November 14, 2016

Onconova Therapeutics, Inc. Reports Recent Business Highlights and Third Quarter 2016 Financial Results

NEWTOWN, Pa., Nov. 14, 2016 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ:ONTX), a Phase 3 clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, today provided a corporate update and reported financial results for the third quarter ended September 30, 2016.

"Onconova continues to reach important milestones in the development of rigosertib for patients with myelodysplastic syndromes (MDS). In July, our partner SymBio Pharmaceuticals announced the enrollment of the first patient in Japan for our INSPIRE pivotal trial for rigosertib in 2nd-line higher-risk MDS (HR-MDS). In September, we announced the results of a successful End-of-Phase 2 meeting with the FDA for oral rigosertib in combination with azacitidine for 1st-line HR-MDS patients," said Ramesh Kumar, Ph.D., President and CEO of Onconova. "We are pleased with the progress of our oral rigosertib development program, as well as the INSPIRE trial that is now running on four continents with more than 150 trial-sites in 15 countries."

Recent Business Highlights:

Progress in Oral Rigosertib Combination with Azacitidine for 1st-line HR-MDS

- Following evaluation of 54 enrolled patients in the Phase 2 Trial 09-08 of oral rigosertib plus azacitidine, Onconova conducted an End-of-Phase 2 meeting during which updated results from this trial were discussed with the FDA. Based on these discussions, and guidance from the Agency, Onconova will design a randomized, controlled Phase 3 clinical trial comparing the combination of oral rigosertib plus azacitidine to azacitidine plus placebo in hypomethylating agent (HMA) naïve HR-MDS patients. This sizable population of MDS patients not previously treated with HMAs is a poorly met medical need where the front-line treatments (HMAs) are effective for only a fraction of the indicated patients. Notably, in contrast to the INSPIRE trial, where the primary efficacy endpoint was Overall Survival (OS), the new pivotal trial will employ Response Rate (RR) as the approval endpoint, permitting more rapid completion and evaluation of the study. The RR will be a composite of complete remission (CR) and partial remission (PR).

Progress in INSPIRE Pivotal Trial of IV Rigosertib in 2nd-line HR-MDS

- The global Phase 3 INSPIRE trial of IV rigosertib in patients who have failed to respond to or progressed with an HMA therapy is now enrolling in the United States, Europe, Australia, and Japan. As of October 3, 2016, 157 sites were open for the INSPIRE trial to recruit patients.
- The INSPIRE trial was recently reviewed in a pre-planned first meeting of the Drug Safety Monitoring Board. Following a review of the safety data of enrolled patients, the Board recommended continuation of the trial without any modifications.

Key Opinion Leader Meeting on Novel Approaches to Targeting RAS

- Onconova hosted an investor event featuring two pioneers in the area of RAS biology, Dr. Channing J. Der of the University of North Carolina, and Dr. E. Premkumar Reddy of Mount Sinai School of Medicine. The meeting focused on novel approaches for targeting the RAS pathway and highlighted the therapeutic potential for rigosertib as a novel RAS-directed therapy. A replay of the webcast for this event can be found by clicking the following link: http://lifesci.rampard.com/20161017/reg.jsp.

Recent Rigosertib Publications

- Two peer-reviewed articles describing clinical and non-clinical studies with rigosertib in MDS were published in *Expert Review of Anticancer Therapy* (link to article) and *Expert Opinion on Orphan Drugs* (link to article).

Upcoming Events

- Presentation of updated data from 09-08 combination therapy trial at ASH Annual Meeting: December 2016

- Presentations highlighting safety and tolerability in more than 500 patients, and analysis of previously completed randomized clinical trial of rigosertib at ASH Annual Meeting: December 2016
- Completion of site activation for INSPIRE trial: 1Q2017

Third Quarter 2016 Financial Results

- Cash, cash equivalents and marketable securities as of September 30, 2016, totaled $25.8 million, compared to $19.8 million as of December 31, 2015.
- Total net revenue was $1.7 million for the third quarter of 2016 and $5.4 million for the nine months ended September 30, 2016, compared to $1.6 million and $1.9 million, respectively, for the comparable periods in 2015.
- Research and development expenses were $4.0 million for the third quarter of 2016 and $15.4 million for the nine months ended September 30, 2016, compared to $5.3 million and $21.3 million, respectively, for the comparable periods in 2015.
- General and administrative expenses were $2.0 million for the third quarter of 2016 and $7.2 million for the nine months ended September 30, 2016, compared to $2.2 million and $7.8 million, respectively, for the comparable periods in 2015.

About Onconova Therapeutics, Inc.

Onconova Therapeutics is a Phase 3 clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer. Onconova's clinical and pre-clinical stage drug development candidates are derived from its extensive chemical library and are designed to work against specific cellular pathways that are important in cancer cells, while causing minimal damage to normal cells. The Company's most advanced product candidate, rigosertib, is a small molecule inhibitor of cellular signaling and acts as a RAS mimetic. These effects of rigosertib appear to be mediated by direct binding of the compound to the RAS-binding domain (RBD) found in many RAS effector proteins, including the Raf kinases and PI3K. Rigosertib is protected by issued patents (earliest expiry in 2026) and has been awarded Orphan Designation for MDS in the United States, Europe and Japan. In addition to rigosertib, two other candidates are clinical stage, and several candidates are in pre-clinical stages. 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 trial involving more than 800 patients, and is currently being evaluated in the randomized Phase 3 global INSPIRE trial as 2nd-line treatment for patients with higher-risk MDS, after failure of hypomethylating agent, or HMA, therapy. This formulation is suited for patients with advanced disease and provides long duration of exposure and ensures adequate dosing under a controlled setting.

About INSPIRE

The **IN**ternational **S**tudy of **P**hase III **I**V **R**igos**E**rtib, or INSPIRE, is based on 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 nine months of 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. The trial will enroll approximately 225 patients 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 and an interim analysis is anticipated. 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 a more convenient dosing for use where the duration of treatment may extend to multiple years. This dosage form also supports 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 sold 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 as a 1st-line treatment for patients with higher-risk MDS. A Phase 2 trial of the combination therapy been fully enrolled and results are expected to be presented in 2016. This novel combination is the subject of an issued US 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, which involve risks and uncertainties. These statements relate to future events or Onconova Therapeutics, Inc.'s future operations, clinical development of Onconova's product candidates and presentation of data with respect thereto, regulatory approvals, expectations regarding the sufficiency of Onconova's cash and other resources to fund operating expenses and capital expenditures, Onconova's anticipated milestones and future expectations and plans and prospects. 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. 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. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including Onconova's need for additional financing and current plans and future needs to scale back operations if adequate financing is not obtained, 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.

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,	
	2016	**2015**	**2016**	**2015**
Revenue	$ 1,651	$ 1,622	$ 5,373	$ 1,859
Operating expenses:				
General and administrative	1,975	2,217	7,229	7,750
Research and development	3,991	5,282	15,377	21,292
Total operating expenses	5,966	7,499	22,606	29,042
Income (loss) from operations	(4,315)	(5,877)	(17,233)	(27,183)
Change in fair value of warrant liability	2,706	-	2,985	-
Other income (expense), net	10	4	28	(32)
Net loss	(1,599)	(5,873)	(14,220)	(27,215)
Net loss attributable to non-controlling interest	-	-	-	44
Net loss attributable to Onconova Therapeutics, Inc.	$ (1,599)	$ (5,873)	$ (14,220)	$ (27,171)
Net loss per share of common stock, basic and diluted	$ (0.29)	$ (2.60)	$ (3.90)	$ (12.35)
Basic and diluted weighted average shares outstanding	5,438,105	2,258,246	3,643,210	2,200,145

ONCONOVA THERAPEUTICS, INC.
Balance Sheets
(in thousands)

	September 30, 2016	December 31, 2015
Assets	**(unaudited)**	
Current assets:		
Cash and cash equivalents	$ 25,778	$ 19,799

Receivables	904	1,504
Prepaid expenses and other current assets	1,218	1,882
Total current assets	27,900	23,185
Property and equipment, net	176	248
Other non-current assets	12	12
Total assets	$ 28,088	$ 23,445
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,071	$ 3,421
Accrued expenses and other current liabilities	4,482	3,729
Deferred revenue	455	455
Total current liabilities	9,008	7,605
Warrant liability	4,406	-
Deferred revenue, non-current	4,659	5,000
Total liabilities	18,073	12,605
Stockholders' equity:		
Preferred stock	-	-
Common stock	68	25
Additional paid-in capital	341,911	328,564
Accumulated other comprehensive loss	(17)	(22)
Accumulated deficit	(332,777)	(318,557)
Total Onconova Therapeutics Inc. stockholders' equity	9,185	10,010
Non-controlling interest	830	830
Total stockholders' equity	10,015	10,840
Total liabilities and stockholders' equity	$ 28,088	$ 23,445

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