

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

NEWTOWN, Pa., Nov. 11, 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 third quarter ended September 30, 2015.

"Onconova continues to advance the development of rigosertib for the unmet needs of patients with myelodysplastic syndromes (MDS)," said Ramesh Kumar, Ph.D., President and CEO of Onconova. "Our pivotal Phase 3 INSPIRE trial is now open at multiple sites and we anticipate enrollment of the first patient shortly. This will mark an important step towards the approval of IV rigosertib as a treatment for higher-risk MDS (HR-MDS). We also look forward to presenting results from a Phase 2 trial of oral rigosertib in combination with azacitidine in MDS and acute myeloid leukemia (AML) patients at the 2015 ASH Annual Meeting this December."

Recent Business Highlights:

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

- A Phase 3 clinical trial, referred to as INSPIRE, is now open at multiple sites in the United States. The INSPIRE trial is a randomized controlled study to assess the efficacy and safety of IV rigosertib in HR-MDS patients who had progressed on, or failed to respond to, previous treatment with hypomethylating agents (HMAs). The trial will enroll approximately 225 patients randomized in a 2:1 ratio into two treatment arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. The primary endpoint of INSPIRE is overall survival and an interim analysis is anticipated.
- INSPIRE will be conducted in the United States, Europe, Australia, Israel, and Japan. The first patient in the INSPIRE trial is anticipated in 2015. Four U.S. sites have been activated and are screening patients. Clinical Trial Applications (CTAs) for INSPIRE have been filed in several European countries and the first CTA has been cleared by the Medicines and Healthcare Products Regulatory Agency in the U.K.
- The INSPIRE study will be supported by Onconova's rigosertib partners. Per the Company's development and licensing agreement with Baxalta, Onconova's commercialization partner in Europe, Baxalta will pay for half of the costs for the trial up to a specified cap. Onconova's development and commercialization partner in Japan and Korea, Symbio Pharmaceuticals, Ltd., intends to participate in the trial by enrolling patients in Japan.

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

- Onconova is approaching full enrollment in the Phase 2 portion of an open label Phase 1/2 clinical trial, designated 09-08, evaluating oral rigosertib in combination with the approved dose of injectable azacitidine for patients with HR-MDS and AML. The Phase 2 combination study includes both de novo patients (i.e. not previously treated with HMAs) and patients who failed treatment with a previous HMA.
- Consistent with reported Phase 1 results, Bone Marrow Complete Responses (or BMCR), assessed by the International Working Group (or IWG) and Bone Marrow Blast (or BMBL) criteria, have been observed in a majority of the 18 currently evaluable MDS patients. These and additional data from Phase 2 patients yet to be evaluated are the subject of an oral presentation at the upcoming American Society of Hematology (ASH) Annual Meeting in December.

Upcoming Events

- Enrollment of the first patient in the Phase 3 INSPIRE trial: 4Q2015
- Presentation of Phase 2 data from oral rigosertib combination trial in MDS and AML: 4Q2015
- Analyst and investor KOL event in New York, NY to review results and discuss the path forward following the Phase 2 oral rigosertib combination trial in MDS and AML: 4Q2015
- Publication of results from the HR-MDS ONTIME trial: 4Q2015
- Enrollment of patients for the INSPIRE study in Europe and Japan: 1H2016

Third Quarter 2015 Financial Results

- Cash, cash equivalents, and marketable securities as of September 30, 2015 totaled \$22.2 million, compared to \$25.4 million as of June 30, 2015. During the third quarter, Onconova sold 1,940,103 shares through Cantor Fitzgerald for net

proceeds of \$4.7 million. On October 8, 2015, Onconova entered into a \$16.5 million share purchase agreement and registration rights agreement with Lincoln Park Capital Fund. Upon signing the agreements, Lincoln Park Capital Fund made an initial purchase of 846,755 shares of the Company's common stock for \$1.5 million and received an additional 200,000 shares as consideration for entering into the purchase agreement.

- Total net revenue was \$1.6 million for the third quarter of 2015 and \$1.9 million for the nine months ended September 30, 2015, compared to \$0.1 and \$0.7 million, respectively, for the comparable periods in 2014. Revenues in the third quarter of 2015 primarily consisted of contractual cost sharing revenue from Baxalta for the INSPIRE trial.
- Research and development expenses were \$5.3 million for the third quarter of 2015 and \$21.3 million for the nine months ended September 30, 2015, compared to \$11.9 and \$39.0 million, respectively, for the comparable periods in 2014.
- General and administrative expenses were \$2.2 million for the third quarter of 2015 and \$7.8 million for the nine months ended September 30, 2015, compared to \$3.1 and \$12.0 million, respectively, for the comparable periods in 2014.

About Onconova Therapeutics, Inc.

Onconova Therapeutics is a Phase 3 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 for rigosertib are being conducted at MDS Centers of Excellence in the United States, Europe, and the Asia-Pacific region. Rigosertib is protected by issued patents (earliest expiry in 2026) and has been awarded Orphan Designation for MDS in the United States, Europe and Japan.

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 Onconova's 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 Onconova's clinical trials and regulatory approval of protocols, and those discussed under the heading "Risk Factors" in Onconova's 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. Onconova undertakes 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)

	September 30, December 31,	
	2015	2014
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 22,197	\$ 43,582

Receivables	1,535	132
Prepaid expenses and other current assets	1,902	3,066
Restricted cash	50	125
Total current assets	25,684	46,905
Property and equipment, net	273	420
Other non-current assets	12	12
Total assets	<u>\$ 25,969</u>	<u>\$ 47,337</u>

Liabilities and stockholders' equity

Current liabilities:

Accounts payable	\$ 3,190	\$ 4,027
Accrued expenses and other current liabilities	5,012	5,777
Deferred revenue	455	455
Total current liabilities	8,657	10,259
Deferred revenue, non-current	13,114	13,455
Other	-	1
Total liabilities	<u>21,771</u>	<u>23,715</u>

Stockholders' equity:

Preferred stock	-	-
Common stock	237	217
Additional paid-in capital	324,898	317,122
Accumulated other comprehensive loss	(18)	(13)
Accumulated deficit	(321,749)	(294,578)
Total Onconova Therapeutics Inc. stockholders' equity	3,368	22,748
Non-controlling interest	830	874
Total stockholders' equity	4,198	23,622
Total liabilities and stockholders' equity	<u>\$ 25,969</u>	<u>\$ 47,337</u>

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

	Three Months Ended September		Nine Months Ended September	
	30,		30,	
	2015	2014	2015	2014
Revenue	\$ 1,622	\$ 114	\$ 1,859	\$ 686
Operating expenses:				
General and administrative	2,217	3,116	7,750	12,033
Research and development	5,282	11,886	21,292	39,038
Total operating expenses	7,499	15,002	29,042	51,071
Income (loss) from operations	(5,877)	(14,888)	(27,183)	(50,385)
Change in fair value of warrant liability	-	1	-	20
Other income (expense), net	4	(20)	(32)	(38)
Net loss	(5,873)	(14,907)	(27,215)	(50,403)
Net loss attributable to non-controlling interest	-	29	44	93
Net loss attributable to Onconova Therapeutics, Inc.	<u>\$ (5,873)</u>	<u>\$ (14,878)</u>	<u>\$ (27,171)</u>	<u>\$ (50,310)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.26)</u>	<u>\$ (0.69)</u>	<u>\$ (1.23)</u>	<u>\$ (2.32)</u>

Basic and diluted weighted average shares
outstanding

22,582,464

21,691,017

22,001,451

21,639,764

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