Oncternal Receives Fast Track Designation for TK216 in Relapsed or Refractory Ewing Sarcoma

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SAN DIEGO, June 20, 2016 — Oncternal Therapeutics, Inc., a clinical-stage oncology company developing first-in-class therapies for rare and common malignancies, today announced that its ets-family inhibitor TK216 has received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for the treatment of patients with Ewing sarcoma who have relapsed or are refractory to standard of care therapy. Oncternal is in the process of initiating a first-in-human Phase 1 trial in relapsed or refractory Ewing sarcoma. More information can be found at ClinicalTrials.gov, including participating sites: Memorial Sloan Kettering Cancer Center in New York City, UCLA Jonsson Comprehensive Cancer Center in Los Angeles, and MD Anderson Cancer Center in Houston.

James Breitmeyer, M.D., Ph.D., Oncternal's President and CEO, commented: "We are very pleased that the FDA has awarded Fast Track Designation for TK216 in Ewing sarcoma patients who have failed standard of care therapy. This rare bone cancer strikes children and young adults and there are few treatment alternatives, so it is imperative that we rapidly advance new therapeutics that have the potential to extend the lives of these patients. We look forward to beginning enrollment and dosing of Ewing sarcoma patients shortly in our Phase 1 trial of TK216."

The FDA describes Fast Track as a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to patients earlier by enabling more frequent communications with the agency to address potential questions and requirements, and to streamline regulatory submissions.

TK216 is a first-in-class small molecule that inhibits the biological activity of *ets*-family transcription factor oncoproteins in a variety of tumor types, stopping cancer cell growth and tumor formation. In Ewing sarcoma, it is designed to target a single and well-characterized genetic mutation that causes the disease. TK216 is based upon the discoveries of Jeffrey A. Toretsky, M.D. at Georgetown University, who conducted extensive research on the *ets*-family of oncogenes that cause or drive tumor growth in a number of solid and hematologic malignancies. Oncternal and Georgetown are also planning clinical studies in glioblastoma, prostate cancer and lymphoma in the next year.