

Onconova Therapeutics, Inc. Reports Second Quarter 2013 Financial and Operational Results

NEWTOWN, Pa., Sept. 6, 2013 (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 second quarter ended June 30, 2013.

"Onconova has made significant progress over the past few months," commented Ramesh Kumar, Ph.D., President and CEO of Onconova. "We recently announced complete enrollment of the Phase 3 trial of intravenous (IV) rigosertib in patients with higher risk myelodysplastic syndromes (MDS) and presented data from trials testing oral rigosertib in lower risk MDS and solid tumors. Further, the successful completion of our initial public offering will help continue the advancement of rigosertib, our lead clinical candidate, through upcoming, multiple development milestones."

Recent Business Highlights

- Onconova closed its initial public offering of common stock on July 30, 2013, raising net proceeds of \$79.6 million.
- In June 2013, Onconova reported interim response and safety data from a trial testing front-line oral rigosertib in transfusion-dependent, lower risk MDS patients.
- In May 2013, Onconova announced reaching its enrollment goal for the Phase 3 trial of IV rigosertib in patients with higher risk MDS.
- In May 2013, Onconova initiated a multi-center Phase 2 trial with oral rigosertib in transfusion-dependent, lower risk MDS patients who have failed treatment with erythropoiesis-stimulating agents.
- In April 2013, Onconova announced results from a Phase 1 trial of oral rigosertib in patients with various advanced solid tumors refractory to standard therapy, including patients with head and neck cancers who had previously failed platinum-based therapy. Based on these results we initiated a Phase 2 trial in relapsed or metastatic head and neck cancers.

Second Quarter and Six Months 2013 Financial Results

- Total net revenue for the second quarter of 2013 was \$0.6 million and \$1.7 million for the six months ended June 30, 2013, compared to \$0.2 million and \$0.4 million for the comparable periods in 2012. The increase resulted from recognition of collaboration revenue from our license and development agreement for rigosertib with Baxter International, Inc.
- Research and development expenses were \$10 million for the second quarter of 2013 and \$22.8 million for the six months ended June 30, 2013, compared to \$6.8 million and \$15.2 million for the comparable periods in 2012. The increase was largely driven by added costs related to clinical studies of rigosertib.
- General and administrative expenses were \$3.1 million for the second quarter of 2013 and \$6.5 million for the six months ended June 30, 2013, compared to \$1.6 million and \$4.1 million for the comparable periods in 2012. The increase was largely driven by incremental expenses to support our anticipated public company operations as well as increased stock-based compensation expense and other costs to support the Company's growth.
- Net loss was \$12.6 million for the second quarter of 2013 and \$27.4 million for the six months ended June 30, 2013, compared to \$7.4 million and \$18.2 million for the comparable periods in 2012.
- Cash and cash equivalents as of June 30, 2013 totaled \$51.2 million (which does not include the \$79.6 million in net proceeds from the Company's initial public offering) compared to \$81.5 million at December 31, 2012.

Upcoming Milestones

- Presentation of overall results from the Phase 2 trial of oral rigosertib in transfusion-dependent, lower risk MDS at the American Society of Hematology, or ASH, Annual Meeting in December 2013.
- Interim analysis of 150 patients in the Phase 3 trial of IV rigosertib plus gemcitabine in metastatic pancreatic cancer in either the fourth quarter of 2013 or the first quarter of 2014.
- Top-line survival results from the Phase 3 trial of IV rigosertib in higher risk MDS in either the fourth quarter of 2013 or 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 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, Section 21E of the Securities Exchange Act of 1934 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, milestone or royalty payments from Onconova's collaborators, 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.

Balance Sheets

(in thousands)

	<u>June 30,</u>	<u>December 31,</u>
	<u>2013</u>	<u>2012</u>
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 51,181	\$ 81,527
Prepaid expenses and other current assets	5,867	1,725
Total current assets	57,048	83,252
Property and equipment, net	729	463
Other non-current assets	137	137
Total assets	<u>\$ 57,914</u>	<u>\$ 83,852</u>
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 4,410	\$ 5,517
Accrued expenses and other current liabilities	5,388	3,987
Option liability	--	11,967
Deferred revenue	3,509	3,907
Total current liabilities	13,307	25,378
Deferred revenue, non-current	14,136	15,421
Other	47	44
Total liabilities	<u>27,490</u>	<u>40,843</u>
Redeemable convertible preferred stock	203,366	201,315
Stockholders' deficit:		
Common stock	26	26
Additional paid in capital	22,787	10,021

Accumulated other comprehensive income	5	--
Accumulated deficit	<u>(195,760)</u>	<u>(168,353)</u>
Total stockholders' deficit	<u>(172,942)</u>	<u>(158,306)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	<u>\$ 57,914</u>	<u>\$ 83,852</u>

ONCONOVA THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations (unaudited)
(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Revenue	\$ 591	\$ 220	\$ 1,707	\$ 418
Operating expenses:				
General and administrative	3,117	1,627	6,463	4,087
Research and development	<u>10,047</u>	<u>6,776</u>	<u>22,803</u>	<u>15,224</u>
Total operating expenses	<u>13,164</u>	<u>8,403</u>	<u>29,266</u>	<u>19,311</u>
Loss from operations	(12,573)	(8,183)	(27,559)	(18,893)
Change in fair value of warrant liability	(2)	999	12	390
Interest expense	(2)	(230)	(2)	(251)
Other income (expense), net	<u>15</u>	<u>(2)</u>	<u>142</u>	<u>539</u>
Net loss	(12,562)	(7,416)	(27,407)	(18,215)
Accretion of redeemable convertible preferred stock	<u>(1,032)</u>	<u>(927)</u>	<u>(2,051)</u>	<u>(2,158)</u>
Net loss applicable to common stockholders	<u>\$ (13,594)</u>	<u>\$ (8,343)</u>	<u>\$ (29,458)</u>	<u>\$ (20,373)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (5.21)</u>	<u>\$ (3.84)</u>	<u>\$ (11.29)</u>	<u>\$ (9.37)</u>
Basic and diluted weighted average shares outstanding	<u>2,609,495</u>	<u>2,173,549</u>	<u>2,608,450</u>	<u>2,173,549</u>

CONTACT: Onconova Therapeutics

Benjamin Hoffman, 267-759-3680

bhoffman@onconova.us

or

Media:

MacDougall Biomedical Communications

Chris Erdman, 781-235-3060

chris@macbiocom.com