Oncternal Therapeutics Provides Business Update and Announces Third Quarter 2022 Financial Results

November 3, 2022

- *Initiated Phase 3 global registrational Study ZILO-301 of our zilovertamab product candidate targeting ROR1 in combination with ibrutinib for the treatment of patients with MCL*
- *Received acceptance for an oral presentation at the 64th ASH Annual Meeting and Exposition for the update of results from the ongoing Phase 1/2 study of zilovertamab and ibrutinib in patients with MCL and CLL*
- *Obtained IND clearance from U.S. FDA for ONCT-808, our autologous CAR T product candidate targeting ROR1, for the treatment of aggressive B-cell lymphoma, including those that have failed prior CD19 CAR T treatment, with initial clinical data readout expected in 2023*
- *Executing IND enabling studies for ONCT-534, the lead candidate in our novel dual-action androgen receptor inhibitor (DAARI) program; pre-IND feedback from U.S. FDA expected in December 2022*
- *Existing cash runway expected to fund operations into the first half of 2024 with $70.6 million in cash and cash equivalents and no debt as of September 30, 2022*
- *Management to host webcast today at 5:00 pm ET*

SAN DIEGO, Nov. 03, 2022 (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 financial results for the third quarter of 2022.

“This past quarter was a pivotal one for Oncternal’s leading ROR1 programs, highlighted by initiation of the Company’s first global registrational clinical study for zilovertamab in MCL and the FDA clearance of the IND for ONCT-808, our ROR1 targeting CAR T product candidate, for the treatment of patients with advanced aggressive B-cell lymphoma,” said James Breitmeyer, M.D., Ph.D., Oncternal’s President and CEO. “These exciting developments are backed by a strong clinical data foundation, as highlighted by acceptance of our zilovertamab Phase 1/2 data update in MCL and CLL for an oral presentation at the upcoming American Society of Hematology (ASH) annual meeting in December. We are now looking forward to ramping up site enrollment for our Phase 3 clinical study globally, to the initiation of our first CAR T Phase 1/2 study from which we expect an initial clinical data readout next year, and to the further advancement towards the clinic of ONCT-534, our DAARI product candidate that may address key resistance mechanisms in metastatic prostate cancer. We continue to exercise prudent cash management and expect our existing cash and cash equivalents will last into the first half of 2024.”

Recent Highlights

- Initiated the Phase 3 global registrational study of zilovertamab, Study ZILO-301 (NCT05431179), for the treatment of patients with relapsed/refractory mantle cell lymphoma (MCL)
- Received a ‘Study May Proceed’ letter from the U.S. Food and Drug Administration (FDA), 30 days after submitting our Investigational New Drug (IND) application for our Phase 1/2 study of ONCT-808, an autologous chimeric antigen receptor (CAR) T therapy targeting ROR1, in patients with aggressive B-cell lymphoma, including those who have failed previous CD19 CAR T treatment

Expected Upcoming Milestones

- Zilovertamab, our ROR1 antibody program
  - Opening of sites outside of the U.S. for global clinical registrational Phase 3 Study ZILO-301, in the first quarter of 2023
  - Interim clinical data update for patients with MCL and CLL treated with zilovertamab plus ibrutinib in ongoing Phase 1/2 Study CIRM-0001, as oral presentation at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition in December 2022
- ONCT-808, lead candidate in our autologous ROR1-targeted CAR T cell therapy program
  - Initiation of Phase 1/2 Study in patients with aggressive B-cell lymphoma in the first quarter of 2023
  - Initial clinical data update in 2023
- ONCT-534, lead candidate in our DAARI program
  - U.S. FDA pre-IND feedback in December 2022

Third Quarter 2022 Financial Results

Our grant revenue was $0.4 million for the third quarter ended September 30, 2022. Our grant revenue is derived from two research and development grant awards from the National Institutes of Health (NIH).

Our total operating expenses for the third quarter ended September 30, 2022 were $11.7 million, including $2.0 million in non-cash stock-based compensation expense. Research and development expenses for the quarter totaled $8.4 million, and general and administrative expenses for the quarter totaled $3.3 million. Net loss for the third quarter was $11.1 million, or a loss of $0.21 per share, basic and diluted.

As of September 30, 2022, we had approximately 55.5 million shares of common stock outstanding, $70.6 million in cash and cash equivalents and no debt. Based on our current operating plan, we believe these funds will be sufficient to fund our operations into the first half of 2024. Our cash guidance is subject to a number of assumptions, including those related to the pace of our research and clinical development programs, among other aspects of our business and the geopolitical environment.

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. The lead clinical program is zilovertamab, an investigational monoclonal antibody designed to inhibit the function of Receptor Tyrosine Kinase-Like Orphan Receptor 1 (ROR1). ZILO-301, a global Phase 3 Study to evaluate zilovertamab in combination with ibrutinib for the treatment of patients with relapsed/refractory mantle cell lymphoma (MCL) has been initiated (NCT05431179). Zilovertamab continues to be evaluated in an ongoing Phase 1/2 study in combination with ibrutinib for the treatment of patients with MCL and chronic lymphocytic leukemia (CLL), and this trial was recently amended to include patients with marginal zone lymphoma (MZL) (NCT03088878). Zilovertamab is also being evaluated in two investigator-initiated studies, including a Phase 2 clinical trial of zilovertamab in combination with venetoclax, a Bcl-2 inhibitor, in patients with relapsed/refractory CLL, and in a Phase 1b study of zilovertamab in combination with docetaxel in patients with metastatic castration-resistant prostate cancer (mCRPC). Oncternal is also moving into the clinic with ONCT-808, an autologous chimeric antigen receptor T (CAR T) cell therapy that targets ROR1, with an active U.S. IND as of the end of September 2022 for the treatment of patients with relapsed or refractory aggressive B-cell lymphoma, including patients who have failed previous CD19 CAR T treatment. The preclinical pipeline also includes ONCT-534, a dual-action androgen receptor inhibitor (DAARI) that is undergoing final IND-enabling studies, as a potential treatment for castration resistant prostate cancer, including those with unmet medical need due to resistance to approved, standard of care androgen receptor inhibitors. More information 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 development programs, including the anticipated timing for announcing additional preclinical and clinical data; timing of reaching any milestones, including the initiation of planned clinical studies; timing for regulatory communications; Oncternal’s expected cash runway; and the potential that Study ZILO-301 can serve as a registrational clinical trial. 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; we have not conducted head-to-head studies of zilovertamab in combination with ibrutinib compared to ibrutinib monotherapy and data from separate studies may not be directly comparable due to the differences in study protocols, conditions and patient populations; 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; later developments with the FDA may be inconsistent with the minutes from the completed end of Phase 2 meeting, including that the proposed Study ZILO-301 that may not support registration of zilovertamab in combination with ibrutinib which is a review issue with the FDA upon submission of a BLA; 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)

	September 30, 2022 (Unaudited)	December 31, 2021
Cash and cash equivalents	$ 70,628	$ 90,765
Total assets	76,170	93,585
Total liabilities	7,626	5,465

Accumulated deficit	(146,900)	(114,130)
Total stockholders' equity	68,544	88,120

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Grant revenue	$ 382	$ 2,128	$ 1,319	$ 3,759
Operating expenses:				
Research and development	8,442	8,963	24,182	18,068
General and administrative	3,265	2,802	10,169	8,977
Total operating expenses	11,707	11,765	34,351	27,045
Loss from operations	(11,325)	(9,637)	(33,032)	(23,286)
Interest income	200	7	262	26
Net loss	$ (11,125)	$ (9,630)	$ (32,770)	$ (23,260)
Net loss per share, basic and diluted	$ (0.21)	$ (0.19)	$ (0.64)	$ (0.47)
Weighted-average shares outstanding, basic and diluted	54,212	49,393	51,252	49,285

Source: Oncternal Therapeutics