



May 13, 2015

## **Onconova Announces Multiple Rigosertib Clinical Data Presentations at the 2015 ASCO Annual Meeting**

### **Data Regarding Prognostic Factors and Intermediate Clinical Endpoints for Rigosertib in Higher-Risk MDS (HR-MDS)**

NEWTOWN, Pa., May 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 announced that two abstracts are being presented at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL, May 29 - June 2, 2015.

#### **Data Analysis of Phase 3 ONTIME Trial:**

##### **Abstract #7092**

**Title:** Prognostic and predictive value of IPSS-R in assessing overall survival (OS) in a phase III study of rigosertib in second-line higher-risk (HR) MDS patients.

**Date:** Sunday, May 31, 2015

**Time:** 8:00 AM - 11:30 AM

**Session:** Leukemia, Myelodysplasia, and Transplantation

**Location:** McCormick Place, S Hall A

**Presenter:** Lewis R. Silverman, MD, Division of Hematology/Oncology, Icahn School of Medicine at Mount Sinai, New York, NY

##### **Abstract #7017**

**Title:** Correlation of overall survival (OS) with bone marrow blast (BMBl) response in patients (pts) with myelodysplastic syndrome.

**Date:** Sunday, May 31, 2015

**Time:** 8:00 AM - 11:30 AM

**Session:** Leukemia, Myelodysplasia, and Transplantation

**Location:** McCormick Place, S Hall A

**Presenter:** Lewis R. Silverman, MD, Division of Hematology/Oncology, Icahn School of Medicine at Mount Sinai, New York, NY

#### **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.

#### **About the ONTIME Trial**

The ONTIME Trial, a Phase 3 multi-center, randomized, controlled study assessed the efficacy and safety of rigosertib 72-hour continuous intravenous infusion plus best supportive care (BSC) compared to BSC alone, in higher-risk MDS patients with excess blasts (5% to 30% bone marrow blasts), who had progressed on, failed or relapsed after treatment with HMAs. Results of stratified and exploratory subgroup analyses, demonstrating heterogeneity in the study population, were presented at the 2014 American Society of Hematology Annual Meeting (Garcia-Manero et al., Abstract 163). The ONTIME trial did not meet its primary endpoint in the intent-to-treat population, but improvements in median overall survival (mOS) were observed in various pre-specified and exploratory subgroups of patients, including "primary HMA failure" patients (those who had progressed on or failed to respond to previous treatment with HMAs) and patients in the Revised International Prognostic Scoring System (IPSS-

R) Very High Risk category (IPSS-R calculates a risk score for MDS patients based on the location and type of chromosome abnormalities, number and degree of cytopenias, and percentage of bone marrow blasts observed at diagnosis). Among the 184 patients (62% of patients in the trial) with primary HMA failure, mOS was 8.6 months in the rigosertib arm (127 patients) compared to 5.3 months in the best supportive care arm (57 patients), with a hazard ratio of 0.69 and a p value of 0.040. Among the 134 patients (45% of patients in the trial) who were in the IPSS-R Very High Risk category, mOS was 7.6 months in the rigosertib arm (93 patients) compared to 3.2 months in the best supportive care arm (41 patients), with a hazard ratio of 0.56 and a p value of 0.005. Further, the safety and tolerability of rigosertib IV in the ONTIME trial was acceptable.

## 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 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.

CONTACT: Onconova Therapeutics

Benjamin Hoffman, 267-759-3036

[bhoffman@onconova.us](mailto:bhoffman@onconova.us)

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