TRACON Pharmaceuticals, 3D Medicines and Jiangsu Alphamab Announce Partnership for Development of Subcutaneous PD-L1 Single-Domain Antibody in Soft Tissue Sarcoma

December 20, 2019

Company to Host Investor Conference Call Today at 8:30 a.m. ET / 5:30 a.m. PT

Envafolimab represents a potential best-in-class PD-L1 inhibitor that is injectable subcutaneously without the need for an adjuvant

Envafolimab has been dosed in more than 650 patients in the U.S., China and Japan, and is currently being evaluated in registrational trials in China in patients with high microsatellite instability ("MSI-H") cancer and biliary tract cancer

Immune checkpoint inhibitors targeting the PD-1 or PD-L1 pathway have demonstrated activity in multiple soft tissue sarcoma subtypes, including undifferentiated pleomorphic sarcoma (UPS)

TRACON intends to initiate a registration enabling study of envafolimab in the sarcoma subtype of UPS in 2020

SAN DIEGO, Dec. 20, 2019 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, announced today that it has signed a collaborative partnership agreement with 3D Medicines (Beijing) Co., Ltd., a China-based biopharmaceutical company focused on cancer precision medical treatment, and Jiangsu Alphamab Biopharmaceuticals Co., Ltd., a wholly-owned subsidiary of Alphamab Oncology (HKEX: 9966) and a China-based clinical stage biopharmaceutical company primarily engaging in research and development, manufacturing and commercialization of biologics of oncology, for the development of envafolimab, also known as KN035, a PD-L1 single-domain antibody administered by subcutaneous injection, for development in soft tissue sarcoma in North America.

TRACON and 3D Medicines and Jiangsu Alphamab entered into a product development collaboration whereby TRACON will be responsible for the clinical development and commercialization of envafolimab in soft tissue sarcoma in North America, with the majority of the development activities expected to occur in the U.S. TRACON will bear the costs of clinical trials and 3D Medicines and Jiangsu Alphamab will supply envafolimab at pre-negotiated prices.

TRACON will be responsible for commercializing envafolimab for sarcoma in North America, except in certain circumstances involving the approval of envafolimab for other indications in North America, in which case TRACON has the option to co-market envafolimab for sarcoma in North America.

If TRACON has responsibility for commercialization under the Collaboration Agreement, it will owe 3D Medicines and Jiangsu Alphamab escalating double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits, which amounts shall be split between 3D Medicines and Jiangsu Alphamab as negotiated. If 3D Medicines and Jiangsu Alphamab have responsibility for commercialization under the Collaboration Agreement, TRACON will be entitled to (a) escalating double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits if TRACON has chosen to not co-market envafolimab in sarcoma or (b) a 50% royalty on net sales of envafolimab for sarcoma in North America if TRACON has chosen to co-market envafolimab in sarcoma.

At the American Society of Clinical Oncology 2019 meeting, data were presented from the SARC 028 clinical study demonstrating that the PD-1 inhibitor Keytruda® (pembrolizumab) achieved a 23% response rate in 40 patients with UPS, irrespective of PD-L1 expression in the tumor specimen. Additional data published subsequently indicate that Keytruda achieved more than a 50% objective response rate in cutaneous angiosarcoma. In a separate study, the PD-L1 inhibitor Tecentriq® (atezolizumab) achieved a more than 40% objective response rate in alveolar soft part sarcoma.

"Given the activity of other PD-1 and PD-L1 inhibitors in sarcoma, we believe a registration enabling study of envafolimab in the sarcoma subtype of UPS will be meaningful to patients and providers, and is strategically aligned with TRACON's mission to rapidly develop and commercialize drugs targeting unmet need indications in the U.S.," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "We expect to discuss our plan of initiating a pivotal trial of envafolimab in UPS with the U.S. FDA in early 2020. Our ultimate goal is to enable a biomarker directed approach for treatment with envafolimab in patients with multiple types of soft tissue sarcoma."

UPS accounts for 10% of new cases of soft tissue sarcoma in the United States and TRACON estimates that it represents a potential market of $200M without considering a price premium to the reference PD-1 inhibitors Opdivo® (nivolumb) and Keytruda® (pembrolizumab). Approval in soft tissue sarcoma subtypes other than UPS could increase the market opportunity significantly.

"We believe that collaboration with TRACON will give cancer patients an option for a subcutaneous injection in the United States. In earlier clinical trials, the safety and efficacy profiles of envafolimab are comparable to other PD-1/PD-L1 antibodies in the market," said John Gong, CEO of 3D Medicines.

Dr. Ting Xu, Chairman and CEO of Alphamab Oncology, added, "The collaboration is an important part of envafolimab's global development strategy. As the most advanced single domain antibody in IO with the advantage of a subcutaneous dosage, we are confident it will bring a valuable option for

cancer patients."

Investor Conference Call

The Company will hold a conference call today at 8:30 a.m. ET / 5:30 a.m. PT to provide further details on the agreement and envafolimab. The dial-in numbers are (877) 407-0784 for domestic callers and (201) 689-8560 for international callers. Please use passcode 13697590. A live webcast of the conference call will be available at http://public.viavid.com/index.php?id=137389.

After the live webcast, a replay will remain available on TRACON's website for 60 days.

About Envafolimab

Envafolimab is a novel, single-domain antibody against PD-L1 that is administered by subcutaneous injection without the need for an adjuvant at a dose of 300 mg on a every 2 week schedule, and PK suggest a prolonged half-life that would support a less frequent dosing schedule. Envafolimab is currently dosing in Phase 1 trials in the US and Japan and is being studied in China in a Phase 2 registration trial as a single agent in MSI-H tumor patients, and in combination with gemcitabine and oxaliplatin in a Phase 3 registration trial in biliary tract cancer. Subject to positive data from the MSI-H registrational trial, 3D Medicines plans to file a BLA in China for envafolimab in 2020 based on overall response rate in MSI-H patients. The filing would be based on the principle in China that the response rate is required to be similar to the response rate for Keytruda and Opdivo in MSI-H patients from separate clinical trials per the product package inserts.

About TRACON

TRACON develops targeted therapies for cancer and ophthalmic diseases. The Company's clinical-stage pipeline includes: DE-122, the ophthalmic formulation of carotuximab, an endoglin antibody that is being developed for patients with wet AMD through a license to Santen Pharmaceutical Company Ltd.; TRC102, a small molecule drug being developed for the treatment of lung cancer; TRC253, a small molecule drug being developed for the treatment of prostate cancer; and TJ004309, a CD73 antibody being developed for the treatment of advanced solid tumors. TRACON is actively seeking additional corporate partnerships whereby it leads 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 candidates, visit TRACON's website at www.traconpharma.com.

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. We are building our 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.

About Jiangsu Alphamab

Jiangsu Alphamab is a wholly-owned principal operating subsidiary of Alphamab Oncology, a company incorporated in the Cayman Islands with limited liability and listed on the main board of the Hong Kong Stock Exchange (stock code: 09966). Alphamab Oncology is a leading clinical-stage biopharmaceutical company in China with a fully-integrated proprietary biologics platform in bispecific and protein engineering. Its differentiated in-house pipeline consists of eight oncology drug candidates, including four in the phase I-III clinical trial development stage. Alphamab Oncology has developed various technologies and platforms of antibody-based therapies for oncology treatment and expertise in this regard. Benefitting from its proprietary protein engineering platforms and structure-guided molecular modeling expertise, Alphamab Oncology is able to create a new generation of multi-functional bio-macromolecule new drugs that benefit patients globally.

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, 3D Medicines' and Jiangsu Alphamab's plans to further develop envafolimab, potential benefits of the collaboration between TRACON, 3D Medicines and Jiangsu Alphamab, expectations regarding the timing of regulatory submissions and clinical trials, potential payments and activities under the collaboration with 3D Medicines and Jiangsu Alphamab, expected development milestones, TRACON's plans to leverage its product development platform and potential benefits derived from the platform, and potential utility of TRACON's product candidates. 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; 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; 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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