Oncternal Therapeutics Announces First Patient Dosed in Phase 1/2 Study of ROR1 targeting autologous CAR T, ONCT-808, in patients with relapsed or refractory aggressive B-cell lymphoma

June 6, 2023

SAN DIEGO, June 06, 2023 (GLOBE NEWSWIRE) -- Oncternal Therapeutics, Inc. (Nasdaq: ONCT), a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies, today announced that the first patient has been dosed in the Phase 1/2 dose escalation/dose expansion study of ONCT-808, the company's ROR1 targeting autologous CAR T cell therapy.

"We are excited to announce the first patient, who had failed previous CD19 CAR T therapy, has been treated with ONCT-808," said James Breitmeyer, M.D., Ph.D., Oncternal's President and CEO. "We believe ONCT-808 has the potential to produce robust and durable responses for patients suffering from aggressive lymphoma. It builds on our extensive clinical experience with zilovertamab, as well as that with zilovertamab vedotin, an antibody drug conjugate, which has shown that ROR1 can be targeted without unwanted off-tumor, on-target activity. We particularly appreciate that this first patient is under the care of Dr. Michael Wang, Endowed Professor in the Department of Lymphoma & Myeloma at the MD Anderson Cancer Center in Houston, Texas."

ONCT-808 is a ROR1 targeting autologous CAR T cell therapy that is being tested in a Phase 1/2 clinical trial for the treatment of patients with relapsed or refractory aggressive B-cell lymphoma, including those who have failed previous CD19 CAR T therapy. Preclinical models show robust and specific activity against ROR1 expressing cells from multiple tumor types. Oncternal has developed a manufacturing process that is reproducible, scalable, and only 8 days in duration. The company expects to present initial clinical data in late 2023, with additional clinical data readouts in 2024.

About Study ONCT-808-101
Study ONCT-808-101 is a Phase 1/2, single-arm, open-label, multi-center study to evaluate the safety and tolerability, pharmacokinetics, and anti-tumor activity of ONCT-808 in subjects with aggressive B cell lymphoma, including large B-cell lymphoma (LBCL) and mantle cell lymphoma (MCL). After the safety and tolerability of ONCT-808 have been assessed to select the recommended Phase 2 dose (RP2D) in Phase 1, Phase 2 will commence to further validate the dose and evaluate the safety and efficacy of ONCT-808. In Phase 2, subjects with LBCL or MCL will be enrolled into 2 separate dose expansion cohorts. Current leading clinical sites for ONCT-808-101 are the MD Anderson Cancer Center in Houston, TX, the Dana-Farber Cancer Institute in Boston, MA, the City of Hope Comprehensive Cancer Center in Duarte, CA and the Mass General Cancer Center in Boston, MA.

About Oncternal Therapeutics
Oncternal Therapeutics is a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies for the treatment of patients with cancers that have critical unmet medical need. Oncternal pursues drug development targeting promising, yet untapped biological pathways implicated in cancer generation or progression, focusing on hematological malignancies and prostate cancer. ONCT-808 is an investigational autologous chimeric antigen receptor T (CAR T) cell therapy that targets Receptor Tyrosine Kinase-Like Orphan Receptor 1 (ROR1) using the binding domain from zilovertamab. ONCT-808 has demonstrated activity in preclinical models against multiple hematological malignancies and solid tumors and has been shown to be specific for cancer cells expressing ROR1. Oncternal has developed a robust and reproducible manufacturing process that has the potential to reduce the time patients must wait for their individual CAR T product to be produced, compared with approved CAR T products. Oncternal has initiated Study ONCT-808-101 (NCT05588440) for the treatment of patients with relapsed or refractory aggressive B-cell lymphoma, including patients who have failed previous CD19 CAR T treatment. ONCT-534 is a dual-action androgen receptor inhibitor (DAARI) with preclinical activity in prostate cancer models against both unmutated androgen receptor (AR), and against multiple forms of AR aberrations. It is a potential treatment for patients with mCRPC and unmet medical need because of resistance to androgen receptor inhibitors, including those with AR amplification, mutations in the AR ligand binding domain (LBD), or splice variants with loss of the AR LBD. Final IND-enabling studies for ONCT-534 have been completed. Zilovertamab is an investigational monoclonal antibody designed to inhibit the function of ROR1. Zilovertamab has been evaluated in a Phase 1/2 Study CIRM-0001 (NCT03088878) in combination with ibrutinib for the treatment of patients with MCL, chronic lymphocytic leukemia (CLL) and marginal zone lymphoma (MZL). Zilovertamab is also being evaluated in two investigator-initiated studies: a Phase 2 clinical trial of zilovertamab in combination with venetoclax, a Bcl-2 inhibitor, in patients with R/R CLL (NCT04501939), and a Phase 1b study of zilovertamab in combination with docetaxel in patients with metastatic castration-resistant prostate cancer (NCT05156905). More information on our company and programs is available at https://oncternal.com/.

Forward-Looking Information
Oncternal cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negatives of these terms or other similar expressions. These statements are based on Oncternal's current beliefs and expectations. Forward-looking statements include statements regarding the anticipated timing for announcing additional preclinical and clinical data. Forward-looking statements are subject to risks and uncertainties inherent in Oncternal's business, including risks associated with the clinical development and process for obtaining regulatory approval of Oncternal's product candidates, such as potential delays in the commencement, enrollment and completion of clinical trials; the risk that interim results of a clinical trial do not predict final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, as follow-up on the outcome of any particular patient continues, and as more patient data become available; and other risks described in Oncternal's filings with the U.S. Securities and Exchange Commission. All forward-looking statements in this press release are current only as of the date hereof and, except as required by applicable law, Oncternal undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Contact Information:

Investors
Richard Vincent
858-434-1113
rvincent@oncternal.com

Media
Corey Davis, Ph.D.
LifeSci Advisors
212-915-2577
cdavis@lifesciadvisors.com

Source: Oncternal Therapeutics