

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

NEWTOWN, Pa., Aug. 13, 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 three and six months ended June 30, 2015.

"Following receipt of regulatory guidance, we have completed the design of a proposed Phase 3 pivotal trial for IV rigosertib in patients with higher-risk myelodysplastic syndrome (HR-MDS) after failure of hypomethylating agent (HMA) therapy. We are finalizing our IND submission for the trial and intend to initiate enrollment in this study in the second half of 2015," said Ramesh Kumar, Ph.D., President and CEO of Onconova. "In addition, a Phase 2 trial of oral rigosertib in combination with azacitidine in MDS and AML is approaching full enrollment. We expect to present data from this study later this year."

Recent Business Highlights:

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

- | A randomized controlled Phase 3 trial, referred to as 04-30, has been designed following discussions with FDA and EMA, input from key opinion leaders and incorporating learnings from the ONTIME study. This trial would enroll patients under 80 years of age who had progressed on or failed to respond to previous treatment with HMAs within the first nine months of HMA treatment and had HMA therapy discontinued within six months prior to enrollment in the 04-30 trial. The primary endpoint of this study is overall survival, and an interim analysis is anticipated. An IND and CTA are in preparation and are expected to be submitted this quarter. We expect the Phase 3 clinical trial to be conducted at approximately 100 sites in more than ten countries. We expect to begin enrolling patients in this trial later this year, though our ability to conduct the trial as planned will require us to obtain additional financing.

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

- | Our clinical trial of oral rigosertib in combination with azacitidine for the treatment of front-line and second-line HR-MDS and AML, referred to as 09-08, is based on previously published preclinical data demonstrating synergistic activity of this combination. Updated Phase 1 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 the second quarter of 2015. These data demonstrated the tolerability and activity of the combination therapy in MDS and AML patients, including patients who had previously been treated with an HMA.
- | The Phase 2 portion of the 09-08 trial is designed to assess whether treatment with rigosertib in combination with azacitidine reduces the number of bone marrow blasts, improves peripheral blood counts and delays signs of disease progression in patients with MDS and AML. Thus far, 33 patients, including 28 MDS patients, have received the recommended Phase 2 dose in this study. Phase 2 data are expected to be presented at a scientific conference later this year.

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

- | Enrollment in an extension of a Phase 2 trial of oral rigosertib, referred to as 09-05, to

assess the utility of DNA methylation patterns for the identification of LR-MDS patients likely to respond to treatment, is now complete. Onconova is collaborating with a methylation genomics company to refine this test and expects to announce results this year.

Upcoming Events

- | Filing of IND and CTA relating to Phase 3 trial 04-30: 3Q2015
- | Initiation of Phase 3 trial of IV rigosertib in HR-MDS: 2H2015
- | Presentation of Phase 2 data from the 09-08 oral rigosertib combination trial in MDS and AML: 4Q2015
- | Publication or presentation of results from the HR-MDS ONTIME trial: 4Q2015

Second Quarter 2015 Financial Results

- | Cash, cash equivalents, and marketable securities as of June 30, 2015 totaled \$25.4 million, compared to \$33.7 million as of March 31, 2015.
- | Total net revenue was \$0.1 million for the second quarter of 2015 and \$0.2 million for the six months ended June 30, 2015, compared to \$0.1 and \$0.6 million for the comparable periods in 2014.
- | Research and development expenses were \$6.5 million for the second quarter of 2015 and \$16.0 million for the six months ended June 30, 2015, compared to \$12.9 and \$27.2 million for the comparable periods in 2014.
- | General and administrative expenses were \$2.6 million for the second quarter of 2015 and \$5.5 million for the six months ended June 30, 2015, compared to \$4.0 and \$8.9 million for the comparable periods in 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.

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)

	June 30, 2015	December 31, 2014
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents	\$ 25,358	\$ 43,582
Prepaid expenses and other current assets	2,017	3,198
Restricted cash	50	125
Total current assets	27,425	46,905
Property and equipment, net	300	420
Other non-current assets	12	12
Total assets	\$ 27,737	\$ 47,337
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,185	\$ 4,027
Accrued expenses and other current liabilities	5,295	5,777
Deferred revenue	455	455
Total current liabilities	9,935	10,259
Deferred revenue, non-current	13,227	13,455
Other	-	1
Total liabilities	23,162	23,715
Stockholders' equity:		
Preferred stock	-	-
Common stock	217	217
Additional paid-in capital	319,418	317,122
Accumulated other comprehensive income	(14)	(13)
Accumulated deficit	(315,876)	(294,578)
Total Onconova Therapeutics Inc. stockholders' equity	3,745	22,748
Non-controlling interest	830	874
Total stockholders' equity	4,575	23,622
Total liabilities and stockholders' equity	\$ 27,737	\$ 47,337

ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations (unaudited)

(in thousands, except share and per share amounts)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Revenue	\$ 123	\$ 125	\$ 237	\$ 572
Operating expenses:				
General and administrative	2,568	3,985	5,533	8,917
Research and development	6,512	12,904	16,010	27,152
Total operating expenses	9,080	16,889	21,543	36,069
Income (loss) from operations	(8,957)	(16,764)	(21,306)	(35,497)
Change in fair value of warrant liability	-	3	-	19
Other income (expense), net	(18)	(19)	(36)	(18)
Net loss	(8,975)	(16,780)	(21,342)	(35,496)
Net loss attributable to non-controlling interest	20	27	44	64
Net loss attributable to Onconova Therapeutics, Inc.	<u>\$ (8,955)</u>	<u>\$ (16,753)</u>	<u>\$ (21,298)</u>	<u>\$ (35,432)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.41)</u>	<u>\$ (0.77)</u>	<u>\$ (0.98)</u>	<u>\$ (1.64)</u>
Basic and diluted weighted average shares outstanding	<u>21,709,054</u>	<u>21,658,625</u>	<u>21,706,130</u>	<u>21,613,713</u>

CONTACT: Onconova Therapeutics

Benjamin Hoffman, 267-759-3036

bhoffman@onconova.us