Oncternal Therapeutics Provides Business Update and Announces Third Quarter 2023 Financial Results

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- *The first patient was dosed in our Phase 1/2 study for ONCT-534, our dual-action androgen receptor inhibitor, for the treatment of patients with advanced prostate cancer who are resistant to approved androgen receptor pathway inhibitors*
- *Additional patients were treated in our ongoing Phase 1/2 study for ONCT-808, our ROR1-targeting autologous CAR T cell therapy, for the treatment of patients with relapsed or refractory aggressive B-cell lymphoma, including patients that have failed prior CD19 CAR T treatment; initial data readout expected in December 2023*
- *Cash, cash equivalents and short-term investments totaled $40.3 million as of September 30, 2023; cash runway projected into 2025*
- *Management to host webcast today at 5:00 pm ET*

SAN DIEGO, Nov. 09, 2023 (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 third quarter 2023 financial results.

“We continue to execute on our plan to advance both ONCT-534, our dual-action AR inhibitor for patients with advanced prostate cancer who have relapsed or are refractory to treatment with AR pathway inhibitors, and ONCT-808, our ROR1-targeting autologous CAR T for patients with aggressive B cell lymphoma, including those who relapse after CD19 CAR T treatment, towards potential significant clinical inflection points by mid-2024,” said James Breitmeyer, M.D., Ph.D., Oncternal’s President and CEO. “We believe ONCT-534 can address a significant unmet medical need for patients with advanced metastatic prostate cancer, especially those with splice variants of the androgen receptor, mutations in the ligand-binding domain of the AR, or AR amplification, common mechanisms of resistance to treatment with approved AR pathway inhibitors. With ONCT-808, we have seen encouraging expansion and persistence of CAR expressing T cells in our first advanced B-NHL patient, which we believe has been associated with positive responses for other CAR T therapies. We look forward to presenting an initial data update by the end of 2023.”

Recent Highlights

- In October 2023, we announced that the first patient with metastatic castration-resistant prostate cancer (mCRPC) had been dosed in the Phase 1/2 dose escalation/dose expansion study of ONCT-534, our novel dual-action androgen receptor inhibitor (DAARI)
- In October 2023, the U.S. Food and Drug Administration granted fast track designation for the treatment of adult patients with relapsed or refractory mCRPC resistant to androgen receptor pathway inhibitors (ARPIs)
- In September and October 2023, we announced the establishment and expansion of our Prostate Cancer Scientific Advisory Board (SAB), which includes distinguished academic and industry leaders in the prostate cancer field, who will provide guidance for the clinical development of ONCT-534

Expected Upcoming Milestones

- ONCT-808, our autologous ROR1-targeted CAR T cell therapy
  - Initial clinical data available by the end of 2023
  - Additional clinical data readouts in 2024
- ONCT-534, our dual-action androgen receptor inhibitor
  - Initial clinical data available in the first half of 2024

Third Quarter 2023 Financial Results

Our grant revenue was $0.2 million for the third quarter ended September 30, 2023. Our total operating expenses for the third quarter ended September 30, 2023 were $10.6 million, including $1.7 million in non-cash stock-based compensation expense. Research and development expenses for the quarter totaled $7.5 million, and general and administrative expenses for the quarter totaled $3.1 million. Interest income for the quarter totaled $0.5 million. Net loss for the quarter was $9.9 million, or a loss of $0.17 per share, basic and diluted. As of September 30, 2023, we had approximately 59.0 million shares of common stock outstanding, $40.3 million in cash, cash equivalents and short-term investments and no debt. We believe these funds will be sufficient to fund our 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-534 is an investigational 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 aberration. It is a potential treatment for patients with mCRPC with 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. Oncternal has initiated Study ONCT-534-101 (NCT05917470), which is open and enrolling 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.

Contact Information:

Investors
Richard Vincent
858-434-1113
rvincent@oncternal.com

Media
Corey Davis, Ph.D.
LifeSci Advisors
212-915-2577
cdavis@lifesciadvisors.com

Oncternal Therapeutics, Inc.
Condensed Consolidated Balance Sheets Data
(in thousands)

	September 30, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	$ 40,305	$ 63,724
Total assets	43,195	68,651
Total liabilities	6,199	7,682
Accumulated deficit	(188,615)	(158,300)
Total stockholders' equity	36,996	60,969

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

	Three Months Ended September 30,	Nine Months Ended September 30,

	2023	2022	2023	2022
Grant revenue	$ 179	$ 382	$ 488	$ 1,319
Operating expenses:				
Research and development	7,475	8,442	23,083	24,182
General and administrative	3,094	3,265	9,483	10,169
Total operating expenses	10,569	11,707	32,566	34,351
Loss from operations	(10,390)	(11,325)	(32,078)	(33,032)
Interest income	528	200	1,763	262
Net loss	$ (9,862)	$ (11,125)	$ (30,315)	$ (32,770)
Net loss per share, basic and diluted	$ (0.17)	$ (0.21)	$ (0.52)	$ (0.64)
Weighted-average shares outstanding, basic and diluted	58,964	54,212	58,738	51,252

Source: Oncternal Therapeutics