Onconova Therapeutics Reports Corporate Update and Announces Second Quarter 2023 Financial Results

Aug 10, 2023

Anticipate topline results from the Phase 1 monotherapy and Phase 1/2 combination study with letrozole in Q4 2023

Plans are underway for a registrational trial with rigosertib in patients with RDEB-associated squamous cell carcinoma based on a constructive Type B FDA meeting held in June

Company to host conference call and webcast at 4:30 p.m. ET on Thursday, August 10, 2023

NEWTOWN, Pa., Aug. 10, 2023 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX), ("Onconova" or "the Company"), a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer, today reported second quarter 2023 financial results and provided an update on recent pipeline progress. Management plans to host a conference call and live webcast at 4:30 p.m. ET today to discuss these results.

"We are very encouraged about the recent progress that the Onconova team has made for our two lead programs, narazaciclib, a differentiated multikinase CDK4/6 inhibitor targeting proteins involved in resistance pathways, and rigosertib, a cell signaling inhibitor, over the last few months, while effectively managing our financial resources. In addition, we are pleased that Victor Moyo, M.D., a highly experienced and successful clinical researcher and drug developer, has agreed to join the Company as Consulting Chief Medical Officer. We look forward to sharing several important updates in the coming months," said Steve Fruchtman, M.D., President and Chief Executive Officer.

Dr. Fruchtman continued, "For narazaciclib, our efforts have been dedicated to completing a Phase 1 program and defining a recommended Phase 2 dose to support evaluation of narazaciclib in a randomized trial. Onconova believes this CDK4/6 compound has the potential to provide differentiated efficacy based on targeting proteins that have been implicated in resistance mechanisms and the potential for an improved safety profile. We are pleased to see target engagement based on an assay measuring proliferation. We expect to report the results from our Phase 1 monotherapy and Phase 1/2 combination study with letrozole in Q4 2023. The readout will include safety, pharmacokinetics and the definition of a recommended Phase 2 dose."

Dr. Fruchtman concluded, "For rigosertib, we continue to believe this rigosertib's unique action on cell signaling pathways, including K-RAS and PLK-1, combined with an acceptable safety profile, could position it as an attractive anti-cancer agent. In June, we had a constructive Type B meeting with the FDA for the use of rigosertib monotherapy in the lead, ultra-rare indication of RDEB-associated squamous cell carcinoma. Based on that meeting and the impressive clinical responses in previously refractory patients we have seen and presented at major medical meetings, we plan to design a registrational trial and will look to provide an update on next steps in H1 2024. In the meantime, we continue to support two investigator sponsored studies for rigosertib, underway in melanoma and KRAS mutated non-small cell lung cancer which includes any KRAS mutation that may be present."

Second Quarter Financial Results
Cash and cash equivalents as of June 30, 2023, were $29.7 million, compared to $38.8 million as of December 31, 2022. The Company believes that its cash and cash equivalents will be sufficient to fund ongoing clinical trials and business into the second quarter of 2024.

Research and development expenses were $2.5 million for the second quarter of 2023, compared with $2.0 million for the second quarter of 2022.

General and administrative expenses were $2.2 million for the second quarter of 2023, compared with $2.1 million for the second quarter of 2022.

Net loss for the second quarter of 2023 was $4.3 million, or $0.20 per share on 21.0 million weighted shares outstanding, compared with a net loss of $4.0 million, or $0.19 per share for the second quarter of 2022 on 20.9 million weighted shares outstanding.

Conference Call and Webcast Information
Interested parties who wish to participate in the conference call may do so by dialing:

- (800) 715-9871 for domestic and
- (646) 307-1963 for international callers and
- Using conference ID 9506701

Those interested in listening to the conference call via the internet may do so by visiting the investors and media page on the Company's website at www.onconova.com and clicking on the webcast link. In addition to the live webcast, a replay will be available on the Onconova website for 90 days following the call.

About Onconova Therapeutics, Inc.
Onconova Therapeutics is a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer. The Company's product candidates include proprietary targeted anti-cancer agents designed to disrupt specific cellular pathways that are important for cancer cell proliferation.

Onconova's novel, proprietary multi-kinase inhibitor narazaciclib (formerly ON 123300) is being evaluated in a Phase 1/2 combination trial with the estrogen blocker, letrozole, in advanced low grade endometrial cancer (NCT05705505). Based on preclinical and clinical studies of CDK 4/6 inhibitors, Onconova is also evaluating opportunities for combination studies with narazaciclib and letrozole in additional indications.

Onconova's product candidate rigosertib is being studied in multiple investigator-sponsored studies. These studies include a dose-escalation and expansion Phase 1/2a study of oral rigosertib in combination with nivolumab in patients with KRAS+ non-small cell lung cancer (NCT04263090), a Phase 2 program evaluating oral or IV rigosertib monotherapy in advanced squamous cell carcinoma complicating recessive dystrophic epidermolysis bullosa (RDEB-associated SCC (NCT03786237, NCT04177498), and a Phase 2 trial evaluating rigosertib in combination with pembrolizumab in patients with metastatic melanoma (NCT05764395).

For more information, please visit www.onconova.com.

Forward Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and involve risks and uncertainties. These statements relate to Onconova's expectations regarding its clinical development and trials, its product candidates and its business and financial position. Onconova has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "preliminary," "encouraging," "approximately" or other words that convey uncertainty of future events or outcomes. Although Onconova believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including the success and timing of Onconova's clinical trials, investigator-sponsored trials, regulatory agency and institutional review board approvals of protocols, Onconova's collaborations, market conditions and those discussed under the heading "Risk Factors" in Onconova's most recent Annual Report on Form 10-K and quarterly reports on Form 10-Q. Any forward-looking statements contained in this release speak only as of its date. Onconova undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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ONCONOVA THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2023	December 31, 2022
Assets	*(unaudited)*	
Current assets:		
Cash and cash equivalents	$ 29,729	$ 38,757
Receivables	17	29
Prepaid expenses and other current assets	704	561
Total current assets	30,450	39,347
Property and equipment, net	17	24
Other non-current assets	1	1
Total assets	$ 30,468	$ 39,372
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,071	$ 3,860
Accrued expenses and other current liabilities	3,369	3,960
Deferred revenue	226	226
Total current liabilities	8,666	8,046
Deferred revenue, non-current	2,904	3,017
Total liabilities	11,570	11,063
Stockholders' equity:		
Preferred stock	-	-
Common stock	210	209
Additional paid in capital	492,424	491,816

Accumulated other comprehensive loss	(28)	(33)
Accumulated deficit	(473,708)	(463,683)
Total stockholders' equity	18,898	28,309
Total liabilities and stockholders' equity	$ 30,468	$ 39,372

ONCONOVA THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations (unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six months months ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenue	$ 57	$ 57	$ 113	$ 113
Operating expenses:				
General and administrative	2,211	2,139	4,324	4,325
Research and development	2,456	2,038	6,536	4,040
Total operating expenses	4,667	4,177	10,860	8,365
Loss from operations	(4,610)	(4,120)	(10,747)	(8,252)
Change in fair value of warrant liability	-	-	-	-
Other income, net	360	96	722	106
Net loss	(4,250)	(4,024)	(10,025)	(8,146)
Net loss per share of common stock, basic and diluted	$ (0.20)	$ (0.19)	$ (0.48)	$ (0.39)
Basic and diluted weighted average shares outstanding	20,979,766	20,904,085	20,970,022	20,904,085