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

Aug 10, 2023 at 4:01 PM EDT

- *Obtained U.S. FDA IND clearance 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 signaling inhibitors*
- *Dosed the first patient in our 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*
- *Cash runway extended into 2025, with $45.5 million in cash, cash equivalents and short-term investments and no debt as of June 30, 2023*
- *Management to host webcast today at 5:00 pm ET*

SAN DIEGO, Aug. 10, 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 second quarter 2023 financial results.

“Oncternal is executing on its strategy to deliver significant value inflection points for our two clinical programs. The clearance of the IND for ONCT-534, our dual-action androgen receptor inhibitor, represents a major milestone for Oncternal and a new potential option for patients suffering from mCRPC. We have received support from top prostate cancer experts in the United States and Europe. We reiterate our guidance to dose the first patient later this year, with initial clinical data in the first half of 2024. Resistance to standard of care androgen receptor signaling inhibitors such as enzalutamide and abiraterone represents a significant unmet medical need. Pre-clinical studies have shown that ONCT-534 may directly address the most common resistance mechanisms, such as androgen receptor ligand-binding domain mutations and AR-V7 splice variants,” said James Breitmeyer, M.D., Ph.D., Oncternal’s President and CEO. “The dosing of the first patient with ONCT-808, our ROR1 targeting autologous CAR T therapy, represents a significant milestone for patients suffering from aggressive B-cell lymphomas. We look forward to a data update later this year in this area of significant unmet medical need.”

Recent Highlights

- In August 2023, we received a ‘Study May Proceed’ letter from the U.S. Food and Drug Administration (FDA), less than 30 days after submitting our Investigational New Drug (IND) application for ONCT-534, our novel dual-action androgen receptor inhibitor (DAARI) to support a Phase 1/2 clinical trial in patients with metastatic castration-resistant prostate cancer (mCRPC) who are resistant to currently available androgen receptor (AR) inhibitor drugs such as enzalutamide and abiraterone
- In June 2023, we announced that the first patient has been dosed in the Phase 1/2 dose escalation/dose expansion study of ONCT-808, our ROR1 targeting autologous CAR T cell therapy (NCT05588440)

Expected Upcoming Milestones

- ONCT-808, our autologous ROR1-targeted CAR T cell therapy
  - Initial clinical data available by the end of 2023
  - Additional clinical readouts in 2024
- ONCT-534, our dual-action androgen receptor inhibitor
  - Phase 1/2 clinical study initiation in the third quarter of 2023
  - Initial clinical data available in the first half of 2024

Second Quarter 2023 Financial Results

Our grant revenue was $0.1 million for the second quarter ended June 30, 2023. Our total operating expenses for the second quarter ended June 30, 2023 were $9.7 million, including $1.7 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 $9.0 million, or a loss of $0.15 per share, basic and diluted. As of June 30, 2023, we had approximately 58.7 million shares of common stock outstanding, $45.5 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-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. 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-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. 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 aberrations. It is a potential treatment for patients with relapsed or refractory metastatic castration-resistant prostate cancer (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. ONCT-534 has an active U.S. IND, and a Phase 1/2 clinical trial is being opened. Zilovertamab is an investigational monoclonal antibody designed to inhibit the function of ROR1. Zilovertamab showed evidence of antitumor activity and was well tolerated in Phase 1/2 Study CIRM-0001 (NCT03088878) in combination with ibrutinib for the treatment of patients with mantle cell lymphoma, chronic lymphocytic leukemia (CLL) and marginal zone lymphoma. Zilovertamab is 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 relapsed/refractory (R/R) CLL (NCT04501939), and a Phase 1b study of zilovertamab in combination with docetaxel in patients with mCRPC (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; statements regarding Oncternal’s development programs, including the anticipated timing for announcing additional preclinical and clinical data; the timing of reaching milestones, including the enrollment on clinical studies; and the timing for regulatory filings and communications. 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)

	June 30, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	$ 45,503	$ 63,724
Total assets	50,773	68,651
Total liabilities	5,589	7,682
Accumulated deficit	(178,753)	(158,300)
Total stockholders' equity	45,184	60,969

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Grant revenue	$ 106	$ 191	$ 309	$ 937
Operating expenses:				
Research and development	6,577	8,761	15,608	15,740
General and administrative	3,074	3,225	6,389	6,904
Total operating expenses	9,651	11,986	21,997	22,644
Loss from operations	(9,545)	(11,795)	(21,688)	(21,707)
Interest income	579	54	1,235	62
Net loss	$ (8,966)	$ (11,741)	$ (20,453)	$ (21,645)

Net loss per share, basic and diluted	$ (0.15)	$ (0.23)	$ (0.35)	$ (0.44)
Weighted-average shares outstanding, basic and diluted	58,722	50,064	58,623	49,748

Source: Oncternal Therapeutics