May 14, 2015

Onconova Therapeutics, Inc. Reports Recent Business Highlights and First Quarter 2015 Financial Results

NEWTOWN, Pa., May 14, 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 first quarter ended March 31, 2015.

"We recently submitted to FDA and EMA a clinical trial protocol for a pivotal study of IV rigosertib in patients with higher-risk myelodysplastic syndrome (HR-MDS) after failure of hypomethylating agent (HMA) therapy. We look forward to completing the regulatory process and initiating the enrollment for this study in 2015, pending receipt of appropriate financing," said Ramesh Kumar, Ph.D., President and CEO of Onconova. "In addition, we expect to achieve multiple rigosertib clinical development goals this year, including complete enrollment of the Phase 2 study assessing whether treatment with rigosertib, in combination with azacitidine, is safe and has beneficial effects on bone marrow function, peripheral blood counts and signs and symptoms of disease progression in patients with HR-MDS and AML."

Recent Business Highlights:

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

- A clinical trial protocol along with briefing materials were submitted for regulatory review to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for a global pivotal study of IV rigosertib in patients with HR-MDS for whom prior treatment with approved HMAs has failed. Specifically, a request for a Type A meeting has been made to the FDA and a request for scientific advice has been made to the EMA. The new Phase 3 randomized controlled trial of IV rigosertib derives from knowledge gained from the ONTIME trial and is based on guidance received from previous consultations with FDA and EMA. The proposed primary endpoint for the new trial is overall survival. Additional details of the trial design and plan, including postings on national clinical trials registration databases, will be available following completion of the regulatory review process in the U.S. and Europe.

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. Initial Phase 1 results from this study, referred to as the 09-08 trial, were presented at the 2014 ASH conference. Updated results and translational studies supporting the therapeutic rationale for the rigosertib/azacitidine combination were the subject of two presentations at the 13th International Symposium on Myelodysplastic Syndromes in April-May 2015.

- The Phase 2 portion of the 09-08 trial is designed to assess whether treatment with rigosertib, in combination with azacitidine, is safe and has a beneficial effect on bone marrow function, peripheral blood counts and symptoms of disease progression in patients with MDS and AML. Enrollment in the Phase 2 portion of this trial is expected to be completed in the second half of this year.

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

- An extension of a Phase 2 clinical trial of oral rigosertib, referred to as 09-05, is underway to assess the utility of DNA methylation patterns for the identification of LR-MDS patients most likely to respond. Enrollment in this extension cohort is now complete. Onconova is collaborating with a methylation genomics company to refine this test and expects to announce results later this year.

- Enrollment in a second Phase 2 clinical trial of oral rigosertib, referred to as 09-07, is complete. Onconova expects to present data from this trial in the second half of 2015.

Operational Update

- As part of ongoing efforts to reduce operating losses and cash expenditures, the Company reduced its workforce by approximately 35% and terminated the lease for one of its two U.S. office facilities during the first quarter of 2015.

Upcoming Events

- Completion of regulatory review of new pivotal trial protocol
- Initiation of Phase 3 trial of IV rigosertib in HR-MDS, subject to regulatory approvals and receipt of appropriate financing: 2H2015
- Presentation of analyses from ONTIME trial at American Society of Clinical Oncology (ASCO) and European Hematology Association (EHA) annual meetings: Q22015
- Completion of enrollment in 09-08 trial: 2H2015
- Publication or presentation of results from LR-MDS 09-05 and 09-07 trials: 2H2015

First Quarter 2015 Financial Results

- Cash, cash equivalents, and marketable securities as of March 31, 2015 totaled $33.7 million, compared to $43.6 million as of December 31, 2014.
- Total net revenue was $0.1 million for the first quarter of 2015 compared to $0.4 million for the first quarter of 2014.
- Research and development expenses were $9.5 million for the first quarter of 2015 compared to $14.2 million for the first quarter of 2014.
- General and administrative expenses were $3.0 million for the first quarter of 2015 compared to $4.9 million for the first quarter of 2014.

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 our 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 our clinical trials and regulatory approval of protocols, and 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)

	March 31, 2015	December 31, 2014
Assets	**(unaudited)**	
Current assets:		
Cash and cash equivalents	$ 33,698	$ 43,582
Prepaid expenses and other current assets	2,605	3,198
Restricted cash	50	125
Total current assets	36,353	46,905
Property and equipment, net	348	420
Other non-current assets	12	12
Total assets	$ 36,713	$ 47,337
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,857	$ 4,027
Accrued expenses and other current liabilities	6,452	5,777
Deferred revenue	455	455
Total current liabilities	10,764	10,259
Deferred revenue, non-current	13,341	13,455
Other	--	1
Total liabilities	24,105	23,715
Stockholders' equity:		
Preferred stock	--	--
Common stock	217	217
Additional paid-in capital	318,505	317,122
Accumulated other comprehensive income	(43)	(13)
Accumulated deficit	(306,921)	(294,578)
Total Onconova Therapeutics Inc. stockholders' equity	11,758	22,748
Non-controlling interest	850	874
Total stockholders' equity	12,608	23,622
Total liabilities and stockholders' equity	$ 36,713	$ 47,337

Onconova Therapeutics, Inc.

Condensed Consolidated Statements of Operations (unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2015	**2014**
Revenue	$ 114	$ 447
Operating expenses:		
General and administrative	2,965	4,932
Research and development	9,498	14,248
Total operating expenses	12,463	19,180
Income (loss) from operations	(12,349)	(18,733)
Change in fair value of warrant liability	--	16
Other income (expense), net	(18)	1
Net loss	(12,367)	(18,716)
Net loss attributable to non-controlling interest	24	37
Net loss attributable to Onconova Therapeutics, Inc	$ (12,343)	$ (18,679)
Net loss per share of common stock, basic and diluted	$ (0.57)	$ (0.87)
Basic and diluted weighted average shares outstanding	21,703,173	21,568,302

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