Oncternal Therapeutics Provides Business Update and Announces First Quarter 2024 Financial Results

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- *Fourth dosing cohort at 300 mg per day is fully enrolled for the Phase 1/2 study with ONCT-534, our dual-action androgen receptor inhibitor (DAARI), for patients with advanced prostate cancer who are resistant to approved androgen receptor pathway inhibitors; initial data readout expected in the latter part of the second quarter*
- *Phase 1/2 study for ONCT-808, our ROR1-targeting autologous CAR T cell therapy, for patients with relapsed or refractory aggressive B-cell lymphoma, including patients that have failed prior CD19 CAR T treatment is open and enrolling patients; clinical data update expected in mid-2024*
- *Cash, cash equivalents and short-term investments totaled $27.0 million as of March 31, 2024; cash runway projected into Q1 2025*
- *Management to host webcast today at 5:00 pm ET*

SAN DIEGO, May 09, 2024 (GLOBE NEWSWIRE) -- Oncternal Therapeutics, Inc. (Nasdaq: ONCT), a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies, today provided a business update and reported first quarter 2024 financial results.

“We are encouraged by the fast pace of execution for our clinical programs, and we are looking forward to important clinical data readouts in the coming months. Our Phase 1/2 study of ONCT-534 in patients with R/R mCRPC has advanced swiftly through the initial dose escalation cohorts and we are optimistic, based on preclinical data, that the 300 mg dose may be within the active dose range for antitumor activity. We believe that the novel mechanism of action of ONCT-534, which includes interaction with both the N-terminal and ligand-binding domains of the AR has the potential to address important unmet needs of prostate cancer patients who have progressed after treatment with approved AR pathway inhibitors,” said James Breitmeyer, M.D., Ph.D., Oncternal’s President and CEO. “Our ROR1 CAR T Phase 1/2 study is now open and enrolling patients after implementing protocol amendments. We continue to be encouraged by the initial response signals we observed, and we look forward to reporting additional clinical data in patients with relapsed or refractory aggressive B cell lymphoma, including those who have relapsed after CD19 CAR T treatment.”

Recent Highlights

- In April 2024, we announced that the first patient had been dosed in the fourth cohort of our Phase 1/2 study of ONCT-534 for the treatment of patients with advanced prostate cancer who are relapsed or refractory to approved androgen receptor pathway inhibitors (ARPI). Patients in the fourth dosing cohort will receive 300 mg of ONCT-534 taken orally each day. The fourth cohort is now fully enrolled with three subjects treated.
- Our dose escalation/dose expansion Phase 1/2 Study ONCT-808-101, evaluating our ROR1-targeting autologous CAR T cell therapy, ONCT-808, for the treatment of patients with relapsed or refractory aggressive B-cell lymphoma, is open and enrolling patients. Protocol changes that include modified eligibility criteria, increased monitoring for early infection, and evaluating lower doses have now been implemented.

Expected Upcoming Milestones

- ONCT-534, our dual-action androgen receptor inhibitor
  - Initial clinical data update in the second quarter of 2024
  - Additional clinical data readouts in the fourth quarter of 2024
- ONCT-808, our autologous ROR1-targeted CAR T cell therapy
  - Clinical data update in mid-2024
  - Additional clinical data readouts in the fourth quarter of 2024

First Quarter 2024 Financial Results
Our grant revenue was $0.6 million for the first quarter ended March 31, 2024. Our total operating expenses for the first quarter ended March 31, 2024 were $9.3 million, including $1.4 million in non-cash stock-based compensation expense. Research and development expenses for the quarter totaled $6.0 million, and general and administrative expenses for the quarter totaled $3.3 million. Net loss for the first quarter was $8.4 million, or a net loss of $2.83 per share, basic and diluted. As of March 31, 2024, we had approximately 3.0 million shares of common stock outstanding, $27.0 million in cash, cash equivalents and short-term investments and no debt. These funds are expected to be sufficient to fund our operations into the first quarter of 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-534 is an investigational dual-action androgen receptor inhibitor (DAARI) with demonstrated preclinical activity in prostate cancer models against both

unmutated androgen receptor (AR), and against multiple forms of AR aberration. It is a potential treatment for patients with mCRPC with unmet medical need because of resistance to androgen receptor pathway inhibitors, including those with AR amplification, mutations in the AR ligand binding domain (LBD), or splice variants with loss of the AR LBD. Study ONCT-534-101 (NCT05917470) has completed enrollment in three dose cohorts and continues to enroll and dose patients for treatment with mCRPC. ONCT-808 is an investigational autologous chimeric antigen receptor T (CAR T) cell therapy that targets Receptor Tyrosine Kinase-Like Orphan Receptor 1 (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 therapy to be produced, compared with currently approved CAR T products. Oncternal has dosed patients under Study ONCT-808-101 (NCT05588440) with relapsed or refractory aggressive B-cell lymphoma, including patients who have failed previous CD19 CAR T treatment. Zilovertamab is an investigational monoclonal antibody designed to inhibit the function of ROR1. Zilovertamab has been evaluated in a Phase 1/2 Study CIRM-0001 (NCT03088878) in combination with ibrutinib for the treatment of patients with mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL) and marginal zone lymphoma (MZL), which resulted in 100% progression free survival (PFS) at 42 months in CLL patients expressing a p53 mutation/del(17p), a population underserved by current treatment options. Zilovertamab is also being evaluated in an investigator-initiated 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 and statements regarding Oncternal’s development programs, including the anticipated timing for study enrollment and announcing clinical data. 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; 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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Oncternal Therapeutics, Inc.
Condensed Consolidated Balance Sheets Data
(in thousands)

	March 31, 2024	December 31, 2023
Cash, cash equivalents and short-term investments	$ 27,027	$ 34,255
Total assets	29,141	36,729
Total liabilities	6,215	6,677
Accumulated deficit	(206,167)	(197,779)
Total stockholders' equity	22,926	30,052

Oncternal Therapeutics, Inc.
Condensed Consolidated Statements of Operations Data
(in thousands, except per share data)

	Three Months Ended March 31,	
	2024	2023
Grant revenue	$ 569	$ 203
Operating expenses:		
Research and development	6,059	9,031

General and administrative	3,289	3,315
Total operating expenses	9,348	12,346
Loss from operations	(8,779)	(12,143)
Interest income	391	656
Net loss	$ (8,388)	$ (11,487)
Net loss per share, basic and diluted	$ (2.83)	$ (3.93)
Weighted-average shares outstanding, basic and diluted	2,959	2,926

Source: Oncternal Therapeutics