March 9, 2016

Onconova Announces Publication of Rigosertib Phase 3 ONTIME Data in Lancet Oncology

-- Online-First Publication Currently Available --

-- First Randomized Trial With Survival Endpoint in Second-Line Myelodysplastic Syndromes (MDS) --

-- New Phase 3 "INSPIRE" Study of IV Rigosertib Currently Enrolling Patients --

NEWTOWN, Pa., March 09, 2016 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ:ONTX), a clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, today announced the publication of results from the ONTIME trial of intravenous (IV) rigosertib in higher-risk myelodysplastic syndromes (HR-MDS) 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," currently appears in the online edition, and will appear in an upcoming print issue of the journal.

The ONTIME trial was a randomized clinical study in HR-MDS patients following the failure of hypomethylating agents (HMAs). Overall survival was the primary endpoint in this international study of 299 patients. Although there was a trend to improvement in overall survival with IV rigosertib, no statistically significant difference was observed in the intention-to-treat (ITT) analysis between treatment and control (best supportive care, BSC) arms. Analyses in multiple clinically-important subgroups suggested that rigosertib may provide a meaningful survival benefit over BSC in some HR-MDS patients, including those with primary HMA failure (i.e., never benefited from first-line treatment with HMAs). Additionally, those HR-MDS patients who were classified as Very High Risk by the International Prognostic Scoring System (Revised), and patients with monosomy 7 or trisomy 8 chromosomal aberrations, showed encouraging overall survival results with rigosertib. Collectively, these results helped define a more homogenous patient population for a new Phase 3 study of IV rigosertib, referred to as INSPIRE, which was initiated by Onconova in the fourth quarter of 2015.

"This publication presents peer-reviewed results of the ONTIME trial with insights into the complexity of MDS, particularly in patients whose disease has failed the available HMA therapies," said Guillermo Garcia-Manero, MD, Chief of the Section of Myelodysplastic Syndromes at The University of Texas MD Anderson Cancer Center, and lead author of the paper. "Rigosertib was well tolerated in patients with a high unmet medical need who have no approved therapeutic options. We are impressed by the trend to notable efficacy in well-defined, well-balanced subgroups of HR-MDS patients with very poor prognosis. Based on these findings, we have designed the new Phase 3 INSPIRE study with IV rigosertib, which is currently enrolling patients."

Steven Fruchtman, MD, Chief Medical Officer of Onconova added, "The INSPIRE trial is now open at multiple sites in the U.S., and we intend to initiate sites in Canada, Europe, Israel, and Australia. In addition, we are pleased that our commercial partner for Japan and Korea, SymBio Pharmaceuticals, Ltd., will also shortly begin enrolling patients for this study in Japan. We believe that publication of the ONTIME results in *Lancet Oncology* serves to highlight an important unmet medical need and the ongoing Phase 3 INSPIRE trial, and broadens the awareness of this pivotal study among physicians and patients."

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 under 80 years of age 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.[1] 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 Rigosertib

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. 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 leading institutions 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.

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.

References

[1]National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Myelodysplastic Syndromes. Version 1.2016.

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.

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