March 26, 2015

Onconova Therapeutics, Inc. Reports Recent Business Highlights and Fourth Quarter and Year-End 2014 Financial Results

Company Outlines Key Objectives for 2015

NEWTOWN, Pa., March 26, 2015 (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 year ended December 31, 2014.

"We remain committed to developing rigosertib for patients with myelodysplastic syndromes (MDS)," said Ramesh Kumar, Ph.D., President and CEO of Onconova. "Regulatory interactions with U.S. and European agencies continue, and are helping define a path forward for rigosertib in patients with higher-risk MDS (HR-MDS). We intend to submit a pivotal study protocol for rigosertib IV in HR-MDS for review in the U.S. and Europe in the second quarter. Furthermore, our clinical trial of oral rigosertib in combination with azacitidine as a treatment for patients with HR-MDS and acute myeloid leukemia (AML) continues to progress. Interim Phase 2 results will be presented at the International Symposium on Myelodysplastic Syndromes in May."

Recent Business Highlights:

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

- Currently, there are no approved second-line therapies for HR-MDS patients. Based on the results of the subgroup analysis of ONTIME data, Onconova has explored various potential approval pathways. Due to the heterogeneity of patients enrolled in our ONTIME trial, and the key finding that subgroups with higher prognostic risk appeared to derive a greater benefit from rigosertib treatment, we have discussed the clinical protocol design and indication for the new Phase 3 trial with the FDA and EMA. Based on their feedback, a protocol for a global, randomized, controlled, pivotal trial in a more homogeneous HR-MDS patient population is currently being developed for regulatory review.

Development of Oral Rigosertib in Combination with Azacitidine for MDS and AML Patients

- Onconova's clinical trial of oral rigosertib in combination with azacitidine for the treatment of front-line and second-line HR-MDS and AML patients continues to progress. Positive Phase 1 results from this study were presented at the 2014 ASH conference. The Phase 2 portion of this trial is designed to assess whether treatment with rigosertib, in combination with azacitidine, has a beneficial effect on bone marrow function, peripheral blood counts and symptoms of disease progression in patients with MDS and AML. Thirty-nine patients have been enrolled in the Phase 1/2 trial, including 24 patients enrolled at the Phase 2 dose.

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

- An extended portion of a Phase 2 clinical trial is underway to assess the utility of bone marrow DNA methylation patterns for the identification of patients more likely to respond to oral rigosertib. Onconova is collaborating with a methylation genomics company to refine this test and expects to announce these study results later this year.

Operational Update

- As part of Onconova's ongoing efforts to reduce its operating losses and cash expenditures, the Company recently reduced its workforce by approximately 35%, and terminated the lease for one of its two U.S. office facilities.

Upcoming Events

- Submission of Phase 3 HR-MDS protocol for regulatory review: 2Q2015
- Initiation of Phase 3 trial of IV rigosertib in HR-MDS, subject to regulatory approvals and financing: 2H2015
- Presentation of interim Phase 2 data for combination of oral rigosertib and azacitidine at 2015 International Symposium on Myelodysplastic Syndromes: 2Q2015

2014 Financial Results

- Cash, cash equivalents, and marketable securities as of December 31, 2014 totaled $43.6 million, compared to $100.0 million at December 31, 2013.
- Total net revenue was $0.1 million for the fourth quarter of 2014 and $0.8 million for the year ended December 31, 2014, compared to $1.9 million for the fourth quarter of 2013 and $4.8 million for the year ended December 31, 2013.
- Research and development expenses were $10.4 million for the fourth quarter of 2014 and $49.4 million for the year ended December 31, 2014, compared to $12.1 million for the fourth quarter of 2013 and $50.2 million for the year ended December 31, 2013.
- General and administrative expenses were $3.1 million for the fourth quarter of 2014 and $15.1 million for the year ended December 31, 2014, compared to $4.4 million for the fourth quarter of 2013 and $16.8 million for the year ended December 31, 2013.
- Net loss was $13.4 million for the fourth quarter of 2014 and $63.8 million for the year ended December 31, 2014, compared to $14.6 million for the fourth quarter of 2013 and $62.6 million for the year ended December 31, 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 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 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 formation of blood cells that often converts 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 Europe.

About the ONTIME Trial

The ONTIME Trial, a Phase 3 multi-center, randomized, controlled study assessed the efficacy and safety of rigosertib 72-hour continuous intravenous infusion plus best supportive care (BSC) compared to BSC alone, in higher-risk MDS patients with excess blasts (5% to 30% bone marrow blasts), who had progressed on, failed or relapsed after treatment with HMAs. Two hundred ninety-nine MDS patients were enrolled at 89 sites in the U.S. and Europe. Patients were randomized at a 2:1 ratio into two treatment arms: best supportive care plus rigosertib 1,800 mg/24 hours administered as a 72-hr continuous infusion on Days 1, 2, and 3 of a 2-week cycle for the first eight 2-week cycles, then every 4 weeks thereafter versus BSC alone. The primary endpoint of the trial is median overall survival. Secondary endpoints include overall response, complete bone marrow response, hematological improvements, transition time to acute myeloid leukemia, and quality of life improvement. The ONTIME trial was conducted under a Special Protocol Agreement (SPA) from the FDA and following Scientific Advice from European regulatory agencies. Top-line results, announced in 1Q2014, indicated that the study did not meet its primary endpoint for the intent-to-treat population. Results of stratified and exploratory subgroup analyses, demonstrating heterogeneity in the study population, were presented at the 2014 ASH conference.

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-K and 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 Sheet

(in thousands)

	December 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 43,582	$ 60,009
Marketable securities	--	39,994
Prepaid expenses and other current assets	3,323	4,387
Total current assets	46,905	104,390
Property and equipment, net	420	626
Other non-current assets	12	137
Total assets	$ 47,337	$ 105,153
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,027	$ 3,710
Accrued expenses and other current liabilities	5,777	5,840
Deferred revenue	455	788
Total current liabilities	10,259	10,338
Deferred revenue, non-current	13,455	13,909
Other	1	6
Total liabilities	23,715	24,253
Stockholders' equity:		
Preferred stock	--	--
Common stock	217	215
Additional paid in capital	317,122	311,093
Accumulated other comprehensive income	(13)	1
Accumulated deficit	(294,578)	(230,896)
Total Onconova Therapeutics Inc. stockholders' equity	22,748	80,413
Non-controlling interest	874	487
Total stockholders' equity	23,622	80,900
Total liabilities and stockholders' equity	$ 47,337	$ 105,153

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,	
	2014	2013	2014	2013

Revenue	$ 114	$ 1,930	$ 800	$ 4,753
Operating expenses:				
General and administrative	3,086	4,403	15,119	16,793
Research and development	10,387	12,086	49,425	50,182
Total operating expenses	13,473	16,489	64,544	66,975
Income (loss) from operations	(13,359)	(14,559)	(63,744)	(62,222)
Change in fair value of warrant liability	--	61	20	42
Other income, net	(14)	(127)	(52)	59
Net loss before income taxes	(13,373)	(14,625)	(63,776)	(62,121)
Income taxes	19	3	19	435
Net loss	(13,392)	(14,628)	(63,795)	(62,556)
Net loss attributable to non-controlling interest	20	13	113	13
Net loss attributable to Onconova Therapeutics, Inc.	(13,372)	(14,615)	(63,682)	(62,543)
Accretion of redeemable convertible preferred stock	--	--	--	(2,320)
Net loss applicable to common stockholders	$ (13,372)	$ (14,615)	$ (63,682)	$ (64,863)
Net loss per share of common stock, basic and diluted	$ (0.62)	$ (0.68)	$ (2.94)	$ (6.12)
Basic and diluted weighted average shares outstanding	21,694,403	21,419,208	21,653,536	10,594,227

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