March 10, 2014

Onconova Therapeutics, Inc. Reports Fourth Quarter and Year-End 2013 Financial Results and Outlines Key Objectives for 2014

NEWTOWN, Pa., March 10, 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 its year ended December 31, 2013.

"2013 was an important year for Onconova. During the year we completed our initial public offering and fully enrolled the Phase 3 ONTIME trial in higher risk myelodysplastic syndromes (MDS) for our lead product candidate, rigosertib. We announced positive Phase 2 results for rigosertib in patients with transfusion-dependent lower risk MDS opening the path to a pivotal trial in this important underserved patient population," commented Ramesh Kumar, Ph.D., President and CEO of Onconova. "Last month, we announced top-line analysis of the Phase 3 ONTIME trial. Although the results of this study showed numerical improvement in median overall survival in the rigosertib-treated patients, the observed improvement of 2.4 months did not meet the required level of statistical significance. Encouragingly, a statistically significant improvement in median overall survival was evident in the subset of patients who had progressed on or failed to respond to previous treatment with hypomethylating agents (HMAs). In this group, the overall survival benefit was 3.8 months with Hazard Ratio of 0.67 and p-value of 0.022. These results provide evidence of rigosertib activity in a randomized trial with a survival endpoint in a subset that represents a significant proportion of post-HMA treated MDS patients. We remain committed to discussions with the regulatory authorities in the U.S. and Europe and to advancing rigosertib in order to address important unmet medical needs in MDS and solid tumors," continued Dr. Kumar.

Recent Developments in the Rigosertib Clinical Program

Top-line Analysis of Phase 3 ONTIME Trial of IV Rigosertib in Higher Risk MDS

- The trial enrolled 299 patients with higher risk MDS who had progressed on, failed to respond to, or relapsed after prior therapy with HMAs. The trial did not meet the primary endpoint of statistically significant increase in median overall survival in the intravenous (IV) rigosertib plus best supportive care (BSC) arm compared to BSC only arm.

- A post-hoc analysis demonstrated a statistically significant increase in median overall survival in the subset of patients who had progressed on or failed to respond to previous treatment with HMAs. In this subset of patients (184 of 299 enrolled patients), the median overall survival was 8.5 months in the IV rigosertib plus BSC arm compared to 4.7 months in BSC only arm (Hazard Ratio=0.67; p-value=0.022).

- Preliminary analysis indicates that rigosertib was generally well tolerated in the study population.

Further Development and Potential Prognostic Tool in Lower Risk MDS with Oral Rigosertib

- Based on Phase 2 data presented at the 2013 American Society of Hematology Annual Meeting, we met with the U.S. Food and Drug Administration (FDA) to discuss further development of oral rigosertib for erythropoiesis-stimulating agent (ESA) refractory transfusion-dependent lower risk MDS patients. As a result of this dialogue, we have designed a pivotal Phase 3 protocol. We intend to seek a Special Protocol Assessment (SPA) for this randomized, double-blind, placebo-controlled study in lower risk MDS patients who do not respond to ESAs and are dependent on packed red blood cell transfusions to alleviate their anemia. Trial size, entry criteria, secondary endpoints, and the statistical analysis plan will be finalized during the SPA process. We project to start enrollment in the Phase 3 study in the second half of 2014 at multiple sites in the U.S. and Europe.

- Currently, a validation cohort of 20 lower risk MDS patients is being enrolled in a Phase 2 trial with the objective of assessing the value of a prognostic genomic methylation marker for future studies. The FDA has encouraged us to discuss these results with them for potential integration of this analytical tool in the pivotal study. We expect to report on these studies and discussions in the second half of 2014. We have obtained rights to intellectual property covering this method of prognosis from Columbia University.

Front-line Study in MDS Patients with a Combination of Azacitidine and Oral Rigosertib

- A phase 1/2 study is now underway to evaluate the potential synergistic activity of rigosertib and azacitidine. In this study, the indicated dose of azacitidine is given in combination with escalating doses of oral rigosertib in successive cohorts. Rigosertib doses of 140-560 mg given two times daily (BID) will be tested. After the dose-finding segment of the trial is

completed, the second part of the trial will evaluate the selected dose in additional patients. A total of up to 40 patients are planned to be enrolled in this study. This study is now running in U.S. sites and has enrolled seven patients. We expect to provide updates on this trial in the second half of 2014.

On Mechanism of Action of Rigosertib

- We recently presented new data on the mode of action of rigosertib. These data indicate that rigosertib binds to the Ras Binding Domain (RBD) found in many signaling proteins, including Raf kinases and PI3K. This specific binding disrupts protein-protein interactions necessary for signal transduction in the cell. The signal transduction inhibitory activity of rigosertib suggests novel ways in which cellular pathways could be interrupted by rigosertib and informs the design of future translational studies.

Key Upcoming Milestones

- Discussions of the ONTIME trial results with regulatory authorities with the goal of determining next steps in advancing development of rigosertib in higher risk MDS. We are seeking a Type A meeting to get regulatory guidance from the FDA and plan to approach the European regulatory agencies in parallel.
- Initiation of a Phase 3 trial for oral rigosertib as first-line treatment for transfusion-dependent lower risk MDS. After we obtain additional regulatory clarity via the SPA mechanism, we plan to initiate this trial at multiple sites in the U.S. and Europe.
- Presentation of ONTIME clinical data at the 2014 American Society of Clinical Oncology Annual Meeting.
- Phase 2 dosing for the combination of oral rigosertib and azacitidine in first-line MDS is projected to start in the second half of 2014.

2013 Financial Results

- Cash, cash equivalents, and marketable securities as of December 31, 2013 totaled $100.0 million, compared to $81.5 million at December 31, 2012.
- Total net revenue was $1.9 million for the fourth quarter of 2013 and $4.8 million for the year ended December 31, 2013, compared to $3.0 million for the fourth quarter of 2012 and $46.2 million for the year ended December 31, 2012. In 2012, the Company entered into a licensing and development agreement with a subsidiary of Baxter International Inc. ("Baxter"). Baxter made an upfront payment of $50 million of which $42.6 million was recognized as revenue in the third quarter of 2012.
- Research and development expenses were $12.1 million for the fourth quarter of 2013 and $50.2 million for the year ended December 31, 2013, compared to $10.6 million for the fourth quarter of 2012 and $52.8 million for the year ended December 31, 2012. In 2012, the Company made a $12.5 million milestone payment in accordance with its license agreement with Temple University and a $1.0 million milestone payment to the Leukemia and Lymphoma Society. There was a decrease in stock-based compensation expense of $3.5 million, resulting primarily from a change in accounting methods in 2013 compared to 2012. These decreases were partially offset by increased clinical and manufacturing spending of $10.2 million and higher personnel-related costs of $4.2 million in 2013 compared to 2012.
- General and administrative expenses were $4.4 million for the fourth quarter of 2013 and $16.8 million for the year ended December 31, 2013, compared to $2.7 million for the fourth quarter of 2012 and $15.7 million for the year ended December 31, 2012. There was a decrease in stock-based compensation expense of $2.4 million, resulting primarily from a change in accounting methods in 2103 compared to 2012. This decrease was offset by an increase of $1.9 million in higher operating costs as a public company and higher personnel-related costs of $1.6 million in 2013 compared to 2012.
- Net loss was $14.6 million for the fourth quarter of 2013 and $62.6 million for the year ended December 31, 2013, compared to $10.3 million for the fourth quarter of 2012 and $29.9 million for the year ended December 31, 2012.

Today's Conference Call at 4:30 PM ET

Onconova will host a conference call and audio webcast to discuss its fourth quarter and year-end financial results this afternoon at 4:30 PM ET. A live webcast will be available at this link or can be accessed by visiting "Events & Presentations" in the Investors and Media section of the Company's website at www.onconova.com. The call can be accessed by dialing (877) 312-5881 (domestic) or (253) 237-1173 (international) five minutes prior to the start time and providing the Conference ID 9033414. A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the Company's website for two weeks following the call.

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 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. In addition to rigosertib, the Company's most advanced product candidate, two other candidates are in clinical trials, and several candidates are in pre-clinical stages. For more information, please visit http://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, 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, expectations regarding the sufficiency of Onconova's cash balance 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 Registration Statement on Form S-1 originally filed with the Securities and Exchange Commission on June 14, 2013, as amended (Registration No. 333-189358).

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 Sheet

(in thousands)

	December 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 60,009	$ 81,527
Marketable securities	39,994	--
Prepaid expenses and other current assets	4,387	1,725
Total current assets	104,390	83,252
Property and equipment, net	626	463
Other non-current assets	137	137
Total assets	$ 105,153	$ 83,852
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,710	$ 5,517
Accrued expenses and other current liabilities	5,840	3,987
Option liability	--	11,967
Deferred revenue	788	3,907
Total current liabilities	10,338	25,378
Deferred revenue, non-current	13,909	15,421
Other	6	44
Total liabilities	24,253	40,843
Redeemable convertible preferred stock	--	201,315

Stockholders' equity (deficit):		
Preferred stock	--	--
Common stock	215	26
Additional paid in capital	311,093	10,021
Accumulated other comprehensive income	1	--
Accumulated deficit	(230,896)	(168,353)
Total Onconova Therapeutics Inc. stockholders' equity (deficit)	80,413	(158,306)
Non-controlling interest	487	--
Total stockholders' equity (deficit)	80,900	(158,306)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 105,153	$ 83,852

Onconova Therapeutics, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2013	**2012**	**2013**	**2012**
Revenue	$ 1,930	$ 2,969	$ 4,753	$ 46,190
Operating expenses:				
General and administrative	4,403	2,698	16,793	15,707
Research and development	12,086	10,576	50,182	52,762
Total operating expenses	16,489	13,274	66,975	68,469
Income (loss) from operations	(14,559)	(10,305)	(62,222)	(22,279)
Change in fair value of warrant liability	61	2	42	367
Interest expense	(1)	--	(4)	(8,608)
Other income, net	(126)	41	63	608
Net loss before income taxes	(14,625)	(10,262)	(62,121)	(29,912)
Income taxes	3	--	435	--
Net loss	(14,628)	(10,262)	(62,556)	(29,912)
Net loss attributable to non-controlling interest	13	--	13	--
Net loss attributable to Onconova Therapeutics, Inc.	(14,615)	(10,262)	(62,543)	(29,912)
Accretion of redeemable convertible preferred stock	--	(1,010)	(2,320)	(3,953)
Net loss applicable to common stockholders	$ (14,615)	$ (11,272)	$ (64,863)	$ (33,865)
Net loss per share of common stock, basic and diluted	$ (0.68)	$ (4.89)	$ (6.12)	$ (15.35)
Basic and diluted weighted average shares outstanding	21,419,208	2,305,315	10,594,227	2,206,888

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