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

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- *No dose-limiting toxicities or concerning side effects in our 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; 1200 mg cohort for ONCT-534 given orally once daily enrolled and treated; initial data readout expected in the third quarter of 2024*
- *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 is open and enrolling patients; clinical data update expected in the fourth quarter of 2024*
- *Cash, cash equivalents and short-term investments totaled $21.4 million as of June 30, 2024; cash runway projected into Q1 2025*
- *Management to host webcast today at 5:00 pm ET*

SAN DIEGO, Aug. 08, 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 second quarter 2024 financial results.

“Our Phase 1/2 study of ONCT-534 in patients with R/R mCRPC continues to advance through dose escalation cohorts without dose-limiting toxicities or concerning side effects. We are encouraged by the high pace of enrollment in the study and look forward to sharing initial clinical and biomarker data later in the third quarter,” said James Breitmeyer, M.D., Ph.D., Oncternal’s President and CEO. “Our Phase 1/2 study of ONCT-808, our autologous ROR1 CAR T, is open and enrolling patients. We remain encouraged we will find the optimal dose to address the high unmet need of patients with relapsed or refractory aggressive B cell lymphoma, including those who have relapsed after CD19 CAR T treatment.”

Recent Highlights

- In July 2024, we announced that enrollment was complete and three patients dosed in the sixth 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 sixth dosing cohort are being given 1200 mg of ONCT-534 orally once per day.
- 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, including patients that have failed prior CD19 CAR T treatment, is open and enrolling patients. Protocol changes that include modified eligibility criteria, increased monitoring for early infection, and evaluating lower doses of ONCT-808 have now been implemented.

Expected Upcoming Milestones

- ONCT-534, our dual-action androgen receptor inhibitor
  - Initial clinical data in the third 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 the fourth quarter of 2024

Second Quarter 2024 Financial Results
Our grant revenue was $0.8 million for the second quarter ended June 30, 2024. Our total operating expenses for the second quarter ended June 30, 2024 were $9.7 million, including $1.4 million in non-cash stock-based compensation expense. Research and development expenses for the quarter totaled $6.6 million, and general and administrative expenses for the quarter totaled $3.1 million. Net loss for the first quarter was $8.6 million, or a net loss of $2.89 per share, basic and diluted. As of June 30, 2024, we had approximately 3.0 million shares of common stock outstanding, $21.4 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 and dosing in six dose

cohorts for the treatment of patients 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
(Unaudited; in thousands)

	June 30, 2024	December 31, 2023
Cash, cash equivalents and short-term investments	$ 21,429	$ 34,255
Total assets	23,859	36,729
Total liabilities	8,105	6,677
Accumulated deficit	(214,726)	(197,779)
Total stockholders' equity	15,754	30,052

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Grant revenue	$ 801	$ 106	$ 1,370	$ 309
Operating expenses:				
Research and development	6,612	6,577	12,671	15,608
General and administrative	3,052	3,074	6,341	6,389
Total operating expenses	9,664	9,651	19,012	21,997
Loss from operations	(8,863)	(9,545)	(17,642)	(21,688)
Interest income	304	579	695	1,235
Net loss	$ (8,559)	$ (8,966)	$ (16,947)	$ (20,453)

Net loss per share, basic and diluted	$ (2.89)	$ (3.05)	$ (5.73)	$ (6.98)
Weighted-average shares outstanding, basic and diluted	2,960	2,936	2,960	2,931

Source: Oncternal Therapeutics