# Oncternal Therapeutics Announces FDA Granted Fast Track Designation for ONCT-534 for the Treatment of Metastatic Castration-Resistant Prostate Cancer

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SAN DIEGO, Oct. 26, 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 U.S. Food and Drug Administration (FDA) has designated ONCT-534, its novel dual-acting androgen receptor inhibitor (DAARI), as a Fast Track development program for the investigation of the treatment of patients with relapsed or refractory metastatic castration-resistant prostate cancer (mCRPC) resistant to approved androgen receptor pathway inhibitors (ARPIs).

“The receipt of Fast Track designation for ONCT-534 supports our belief that patients with mCRPC who relapse after treatment with ARPIs such as enzalutamide or abiraterone, represent an important unmet medical need,” said James Breitmeyer, M.D., Ph.D., Oncternal’s President and CEO. “We believe that due to ONCT-534’s novel mechanism of action, it may address important androgen receptor (AR) escape mechanisms that result in resistance to currently approved ARPIs. We look forward to working with FDA, investigators, and industry collaborators to bring ONCT-534 to patients as quickly as possible.”

ONCT-534 interacts with both the N-terminal domain and the ligand-binding domain (LBD) of the AR, inhibiting cell growth and inducing AR degradation. Preclinical studies have shown activity in prostate cancer models against both unmutated AR, and against multiple mutations, including AR amplification, mutations in the AR LBD, and splice variants with loss of the AR LBD.

**About Study ONCT-534-101**
Study ONCT-534-101 is a Phase 1/2, single-arm, open-label, multi-center study to evaluate the safety and tolerability, pharmacokinetics, and preliminary anti-tumor activity of ONCT-534 in patients with mCRPC who have relapsed or are refractory to approved ARPIs including enzalutamide, abiraterone, apalutamide and daralutamide. After the safety and tolerability and preliminary antitumor activity of ONCT-534 have been assessed in Phase 1, Phase 2 will commence to further evaluate the safety and preliminary antitumor activity of ONCT-534 to allow for selecting an optimal dose.

**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-534 is an investigational 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 aberration. It is a potential treatment for patients with mCRPC and unmet medical need because of resistance to androgen receptor pathway inhibitors (ARPIs), including those with AR amplification, mutations in the AR ligand binding domain (LBD), or splice variants with loss of the AR LBD. Oncternal has initiated Study ONCT-534-101 (NCT05917470) for the treatment of patients with mCRPC. 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 lymphomas, including patients who have failed previous CD19 CAR T treatment. 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 mCRPC (NCT05156905). More information on our company and programs is available at https://oncternal.com/.

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