

May 12, 2014

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

NEWTOWN, Pa., May 12, 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 first quarter ended March 31, 2014.

"Onconova remains committed to developing rigosertib for the unmet medical needs of MDS patients. We recently announced top-line results of the Phase 3 ONTIME trial in higher risk myelodysplastic syndromes (MDS) and are in the process of discussing these results with regulatory authorities in the U.S. and Europe," said Ramesh Kumar, Ph.D., President and CEO of Onconova. "In addition, we continue to advance the oral rigosertib development program by evaluating a prognostic genomic methylation marker to identify lower risk MDS patients who could benefit from this promising therapy. During the quarter we also expanded our program in solid tumors with the initiation of a Phase 1 trial of oral rigosertib in combination with platinum-based chemoradiotherapy in head and neck cancer," continued Dr. Kumar.

Recent Business Highlights

Top-line Results from the ONTIME Trial of Intravenous (IV) Rigosertib in Higher Risk MDS

- In February, the Company announced results from the ONTIME trial. Although the trial did not meet the primary endpoint of statistically significant improvement in median overall survival in the IV rigosertib plus best supportive care (BSC) arm, a pre-planned subset analysis demonstrated an increase in median overall survival in patients with primary hypomethylating agent (HMA) failure (i.e., patients with MDS who had progressed on or failed to respond to previous treatment with HMAs). This subgroup, which comprised 62% of the patients enrolled in the ONTIME trial, has a short life expectancy and currently no approved therapeutic options.

Development of Oral Rigosertib in Lower Risk MDS

- We continue our dialogue with the regulatory agencies in the U.S. and Europe towards establishing the parameters for a pivotal trial. We are enrolling a cohort of 20 patients to explore a prognostic genomic methylation marker first announced at the 2013 American Society of Hematology Annual Meeting and collecting additional supportive data from ongoing Phase 2 studies.

Combination Therapy in Front-line MDS Patients with Oral Rigosertib and Azacitidine

- A Phase 1/2 study of oral rigosertib plus azacitidine in higher risk MDS patients is in the dose escalation stage at two sites in the U.S. Following completion of Phase 1, the Phase 2 portion of the trial will expand to include additional sites in the U.S. and Europe. This study is based on previously published data demonstrating synergistic activity of this combination.

Initiation of a Phase 1 Study of Oral Rigosertib in Combination with Platinum-based Chemoradiotherapy

- This multicenter trial will determine the maximum tolerated dose of oral rigosertib when administered with concurrent cisplatin and radiotherapy in patients with head and neck cancer. This trial will assess the safety, tolerability, and activity of this combination.

Presentations at the American Association for Cancer Research Annual Meeting

- Seven scientific presentations highlighted data relating to the molecular mechanism of action of rigosertib and two preclinical programs targeting PLK2 and CDK4/ARK5 kinases.

Key Upcoming Milestones

- Discussions with U.S. and European regulatory authorities regarding development of rigosertib in higher risk MDS: second and third quarters of 2014.
- Clarity on the utility of a prognostic genomic methylation marker for transfusion-dependent lower risk MDS patients: second half of 2014.

- Start of Phase 2 stage of the combination trial of oral rigosertib and azacitidine in first-line MDS: second half of 2014.

First Quarter 2014 Financial Results

- Cash, cash equivalents, and marketable securities as of March 31, 2014 totaled \$84.6 million, compared to \$100.0 million as of December 31, 2013.
- Total net revenue was \$0.4 million for the first quarter of 2014, compared to \$1.1 million for the first quarter of 2013.
- Research and development expenses were \$14.2 million for the first quarter of 2014, compared to \$12.8 million for the first quarter of 2013.
- General and administrative expenses were \$4.9 million for the first quarter of 2014, compared to \$3.3 million for the first quarter of 2013.

Today's Conference Call at 4:30 PM ET

Onconova will host a conference call and audio webcast to discuss its first quarter 2014 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 and 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 42257958. 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 Annual Report on Form 10-K for the year ended December 31, 2013 filed by Onconova with the Securities and Exchange Commission on March 20, 2014.

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)

	March 31, 2014	December 31, 2013
Assets	(unaudited)	
Current assets:		

Cash and cash equivalents	\$ 54,624	\$ 60,009
Marketable securities	29,999	39,994
Prepaid expenses and other current assets	<u>4,401</u>	<u>4,387</u>
Total current assets	89,024	104,390
Property and equipment, net	557	626
Other non-current assets	<u>137</u>	<u>137</u>
Total assets	<u>\$ 89,718</u>	<u>\$ 105,153</u>

Liabilities and stockholders' equity

Current liabilities:

Accounts payable	\$ 3,302	\$ 3,710
Accrued expenses and other current liabilities	7,799	5,840
Deferred revenue	<u>455</u>	<u>788</u>
Total current liabilities	11,556	10,338
Deferred revenue, non-current	13,795	13,909
Other	<u>3</u>	<u>6</u>
Total liabilities	<u>25,354</u>	<u>24,253</u>

Stockholders' equity:

Preferred stock	--	--
Common stock	217	215
Additional paid in capital	313,272	311,093
Accumulated other comprehensive income	--	1
Accumulated deficit	<u>(249,575)</u>	<u>(230,896)</u>
Total Onconova Therapeutics Inc. stockholders' equity	63,914	80,413
Non-controlling interest	<u>450</u>	<u>487</u>
Total stockholders' equity	<u>64,364</u>	<u>80,900</u>
Total liabilities and stockholders' equity	<u>\$ 89,718</u>	<u>\$ 105,153</u>

Onconova Therapeutics, Inc.

Condensed Consolidated Statements of Operations (unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2014	2013
Revenue	\$ 447	\$ 1,116
Operating expenses:		
General and administrative	4,932	3,346
Research and development	<u>14,248</u>	<u>12,756</u>
Total operating expenses	<u>19,180</u>	<u>16,102</u>
Income (loss) from operations	(18,733)	(14,986)
Change in fair value of warrant liability	16	14
Other income, net	<u>1</u>	<u>127</u>
Net loss	(18,716)	(14,845)
Net loss attributable to non-controlling interest	<u>37</u>	<u>--</u>
Net loss attributable to Onconova Therapeutics, Inc.	(18,679)	(14,845)

Accretion of redeemable convertible preferred stock	<u> -- </u>	<u> (1,019)</u>
Net loss applicable to common stockholders	<u> \$ (18,679)</u>	<u> \$ (15,864)</u>
Net loss per share of common stock, basic and diluted	<u> \$ (0.87)</u>	<u> \$ (6.08)</u>
Basic and diluted weighted average shares outstanding	<u> 21,568,302</u>	<u> 2,607,406</u>

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