Oncternal Therapeutics Initiates Global Registrational Phase 3 Study of Zilovertamab for Patients with MCL

September 27, 2022

SAN DIEGO, Sept. 27, 2022 (GLOBE NEWSWIRE) -- Oncternal Therapeutics, Inc. (Nasdaq: ONCT), a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies, today announced the initiation of its Phase 3 global registrational study of zilovertamab, ZILO-301 (NCT05431179), for the treatment of patients with relapsed/refractory mantle cell lymphoma (MCL). The Company obtained its first Institutional Review Board (IRB) approval for the study and expects to promptly begin patient screening and enrollment.

“The initiation of the first Phase 3 study of zilovertamab, ZILO-301, represents a key milestone for Oncternal, our partners, investors and patients with R/R MCL,” said James Breitmeyer, M.D., Ph.D., Oncternal’s President and CEO. “We are looking forward to opening between 50-100 sites across the globe to support what we expect to be the first BLA approval of zilovertamab. ZILO-301 also represents the first registrational study for a therapeutic targeting the novel ROR1 pathway, which we believe can help address significant unmet needs in multiple hematological malignancies and other solid tumors.”

About ZILO-301
The Phase 3 clinical trial entitled “A Randomized, Double-blind, Placebo-controlled, Multicenter Study of Zilovertamab (A ROR1 Antibody) Plus Ibrutinib Versus Ibrutinib Plus Placebo in Subjects with Relapsed or Refractory Mantle Cell Lymphoma” (NCT05431179) will evaluate the potential benefit of zilovertamab for patients who have only experienced stable disease (SD) or a partial response (PR) after having received four months of oral ibrutinib therapy (560 mg daily) during the open-label lead-in phase of the study. Patients with such an inadequate response (PR or SD) will be randomized (1:1) to receive zilovertamab (600mg administered by IV every 2 weeks for 3 administrations and then every 4 weeks thereafter) or placebo, while continuing to receive oral ibrutinib. Across 50-100 international sites, the study aims to enroll 365 patients and to randomize approximately 250 patients after the 4-month lead-in phase.

An interim analysis, designed to support submission of a BLA seeking accelerated FDA approval, will be conducted based on an endpoint of Objective Response Rate (ORR) plus Duration of Response (DOR). The final analysis, intended to support regular FDA approval, will be based on a primary endpoint of progression-free survival (PFS). Secondary efficacy endpoints include ORR, DOR, Complete Response (CR) Rate, Overall Survival (OS), and the proportion of subjects experiencing grade 3 or 4 neutrophil count decrease.

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 developing ONCT-808, an autologous chimeric antigen receptor T (CAR T) cell therapy that targets ROR1. Oncternal submitted its first IND for ONCT-808 in August 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 early-stage 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 potential that Study ZILO-301 can serve as a registrational clinical trial; and the expected screening and enrollment of Study ZILO-301. 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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Source: Oncternal Therapeutics