Onconova Therapeutics Announces Business Highlights and Financial Results for Third Quarter 2018

November 13, 2018

Conference Call Today at 9:00 a.m. Eastern Time

NEWTOWN, Pa., Nov. 13, 2018 (GLOBE NEWSWIRE) -- **Onconova Therapeutics, Inc. (Nasdaq: ONTX)**, a Phase 3 stage biopharmaceutical company focused on developing rigosertib, a novel small molecule drug candidate to treat cancer, with a primary focus on Myelodysplastic Syndromes (MDS), today provided a corporate update and announced financial results for the third quarter of 2018, ended September 30, 2018.

"During the third quarter, we strengthened our intellectual property for rigosertib by expanding the geographical coverage of our patents and extending patent protection to 2037. We also completed a 1-for-15 reverse split of our common stock in order to regain compliance with Nasdaq's requirements," stated Dr. Ramesh Kumar, Chief Executive Officer. "These accomplishments, combined with the $28.75 million financing completed in May, position us to drive toward many near-term value-inflection points and business development opportunities."

Steven M. Fruchtman, M.D., President of Onconova, said, "As we continue enrollment toward our target of 360 randomized patients in our Phase 3 INSPIRE trial with intravenous rigosertib, the safety and efficacy data from an expanded Phase 2 trial of oral rigosertib in combination with azacitidine will be presented at an oral session on MDS at the 2018 ASH conference. We are advancing this combination for HMA naïve higher-risk MDS patients toward a Phase 3 trial protocol under the Special Protocol Assessment (SPA) process in the fourth quarter of 2018."

Third Quarter and Recent Highlights

- Richard Woodman, M.D., most recently Senior Vice President and Head of U.S. Oncology Clinical Development and Medical Affairs for Novartis, joined Onconova on November 5, 2018, as Chief Medical Officer and Senior Vice President of Research & Development. In this role, Ric's expertise will help optimize the development of rigosertib for patients with unmet medical needs in MDS and cancer.

- A new composition of matter patent, No. 10,098,862, covering oral and IV formulations of rigosertib, was issued by the United States Patent and Trademark Office in October. This new patent extends protection for the Company's lead product candidate, rigosertib, to 2037. Foreign equivalent patents are in process, and once issued, will expand the geographical coverage for rigosertib.

- In September, Onconova effected a 1-for-15 reverse split of its common stock aimed at continued compliance with Nasdaq's requirements. The reverse split also enhances the investment opportunity in Onconova among a broader group of investors.

- Four abstracts relating to the Company's lead product candidate, rigosertib, were accepted for presentation at the 60th American Society of Hematology (ASH) Annual Meeting & Exposition in San Diego, California, taking place December 1-4, 2018. On Saturday, December 1, Dr. Shyamala Navada, Assistant Professor, Medicine, Hematology and Medical Oncology at the Icahn School of Medicine at Mount Sinai in New York, on behalf of her co-investigators, will present data from the expanded Phase 2 trial of rigosertib plus azacitidine combination. Two additional presentations will highlight the PK/PD and safety clinical data from patients treated with this combination therapy, and the fourth will demonstrate a biomarker to predict a response to rigosertib.

- Onconova's novel CDK4/6+ARK5 inhibitor ON 123300 is now in an advanced pre-IND stage with expected IND filing in the first half of 2019. This program is partnered in Greater China with the Company's development partner HanX Biopharmaceuticals.

Upcoming Milestones

- Based on end-of-Phase 2 meetings with the FDA and updated data from the expanded trial, Onconova expects to file a Phase 3 protocol under the Special Protocol Assessment (SPA) process. This filing will be followed by similar submissions in Europe and Japan (the latter by Onconova's Japan/Korea partner, SymBio). After the SPA process is completed, the pivotal trial for the combination product for front-line (HMA naïve) higher-risk MDS patients is ready to be initiated, with additional funding from financing and/or business development activities.

- For the pivotal Phase 3 INSPIRE study, target enrollment is 360 randomized patients and the Company continues to project completion in the second half of 2019. Top-line data will be available after 288 death events.

- The RASopathies program is advancing under a CRADA with the National Cancer Institute. The NCI is carrying out PK/PD and dose escalation studies in preclinical models to prepare for dosing of pediatric patients with single agent rigosertib. A clinical trial protocol concept has been developed and is under review. Based on NCI guidance, the Company expects the first patient to be treated in the first half of 2019.

- Rigosertib studies alone or in combination with immuno-oncology agents in solid tumors driven by RAS mutations are in development.

- IND filing for Dual CDK 4/6 + ARK5 inhibitor ON 123300 (IND studies funded by HanX Biopharmaceuticals) is expected to be submitted in the first half of 2019.

Third Quarter 2018 Financial Results

Cash and cash equivalents at September 30, 2018, totaled $22.4 million, compared to $4.0 million at December 31, 2017.

Net loss was $5.3 million for the third quarter ended September 30, 2018, compared to a net loss of $7.0 million for the third quarter ended September 30, 2017. Research and development expenses were $4.0 million for the third quarter ended September 30, 2018, and $5.1 million for the comparable period in 2017. General and administrative expenses were $1.7 million for the third quarter ended September 30, 2018, and $1.7 million for comparable period in 2017.

Net loss was $14.8 million for the nine months ended September 30, 2018, compared to a net loss of $17.9 million for the nine months ended September 30, 2017.

The Company will host a conference call today at 9:00 a.m. Eastern Time to provide a corporate update and discuss third quarter 2018 financial results. Interested parties may access the call by dialing toll-free (855) 428-5741 from the U.S., or (210) 229-8823 internationally, and using conference ID: 3355668. The call will also be webcast live. Please visit the Investor Relations page of the Company's website at https://investor.onconova.com/ to access the webcast. A replay will be available for 90 days.

About Onconova Therapeutics, Inc.

Onconova Therapeutics, Inc. is a Phase 3-stage biopharmaceutical company focused on discovering and developing novel small molecule drug candidates to treat cancer, with a primary focus on Myelodysplastic Syndromes (MDS). Rigosertib, Onconova's lead candidate, is a proprietary Phase 3 small molecule agent, which the Company believes blocks cellular signaling by targeting RAS effector pathways. Using a proprietary chemistry platform, Onconova has created a pipeline of targeted agents designed to work against specific cellular pathways that are important in cancer cells. Onconova has three product candidates in the clinical stage and several pre-clinical programs. 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. For more information, please visit http://www.onconova.com.

About IV Rigosertib

The intravenous form of rigosertib has been employed in Phase 1, 2, and 3 clinical trials involving more than 800 patients, and is currently being evaluated in a randomized Phase 3 international INSPIRE trial for patients with higher-risk MDS, after failure of hypomethylating agent, or HMA, therapy.

About INSPIRE

The INternational Study of Phase III IV RigosErtib, or INSPIRE, was finalized following guidance received from the U.S. Food and Drug Administration and European Medicines Agency and derives from the findings of the ONTIME Phase 3 trial. INSPIRE is a multi-center, randomized controlled study to assess the efficacy and safety of IV rigosertib in HR-MDS patients who had progressed on, failed to respond to, or relapsed after previous treatment with an HMA within the first 9 months or 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. Following interim analysis in early 2018, the independent Data Monitoring Committee recommended that the trial continue with an expansion in enrollment to 360 patients based on a pre-planned sample size re-estimation. Patients are randomized at a 2:1 ratio into two treatment arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. The primary endpoint of INSPIRE is overall survival. 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 Oral Rigosertib

The oral form of rigosertib was developed to provide more convenient dosing for use where the duration of treatment may extend to multiple years. This dosage form may also support many combination therapy modalities. To date, 368 patients have been treated with the oral formulation of rigosertib. Initial studies with single-agent oral rigosertib were conducted in hematological malignancies, lower-risk MDS, and solid tumors. Combination therapy of oral rigosertib with azacitidine and chemoradiotherapy has also been explored. 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 preliminary results were presented in 2016. This novel combination is the subject of an issued U.S. patent with earliest expiration in 2028.

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 Onconova's ability to continue as a going concern, the need for additional financing, the success and timing of Onconova's clinical trials and regulatory approval of protocols, 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.

General Contact

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FINANCIAL TABLES FOLLOW

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

	September 30, 2018	December 31, 2017
Assets	*(unaudited)*	
Current assets:		
Cash and cash equivalents	$ 22,384	$ 4,024
Receivables	24	59
Prepaid expenses and other current assets	696	820
Total current assets	23,104	4,903
Property and equipment, net	20	64
Other non-current assets	12	12
Total assets	$ 23,136	$ 4,979
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,264	$ 6,186
Accrued expenses and other current liabilities	3,488	3,335
Deferred revenue	455	455
Total current liabilities	8,207	9,976
Warrant liability	319	1,773
Deferred revenue, non-current	3,750	4,091
Total liabilities	12,276	15,840
Stockholders' deficit:		
Preferred stock	-	-
Common stock	57	8
Additional paid in capital	387,055	350,614
Accumulated other comprehensive income	(7)	3
Accumulated deficit	(376,245)	(362,316)
Total Onconova Therapeutics Inc., stockholders' equity (deficit)	10,860	(11,691)
Non-controlling interest	-	830
Total stockholders' equity (deficit)	10,860	(10,861)
Total liabilities and stockholders' equity (deficit)	$ 23,136	$ 4,979

All common stock, equity, share and per share amounts have been retroactively adjusted to reflect a one-for-fifteen reverse stock split which was effective September 25, 2018.

ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations (unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Revenue	$ 120	$ 110	$ 1,169	$ 644
Operating expenses:				
General and administrative	1,729	1,728	5,672	5,623
Research and development	3,985	5,141	12,632	14,641
Total operating expenses	5,714	6,869	18,304	20,264
Income (loss) from operations	(5,594)	(6,759)	(17,135)	(19,620)
Gain on dissolution of GBO	-	-	693	-
Change in fair value of warrant liability	129	(210)	1,454	1,716
Other income, net	117	8	229	19
Net loss	(5,348)	(6,961)	(14,759)	(17,885)
Net loss attributable to non-controlling interest	-	-	(163)	-
Net loss applicable to common stockholders	$ (5,348)	$ (6,961)	$ (14,922)	$ (17,885)
Net loss per share of common stock, basic and diluted	$ (0.94)	$ (10.60)	$ (4.14)	$ (31.37)
Basic and diluted weighted average shares outstanding	5,674,125	656,744	3,601,679	570,123

All common stock, equity, share and per share amounts have been retroactively adjusted to reflect a one-for-fifteen reverse stock split which was effective September 25, 2018.