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

November 11, 2021

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

NEWTOWN, Pa., Nov. 11, 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 September 30, 2021, and provided a business update.

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

- The Phase 1 solid tumor studies of narazaciclib (formerly ON 123300) in the United States and China are ongoing with no dose-limiting toxicities observed to-date. The trials are currently enrolling in their second and fourth dose cohorts, respectively.
- The investigator-initiated Phase 1/2a trial evaluating rigosertib in combination with the checkpoint inhibitor nivolumab in KRAS mutated (KRAS+) non-small cell lung cancer (NSCLC) continues to enroll patients in its dose-expansion cohort. Preliminary data showed that the doublet was well-tolerated and an encouraging signal of efficacy in an extensively pre-treated patient population with 2 partial responses out of 7 evaluable patients, with another patient showing stable disease, which gives objective response and disease control rates of 29% and 43%, respectively.
- The investigator-initiated Phase 2 trial evaluating rigosertib monotherapy in advanced squamous cell carcinoma associated with recessive dystrophic epidermolysis bullosa (RDEB-associated SCC) continues to progress. Promising evidence of rigosertib's clinical activity targeting the complication of squamous cell carcinoma in this indication has been observed and the Company plans to provide additional data from the trial at an upcoming medical meeting.
- The Company strengthened its balance sheet with gross proceeds of $21 million through an underwritten public offering.

Management Commentary

"Our progress during the third quarter has us on track to achieve milestones across our pipeline," said Steven M. Fruchtman, M.D., President and Chief Executive Officer of Onconova. "In our lead narazaciclib program, the advancement of our complementary Phase 1 studies has us on track to identify a recommended Phase 2 dose in the first half of 2022 and then initiate a Phase 2 safety and efficacy study in the second half. This Phase 2 study will focus on multiple oncology indications with high unmet need, including CDK 4/6 inhibitor refractory HR+ HER2- metastatic breast cancer. Preclinical studies have shown that narazaciclib may be able overcome resistance to approved CDK 4/6 inhibitors, and therefore may have an improved on-target toxicity profile. We believe this positions narazaciclib as a potentially important therapeutic in a multi-billion-dollar drug class. We look forward to evaluating this hypothesis through narazaciclib's continued clinical development."

Dr. Fruchtman continued, "Outside our narazaciclib program, we recently reported very encouraging data from the Phase 1/2a investigator-initiated study (IIS) of oral rigosertib plus the PD-1 checkpoint inhibitor nivolumab in advanced KRAS+ NSCLC. These data showed partial responses across multiple KRAS variants in patients who previously failed the standard of care including PD-1 checkpoint inhibitors. This suggests rigosertib may augment the efficacy of checkpoint inhibitors and could differentiate it from competing RAS pathway modulators that target a particular KRAS mutation. Looking ahead, we expect to provide an additional data update from this study in 2022 and begin an additional IIS evaluating rigosertib in combination with anti-PD-1 therapy in malignant melanoma in the first half of next year. Through the progression of these and our other IIS in RDEB-associated SCC, we aim to generate value and address the needs of patients through rigosertib's development, while maintaining our primary focus on our lead narazaciclib program."

Third Quarter Financial Results

Cash and cash equivalents as of September 30, 2021, were $59.4 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 two years.

Research and development expenses were $1.8 million for the third quarter of 2021, compared with $4.2 million for the third quarter of 2020. The decrease was primarily related to higher costs related to the INSPIRE study in the 2020 period.

General and administrative expenses were $2.3 million for the third quarter of 2021, compared with $2.1 million for the third quarter of 2020.

Net loss for the third quarter of 2021 was $3.5 million, or $0.22 per share on 16.0 million weighted average shares outstanding, compared with a net loss for the third quarter of 2020 of $6.2 million, or $0.52 per share on 12.1 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 third 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 5367655.

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-initiated study program, including in a dose-escalation and expansion Phase 1/2a investigator-initiated 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.

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

	September 30 2021	December 31, 2020
Assets	*(unaudited)*	
Current assets:		
Cash and cash equivalents	$ 59,378	$ 19,025
Receivables	29	37
Prepaid expenses and other current assets	529	722
Total current assets	59,936	19,784
Property and equipment, net	42	52
Other non-current assets	12	150
Total assets	$ 59,990	$ 19,986
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,050	$ 4,833
Accrued expenses and other current liabilities	2,749	4,962
Deferred revenue	226	226
Total current liabilities	7,025	10,021
Warrant liability	-	321
Deferred revenue, non-current	3,299	3,469

Total liabilities	10,324	13,811
Stockholders' equity:		
Preferred stock	-	-
Common stock	209	124
Additional paid in capital	490,418	434,593
Accumulated other comprehensive (loss) income	(6)	14
Accumulated deficit	(440,955)	(428,556)
Total stockholders' equity	49,666	6,175
Total liabilities and stockholders' equity	$ 59,990	$ 19,986

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

	Three Months Ended September 30,		Nine months months ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenue	$ 57	$ 66	$ 170	$ 174
Operating expenses:				
General and administrative	2,284	2,147	7,351	6,548
Research and development	1,763	4,193	5,552	12,364
Total operating expenses	4,047	6,340	12,903	18,912
Loss from operations	(3,990)	(6,274)	(12,733)	(18,738)
Change in fair value of warrant liability	530	56	321	(63)
Other income (loss,) net	7	(23)	13	73
Net loss	(3,453)	(6,241)	(12,399)	(18,728)
Net loss per share of common stock, basic and diluted	$ (0.22)	$ (0.52)	$ (0.80)	$ (1.65)
Basic and diluted weighted average shares outstanding	15,979,180	12,058,508	15,463,720	11,353,169