TRACON expects the trial to enroll 160 patients with UPS or MFS who have progressed following one or two lines of prior treatment and have not received an immune checkpoint inhibitor, with 80 patients enrolled into cohort A of treatment with single agent envafolimab and 80 patients enrolled in cohort B of treatment with envafolimab and Yervoy. The primary endpoint is ORR by blinded independent central review with duration of response a key secondary endpoint.

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 PD-L1 single-domain antibody given by rapid subcutaneous injection that is being studied in the pivotal ENVASARC trial for sarcoma; TRC102, a Phase 2 small molecule drug candidate 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.

About Alphamab Oncology

Alphamab Oncology is focusing on innovation, production and commercialization of anti-tumor drugs. On December 12, 2019, the Company was listed in the mainboard of Hong Kong Stock Exchange with stock code 9966.

Alphamab has fully integrated proprietary biologics platforms in bi-specifics and protein engineering. Its highly differentiated in-house pipeline includes fifteen tumor monoclonal antibodies and bispecific antibodies and a Covid-19 multifunctional antibody. Four products have advanced into phase I-III clinical trials or pre-marketing stage in China, the United States, Japan and Australia. The BLA for Envafolimab (KN035) has been accepted and granted Priority Review by the National Medical Products Administration (NMPA).

The Company also has state-of-the-art manufacturing capabilities designed and built to meet NMPA and EU/FDA's cGMP standards and a complete quality system which has passed the on-site inspection of an European Union qualified person. Alphamab Oncology is committed to building a global leading, multi-dimensional drug development and commercialization platform, focusing on multifunctional biological innovative drugs, and to benefit patients in China and around the world.

About 3D Medicines

3D Medicines is a clinical-stage biopharmaceutical company focused on the development of differentiated next-generation immuno-oncology drugs for cancer patients. The world's first subcutaneous injection PD-L1 antibody Envafolimab (KN035), is currently under clinical development in the United States, China and Japan. 3D Medicines is building a pipeline targeting major indications through combination strategy, either with in-house assets or in collaboration with partners around the world. With a professional team in the China and US, 3D Medicines is capable of conducting global clinical development and registration.

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 plans to further develop envafolimab, expectations regarding the timing and scope of clinical trials and availability of clinical data, expected development and regulatory milestones and timing thereof, the potential benefits of Orphan Drug Designation, 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 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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