August 15, 2016

Onconova Therapeutics, Inc. Reports Recent Business Highlights and Second Quarter 2016 Financial Results

NEWTOWN, Pa., Aug. 15, 2016 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ:ONTX), a Phase 3 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, 2016.

"We are encouraged by the progress of our global Phase 3 trial of our lead product candidate, rigosertib, for patients with myelodysplastic syndromes (MDS). The INSPIRE trial is actively enrolling patients in the U.S., Europe and Japan, and we have recently opened trial sites in Israel and Australia, bringing us more than two-thirds of the way to our target of approximately 135 sites worldwide. The enrollment of patients in Japan by our Japan/Korea partner, SymBio Pharmaceuticals, is further accelerating this important pivotal trial," said Ramesh Kumar, Ph.D., President and CEO of Onconova. "As a result of the completion of our oversubscribed rights offering in July, we believe we are positioned to deliver multiple key milestones in 2016 and 2017, including opening additional INSPIRE trial sites, pre-planned interim analysis and enrollment of approximately 225 patients. Finally, we have initiated discussions with U.S. and European regulatory authorities towards formal End-of-Phase 2 meetings to define the pathway forward for further development of oral rigosertib. We intend to provide an update on these discussions later this year."

Recent Business Highlights:

Completion of $17.4 Million Oversubscribed Financing

- On July 29, 2016, Onconova closed its oversubscribed rights offering. Although the number of units able to be sold was capped at a maximum of 4,256,186 units (or approximately $17.4 million in gross proceeds), there was a total demand for approximately 4.9 million units in the rights offering.
- Overall, 4,256,186 units consisting of a total of 3,599,786 shares of common stock, pre-funded warrants to purchase an additional 656,400 shares of common stock, and 3,192,022 tradable warrants were issued in this offering.
- Including the net proceeds from the rights offering of approximately $15.8 million, Onconova had cash and cash equivalents of approximately $27.6 million at July 31, 2016.

Progress in INSPIRE Pivotal Trial of Rigosertib in Higher-risk MDS (HR-MDS)

- The global INSPIRE trial is now enrolling patients in the United States, Europe and Japan. As of July 31, 2016, 103 sites, including 27 in the U.S., were open and recruiting patients. The first patient in Japan was enrolled in the trial in July by our partner, SymBio Pharmaceuticals, Inc.

Progress in Oral Rigosertib Combination with Azacitidine

- Updated results from the Phase 2 trial 09-08 were presented in June 2016 at the 21st Congress of the European Hematology Association. Notably, the interim overall response rate was 77% (23 of 30 patients) among evaluable first- or second-line HR-MDS patients treated with oral rigosertib in combination with azacitidine. This trial is now fully enrolled and End-of-Phase 2 meetings to discuss the next stage of development with regulatory authorities in the U.S. and Europe are expected to occur in the second half of 2016.

Upcoming Events

- Enrollment of patients in Israel, Australia and Canada for INSPIRE trial: 3Q2016
- Key Opinion Leader investor event to discuss the potential future applications of the RAS-directed Mechanism of Action in oncology and for rigosertib: 3Q2016
- End-of-Phase 2 meeting with FDA and European authorities to discuss trial results and future development plan for oral rigosertib in combination with azacitidine: 2H2016

Second Quarter 2016 Financial Results

- Cash, cash equivalents, and marketable securities as of June 30, 2016 totaled $12.8 million, compared to $19.8 million as of December 31, 2015.
- Total net revenue was $2.2 million for the second quarter of 2016 and $3.7 million for the six months ended June 30, 2016, compared to $0.1 million and $0.2 million, respectively, for the comparable periods in 2015.
- Research and development expenses were $5.6 million for the second quarter of 2016 and $11.4 million for the six months ended June 30, 2016, compared to $6.5 million and $16.0 million, respectively, for the comparable periods in 2015.
- General and administrative expenses were $2.1 million for the second quarter of 2016 and $5.3 million for the six months ended June 30, 2016, compared to $2.6 million and $5.5 million, respectively, for the comparable periods in 2015.

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. The Company's most advanced product candidate, rigosertib, is a small molecule inhibitor of cellular signaling and acts as a RAS mimetic. These effects of rigosertib appear to be mediated by direct binding of the compound to the RAS-binding domain (RBD) found in many RAS effector proteins, including the Raf kinases and PI3K. 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. In addition to rigosertib, two other candidates are clinical stage, and several candidates are in pre-clinical stages. For more information, please visit http://www.onconova.com.

About IV Rigosertib

The intravenous form of rigosertib has been employed in Phase 1, 2, and 3 clinical trial involving more than 800 patients, and is currently being evaluated in the randomized Phase 3 global INSPIRE trial as 2nd-line treatment for patients with higher-risk MDS, after failure of hypomethylating agent, or HMA, therapy. This formulation is suited for patients with advanced disease and provides long duration of exposure and ensures adequate dosing under a controlled setting.

About INSPIRE

The **IN**ternational **S**tudy of **P**hase III **I**V **R**igos**E**rtib, or INSPIRE, is based on guidance received from the U.S. Food and Drug Administration and European Medicines Agency and derives from the findings of the ONTIME Phase 3 trial. INSPIRE is a multi-center, randomized controlled study to assess the efficacy and safety of IV rigosertib in HR-MDS patients who had progressed on, failed to respond to, or relapsed after previous treatment with an HMA within the first nine months of initiation of HMA treatment. This time frame optimizes the opportunity to respond to treatment with an HMA prior to declaring treatment failure, as per NCCN Guidelines. The trial will enroll approximately 225 patients randomized at 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. Full details of the INSPIRE trial, such as inclusion and exclusion criteria, as well as secondary endpoints, can be found on clinicaltrials.gov (NCT02562443).

About Oral Rigosertib

The oral form of rigosertib was developed to provide a more convenient dosing for use where the duration of treatment may extend to multiple years. This dosage form also supports many combination therapy modalities. To date, more than 350 patients have been treated with the oral formulation of rigosertib. Initial studies with single-agent oral rigosertib were conducted in hematological malignancies, lower-risk MDS and sold tumors. Combination therapy of oral rigosertib with azacitidine and chemoradiotherapy has also been explored. Currently, oral rigosertib is being developed as a combination therapy together with azacitidine as a 1st-line treatment for patients with higher-risk MDS. A Phase 2 trial of the combination therapy been fully enrolled and results are expected to be presented in 2016. This novel combination is the subject of an issued US patent with earliest expiration in 2028.

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," "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 Statements of Operations (unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue	$ 2,248	$ 123	$ 3,722	$ 237
Operating expenses:				
General and administrative	2,083	2,568	5,254	5,533
Research and development	5,564	6,512	11,386	16,010
Total operating expenses	7,647	9,080	16,640	21,543
Income (loss) from operations	(5,399)	(8,957)	(12,918)	(21,306)
Change in fair value of warrant liability	8	-	279	-
Other income (expense), net	10	(18)	18	(36)
Net loss	(5,381)	(8,975)	(12,621)	(21,342)
Net loss attributable to non-controlling interest	-	20	-	44
Net loss attributable to Onconova Therapeutics, Inc.	$ (5,381)	$ (8,955)	$ (12,621)	$ (21,298)
Net loss per share of common stock, basic and diluted	$ (1.96)	$ (4.13)	$ (4.61)	$ (9.81)
Basic and diluted weighted average shares outstanding	2,740,211	2,170,905	2,735,901	2,170,613

ONCONOVA THERAPEUTICS, INC.

Balance Sheets

(in thousands)

	June 30, 2016	December 31, 2015
Assets	**(unaudited)**	
Current assets:		
Cash and cash equivalents	$ 12,818	$ 19,799
Receivables	2,147	1,504
Prepaid expenses and other current assets	1,025	1,882
Total current assets	15,990	23,185
Property and equipment, net	200	248
Other non-current assets	12	12
Total assets	$ 16,202	$ 23,445

Liabilities and stockholders' equity

Current liabilities:		
Accounts payable	$ 2,801	$ 3,421
Accrued expenses and other current liabilities	5,839	3,729
Deferred revenue	455	455
Total current liabilities	9,095	7,605
Warrant liability	287	-
Deferred revenue, non-current	4,773	5,000
Total liabilities	14,155	12,605
Stockholders' equity:		
Preferred stock	-	-
Common stock	27	25
Additional paid-in capital	332,387	328,564
Accumulated other comprehensive loss	(19)	(22)
Accumulated deficit	(331,178)	(318,557)
Total Onconova Therapeutics Inc. stockholders' equity	1,217	10,010
Non-controlling interest	830	830
Total stockholders' equity	2,047	10,840
Total liabilities and stockholders' equity	$ 16,202	$ 23,445

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