TRACON Pharmaceuticals and Eucure Biopharma, a Subsidiary of Biocytogen, Announce Partnership for Development of Clinical Stage CTLA-4 Antibody YH001

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YH001 is a potential best-in-class CTLA-4 antibody with enhanced ADCC and CDC effector functions

YH001 is currently being dosed in multiple Phase 1 oncology trials sponsored by Eucure Biopharma in Australia and China

TRACON intends to initiate a Phase 1 trial of YH001 in combination with envafolimab in soft tissue sarcoma as well as to study YH001 in multiple other selected tumor types

SAN DIEGO, Oct. 11, 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., announced today that it has entered into a collaborative partnership agreement with Eucure Biopharma, a subsidiary of Biocytogen Pharmaceuticals (Beijing) Co., Ltd. (Biocytogen), and a China-based clinical stage biopharmaceutical company primarily focused on the research and development of biologics, for the development of YH001, a CTLA-4 antibody with enhanced ADCC and CDC effector functions, for development in multiple oncology indications, including soft tissue sarcoma, in North America.

Under the terms of the agreement, TRACON will be responsible for the clinical development and commercialization of YH001 in multiple oncology indications 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 Eucure Biopharma will supply YH001. TRACON will be responsible for commercializing YH001 in multiple oncology indications in North America and will owe Eucure Biopharma escalating double digit royalties on net sales.

YH001 was developed to potently inhibit CTLA-4 binding to the CD80/CD86 receptors and deplete regulatory T cells through enhanced ADCC and CDC effector functions. YH001 demonstrated superior activity *in vitro* and in transgenic syngeneic tumor models compared to ipilimumab (Yervoy®), both as a single agent and when combined with a PD-(L)1 antibody.

“We are focused on advancing a dual checkpoint inhibitor strategy focused on the PD-(L)1 and CTLA-4 pathways, that we expect to leverage in sarcoma by combining YH001 with envafolimab, our novel, single-domain PD-L1 antibody, in sarcoma. Going forward, we intend to use YH001 rather than Yervoy in our future dual checkpoint inhibition trials in sarcoma, which we anticipate will result in meaningful cost savings from not needing to purchase Yervoy at retail prices,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “Moreover, we expect to study YH001 in other solid tumors in combination with PD-(L)1 antibodies, including in patients who have progressed on prior PD-(L)1 treatment.”

“We believe that this collaboration with TRACON has potential to provide cancer patients in the United States with a best-in-class CTLA-4 checkpoint inhibitor. YH001 was optimized using Biocytogen’s discovery labs and proprietary transgenic mouse models to inhibit CTLA-4 binding and to deplete regulatory cells. In our ongoing Phase 1 clinical trials, YH001 has been tolerable as a single agent and in combination with the PD-1 antibody toripalimab,” said Dr. Yuelei Shen, CEO of Biocytogen and Eucure Biopharma.

About YH001

YH001 is an IgG1 antibody against CTLA-4 that 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 is being 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). In July 2021, the U.S. Food and Drug Administration (FDA) approved the Investigational New Drug application to initiate multiple phase II clinical trials for YH001 in the United States.

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, as well as in a Phase 2 pivotal trial as a single agent in MSI-H/dMMR advanced solid tumor patients 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. 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 KEYNOTE-164.

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 Eucure Biopharma

Eucure Biopharma, a subsidiary of Biocytogen, is a China based innovative biotechnology company with global vision, specializing in developing innovative antibody drugs with independent intellectual property rights. Relying on a strong clinical development team with extensive experience, the company has established a product pipeline for more than 10 targets. At present, three products have received clinical trial approvals in the US and China including that two products have obtained the phase II clinical approval from the FDA and have initiated the global phase II clinical trial, two products have entered the phase I clinical trial in China, four products have entered Phase I clinical stages in Australia. These lay a solid foundation for the development of Eucure Biopharma. As a wholly owned subsidiary of Biocytogen, Eucure Biopharma is focused on clinical development. Biocytogen is an international biotechnology company driven by innovative technology and committed to becoming the global birthplace of new drugs, with a mission to focus on technological innovation, continuously produce new drugs, and safeguard human health. For more information, please visit www.eucure.com.

About Biocytogen

Biocytogen Pharmaceuticals (Beijing) Co., Ltd. is a global biotech company that drives the research and development of new drugs with innovative technologies. The company is committed to becoming a global headstream of new drugs and bringing the benefits to patients around the world as its mission. Based on the fully human antibody RenMab™ and RenLite™ mice for fully human antibodies production with robust humoral responses, highly diverse antibody repertoire and superior affinity, Biocytogen has integrated its platforms in single-cell antibody discovery, gene editing, large-scale animal model supply, and screening to form a new approach to streamline the entire drug development process. Biocytogen actively promotes the independent and cooperative development of new drugs. For more, please visit http://en.biocytogen.com.cn/

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 Eucure's plans to further develop YH001, potential benefits of the collaboration between TRACON and Eucure, expectations regarding the timing, design and scope of clinical trials, potential payments and activities under the collaboration with Eucure, expected development milestones, and potential benefits of YH001 and 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 impact of 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 the collaboration agreement with Eucure Biopharma is 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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