TRACON Pharmaceuticals Announces Approval of IND for CTLA-4 Antibody YH001 for the Treatment of Front-line Sarcoma Patients in Combination with Envafolimab

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SAN DIEGO, Aug. 29, 2022 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals, Inc. (Nasdaq: TCON), a clinical stage biopharmaceutical company utilizing a cost-efficient, CRO-independent product development platform to advance its pipeline of novel targeted cancer therapeutics and to partner with other life science companies, today announced that the U.S. Food and Drug Administration (FDA) has approved the Investigational New Drug (IND) application for the initiation of a Phase 1/2 clinical trial of YH001 in combination with envafolimab and doxorubicin for the treatment of sarcoma patients, including patients who have not received prior therapy.

The Phase 1/2 trial will assess the safety and efficacy of YH001 and envafolimab in patients with the rare sarcoma subtypes of alveolar soft part sarcoma and chondrosarcoma. Additionally, the safety and efficacy of the combination of YH001, envafolimab and doxorubicin will be assessed in the more prevalent sarcoma subtypes of leiomyosarcoma and dedifferentiated liposarcoma.

"We are pleased to receive approval from the FDA to initiate our triplet combination therapy trial in sarcoma, which includes our potentially best-in-class CTLA-4 antibody YH001 and the only subcutaneous checkpoint inhibitor approved anywhere in the world, envafolimab," said Charles Theuer, M.D., Ph.D., TRACON's Chief Executive Officer. "We look forward to enrolling patients in this trial and giving patients additional options for their sarcoma treatment."

About YH001

YH001, an IgG1 antibody against CTLA-4 invented by Biocytogen, the parent company of Eucure Biopharma, and licensed by TRACON, has shown enhanced antibody dependent cellular cytotoxicity (ADCC) and complement dependent cytotoxicity (CDC) *in vitro*. In preclinical studies YH001 demonstrated superior T cell activation and superior tumor growth inhibition activity compared to ipilimumab. YH001 also demonstrated superior activity compared to ipilimumab in human transgenic mouse tumor models when combined with a PD-(L)1 antibody. In these models, single agent YH001 depleted regulatory T cells and increased CD8+ T cells in tumor tissue. YH001 has been dosed as a single agent in a Phase 1 trial in China (NCT04699929) and in combination with the PD-1 antibody toripalimab in a Phase 1 trial in Australia (NCT04357756).

About the Phase 1/2 Clinical Trial of YH001, envafolimab and doxorubicin (NCT05448820)

The Phase 1/2 clinical trial is a multicenter, open label study of YH001 initially given in combination with envafolimab, and then given in combination with envafolimab plus doxorubicin in patients with advanced or metastatic sarcoma, followed by Phase 2 cohorts of patients with select histologies of advanced or metastatic sarcoma, including treatment naive patients. The primary objective of the Phase 1 portion of the trial is to determine the recommended phase 2 dose of YH001 in combination with envafolimab and in combination with envafolimab with doxorubicin. The primary objective of the Phase 2 portion is to determine the objective response rate (ORR) of the combination of YH001 and envafolimab in patients with alveolar soft part sarcoma and chondrosarcoma and the ORR of the combination of YH001, envafolimab and doxorubicin in patients with leiomyosarcoma and dedifferentiated liposarcoma.

About Envafolimab

Envafolimab (KN035), a single-domain antibody against PD-L1 invented by Alphamab Oncology and licensed by TRACON, is the first approved subcutaneously injected PD-(L)1 inhibitor. Envafolimab was approved by the Chinese 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 United States 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 TRACON

TRACON is a clinical-stage biopharmaceutical company utilizing a cost-efficient, CRO-independent, product development platform to advance its pipeline of novel targeted cancer therapeutics and to partner with other life science companies. 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 through a profit-share or revenue-share partnership, or through franchising TRACON's product development platform. TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the United States or who wish to become CRO-independent. 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, including enrollment, expected development and regulatory milestones and timing thereof and the potential benefits, utility, safety and efficacy of product candidates. 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 pharmaceutical product candidates; whether TRACON or others will be able to complete, enroll or initiate clinical trials on TRACON’s expected timelines, if at all, including due to risks associated with the COVID-19 pandemic or other geopolitical events; the fact that future clinical results may not be consistent with preliminary results or results from prior trials; 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 on favorable terms or at all; the regulatory approval of competitive products in the market; 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 except as required by law.

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