TRACON Pharmaceuticals Announces Acceptance of the Envafolimab (KN035) NDA by the NMPA in China for Priority Review

January 19, 2021

NDA was Submitted in November by TRACON's Corporate Partners, Alphamab Oncology and 3D Medicines, in the Indication of MSI-H/dMMR Cancer, Including Colorectal and Gastric Cancer

SAN DIEGO, Jan. 19, 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 its corporate partners, Alphamab Oncology and 3D Medicines, received notification that the New Drug Application (NDA) for envafolimab was granted priority review by the Center for Drug Evaluation of the National Medical Products Administration (NMPA) in the indication of MSI-H/dMMR cancer.

"We congratulate our partners on the acceptance of the initial regulatory submission for envafolimab in China for priority review, which marks another important milestone in the development and potential commercialization of this promising program," said Charles Theuer, M.D., Ph.D., TRACON Chief Executive Officer. "In addition to the registration trial in MSI-H/dMMR advanced solid tumors in China, envafolimab is being studied in two other registration trials, a randomized Phase 3 trial in biliary tract cancer in China being conducted by Alphamab and 3D Medicines, and our ENVASARC trial in sarcoma in the U.S., which has now dosed multiple patients."

About Priority Review by the NMPA

Priority review is a procedure established to encourage the research and development of new drugs and accelerate the review and approval of new drugs with obvious clinical value and urgent clinical needs. According to the new "Drug Registration Rules" (SAMR Order No.27) and Working Procedures for Priority Review and Approval of Drug Marketing Authorization (Interim) (No. 82 of 2020) implemented on July 1, and July 7, 2020, respectively, once granted Priority Review, the NMPA will prioritize the review process and resources for applications with expected shorter review timelines.

About Envafolimab (KN035)

Envafolimab (KN035), a novel, single-domain antibody against PD-L1, is the first subcutaneously injected PD-(L)1 inhibitor to be studied in registration trials. Envafolimab is currently being studied in the ENVASARC Phase 2 registration trial in the U.S. sponsored by TRACON, as well as in a Phase 2 registration trial as a single agent in MSI-H/dMMR advanced solid tumor patients and a Phase 3 registration trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China 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 registration 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 KEYNOTE-164.

About ENVASARC (NCT04480502)

The ENVASARC registration 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 subcutaneous PD-L1 single-domain antibody being developed in a registration trial for the treatment of sarcoma; TRC253, a small molecule drug candidate for the treatment of prostate cancer; TRC102, a Phase 2 small molecule drug candidate being developed for the treatment of lung cancer and glioblastoma; 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 a biopharmaceutical company focusing on innovative biologics medicine for oncology. 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 pipeline includes eight anti-tumor drug candidates including mainly bi-specifics, and a COVID-19 multifunctional antibody. Four products have advanced into phase I-III clinical trials in China, the United States, and Japan. 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 a 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. Visit http://www.alphamabonc.com for more information.

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 TRACON's and its collaboration partners’ plans to further develop product candidates, expectations regarding the timing and scope of clinical trials and availability of clinical data, potential benefits of priority review by the NMPA, expected development and regulatory milestones and timing thereof, 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.

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

Investor Contact:
Brian Ritchie
LifeSci Advisors LLC
212-915-2578
britchie@lifesciadvisors.com

Source: TRACON Pharmaceuticals, Inc.