Oncternal Opens its CIRLL Study, a Combo Trial of Cirmtuzumab with Ibrutinib in B-Cell Malignancies

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First Mantle Cell Lymphoma Patient Dosed

SAN DIEGO, May 15, 2018 – Oncternal Therapeutics, Inc., a clinical-stage biotechnology company developing first-in-class therapies for rare and common malignancies, today announced its opening of the CIRLL study (Cirmtuzumab and Ibrutinib targeting ROR1 for Lymphoma and Leukemia), a Phase 1b/2 clinical trial evaluating cirmtuzumab in combination with ibrutinib for the treatment of patients with B-cell malignancies, including mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL)/small lymphocytic leukemia (SLL). Oncternal is conducting this study in collaboration with researchers at the University of California San Diego (UC San Diego) School of Medicine and the California Institute for Regenerative Medicine (CIRM). In addition to UC San Diego, CIRLL study sites now include MD Anderson Cancer Center in Houston, where the first MCL patient was dosed, as well as Columbia University Medical Center and Northwell Health, both in New York.

"There remains significant unmet medical need for patients with B-cell malignancies because current drug treatments can induce partial responses, but these are temporary. It is our hope that adding cirmtuzumab to standard of care ibrutinib will induce complete responses that may be durable," said James Breitmeyer, M.D., Ph.D., Oncternal's President and CEO. "Our collaboration with Dr. Thomas Kipps of UC San Diego has shown that cirmtuzumab and ibrutinib synergistically block multiple signaling pathways that are important in the pathogenesis and progression of B-cell lymphomas and leukemias and provide a strong rationale for combination therapy."

The CIRLL study is a multi-center clinical trial to evaluate the combination of cirmtuzumab and ibrutinib in patients with previously treated MCL or CLL/SLL who have not received previous Bruton's tyrosine kinase (BTK) inhibitor therapy. A total of 117 patients will be enrolled.

An initial dose-finding portion of the study will determine the optimal dose of cirmtuzumab to administer when given with the approved dose of ibrutinib, and then confirm this dose in an expansion cohort. The study will then randomize patients to receive the combination of cirmtuzumab plus ibrutinib compared to ibrutinib alone. The objective is to demonstrate that a significantly greater number of patients will achieve a durable complete response when treated with cirmtuzumab plus ibrutinib compared with those treated with ibrutinib alone. The study could serve as the basis of registration if robust.

Further information on this study can be found on https://www.clinicaltrials.gov/under the study ID number NCT03420183.

About Cirmtuzumab

Cirmtuzumab is a first-in-class humanized monoclonal antibody that binds with high affinity to a biologically important epitope on ROR1 (Receptor-tyrosine kinase-like Orphan Receptor 1). ROR1 is a type 1 transmembrane protein expressed on the plasma membrane with an extracellular domain that is essential for ligand binding and signal transduction. Cirmtuzumab binds to many different types of cancer cells, but does not recognize normal human tissues. Tumor cells that express ROR1 have stem-cell like features that are associated with the dedifferentiated oncogenic state. When expressed by hematologic malignancies such as mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL), and small lymphocytic leukemia (SLL), ROR1 acts as a receptor for the tumor growth factor Wnt5a. When cirmtuzumab binds to ROR1, it blocks Wnt5a activation and inhibits tumor-cell proliferation, migration and survival.

About Oncternal Therapeutics

Oncternal Therapeutics is a clinical-stage oncology company developing first-in-class and novel therapies for both rare and common cancers by focusing on targets that are differentially expressed by cancer cells. The company is leveraging its scientific and development expertise, as well as academic collaborations, to rapidly advance its two pipeline products, cirmtuzumab, an anti-ROR1 monoclonal antibody, and TK216, a small molecule that inhibits the biological activity of ets-family transcription factor oncoproteins. In a collaboration with UC San Diego, Oncternal is developing a chimeric antigen receptor expressing T cell (CAR-T) targeting ROR1.

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