March 28, 2016

Onconova Therapeutics, Inc. Reports Recent Business Highlights and Year-end 2015 Financial Results

Company Outlines Key Objectives for 2016

NEWTOWN, Pa., March 28, 2016 (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 fourth quarter and year-ended December 31, 2015.

"Onconova is focused on the execution of the global INSPIRE trial of IV rigosertib. This trial is now enrolling higher-risk MDS patients at multiple U.S. sites and in Europe, and we are initiating additional clinical centers in the U.S. and abroad. Patients have been enrolled in the U.S. and Europe, and we are pleased that our Japan/Korea partner SymBio Pharmaceuticals has announced plans to enroll patients in INSPIRE in Japan," said Ramesh Kumar, Ph.D., President and CEO of Onconova. "In addition, based on the encouraging Phase 2 results for oral rigosertib in combination with azacitidine presented in December 2015, we are planning to define a regulatory path forward with the FDA this year."

Recent Business Highlights:

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

- The global INSPIRE trial is now enrolling patients in the United States and Europe. INSPIRE will be conducted in the United States, Europe, Australia, Israel, and Japan. The first patient in Europe was enrolled this month and sites in Japan are expected to open shortly. The first patient in this trial was enrolled in December 2015 at the MD Anderson Cancer Center.
- Results from Onconova's ONTIME trial were published in the top-tier, peer-reviewed journal, *Lancet Oncology*. The article, titled, "Rigosertib versus best supportive care for patients with high-risk myelodysplastic syndromes after failure of hypomethylating drugs (ONTIME): a randomised, controlled, phase 3 trial," appeared in the March 8, 2016 online edition of the journal.

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

- 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 is fully enrolled. The Phase 2 study included both front-line patients (i.e. not previously treated with HMAs) and patients after failure of treatment with an HMA. Positive interim data from the 09-08 trial were presented at the 2015 American Society of Hematology (ASH) Annual Meeting in December 2015.
- In the presentation at ASH, 30 MDS patients were evaluable for efficacy assessment per 2006 International Working Group, or IWG, criteria. Overall, 23 of 30 patients (77%) responded, including six patients who had complete remissions. Notably, 16 of 19 (84%) HMA-naïve patients had a response to the combination therapy and 7 of 11 (64%) patients whose disease had previously failed HMAs responded. Hematologic improvement was observed in 13 of 26 patients that were evaluable for this part of the analysis.
- Patients received full dose (per label) of azacitidine and the recommended daily Phase 2 dose of oral rigosertib (560 mg in the morning and 280 mg in the afternoon). The combination of oral rigosertib and azacitidine was well tolerated, with a median duration of treatment of 4 months (range 1 to 27 months). Adverse events of Grade $\geq$ 3 experienced across all cycles with the combination included thrombocytopenia (27%), neutropenia (22%), hypokalaemia (5%), hematuria (5%) and diarrhoea (3%).

Operational Update

- On March 3, 2016, the Company received notice from Baxalta US Inc. of Baxalta's election to terminate the September 2012 development and license agreement between Baxalta and the Company for convenience, effective August 30, 2016, following Baxalta's reprioritization review. In accordance with the terms of the development and license agreement, upon termination, the rights that the Company had licensed to Baxalta will revert to the Company at no cost.
- The Company recently cut its workforce by ~17% as an important step towards reducing its operating losses and cash expenditures. Additional cost-optimization measures are being considered for implementation over the next several months.

Upcoming Events

- Enrollment of the first patient in the Phase 3 INSPIRE trial in Japan: 1H2016
- Peer-reviewed publication of mechanism of action of rigosertib: 2Q2016
- Presentation of updated Phase 2 data from oral rigosertib combination trial in MDS: 2Q2016
- End of Phase 2 meeting with FDA to discuss data from oral rigosertib combination trial: 2H2016

2015 Financial Results

- Cash, cash equivalents, and marketable securities as of December 31, 2015 totaled $19.8 million, compared to $43.6 million as of December 31, 2014. Onconova believes that its current cash and cash equivalents, together with anticipated contractual cost-sharing payments from Baxalta for a portion of the INSPIRE trial costs, and in consideration of the cost optimization measures previously noted, will be sufficient to fund its ongoing trials and operations into the first quarter of 2017.
- Net loss was $24.0 million for the year ended December 31, 2015, compared to $63.8 million for the year ended December 31, 2014 due primarily to a 45% reduction in operating expenses and the recognition of deferred revenue in 2015.
- Research and development expenses were $25.9 million for the year ended December 31, 2015, compared to $49.4 million for the year ended December 31, 2014,
- General and administrative expenses were $9.5 million for the year ended December 31, 2015, compared to $15.1 million for the year ended December 31, 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 Sheets
(in thousands)

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 19,799	$ 43,582
Receivables	1,504	132
Prepaid expenses and other current assets	1,882	3,191
Total current assets	23,185	46,905
Property and equipment, net	248	420
Other non-current assets	12	12
Total assets	$ 23,445	$ 47,337
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,421	$ 4,027
Accrued expenses and other current liabilities	3,729	5,777
Deferred revenue	455	455
Total current liabilities	7,605	10,259
Deferred revenue, non-current	5,000	13,455
Other	-	1
Total liabilities	12,605	23,715
Stockholders' equity:		
Preferred stock	-	-
Common stock	255	217
Additional paid in capital	328,334	317,122
Accumulated other comprehensive income	(22)	(13)
Accumulated deficit	(318,557)	(294,578)
Total Onconova Therapeutics Inc. stockholders' equity	10,010	22,748
Non-controlling interest	830	874
Total stockholders' equity	10,840	23,622
Total liabilities and stockholders' equity	$ 23,445	$ 47,337

Onconova Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2015	2014
Revenue	$ 11,456	$ 800
Operating expenses:		
General and administrative	9,533	15,119
Research and development	25,895	49,425
Total operating expenses	35,428	64,544
Income (loss) from operations	(23,972)	(63,744)
Change in fair value of warrant liability		

Interest expense	-	20
Other income, net	(35)	(52)
Net loss before income taxes	(24,007)	(63,776)
Income taxes	16	19
Net loss	(24,023)	(63,795)
Net loss attributable to non-controlling interest	44	113
Net loss attributable to Onconova Therapeutics, Inc.	$ (23,979)	$ (63,682)
Net loss per share of common stock, basic and diluted	$ (1.05)	$ (2.94)
Basic and diluted weighted average shares outstanding	22,739,760	21,653,536

CONTACT:

Onconova Therapeutics
Benjamin Hoffman, 267-759-3036
bhoffman@onconova.us