Oncternal Therapeutics Announces Interim Clinical Data on TK216 in Ewing Sarcoma to Be Presented at the CTOS 2019 Annual Meeting

November 5, 2019

SAN DIEGO--(BUSINESS WIRE)--Nov. 5, 2019-- Oncternal Therapeutics, Inc. (Nasdaq: ONCT), a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies, today announced that interim data on TK216 – an investigational targeted small molecule inhibitor of ETS transcription factor oncoproteins – will be presented at the Connective Tissue Oncology Society (CTOS) 2019 Annual Meeting in Tokyo, Japan, on November 16, 2019. The oral presentation (abstract 3250355) titled “A Phase 1 Dose Escalation Study of Intravenous TK216 in Patients with Relapsed or Refractory Ewing Sarcoma” will be given by Paul A. Meyers, M.D., Chief, Pediatric Sarcoma Service and Vice Chair for Clinical Affairs of Memorial Sloan Kettering Cancer Center.

About TK216

TK216 is an investigational, potentially first-in-class small molecule that is designed to inhibit the biological activity of E26 transformation-specific (ETS) transcription factor oncoproteins, including fusion proteins. Tumorigenic gene fusions involving ETS factors are frequently found in tumors such as Ewing sarcoma and prostate cancer, and ETS factors are often overexpressed in many other tumors, including prostate cancer and acute myeloid leukemia (AML). TK216 was developed based on discoveries of Jeffrey Toretsky, M.D., and his team at Georgetown University, who discovered inhibitors of EWS-FLI1 using a novel chemical screening assay. In preclinical models, TK216 binds to EWS-FLI1 and blocks the interaction between ETS family members and RNA helicase A leading to tumor cell apoptosis.

About the Study

TK216 is being evaluated in a Phase 1 clinical study as a single agent and in combination with vincristine in patients with relapsed or refractory Ewing sarcoma, a rare pediatric cancer that has historically been very challenging to treat effectively, particularly for recurrent and metastatic disease. A dose-finding arm of this study is nearing completion, after which Oncternal intends to begin enrolling patients in an expansion cohort of the study to evaluate the clinical response of treatment with TK216 in combination with vincristine, an approved chemotherapy agent. This multi-center study is actively enrolling patients at six clinical trial centers across the U.S. Additional information about the TK216 study may be accessed at ClinicalTrials.gov (NCT02657005).

About Oncternal Therapeutics

Oncternal Therapeutics is a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies for the treatment of cancers with critical unmet medical need. Oncternal focuses drug development on promising yet untapped biological pathways implicated in cancer generation or progression. The pipeline includes cirmtuzumab, an investigational monoclonal antibody designed to inhibit the ROR1 receptor, a type I tyrosine kinase-like orphan receptor, that is being evaluated in a Phase 1/2 clinical trial in combination with ibrutinib for the treatment of chronic lymphocytic leukemia (CLL) and mantle cell lymphoma (MCL), and TK216, an investigational small-molecule compound that is designed to inhibit E26 transformation specific (ETS) family oncoproteins, that is being evaluated in a Phase 1 clinical trial for patients with Ewing sarcoma alone and in combination with vincristine chemotherapy. In addition, Oncternal has a program to develop a CAR-T therapy that targets ROR1, which is currently in preclinical development as a potential treatment for hematologic cancers and solid tumors. More information is available at www.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 the Company’s current beliefs and expectations. Forward looking statements include statements regarding Oncternal’s beliefs, goals, intentions and expectations, and include Oncternal’s expectation that it is nearing completion of the dose-finding portion of its Phase 1 clinical trial of TK216 in patients with relapsed or refractory Ewing sarcoma and the company’s intention to begin enrolling patients in an expansion cohort thereafter; and Oncternal’s belief that TK216 may address a critical unmet medical need by inhibiting the interaction of between ETS family members and RNA helicase A, thereby shutting down excessive cell proliferation. Forward looking statements are subject to risks and uncertainties, which include, but are not limited to: potential delays in the commencement, enrollment and completion of clinical trials, including due to the lack of availability of a sufficient number of eligible patients and the availability of competing clinical trials for the same group of eligible patients; uncertainties associated with the clinical development and process for obtaining regulatory approval of TK216 and Oncternal’s other product candidates; ; the risk that interim results of a clinical trial do not necessarily 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; the risk that the results seen in a case study of one patient may not predict the results seen in other patients in the clinical trial; the risk that unforeseen adverse reactions or side effects may occur in the course of developing and testing product candidates such as TK216 and Oncternal’s other product candidates; the risk that Oncternal may be unable to obtain sufficient additional capital to continue to advance the development of TK216 and its other product candidates; and other risks described in the Company’s prior press releases as well as in public periodic filings with the U.S. Securities & 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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