Oncternal Therapeutics Provides Business Update and Announces Fourth Quarter and Full Year 2023 Financial Results

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- *Third dosing cohort fully enrolled for 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; initial data readout expected in the second quarter of 2024*
- *Encouraging response signal at initial dose level 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; clinical data update expected in mid-2024*
- *Cash, cash equivalents and short-term investments totaled $34.3 million as of December 31, 2023; cash runway projected into 2025*
- *Management to host webcast today at 5:00 pm ET*

SAN DIEGO, March 07, 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 fourth quarter and full year 2023 financial results.

"We are encouraged by the progress in our clinical programs and their potential to address significant unmet needs in advanced prostate cancer and aggressive B-cell malignancies. Our Phase 1 study of ONCT-534 in patients with R/R mCRPC is progressing through the initial dose escalation portion of the study according to plan and we look forward to an initial clinical readout in the second quarter of this year that will include response readouts from patients dosed at potentially therapeutic levels. We continue to believe that the novel mechanism of action of ONCT-534 and the wealth of preclinical data we generated underpins its potential to address the needs of prostate cancer patients who progress after treatment with approved AR pathway inhibitors," said James Breitmeyer, M.D., Ph.D., Oncternal's President and CEO. "Our ROR1 CAR T program showed encouraging initial response results and we believe that the protocol amendments will further ensure patient safety as we investigate the optimal dose of ONCT-808 for patients with relapsed or refractory aggressive B cell lymphoma, including patients who have relapsed after CD19 CAR T treatment."

Recent Highlights

- In January 2024, we announced that two patients with metastatic castration-resistant prostate cancer (mCRPC) were enrolled into the third dosing cohort (160 mg daily) in the Phase 1/2 dose escalation/dose expansion study of ONCT-534, our novel dual-action androgen receptor inhibitor (DAARI). The third cohort is now fully enrolled.
- In December 2023, we updated the status of 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 who have failed previous CD19 CAR T treatment.
    - Encouraging response signal at the initial dose of $1x10^6$ CAR T cells per kg, with two of the three patients achieving complete metabolic response (CMR) and the third achieving a partial response (PR) by FDG PET-CT.
    - Common adverse events in the initial dosing cohort included decreased blood counts, pneumonia and Grade 1-2 cytokine release syndrome (CRS) as of a 4 December 2023 data cutoff.
    - The first patient treated at the second dose level of $3x10^6$ CAR T cells per kg, an 80-year-old with bulky disease who had received four previous lines of therapy including CD19 CAR T, experienced a Grade 5 (fatal) serious adverse event consistent with CRS and immune effector cell-associated neurotoxicity syndrome (ICANS). No evidence of his lymphoma was found histologically, based on the patient's initial autopsy report.
    - In alignment with the U.S. Food and Drug Administration, the company decided to implement protocol changes that include modified eligibility criteria and testing lower doses for future patients in the study.
- In January 2024, we announced a 1-for-20 reverse stock split of our common stock and regained compliance with Nasdaq's minimum bid price requirement.

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

Fourth Quarter and Full Year 2023 Financial Results
Our grant revenue was $0.3 million for the fourth quarter ended December 31, 2023 and was $0.8 million for the full year 2023. Our total operating expenses for the fourth quarter ended December 31, 2023 were $9.9 million, including $2.2 million in non-cash stock-based compensation expense. Research and development expenses for the quarter totaled $6.7 million, and general and administrative expenses for the quarter totaled $3.3 million. Interest income for the quarter totaled $0.5 million. Net loss for the quarter was $9.2 million, or a loss of $3.11 per share, basic and diluted. For the full year 2023, total operating expenses were $42.5 million, including $7.5 million in non-cash stock-based compensation expense, and our net loss was $39.5 million, or a loss of $13.43 per share, basic and diluted. As of December 31, 2023, we had approximately 2.9 million shares of common stock outstanding, $34.3 million in cash, cash equivalents and short-term investments and no debt. We believe these funds will be sufficient to fund our operations into 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 dosed patients and continues to enroll 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.
Consolidated Balance Sheets Data
(in thousands)

	December 31, 2023	December 31, 2022
Cash, cash equivalents, and short-term investments	$ 34,255	$ 63,724
Total assets	36,729	68,651
Total liabilities	6,677	7,682
Accumulated deficit	(197,779)	(158,300)

Total stockholders' equity	30,052	60,969

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

	Three Months Ended December 31,		Years Ended December 31,	
	2023	**2022**	**2023**	**2022**
Grant revenue	$ 297	$ 171	$ 785	$ 1,490
Operating expenses:				
Research and development	6,670	8,798	29,753	32,980
General and administrative	3,263	3,288	12,746	13,457
Total operating expenses	9,933	12,086	42,499	46,437
Loss from operations	(9,636)	(11,915)	(41,714)	(44,947)
Interest income	472	515	2,235	777
Net loss	$ (9,164)	$ (11,400)	$ (39,479)	$ (44,170)
Net loss per share, basic and diluted	$ (3.11)	$ (4.03)	$ (13.43)	$ (16.80)
Weighted-average shares outstanding, basic and diluted	2,948	2,829	2,940	2,630

Source: Oncternal Therapeutics