TRACON Pharmaceuticals Reports Regulatory Approval of Envafolimab in China

November 29, 2021

First Approval of a Subcutaneously Administered Checkpoint Inhibitor

TRACON's Pivotal U.S. Trial for Envafolimab in Undifferentiated Pleomorphic Sarcoma and Myxofibrosarcoma Continues to Advance as Planned

SAN DIEGO, Nov. 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 reported that its partners Alphamab Oncology (stock code: 9966.HK) and 3D Medicines (Beijing) Co., Ltd. announced that envafolimab (KN035), the world's first single-domain PD-L1 antibody formulated for subcutaneous injection received marketing authorization from the Chinese National Medical Products Administration (NMPA).

Envafolimab was approved for adult patients with microsatellite instability-high (MSI-H) or deficient MisMatch Repair (dMMR) advanced solid tumors, including those patients with advanced colorectal cancer who have experienced disease progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, as well as patients with other advanced solid tumors who have experienced disease progression following prior systemic treatment and have no satisfactory alternative treatment options.

Prior to this approval, all marketed PD-1 and PD-L1 antibody drugs required intravenous infusions. As a subcutaneously administered PD-L1 antibody, envafolimab can be administered within 30 seconds in the physician's office—thereby increasing convenience, shortening treatment time and sparing patients from the risk of infusion reactions.

In a pivotal phase 2 clinical study in patients with advanced dMMR/MSI-H tumors who received one or more lines of treatment, envafolimab demonstrated an objective response rate (ORR) by blinded independent radiographic review (BIRR) of 44.7%, including 12 (11.7%) cases of complete response. Responses were durable, with duration of response at 12 months in responding patients with advanced colorectal cancer (CRC), advanced gastric cancer, other advanced solid tumors, and all responding patients of 89%, 100%, 100%, and 93%, respectively. Median progression-free survival was 11.1 months and the 12-month overall survival rate was 73.6%. The confirmed ORR by BIRR in MSI-H/dMMR 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 treatment and the 33% confirmed ORR reported for KEYTRUDA® in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin and irinotecan treatment in cohort A of the phase 2 KEYNOTE-164 trial. Envafolimab was well tolerated in this study and no cases of immune-related pneumonitis, immune-related colitis, or immune-related nephritis were reported.

"We are pleased the dedication of our partners Alphamab Oncology and 3D Medicines has resulted in the initial approval of the first subcutaneously administered checkpoint inhibitor," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "Importantly, the TRACON sponsored pivotal ENVASARC trial of envafolimab for the treatment of undifferentiated pleomorphic sarcoma (UPS) and myxofibrosarcoma (MFS) in the United States continues to enroll well at 26 sites, and we look forward to the Independent Data Monitoring Committee review of interim efficacy and safety data before the end of the year."

About Envafolimab

Envafolimab (KN035), a single-domain antibody against PD-L1 invented by Alphamab Oncology, is the first subcutaneously injected PD-(L)1 inhibitor approved by the NMPA in November 2021 in adult patients with MSI-H/dMMR advanced solid tumors who failed systemic treatment and have no satisfactory alternative treatment options. In December 2019, Alphamab Oncology, 3D Medicines and TRACON entered into a collaboration whereby TRACON has the right to develop and commercialize envafolimab in soft tissue sarcoma in North America. Envafolimab is currently being studied in the pivotal ENVASARC Phase 2 trial in the U.S. sponsored by TRACON and a Phase 3 pivotal 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.

About ENVASARC (NCT04480502)

The ENVASARC pivotal trial is a multicenter, 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 into 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; YH001, a potential best-in-class CTLA-4 antibody in Phase 1 development; 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 a biopharmaceutical company focusing on innovative biologics medicine for oncology. On December 12, 2019, the Company was listed in the mainboard of the 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 anti-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. In November 2021, envafolimab received marketing authorization from the Chinese National Medical Products Administration (NMPA) for the treatment of previously treated MSI-H/dMMR advanced solid tumors. 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, 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; expected development, regulatory and commercial milestones and timing thereof; potential utility of product candidates; 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 and regulatory approval of novel pharmaceutical products; 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’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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