Oncternal Announces Enrollment Completed and Dosing Initiated for Fifth Dose Cohort of Phase 1/2 Study of ONCT-534 for the Treatment of R/R Metastatic Castration-Resistant Prostate Cancer

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SAN DIEGO, May 30, 2024 (GLOBE NEWSWIRE) -- Oncternal Therapeutics, Inc. (Nasdaq: ONCT), a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies, today announced that enrollment has been completed and dosing initiated for the fifth dose cohort of its Phase 1/2 study of ONCT-534 for the treatment of patients with metastatic castration-resistant prostate cancer who are relapsed or refractory to approved androgen receptor pathway inhibitors (ARPI). Patients in the fifth cohort are receiving ONCT-534, the company's dual-action androgen receptor inhibitor (DAARI), at a dose of 600 mg taken orally once each day. The decision to proceed to this higher dose level was made by the study's Safety Review Committee (SRC) after reviewing data from the fourth dose level of 300 mg ONCT-534 daily. An initial update on ONCT-534 safety and efficacy based on prostate-specific antigen (PSA) levels from this study is expected in the third quarter of 2024 and will include data from this 600 mg dose cohort.

"We are encouraged by the rapid enrollment in the dose escalation portion of our Phase 1/2 study with ONCT-534. The drug has been well tolerated, with no dose limiting toxicities observed to date. We continue to open new sites and patient demand continues to be strong," said Salim Yazji M.D., Chief Medical Officer at Oncternal Therapeutics. "We are looking forward to sharing initial safety and efficacy data soon, which will include a larger, more robust set of clinical and biomarker results, as well as longer follow-up from the initial dosing cohorts."

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 darolutamide. 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 antitumor activity of ONCT-534 to support 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 demonstrated 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 with unmet medical need because of resistance to androgen receptor pathway inhibitors, including those with AR amplification, mutations in the AR ligand binding domain (LBD), or splice variants with loss of the AR LBD. Study ONCT-534-101 (NCT05917470) has completed enrollment in four dose cohorts and continues to enroll and dose patients for treatment 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 therapy to be produced, compared with currently approved CAR T products. Oncternal has dosed patients under Study ONCT-808-101 (NCT05588440) 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 mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL) and marginal zone lymphoma (MZL), which resulted in 100% progression free survival (PFS) at 42 months in CLL patients expressing a p53 mutation/del(17p), a population underserved by current treatment options. Zilovertamab is also being evaluated in an investigator-initiated 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 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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