Oncternal Therapeutics Announces First Patient Dosed in Phase 1/2 Study of Dual-Action AR Inhibitor, ONCT-534, in Patients with Metastatic Castration-Resistant Prostate Cancer

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SAN DIEGO, Oct. 05, 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-534, the company's dual-action androgen receptor inhibitor.

"The dosing of the first patient with ONCT-534 is an important milestone for patients suffering from advanced prostate cancer who have relapsed or are refractory after treatment with AR signaling inhibitors," said Salim Yazji, M.D., Oncternal's Chief Medical Officer. "Preclinical studies suggest that ONCT-534 may address important tumor escape mechanisms that result in resistance to currently available AR inhibitors, such as enzalutamide or abiraterone. We intend to advance the dose escalation portion of the Phase 1/2 Study ONCT-534-101 quickly, and we will be enrolling patients in sites across the U.S. over the coming weeks, and in the United Kingdom in early 2024. We expect to report initial clinical data in the first half of 2024."

ONCT-534 is a dual-action androgen receptor inhibitor (DAARI) that interacts with both the N-terminal domain and the ligand-binding domain (LBD) of the androgen receptor (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 anti-tumor activity of ONCT-534 in patients with metastatic castration-resistant prostate cancer (mCRPC) who have relapsed or are refractory to approved androgen receptor signaling inhibitors (ARSIs) including enzalutamide, abiraterone, apalutamide and darolutamide. After the safety and tolerability of ONCT-534 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-534.

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 inhibitors, 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 lymphoma, 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 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 study enrollment 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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