Onconova Therapeutics Highlights Corporate Progress and Reports Second Quarter 2020 Financial Results

August 12, 2020

- **INSPIRE Phase 3 trial survival events reached**
- **Topline data anticipated Q3-2020**

Conference call and webcast scheduled today, August 12, at 4:30 p.m. ET

NEWTOWN, Pa., Aug. 12, 2020 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX), a Phase 3 stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, with an initial focus on myelodysplastic syndromes (MDS), today reported financial results for the quarter ended June 30, 2020, and provided a business update.

"With INSPIRE recently meeting the number of survival events required by the study's statistical analysis plan, we anticipate reporting topline data by the end of the current quarter," said Steven M. Fruchtman, M.D., President and Chief Executive Officer. "If the data readout demonstrates a significant prolongation of survival for patients randomized to intravenous rigosertib, we believe this could represent a significant medical advancement for patients with higher-risk MDS. Following such data readout, we anticipate submitting a New Drug Application to the FDA to seek approval to commercially launch rigosertib."

Second Quarter 2020 Developments and Recent Highlights

- Pivotal Phase 3 INSPIRE trial reached the required number of survival events for data analysis
- Initiation of and first patient enrollment in a Phase 1/2a study exploring an oral rigosertib plus nivolumab combination in KRAS+ lung cancer patients
- Applications submitted for rigosertib to participate in federally funded human studies in COVID-19 disease based on early-stage preclinical evidence of rigosertib inhibition of SARS-COV-2 replication
- Election of life sciences industry veteran Terri Shoemaker to the Company's Board of Directors
- Nasdaq compliance regained with achievement of dollar bid price listing requirement

Recent Presentations and Scientific Publications

- Presentation of updated aggregated baseline genomic data from HMA-failure patients screened and randomized for the INSPIRE trial, in e-poster form, at the virtual 25th Annual European Hematology Association (EHA) Congress
- Publication in *Molecular Cell* of preclinical data supporting rigosertib's mechanism of action as a targeted anticancer agent
- Publication of Phase 1 results in *Leukemia Research* for oral rigosertib in combination with azacitidine in higher-risk (HR)-MDS and acute leukemia

Additional Expected Company Milestones

- Announcement of topline INSPIRE results by the end of the third quarter of 2020, with data presentation at a major medical meeting later in the year
- FDA review of Phase 2/3 trial protocol of oral rigosertib plus azacitidine in hypomethylating agent (HMA) naïve HR-MDS
- Federal funding agencies review of applications for clinical trials with rigosertib in SARS-COV-2 disease
- Virtual presentation at the 2nd Annual RAS-Targeted Drug Development Summit September 14-16, 2020
- US IND submission planned for 4Q 2020 for next generation CDK 4/6 + ARK5 inhibitor, ON 123300, with first in-human Phase 1 trial anticipated in 1Q 2021, and Phase 1 study commencement in China planned for 2H 2020
- Anticipated launch of Early Access Program with Inceptua Medicines Group in 2H 2020
- Expansion of rigosertib investigator-initiated development program to encompass additional RAS-driven cancers

Second Quarter 2020 Financial Results

Cash and cash equivalents as of June 30, 2020, totaled $27.2 million, compared to $22.7 million as of December 31, 2019. Exercises of common stock warrants from our financing transactions in November and December 2019 have added $9.8 million to our balance sheet since January 1, 2020, and as of August 12, 2020, we have 183,578,267 common shares outstanding. Of the 12.6 million common stock warrants which remain outstanding at August 12, 2020, 80% were in-the-money. Based on current projections, the Company expects that its cash and cash equivalents will be sufficient to fund ongoing trials and operations into the fourth quarter of 2021.

Net loss was $7.4 million for the quarter ended June 30, 2020, compared to $3.6 million for the quarter ended June 30, 2019. Research and

development expenses were $4.8 million for the quarter ended June 30, 2020 and $3.9 million for the comparable period in 2019. General and administrative expenses were $2.6 million for the quarter ended June 30, 2020 and $1.8 million for the comparable period in 2019.

Conference Call and Webcast Information
The Company will host a conference call today, August 12, 2020, at 4:30 p.m. Eastern Time. Interested parties who wish to participate in the conference call may do so by dialing (855) 428-5741 for domestic and (210) 229-8823 for international callers and using conference ID 2875654.

To facilitate an on-time conference call start, Onconova recommends that participants dial in 15 minutes before the 4:30 p.m. ET start time.

Those interested in listening to the conference call via the internet may do so by visiting the investors and media page on the company's website at www.onconova.com and clicking on the webcast link. In addition to the live webcast, a replay will be available on the Onconova website for 90 days following the call.

About Onconova Therapeutics, Inc.
Onconova Therapeutics, Inc. is a Phase 3-stage biopharmaceutical company focused on discovering and developing novel drugs to treat cancer, with an initial focus on myelodysplastic syndromes (MDS). Onconova has a pipeline of proprietary targeted agents designed to work against specific cellular pathways that are important in cancer cells. Advanced clinical trials with the Company's lead compound, rigosertib, are aimed at what the Company believes are unmet medical needs of patients with MDS. Onconova has conducted trials with additional research compounds and has a pre-clinical program with a CDK4/6 and ARK5 inhibitor, ON 123300.

For more information, please visit https://www.onconova.com.

About Myelodysplastic Syndromes
Myelodysplastic syndromes (MDS) are conditions that can occur when the blood-forming cells in the bone marrow become dysfunctional and thus produce an inadequate number of circulating blood cells. It is frequently associated with the presence of blasts or leukemic cells in the marrow. This leads to low numbers of one or more types of circulating blood cells, and to the need for blood transfusions. In MDS, some of the cells in the bone marrow are abnormal (dysplastic) and may have genetic abnormalities associated with them. Different cell types can be affected, although the most common finding in MDS is a shortage of red blood cells (anemia). Patients with higher-risk MDS may progress to the development of acute leukemia.

About Rigosertib
Rigosertib, Onconova's lead candidate, is a proprietary Phase 3 small molecule. A key publication in a preclinical model reported rigosertib's ability to block cellular signaling by targeting RAS effector pathways (Divakar, S.K., et al., 2016: "A Small Molecule RAS-Mimetic Disrupts RAS Association with Effector Proteins to Block Signaling." Cell 165, 643). Onconova is currently in the clinical development stage with oral and IV rigosertib, including clinical trials studying single agent IV rigosertib in second-line higher-risk MDS patients (pivotal Phase 3 INSPIRE trial) and oral rigosertib plus azacitidine in HMA naive and refractory higher-risk MDS patients (Phase 2). Preclinical studies with rigosertib are underway in COVID-19 as well. Patents covering oral and injectable rigosertib have been issued in the US and are expected to provide coverage until at least 2037.

About the INSPIRE Phase 3 Clinical Trial
The clinical trial **IN**ternational **S**tudy of **P**hase 3 IV **R**igos**E**rtib, or INSPIRE, was finalized following guidance received from the U.S. Food and Drug Administration and European Medicines Agency. INSPIRE is a global, multi-center, randomized, controlled study to assess the efficacy and safety of IV rigosertib in higher-risk MDS (HR-MDS) patients who had progressed on, failed to respond to, or relapsed after previous treatment with a hypomethylating agent (HMA) within nine cycles over the course of one year after initiation of HMA treatment. This time frame optimizes the opportunity to respond to treatment with an HMA prior to declaring treatment failure, as per NCCN Guidelines. Patients are randomized at a 2:1 ratio into two study arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. The primary endpoint of INSPIRE is overall survival. The trial continued beyond the pre-specified interim analysis and is nearing its conclusion. Full details of the INSPIRE trial, such as inclusion and exclusion criteria, as well as secondary endpoints, can be found on clinicaltrials.gov (NCT02562443).

About IV Rigosertib
The intravenous form of rigosertib has been studied in Phase 1, 2, and 3 clinical trials involving more than 1000 patients, and is currently being evaluated in a randomized Phase 3 international INSPIRE trial for patients with HR-MDS after failure of HMA therapy.

About Oral Rigosertib
The oral form of rigosertib was developed to provide a potentially more convenient dosage form for use where the duration of treatment may extend to multiple years. This dosage form may also support combination therapy modalities. To date, over 400 patients have been dosed with the oral formulation of rigosertib in clinical trials. Combination therapy of oral rigosertib with azacitidine, the standard of care in HR-MDS, has also been studied. Currently, oral rigosertib is being developed as a combination therapy together with azacitidine for patients with higher-risk MDS who require HMA therapy. A Phase 1/2 trial of the combination therapy has been fully enrolled, and the updated efficacy and safety data was presented at the ASH 2019 Annual Meeting in December 2019.

About SARS-CoV-2 and COVID-19
Severe acute respiratory syndrome due to SARS-CoV-2 has impacted millions of people worldwide and has led to the death of hundreds of thousands of individuals. Collaborative efforts to test many experimental and health authority approved agents are ongoing worldwide to address the global pandemic through the development of therapeutic antiviral drugs to treat COVID-19 infection, and with vaccines to prevent infection with SARS-CoV-2.

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 the INSPIRE Trial and Onconova's other development plans. 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 including the effective termination of the HanX license and securities purchase agreements and plans for partnering certain territories, 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)

	June 30, 2020	December 31, 2019
Assets	*(unaudited)*	
Current assets:		
Cash and cash equivalents	$ 27,228	$ 22,726
Receivables	41	98
Prepaid expenses and other current assets	720	650
Total current assets	27,989	23,474
Property and equipment, net	60	50
Other non-current assets	150	150
Total assets	$ 28,199	$ 23,674
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,148	$ 4,271
Accrued expenses and other current liabilities	3,377	3,795
Deferred revenue	226	226
Total current liabilities	8,751	8,292
Warrant liability	232	113
Deferred revenue, non-current	3,583	3,695
Total liabilities	12,566	12,100
Stockholders' equity:		
Preferred stock	-	-
Common stock	1,742	1,112
Additional paid in capital	429,794	413,879
Accumulated other comprehensive income	(17)	(18)
Accumulated deficit	(415,886)	(403,399)
Total stockholders' equity	15,633	11,574
Total liabilities and stockholders' equity	$ 28,199	$ 23,674

ONCONOVA THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations *(unaudited)*

(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six months months ended June 30,	
	2020	**2019**	**2020**	**2019**

Revenue	$ 56	$ 2,022	$ 108	$ 2,090
Operating expenses:				
General and administrative	2,594	1,760	4,401	4,994
Research and development	4,801	3,895	8,171	7,969
Total operating expenses	7,395	5,655	12,572	12,963
Loss from operations	(7,339)	(3,633)	(12,464)	(10,873)
Change in fair value of warrant liability	(56)	32	(119)	(395)
Other income, net	-	40	96	107
Net loss	(7,395)	(3,561)	(12,487)	(11,161)
Net loss per share of common stock, basic and diluted	$ (0.04)	$ (0.60)	$ (0.08)	$ (1.89)
Basic and diluted weighted average shares outstanding	169,552,619	5,948,471	164,949,353	5,919,446