November 13, 2014

Onconova Therapeutics, Inc. Reports Third Quarter 2014 Financial and Operational Results

Nine Presentations to Highlight Programs Including rigosertib Phase 3 Trial at the ASH Annual Meeting

NEWTOWN, Pa., Nov. 13, 2014 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (Nasdaq:ONTX), a 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, 2014.

"Onconova continues to make progress in all of its development programs focused on myelodysplastic syndromes (MDS)," stated Ramesh Kumar, Ph.D., President and CEO of Onconova. "We are particularly excited to present key data from our Phase 3 ONTIME trial of rigosertib in higher risk MDS patients at the American Society of Hematology (ASH) Annual Meeting, to be held on December 6 through December 9. Three presentations will feature results of subgroup, karyotype and molecular analyses in the ONTIME trial. In addition, we will present new data from clinical trials of oral rigosertib in combination with azacitidine in front-line MDS and AML patients. Finally, we are continuing our discussions with U.S. and European regulatory agencies concerning the paths for approval of rigosertib in higher risk MDS patients. We plan to provide additional detail on our clinical and regulatory plans as information becomes available."

Recent Business Highlights:

Development of Rigosertib IV in Higher Risk MDS (HR-MDS)

- One oral and two poster presentations from the Phase 3 trial of rigosertib IV in patients with HR-MDS will be made at the 2014 ASH Annual Meeting. Discussions regarding the next steps towards regulatory approval following the ONTIME trial continue with both the Food and Drug Administration (FDA) and European national and central regulatory agencies.

Development of Oral Rigosertib in Lower Risk MDS (LR-MDS)

- Recruitment continues in a cohort of 20 LR-MDS patients to explore the utility of a prognostic genomic methylation marker for identification of patients likely to respond to rigosertib.
- Based on the time needed for completion of the prognostic genomic test and the ongoing Phase 2 dosing optimization study, we believe that a pivotal study of oral rigosertib in lower risk MDS patients could commence in the second half of 2015, subject to results, funding and approvals.

Development of Oral Rigosertib in Combination with Azacitidine in MDS & AML Patients

- Phase 1 safety and efficacy results for the combination of oral rigosertib and azacitidine in MDS and acute myeloid leukemia (AML) will be presented at the 2014 ASH Annual Meeting.
- The Phase 2 portion of this trial is currently accruing patients at multiple sites in the U.S. and Europe.

Development of Oral Rigosertib in Head and Neck (H&N) and Other Carcinomas

- Onconova has placed on hold the Phase 1 study of oral rigosertib in combination with chemoradiotherapy (platinum plus radiation) in order to focus its resources on the development of rigosertib in MDS.

Timeline of Planned Events

- Eight presentations highlighting rigosertib and one regarding an earlier stage pipeline compound will be made at the 2014 ASH Annual Meeting.
- Onconova will host a webcast and live investor event on December 12th in New York, NY focusing on rigosertib development for multiple MDS indications. The event will provide access to key opinion leaders working with rigosertib clinical trials in MDS. A status update on our discussions with regulatory agencies will also be provided.

Third Quarter and Nine Months 2014 Financial Results

- Cash, cash equivalents, and marketable securities as of September 30, 2014 totaled $57.3 million, compared to $70.5 million as of June 30, 2014, and $100.0 million as of December 31, 2013.

- Total net revenue was $0.1 million for the third quarter of 2014 and $0.7 million for the nine months ended September 30, 2014, compared to $1.1 and $2.8 million for the comparable periods in 2013.
- Research and development expenses were $11.9 million for the third quarter of 2014 and $39.0 million for the nine months ended September 30, 2014 compared to $15.3 and $38.1 million for the comparable periods in 2013.
- General and administrative expenses were $3.1 million for the third quarter of 2014 and $12.0 million for the nine months ended September 30, 2014, compared to $5.9 and $12.4 million for the comparable periods in 2013.

About Onconova Therapeutics, Inc.

Onconova Therapeutics is a 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 proprietary chemical library and are designed to work against specific cellular pathways that are important in cancer cells, while causing minimal damage to normal cells. In addition to rigosertib, two other candidates, briciclib and recilisib, are clinical stage, and several candidates are in pre-clinical stages. For more information, please visit http://www.onconova.com.

About Rigosertib

Rigosertib is a small molecule that inhibits cellular signaling by acting as a Ras mimetic. This is believed to be mediated by direct binding of rigosertib to the Ras-binding domain (RBD) found in many Ras effector proteins, including the Raf kinases and PI3K. The initial therapeutic focus for rigosertib is myelodysplastic syndromes (MDS), a group of bone marrow disorders characterized by ineffective hematopoiesis that often develop into acute myeloid leukemia (AML). Clinical trials with intravenous (IV) and oral formulations of rigosertib are being conducted at leading institutions in the U.S. and abroad. To date, more than 500 MDS patients have been enrolled in clinical trials with rigosertib. Rigosertib is covered under composition of matter patents issued worldwide. Orphan designation has been granted for rigosertib in MDS in the U.S., Europe and Japan.

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 those discussed under the heading "Risk Factors" in our most recent Annual Report on Form 10-Kand quarterly reports on Form 10-Q.

Any forward-looking statements contained in this release speak only as of its date. We undertake 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 Balance Sheets

(in thousands)

	September 30, 2014	December 31, 2013
Assets	**(unaudited)**	
Current assets:		
Cash and cash equivalents	$ 42,348	$ 60,009
Marketable securities	14,999	39,994
Prepaid expenses and other current assets	4,278	4,387
Total current assets	61,625	104,390
Property and equipment, net	512	626
Other non-current assets	137	137

Total assets	$ 62,274	$ 105,153
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,385	$ 3,710
Accrued expenses and other current liabilities	7,202	5,840
Deferred revenue	455	788
Total current liabilities	13,042	10,338
Deferred revenue, non-current	13,568	13,909
Other	1	6
Total liabilities	26,611	24,253
Stockholders' equity:		
Preferred stock	--	--
Common stock	217	215
Additional paid in capital	316,266	311,093
Accumulated other comprehensive income	(8)	1
Accumulated deficit	(281,206)	(230,896)
Total Onconova Therapeutics Inc. stockholders' equity	35,269	80,413
Non-controlling interest	394	487
Total stockholders' equity	35,663	80,900
Total liabilities and stockholders' equity	$ 62,274	$ 105,153

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,	
	2014	2013	2014	2013
Revenue	$ 114	$ 1,116	$ 686	$ 2,823
Operating expenses:				
General and administrative	3,116	5,927	12,033	12,390
Research and development	11,886	15,293	39,038	38,096
Total operating expenses	15,002	21,220	51,071	50,486
Income (loss) from operations	(14,888)	(20,104)	(50,385)	(47,663)
Change in fair value of warrant liability	1	(31)	20	(19)
Other income, net	(20)	46	(38)	186
Net loss before income taxes	(14,907)	(20,089)	(50,403)	(47,496)
Income taxes	--	432	--	432
Net loss	(14,907)	(20,521)	(50,403)	(47,928)
Net loss attributable to non-controlling interest	29	--	93	--
Net loss attributable to Onconova Therapeutics, Inc	(14,878)	(20,521)	(50,310)	(47,928)
Accretion of redeemable convertible preferred stock	--	(269)	--	(2,320)
Net loss applicable to common stockholders	$ (14,878)	$ (20,790)	$ (50,310)	$ (50,248)
Net loss per share of common stock, basic and diluted	$ (0.69)	$ (1.34)	$ (2.32)	$ (7.23)

Basic and diluted weighted average shares outstanding	21,691,017	15,480,416	21,639,764	6,946,248

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