Oncternal Therapeutics Receives FDA Study May Proceed Letter for ONCT-534, its Novel Dual-action Androgen Receptor Inhibitor, for the Treatment of Patients with Advanced Prostate Cancer

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SAN DIEGO, Aug. 03, 2023 (GLOBE NEWSWIRE) -- Oncternal Therapeutics, Inc. (Nasdaq: ONCT), a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies, today announced the receipt of a Study May Proceed letter from the U.S. Food and Drug Administration (FDA), for a Phase 1/2 dose escalation study of ONCT-534, a novel dual-action androgen receptor inhibitor (DAARI), in patients with metastatic castration-resistant prostate cancer (mCRPC) who have relapsed or are refractory to approved androgen receptor signaling inhibitors (ARSIs). The letter was received prior to the 30-day review date.

“We are very pleased with the FDA’s authorization to proceed with our Phase 1/2 clinical trial of ONCT-534,” said James Breitmeyer, M.D., Ph.D., Oncternal’s President and CEO. “Many men suffering from prostate cancer that has relapsed or is refractory after treatment with standard of care ARSI therapy, such as enzalutamide or abiraterone, need additional treatment alternatives. We believe that ONCT-534’s novel mechanism of action may help address key tumor escape mechanisms that cause such resistance. Preclinical studies suggest that ONCT-534 binds to both the ligand-binding domain (LBD) and N-terminal domain of the androgen receptor (AR), inhibiting AR function and triggering AR protein degradation, even in the presence of ligand-binding domain alterations including mutations and splice variants such as AR-V7. Clinical sites that will conduct the initial dose finding study for ONCT-534 have been selected and we expect to report preliminary data in the first half of 2024”.

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. 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-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. 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 relapsed or refractory metastatic castration-resistant prostate cancer (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. ONCT-534 has an active U.S. IND, and a Phase 1/2 clinical trial is being opened. Zilovertamab is an investigational monoclonal antibody designed to inhibit the function of ROR1. Zilovertamab showed evidence of antitumor activity and was well tolerated in Phase 1/2 Study CIRM-0001 (NCT03088878) in combination with ibrutinib for the treatment of patients with mantle cell lymphoma, chronic lymphocytic leukemia (CLL) and marginal zone lymphoma. Zilovertamab is 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 relapsed/refractory (R/R) CLL (NCT04501939), and a Phase 1b study of zilovertamab in combination with docetaxel in patients with mCRPC (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 Oncternal’s development programs, including the anticipated timing for enrolling Oncternal’s study of ONCT-534 and announcing 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.

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