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

May 4, 2023

- *Phase 1/2 study initiated for ONCT-808, our autologous CAR-T targeting ROR1-expressing hematologic malignancies, with initial clinical data expected in late 2023*
- *Final IND-enabling studies completed for ONCT-534, our novel dual-action androgen receptor inhibitor (DAARI), with expected IND submission in mid-2023*
- *Cash runway extended into 2025, with $54.3 million in cash, cash equivalents and short-term investments and no debt as of March 31, 2023*
- *Management to host webcast today at 5:00 pm ET*

SAN DIEGO, May 04, 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 first quarter 2023 financial results.

“Oncternal is intensely focused on advancing our cell therapy and androgen receptor (AR) inhibitor programs to reach significant clinical inflection points over the coming months. We are excited about the potential of ONCT-808, our ROR1-targeting CAR T, as it builds on the extensive clinical experience with zilovertamab, as well as with zilovertamab vedotin, an antibody drug conjugate, which has shown that ROR1 can be targeted without unwanted off-tumor, on-target activity. We are also enthusiastic about our novel and first-in-class dual-action AR inhibitor, ONCT-534, which demonstrated in preclinical studies that its unique mechanism of action may address significant unmet needs related to AR-resistance mechanisms in patients with metastatic castrate-resistant prostate cancer (mCRPC). We expect to initiate a Phase 1/2 study of ONCT-534 shortly after an IND submission in mid-2023, and to report initial clinical data in the first half of 2024, well within our expected cash runway period,” said James Breitmeyer, M.D., Ph.D., Oncternal’s President and CEO. “Our decision to pause clinical development of zilovertamab with ibrutinib was a necessary step due to a major shift in the Bruton’s tyrosine kinase (BTK) inhibitor landscape, along with the announced plans by Abbvie to withdraw ibrutinib’s FDA accelerated approval in MCL. While we continue to actively explore options to develop zilovertamab through partnerships and collaborations, this decision allowed us to extend our expected cash runway into 2025 and support key clinical catalysts for our cell therapy and prostate cancer programs.”

Recent Highlights

- In January 2023, we obtained our first Institutional Review Board (IRB) approval for the Phase 1/2 study of ONCT-808 of our autologous ROR1 targeting CAR T for patients with aggressive B cell lymphoma (NCT05588440)
- In March 2023, we concluded Investigational New Drug (IND)-enabling studies for ONCT-534, our novel dual-action androgen receptor inhibitor (DAARI) to support a Phase 1/2 clinical trial in patients with mCRPC who are resistant to androgen receptor (AR) inhibitor drugs such as enzalutamide and abiraterone
- In April 2023, we announced that the Phase 3 and the Phase 1/2 studies of zilovertamab in combination with ibrutinib will be closed, based on the rapidly changing commercial landscape for BTK inhibitors

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
  - U.S. IND application submission in mid-2023
  - Phase 1/2 clinical study initiation in the second half of 2023
  - Initial clinical data available in the first half of 2024

First Quarter 2023 Financial Results

Our grant revenue was $0.2 million for the first quarter ended March 31, 2023. Our total operating expenses for the first quarter ended March 31, 2023 were $12.3 million, including $1.9 million in non-cash stock-based compensation expense. Research and development expenses for the quarter totaled $9.0 million, and general and administrative expenses for the quarter totaled $3.3 million. Net loss for the first quarter was $11.5 million, or a loss of $0.20 per share, basic and diluted. As of March 31, 2023, we had approximately 58.7 million shares of common stock outstanding, $54.3 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-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 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 aberrations. 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 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; 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)

	March 31, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	$ 54,317	$ 63,724
Total assets	58,282	68,651
Total liabilities	5,794	7,682
Accumulated deficit	(169,787)	(158,300)
Total stockholders' equity	52,488	60,969

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

	Three Months Ended March 31,	
	2023	2022
Grant revenue	$ 203	$ 746
Operating expenses:		
Research and development	9,031	6,979
General and administrative	3,315	3,679
Total operating expenses	12,346	10,658
Loss from operations	(12,143)	(9,912)
Interest income	656	8

Net loss	$ (11,487)	$ (9,904)
Net loss per share, basic and diluted	$ (0.20)	$ (0.20)
Weighted-average shares outstanding, basic and diluted	58,522	49,429

Source: Oncternal Therapeutics