Oncternal Therapeutics Announces Strategic Reprioritization and Capital Preservation, Extends Cash Runway into 2025

April 3, 2023

- *Zilovertamab Phase 3 Study ZILO-301 and Phase 1/2 Study CIRM-0001 to be closed based on dynamically changing therapeutic landscape*
- *Cash runway extended to 2025, enabling initial clinical data readouts for both ONCT-808, ROR1-tageting CAR T for patients with aggressive lymphomas, and ONCT-534, novel AR inhibitor for patients with resistant mCRPC*
- *Management to host webcast today at 5:00 pm ET*

SAN DIEGO, April 03, 2023 (GLOBE NEWSWIRE) -- Oncternal Therapeutics, Inc. (Nasdaq: ONCT), a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies, today announced a strategic reprioritization based on the rapidly changing commercial landscape for Bruton's tyrosine kinase inhibitors (BTK inhibitors). The Phase 3 study and the Phase 1/2 study of zilovertamab in combination with ibrutinib will be closed, and other project and indirect expenses will be reduced, resulting in extending the expected cash runway into 2025. The projected cash runway will support the clinical advancement of our two pipeline assets ONCT-808 and ONCT-534.

"It is an extremely difficult decision to halt the clinical development of zilovertamab in combination with ibrutinib for patients with hematologic malignancies," said James Breitmeyer, M.D., Ph.D., Oncternal's President and CEO. "The dramatic adoption of recently approved Bruton's tyrosine kinase inhibitors made the continued development of zilovertamab with ibrutinib an unviable commercial opportunity. The decision was not based on any concerns about the safety or efficacy of zilovertamab. Going forward we will focus on reaching clinical proof of concept and data catalysts from the clinical trials of ONCT-808 in patients with resistant aggressive lymphoma, and ONCT-534 in patients with prostate cancer resistant to standard of care androgen receptor inhibitors."

ONCT-808: Our ROR1 targeting autologous CAR T cell therapy is being tested in a recently initiated Phase 1/2 clinical trial for the treatment of patients with relapsed or refractory aggressive B-cell lymphoma, including those who have failed previous CD19 CAR T therapy. Preclinical models show robust and specific activity against ROR1 expressing cells from multiple tumor types. We have developed a manufacturing process that is reproducible, scalable, and only 8 days in duration. We expect to present initial clinical data in late 2023, with additional clinical data readouts in 2024.

ONCT-534: Our novel dual-action androgen receptor inhibitor (DAARI) has concluded IND-enabling studies and we expect to submit an Investigational New Drug Application (IND) in mid-2023. Preclinical models suggest activity directed to both the N-terminal and ligand binding domain (LBD) of the androgen receptor (AR), and activity against the most common forms of resistance to current standard of care AR inhibitors. A Phase 1/2 clinical trial in patients with metastatic castrate-resistant prostate cancer (mCRPC) who are resistant to AR inhibitor treatment is expected to open shortly thereafter. We expect to present initial clinical data in mid-2024.

Zilovertamab: This reprioritization includes closing two studies of zilovertamab in combination with ibrutinib, ongoing Phase 1/2 Study CIRM-0001 and Phase 3 Study ZILO-301, a global registrational study in patients with relapsed/refractory MCL. We plan to continue exploring the potential value of zilovertamab in areas of high unmet medical need. The robust response rates and prolonged PFS seen for MCL and CLL patients expressing TP53 aberrations will be further investigated preclinically and extended into other tumor types, such as lung cancer and prostate cancer. We expect partnerships and collaborations to be essential for executing future late-stage clinical trials of zilovertamab.

In addition, management will continue to drive operational efficiencies and prudent cost reduction and cost containment measures. We estimate that our cash, cash equivalents and short-term investments were $54.3 million, and we had 58.7 million shares of common stock outstanding, as of March 31, 2023, and we expect our cash, cash equivalents and short-term investments to support our planned operations into 2025.

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. ONCT-808 is an investigational autologous chimeric antigen receptor T (CAR T) cell therapy that targets ROR1 using the binding domain from zilovertamab. ONCT-808 has demonstrated activity in preclinical models against multiple hematological malignancies and solid tumors and has been shown to be specific for cancer cells expressing ROR1. Oncternal has developed a robust and reproducible manufacturing process that has the potential to reduce the time patients must wait for their individual CAR T product to be produced, compared with approved CAR T products. Oncternal has initiated Study ONCT-808-101 (NCT05588440) for the treatment of patients with relapsed or refractory aggressive B-cell lymphoma, including patients who have failed previous CD19 CAR T treatment. ONCT-534 is a dual-action androgen receptor inhibitor (DAARI) with preclinical activity in prostate cancer models against both unmutated androgen receptor (AR), and against multiple forms of AR mutation. It is a potential treatment for patients with mCRPC and unmet medical need because of resistance to androgen receptor inhibitors, including those with AR amplification, mutations in the AR ligand binding domain (LBD), or splice variants with loss of the AR LBD. Final IND-enabling studies for ONCT-534 have been completed. Zilovertamab is an investigational monoclonal antibody designed to inhibit the function of Receptor Tyrosine Kinase-Like Orphan Receptor 1 (ROR1). Zilovertamab has been evaluated in Phase 1/2 Study CIRM-0001 (NCT03088878) in combination with ibrutinib for the treatment of patients with MCL, chronic lymphocytic leukemia (CLL) and marginal zone lymphoma (MZL). Zilovertamab is also being evaluated in two investigator-initiated studies: a Phase 2 clinical trial of zilovertamab in combination with venetoclax, a Bcl-2 inhibitor, in patients with R/R CLL (NCT04501939), and a Phase 1b study of zilovertamab in combination with docetaxel in patients with metastatic castration-resistant prostate cancer (NCT05156905). More information on our company and programs 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 Oncternal’s expected cash runway; Oncternal’s estimated cash, cash equivalents and short-term investments and capitalization as of March 31, 2023; the timing of reaching milestones, including the enrollment on clinical studies; the timing for regulatory filings and communications; and future development opportunities for zilovertamab. 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; 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; potential changes in estimated cash, cash equivalents and short-term investments and capitalization based on the completion of financial closing procedures and release of complete results for the quarter ended March 31, 2023; 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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