Onconova Therapeutics Reports Third Quarter 2020 Financial Results and Provides Business Update

November 12, 2020

- ON 123300, our proprietary multi-kinase inhibitor, enters into the clinic for advanced solid tumors
- Investigator-initiated study advances with combination of oral rigosertib and nivolumab in K-RAS mutated non-small cell lung cancer
- Actively evaluating strategic opportunities to further enhance our portfolio

Conference call begins at 4:30 p.m. ET today

NEWTOWN, Pa., Nov. 12, 2020 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX), a biopharmaceutical company focused on discovering and developing novel products to treat cancer, today reported financial results for the quarter ended September 30, 2020 and provided a business update.

Management commentary

“During the third quarter, our product pipeline advanced while we pursued various licensing opportunities. We are particularly pleased that ON 123300, our proprietary, differentiated, first-in-class multi-kinase inhibitor, entered the clinic with HanX Biopharmaceuticals, our partner in China,” said Steven M. Fruchtman, M.D., President and Chief Executive Officer of Onconova. “The HanX Phase 1 dose-escalation study has enrolled three patients to date, and is expected to continue to enroll patients with advanced relapsed/refractory cancer at two sites until the recommended Phase 2 dose is identified.

“In parallel, we are preparing to file an Investigational New Drug application (IND) with the U.S. Food and Drug Administration by the end of this year, with patient enrollment expected to begin in the first quarter of 2021. We expect that our Phase 1 dose-escalation and dose-expansion study in the U.S. will differ from the HanX study in dose regimens and treatment cycles, and believe that data from these two studies will generate important information to inform anticipated later-stage studies. Our plan is to enroll patients with a variety of advanced solid tumors including an initial focus on HR+ HER2- postmenopausal metastatic breast cancer patients with resistance to approved second-generation CDK 4/6 inhibitors, as well as patients diagnosed with advanced non-Hodgkin’s lymphoma based on efficacy data from our preclinical models. We believe that, with its novel mechanism of action targeting both CDK4/6 and ARK5, ON 123300 presents an innovative approach for potentially treating HR+ HER2- metastatic breast cancer that is or has become resistant to the commercial CDK4/6 inhibitors, and potentially other cancers including mantle cell lymphoma, multiple myeloma, advanced colorectal cancer, advanced hepatocellular carcinoma, and inoperable glioblastoma.”

“Important investigator-initiated studies are also underway or planned with oral rigosertib,” added Richard Woodman, M.D, Chief Medical Officer. “We are currently supporting a Phase 1 dose-escalation study at a leading medical center in New York City exploring the use of rigosertib in combination with the PD-1 inhibitor nivolumabin progressive K-RAS mutated non-small cell lung cancer (NSCLC). That study has enrolled five patients to date, and is designed to identify the recommended Phase 2 dose of the combination for future studies. Results are expected in 2021. In addition, an investigator-initiated phase 1b/2 study with rigosertib monotherapy in advanced squamous cell carcinoma associated with recessive dystrophic epidermolysis bullosa has opened, with first-patient-in expected 2021. Additional investigator-initiated preclinical studies with rigosertib are under consideration.”

“Our focus is on advancing our pipeline, and while we believe ON 123300 and oral rigosertib have excellent prospects, we are also engaged in licensing discussions, both for geographic rights to certain of our assets, and evaluating the potential to in-license additional compounds to expand our product portfolio,” Dr. Fruchtman concluded.

Third quarter financial results

Cash and cash equivalents as of September 30, 2020 were $24.2 million, compared with $22.7 million as of December 31, 2019. The Company expects that its cash and cash equivalents will be sufficient to fund ongoing clinical trials and business operations into the first quarter of 2022. During the third quarter of 2020, the Company received $2.7 million from the exercise of warrants.

Research and development expenses were $4.2 million for the third quarter of 2020, compared with $3.5 million for the third quarter of 2019. The increase was primarily related to higher consulting fees and manufacturing costs related to clinical supply for ON 123300, partially offset by lower expenses for the oral rigosertib combination program and the Phase 3 INSPIRE study.

General and administrative expenses were $2.1 million for the third quarter of 2020, compared with $1.6 million for the third quarter of 2019. The increase was due to higher pre-commercialization, insurance, and corporate legal and stockholder meeting expenses.

Net loss for the third quarter of 2020 was $6.2 million, compared with $4.6 million for the comparable prior-year quarter.

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 2020 third quarter, 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 8687160.

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 biopharmaceutical company focused on discovering and developing novel products to treat 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 currently in a dose-escalation and expansion Phase 1 trial in China, and the IND filing in the U.S. is anticipated in the fourth quarter of 2020. Onconova's product candidate, oral rigosertib, is currently in a dose-escalation and expansion Phase 1 investigator-initiated study targeting patients with KRAS+ lung adenocarcinoma in combination with nivolumab. Preclinical work with rigosertib in COVID-19 is ongoing as well. We do not anticipate conducting clinical trials with rigosertib in COVID-19 without securing additional funding. For more information, please visit https://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 expectations regarding its clinical development plans and patents. 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 approval of protocols, Onconova's ability to continue as a going concern, the need for additional financing, our collaborations, 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, 2020	December 31, 2019
Assets	*(unaudited)*	
Current assets:		
Cash and cash equivalents	$ 24,198	$ 22,726
Receivables	46	98
Prepaid expenses and other current assets	757	650
Total current assets	25,001	23,474
Property and equipment, net	56	50
Other non-current assets	150	150
Total assets	$ 25,207	$ 23,674
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,725	$ 4,271
Accrued expenses and other current liabilities	3,339	3,795
Deferred revenue	226	226
Total current liabilities	9,290	8,292

Warrant liability	176	113
Deferred revenue, non-current	3,526	3,695
Total liabilities	12,992	12,100
Stockholders' equity:		
Preferred stock	-	-
Common stock	1,845	1,112
Additional paid in capital	432,499	413,879
Accumulated other comprehensive loss	(2)	(18)
Accumulated deficit	(422,127)	(403,399)
Total stockholders' equity	12,215	11,574
Total liabilities and stockholders' equity	$ 25,207	$ 23,674

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,	
	2020	**2019**	**2020**	**2019**
Revenue	$ 66	$ 63	$ 174	$ 2,153
Operating expenses:				
General and administrative	2,147	1,640	6,548	6,634
Research and development	4,193	3,521	12,364	11,490
Total operating expenses	6,340	5,161	18,912	18,124
Loss from operations	(6,274)	(5,098)	(18,738)	(15,971)
Change in fair value of warrant liability	56	476	(63)	80
Other (loss) income, net	(23)	27	73	135
Net loss	(6,241)	(4,595)	(18,728)	(15,756)
Net loss per share of common stock, basic and diluted	$ (0.03)	$ (0.75)	$ (0.11)	$ (2.63)
Basic and diluted weighted average shares outstanding	180,877,623	6,141,933	170,297,531	5,994,423