Onconova Therapeutics Reports First Quarter 2021 Financial Results and Provides Business Update

May 17, 2021

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

NEWTOWN, Pa., May 17, 2021 (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, 2021 and provided a business update.

Highlights for the first quarter of 2021 and subsequent weeks include:

- The Phase 1 solid tumor study with ON 123300 in China is ongoing with no dose-limiting toxicities observed in the first two cohorts. Enrollment to the third cohort (120 mg) will now proceed.
- The Phase 1 study with ON 123300 in the United States is open for enrollment, and actively screening patients.
- The first patient has been dosed in an investigator-initiated Phase 2 study designed to assess the efficacy and safety of rigosertib in patients with recessive dystrophic epidermolysis bullosa (RDEB)-associated locally advanced/metastatic squamous cell carcinoma (SCC).
- The investigator-initiated Phase 1/2 study evaluating rigosertib in combination with the checkpoint inhibitor nivolumab in KRAS mutated non-small cell lung cancer has progressed nicely and has reached the maximum dose of oral rigosertib per the current protocol.
- The Company strengthened its balance sheet with net proceeds of $35.2 million from two equity offerings; cash and cash equivalents as of March 31, 2021 were $48.0 million. The Company believes it has more than 18 months of cash runway.

Management Commentary

"We are off to a strong start in 2021 and remain focused on advancing our clinical programs, in particular with our lead product candidate ON 123300, a multi-kinase inhibitor that potently targets CDK 4 and 6, which are overexpressed in a number of cancers, including HR+ HER 2- metastatic breast cancer, a potential blockbuster commercial opportunity," said Steven M. Fruchtman, M.D., President and Chief Executive Officer of Onconova. "We are delighted that our partner in China, HanX Biopharmaceuticals, is expected to begin the third cohort of their Phase 1 study at 120 mg per dose and that ON 123300 appears to be well tolerated with no dose-limiting toxicities observed to date. Notably, the HanX study is dosing patients on days 1 to 21 of 28-day cycles, while the U.S. Phase 1 study will be investigating a continuous daily dosing regimen. Collectively, we expect these complementary studies to generate important safety data that will inform the design of subsequent trials and potentially provide preliminary signals of efficacy in patients with advanced cancer."

Dr. Fruchtman continued, "Alongside the progress made with our lead product candidate, we have also seen advancements in several investigator-initiated trials evaluating rigosertib. The first patient was recently dosed in a Phase 2 trial evaluating rigosertib monotherapy in advanced squamous cell carcinoma associated with recessive dystrophic epidermolysis bullosa, a disease with a critical unmet medical need. Additionally, the Phase 1/2 study evaluating rigosertib in combination with the checkpoint inhibitor nivolumab in KRAS mutated non-small cell lung cancer continues to progress and has reached the highest dose per the current protocol. We expect to continue leveraging our relationships with leading cancer centers and industry collaborators to advance these trials and commence additional investigator initiated studies in RAS-driven cancers in combination with checkpoint inhibitors. We expect such an approach to facilitate our near- and long-term growth by allowing us to preserve our primary focus and resources on ON 123300 while simultaneously pursuing opportunities to develop rigosertib in high unmet need indications."

First Quarter Financial Results

Cash and cash equivalents as of March 31, 2021 were $48.0 million, compared with $19.0 million as of December 31, 2020. The Company believes that its cash and cash equivalents will be sufficient to fund ongoing clinical trials and business operations for more than 18 months.

Research and development expenses were $1.9 million for the first quarter of 2021, compared with $3.4 million for the first quarter of 2020. The decrease was primarily related to lower expenses for the oral rigosertib combination program and the completed Phase 3 INSPIRE study in the 2021 period.

General and administrative expenses were $2.2 million for the first quarter of 2021, compared with $1.8 million for the first quarter of 2020. The increase was primarily related to higher special stockholder meeting by proxy expenses and insurance costs in the 2021 period.

Net loss for the first quarter of 2021 was $4.7 million, or $0.02 per share on 219.2 million weighted average shares outstanding, compared with a net loss for the first quarter of 2020 of $5.1 million, or $0.03 per share on 160.3 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 2021, 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 4895447.

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 ON 123300 is planned to begin a dose-escalation and expansion Phase 1 trial in the U.S. in 2Q21, and a dose-escalation and expansion Phase 1 trial is currently underway in China.

Onconova's product candidate rigosertib is being studied in an investigator-initiated study program, including in a dose-escalation and expansion Phase 1 investigator-initiated study targeting patients with KRAS+ non-small cell lung cancer with oral rigosertib in combination with nivolumab. In addition, Onconova continues to conduct preclinical work investigating rigosertib in COVID-19.

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 registered direct offering, its patents and clinical development plans including patient enrollment timelines and indications for its product candidates. Onconova has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "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 and regulatory agency and institutional review board approvals of protocols, Onconova's ability to continue as a going concern, the need for additional financing, 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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(Tables to follow)

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

	March 31, 2021	December 31, 2020
Assets	*(unaudited)*	
Current assets:		
Cash and cash equivalents	$ 48,005	$ 19,025
Receivables	38	37
Prepaid expenses and other current assets	607	722
Total current assets	48,650	19,784
Property and equipment, net	49	52
Other non-current assets	150	150
Total assets	$ 48,849	$ 19,986
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,988	$ 4,833
Accrued expenses and other current liabilities	3,112	4,962

Deferred revenue	226	226
Total current liabilities	7,326	10,021
Warrant liability	957	321
Deferred revenue, non-current	3,413	3,469
Total liabilities	11,696	13,811
Stockholders' equity:		
Preferred stock	-	-
Common stock	2,367	1,859
Additional paid in capital	468,059	432,858
Accumulated other comprehensive (loss) income	(2)	14
Accumulated deficit	(433,271)	(428,556)
Total stockholders' equity	37,153	6,175
Total liabilities and stockholders' equity	$ 48,849	$ 19,986

ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations *(unaudited)*

(in thousands, except share and per share amounts)

	Three months ended March 31,	
	2021	**2020**
Revenue	$ 56	$ 52
Operating expenses:		
General and administrative	2,217	1,807
Research and development	1,937	3,370
Total operating expenses	4,154	5,177
Loss from operations	(4,098)	(5,125)
Change in fair value of warrant liability	(636)	(63)
Other income, net	19	96
Net loss	(4,715)	(5,092)
Net loss per share of common stock, basic and diluted	$ (0.02)	$ (0.03)
Basic and diluted weighted average shares outstanding	219,242,077	160,346,087