Oncternal Therapeutics Receives IND Clearance for ONCT-808, its autologous CAR T Product Candidate Targeting ROR1 for the Treatment of Aggressive B Cell Lymphoma

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SAN DIEGO, Oct. 03, 2022 (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), 30 days after submitting its Investigational New Drug (IND) application for a Phase 1/2 dose escalation study of ONCT-808, an autologous chimeric antigen receptor (CAR) T therapy targeting ROR1, in patients with aggressive B cell non-Hodgkin's lymphoma (B NHL), including those who have failed previous CD19 CAR T treatment.

"We are very pleased with the clearance of our IND application for our lead autologous CAR T product candidate, ONCT-808," said James Breitmeyer, M.D., Ph.D., Oncternal's President and CEO. "This will be our second clinical program focusing on the important ROR1 cancer target, following the initiation of our phase 3 study for our ROR1 antibody zilovertamab, announced last week. ROR1 is an exciting and promising target that is highly expressed in a wide range of cancers and is an ideal candidate for cell therapy applications due to its highly specific tumor expression, and association with tumor survival mechanisms. Our initial dose finding study will enroll patients with aggressive B NHL, including those that have failed prior CD19 therapy, which represent a significant unmet need in the market today. We expect to initiate the study in the coming months and to present interim results at a scientific conference in 2023."

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. The lead clinical program is zilovertamab, an investigational monoclonal antibody designed to inhibit the function of Receptor Tyrosine Kinase-Like Orphan Receptor 1 (ROR1). ZILO-301, a global Phase 3 Study to evaluate zilovertamab in combination with ibrutinib for the treatment of patients with relapsed/refractory mantle cell lymphoma (MCL) has been initiated (NCT05431179). Zilovertamab continues to be evaluated in an ongoing Phase 1/2 study in combination with ibrutinib for the treatment of patients with MCL and chronic lymphocytic leukemia (CLL), and this trial was recently amended to include patients with marginal zone lymphoma (MZL). Zilovertamab is also being evaluated in two investigator-initiated studies, including a Phase 2 clinical trial of zilovertamab in combination with venetoclax, a Bcl-2 inhibitor, in patients with relapsed/refractory CLL, and in a Phase 1b study of zilovertamab in combination with docetaxel in patients with metastatic castration-resistant prostate cancer (mCRPC). Oncternal is also moving into the clinic with ONCT-808, an autologous chimeric antigen receptor T (CAR T) cell therapy that targets ROR1, with an active U.S. IND as of the end of September 2022 for the treatment of patients with relapsed or refractory aggressive B cell lymphoma, including patients who have failed previous CD19 CAR T treatment. The preclinical pipeline also includes ONCT-534, a dual-action androgen receptor inhibitor (DAARI) that is undergoing final IND-enabling studies, as a potential treatment for castration resistant prostate cancer, including those with unmet medical need due to resistance to approved, standard of care androgen receptor inhibitors. More information 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 expected timing of initiation and interim updates for Oncternal's planned study of ONCT-808. 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; we have not conducted head-to-head studies of zilovertamab in combination with ibrutinib compared to ibrutinib monotherapy and data from separate studies may not be directly comparable due to the differences in study protocols, conditions and patient populations; 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; later developments with the FDA may be inconsistent with the minutes from the completed end of Phase 2 meeting, including that the proposed Study ZILO-301 that may not support registration of zilovertamab in combination with ibrutinib which is a review issue with the FDA upon submission of a BLA; 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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