June 15, 2015

Onconova Presents Patient Selection Criteria and Intermediate Clinical Endpoints for Rigosertib in Higher-Risk Myelodysplastic Syndromes (HR-MDS) at EHA Annual Meeting

Data Support Planned Phase 3 Pivotal Trial in HR-MDS

NEWTOWN, Pa., June 15, 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 the presentation of clinical data on rigosertib in HR-MDS at the 20th Congress of the European Hematology Association (EHA) in Vienna, Austria, June 11 - 14, 2015.

Onconova collaborators from the United States and Europe presented multiple posters analyzing subgroup data, key clinical endpoints and eligibility criteria from the completed Phase 3 ONTIME trial of IV rigosertib in patients with HR-MDS previously treated with hypomethylating agents (HMAs). These data are being utilized in the design of a new global Phase 3 trial for IV rigosertib in HR-MDS, which Onconova expects to initiate in 2015, pending receipt of appropriate financing.

Electronic versions of the posters can be accessed by visiting "Posters" under the Investors and Media section of the Onconova website at www.onconova.com.

Abstract number: P616
Title: Overall Survival (OS) and Baseline Disease Characteristics in MDS Patients with Primary HMA Failure in a Randomized, Controlled, Phase III Study of Rigosertib
Primary Author: Guillermo Garcia-Manero, MD, MD Anderson Cancer Center, Houston, TX

Abstract number: P625
Title: Correlation of Overall Survival (OS) with Bone Marrow Blast (BMBL) Response in Patients (Pts) with Myelodysplastic Syndromes (MDS)
Primary Author : Lewis R. Silverman, MD, Division of Hematology/Oncology, Icahn School of Medicine at Mount Sinai, New York, NY

Abstract Number: E1227
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
Primary Author: Lewis R. Silverman, MD; Division of Hematology/Oncology, Icahn School of Medicine at Mount Sinai, New York, NY

Abstract Number: E1226
Title: Subgroup Analyses of a Phase 3 Study in Patients with Myelodysplastic Syndromes Failing HMA Treatment: Identification of a Homogeneous Population Who Benefit from Rigosertib Therapy
Primary Author: Gianluca Gaidano, MD; Amedeo Avogadro University of Eastern Piedmont, Novara, Italy

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).

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