Onconova Therapeutics Reports First Quarter 2022 Financial Results and Provides Business Update

May 11, 2022

Conference call and live webcast at 4:30 p.m. ET today

NEWTOWN, Pa., May 11, 2022 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX), ("Onconova"), a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer, today announced financial results for the three months ended March 31, 2022, and provided a business update.

Highlights for the first quarter of 2022 and recent weeks include:

- The ongoing Phase 1 solid tumor trials of narazaciclib in the United States and China continue to generate encouraging safety data with the maximum tolerated dose not yet reached in either trial. The trial in the United States is currently enrolling into its fourth dose cohort, which is evaluating a 160 mg dose administered orally each day (i.e. continuous daily dosing). The trial in China is enrolling into its fifth dose cohort, which is evaluating a 200 mg dose administered orally once a day on days 1-21 of 28-day cycles. A protocol amendment is being prepared to enable further dose escalation in the trial in China.
- An abstract titled "Narazaciclib's kinase inhibitory activity is differentiated from approved CDK4/6 inhibitors in preclinical models," has been accepted for publication at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting.
- Rigosertib's investigator-sponsored program has seen progress across multiple ongoing and planned trials. The expansion cohort of the Phase 1/2a study of oral rigosertib plus nivolumab in patients with KRAS+ non-small cell lung cancer (NSCLC) continues to enroll patients, as does the Phase 2 trial of rigosertib monotherapy in advanced squamous cell carcinoma associated with recessive dystrophic epidermolysis bullosa (RDEB-associated SCC). A planned Phase 2 trial of rigosertib plus pembrolizumab in patients with metastatic melanoma was recently cleared to proceed by the United States Food and Drug Administration (FDA) following a review of its protocol.

Management Commentary

"We are pleased to be advancing two highly differentiated therapeutic candidates towards near-term milestones with cash runway expected to extend for at least eighteen months," said Steven M. Fruchtman, M.D., President and Chief Executive Officer of Onconova. "We remain on track to identify narazaciclib's recommended Phase 2 dose later this year, which will enable us to move forward into later-stage studies designed to evaluate its safety and efficacy in monotherapy and combination settings. As we finalize the specifics of these upcoming trials, we will continue to be informed by the results of our ongoing Phase 1 program and preclinical studies. The results of these studies to-date set narazaciclib apart from currently approved CDK4/6 inhibitors, and we look forward to building on these data in future trials."

Dr. Fruchtman continued, "Rigosertib's investigator sponsored study program is also moving towards key catalysts. Later this quarter, our collaborators expect to initiate a Phase 2 study evaluating rigosertib plus anti-PD-1 therapy in metastatic melanoma patients refractory to checkpoint blockade. This trial is supported both by preclinical data that demonstrate rigosertib's immunotherapeutic effects, and prior clinical results from the ongoing investigator sponsored study of the rigosertib-anti-PD-1 combination therapy in KRAS-mutated NSCLC. These initial results showed the studied doublet generating responses in refractory patients who previously failed therapy with a checkpoint inhibitor, a finding we hope to replicate in melanoma. We have continued to amass data in NSCLC since this initial readout, and look forward to providing updated results from the ongoing Phase 1/2a trial by the end of the year. The advancement of this and rigosertib's other investigator-sponsored studies is expected to serve as a valuable complement to our narazaciclib program, which remains our core focus."

First Quarter Financial Results

Cash and cash equivalents as of March 31, 2022, were $50.8 million, compared with $55.1 million as of December 31, 2021. The Company believes that its cash and cash equivalents will be sufficient to fund ongoing clinical trials and business operations for at least eighteen months.

Research and development expenses were $2.0 million for the first quarter of 2022, compared with $1.9 million for the first quarter of 2021.

General and administrative expenses were $2.2 million for the first quarter of 2022, compared with $2.2 million for the first quarter of 2021.

Net loss for the first quarter of 2022 was $4.1 million, or $0.20 per share on 20.9 million weighted average shares outstanding, compared with a net loss of $4.7 million, or $0.32 per share for the first quarter of 2021 on 14.6 million weighted average shares outstanding.

Conference Call and Webcast

Onconova will host an investment community conference call today beginning at 4:30 p.m. Eastern Time, during which management will discuss financial results for the first quarter of 2022, provide a business update, and answer questions. Interested parties can participate by dialing (855)

428-5741 (domestic callers) or (210) 229-8823 (international callers) and using conference ID 7369861.

A live webcast of the conference call will be available in the Investors & Media section of the Company's website at www.onconova.com. A replay of the webcast 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 has 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 two separate and complementary Phase 1 dose-escalation and expansion studies. These trials are currently underway in the United States and China.

Onconova's product candidate rigosertib is being studied in an investigator-sponsored study program, including in a dose-escalation and expansion Phase 1/2a investigator-sponsored study with oral rigosertib in combination with nivolumab for patients with KRAS+ non-small cell lung cancer.

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 the timing of Onconova's and investigator-initiated clinical development and data presentation plans, and the mechanisms and indications for Onconova's product candidates. 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-initiated trials and 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.

Company Contact:
Avi Oler
Onconova Therapeutics, Inc.
267-759-3680
ir@onconova.us
https://www.onconova.com/contact/

Investor Contact:
Bruce Mackle
LifeSci Advisors, LLC
646-889-1200
bmackle@lifesciadvisors.com

(Tables to follow)

ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(in thousands)

	March 31, 2022	December 31, 2021
Assets	*(unaudited)*	
Current assets:		
Cash and cash equivalents	$ 50,767	$ 55,070
Receivables	27	28
Prepaid expenses and other current assets	583	332
Total current assets	51,377	55,430
Property and equipment, net	35	38
Other non-current assets	10	10
Total assets	$ 51,422	$ 55,478
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,122	$ 2,757
Accrued expenses and other current liabilities	2,600	3,132
Deferred revenue	226	226

Total current liabilities	5,948	6,115
Deferred revenue, non-current	3,187	3,243
Total liabilities	9,135	9,358
Stockholders' equity:		
Preferred stock	-	-
Common stock	209	209
Additional paid in capital	490,940	490,644
Accumulated other comprehensive loss	(21)	(14)
Accumulated deficit	(448,841)	(444,719)
Total stockholders' equity	42,287	46,120
Total liabilities and stockholders' equity	$ 51,422	$ 55,478

ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)

	Three months ended March 31,	
	2022	**2021**
Revenue	$ 56	$ 56
Operating expenses:		
General and administrative	2,186	2,217
Research and development	2,002	1,937
Total operating expenses	4,188	4,154
Loss from operations	(4,132)	(4,098)
Change in fair value of warrant liability	---	(636)
Other income, net	10	19
Net loss	(4,122)	(4,715)
Net loss per share of common stock, basic and diluted	$ (0.20)	$ (0.32)
Basic and diluted weighted average shares outstanding	20,904,085	14,616,139