Onconova Therapeutics Reports Full Year 2021 Financial Results and Provides Business Update

March 17, 2022

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

NEWTOWN, Pa., March 17, 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 twelve months ended December 31, 2021, and provided a business update.

Highlights for the fourth quarter of 2021 and recent weeks include:

- The Phase 1 solid tumor trials of narazaciclib in the United States and China are ongoing with no dose-limiting toxicities observed to date. The trial in the United States is currently enrolling into its fourth dose cohort, which is evaluating a 160 mg daily dose administered orally on each day of a 28-day treatment cycle. 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 a 28-day treatment cycle. A protocol amendment is being prepared to enable further dose escalation in the trial in China.
- Rigosertib's investigator-sponsored program has seen progress across multiple trials. This is highlighted by continued enrollment in the dose expansion portion of the Phase 1/2a study of oral rigosertib plus nivolumab in patients with KRAS+ non-small cell lung cancer (NSCLC). Additionally, recent single-patient data from a heavily pre-treated participant in the Phase 2 trial of rigosertib monotherapy in advanced squamous cell carcinoma associated with recessive dystrophic epidermolysis bullosa (RDEB-associated SCC) showed a durable complete response without signs of metastatic disease.
- The Company strengthened its team with the appointment of Adar Makovski Silverstein, Ph.D., as Director, Corporate Development.

Management Commentary

"The advancements made across our pipeline over the past months have us on track for an exciting 2022," said Steven M. Fruchtman, M.D., President and Chief Executive Officer of Onconova. "We continue to be pleased with the safety findings from narazaciclib's ongoing Phase 1 program and remain on track to identify a recommended Phase 2 dose in the second half of the year. Narazaciclib shows low nanomolar activity against kinases associated with tumor growth, metastasis, and potentially drug resistance, which differentiates it from currently approved CDK 4/6 inhibitors. We thus believe it may have broad therapeutic potential in monotherapy and combination settings, both in patients showing resistance to approved CDK 4/6 inhibitors and in indications where these agents are not currently approved. Narazaciclib's clinical development plan is designed to test this hypothesis, and we look forward to its continued progress."

Dr. Fruchtman continued, "Beyond our lead program in narazaciclib, we also reported compelling preliminary clinical data from an investigator-sponsored study of rigosertib in RDEB-associated SCC. These data showed a sustained complete response in a patient that was unresponsive to several prior treatments. Though from a single patient, we believe these data represent a potentially powerful observation in this ultra-rare indication given its invariably fatal nature and the lack of effective therapies. Rigosertib's additional investigator-sponsored trials have also shown strong progress, as we are on track to report updated data from the Phase 1/2a study evaluating rigosertib-nivolumab combination therapy in KRAS+ NSCLC this year, and to open a Phase 2 metastatic melanoma trial of oral rigosertib plus pembrolizumab in the first half. Looking ahead, we will continue to leverage the collaborations that form the basis of these trials to pursue rigosertib's clinical development across multiple indications while remaining primarily focused on our lead narazaciclib program."

Full Year Financial Results

Cash and cash equivalents as of December 31, 2021, were $55.1 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 at least two years.

Research and development expenses were $7.3 million for 2021, compared with $16.9 million for 2020. The decrease was primarily related to the Company's focus on its Phase 1 program with narazaciclib, following the completion of the Phase 3 INSPIRE study in 2020.

General and administrative expenses were $9.4 million for 2021, compared with $8.3 million for 2020. The increase was primarily related to costs related to special and annual general meeting expenses in the 2021 period.

Net loss for 2021 was $16.2 million, or $0.96 per share on 16.8 million weighted average shares outstanding, compared with a net loss of $25.2 million, or $2.17 per share for 2020 on 11.6 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 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 8097917.

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.

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

	December 31, 2021	December 31, 2020
Assets	*(unaudited)*	
Current assets:		
Cash and cash equivalents	$ 55,070	$ 19,025
Receivables	28	37
Prepaid expenses and other current assets	332	722
Total current assets	55,430	19,784
Property and equipment, net	38	52
Other non-current assets	10	150
Total assets	$ 55,478	$ 19,986
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,757	$ 4,833
Accrued expenses and other current liabilities	3,132	4,962
Deferred revenue	226	226
Total current liabilities	6,115	10,021

Warrant liability	-	321
Deferred revenue, non-current	3,243	3,469
Total liabilities	9,358	13,811
Stockholders' equity:		
Preferred stock	-	-
Common stock	209	124
Additional paid in capital	490,644	434,593
Accumulated other comprehensive (loss) income	(14)	14
Accumulated deficit	(444,719)	(428,556)
Total stockholders' equity	46,120	6,175
Total liabilities and stockholders' equity	$ 55,478	$ 19,986

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

	Year Ended December 31,	
	2021	**2020**
	(unaudited)	
Revenue	$ 226	$ 231
Operating expenses:		
General and administrative	9,425	8,326
Research and development	7,297	16,898
Total operating expenses	16,722	25,224
Loss from operations	(16,496)	(24,993)
Change in fair value of warrant liability	321	(208)
Other income, net	12	48
Net loss before income taxes	(16,163)	(25,153)
Income tax expense	-	4
Net loss	(16,163)	(25,157)
Net loss per share of common stock, basic and diluted	$ (0.96)	$ (2.17)
Basic and diluted weighted average shares outstanding	16,832,198	11,602,391