

# Onconova Presents Clinical Data from Oral Rigosertib and Azacitidine Combination Study in Higher-Risk Myelodysplastic Syndromes at EHA Annual Meeting

## Interim Data from Fully-Enrolled Phase 2 Trial

NEWTOWN, Pa., June 13, 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 announced the presentation of data by Onconova collaborators from the U.S. and Europe from the ongoing Phase 2 clinical trial of oral rigosertib in combination with azacitidine in patients with either first- or second-line higher-risk myelodysplastic syndromes (HR-MDS) at the 21<sup>st</sup> Congress of the European Hematology Association (EHA) in Copenhagen, Denmark, which took place June 9 — 11, 2016.

The results of this study are being finalized to initiate end of Phase 2 discussions with U.S. and European regulatory agencies to define the next steps in the development plan for this combination therapy. These interim results were initially presented at the Annual Meeting of the American Society of Hematology (ASH) in December 2015.

"We are encouraged by the interim overall response rate results of this Phase 2 trial, which demonstrated that 23 of 30 patients, or 77%, responded to treatment, and anticipate further updates to the data set," stated Steve Fruchtman, M.D., Chief Medical Officer of Onconova. "Of note, 84% of HMA-naïve patients responded to this novel combination. We look forward to discussing these results, and the longer-term follow-up from this study, with U.S. and European regulatory agencies in order to define the next step of development for this combination therapy."

A full copy of the EHA poster entitled, "Results from Phase I/II Study of the Combination of Oral Rigosertib and Azacitidine in Patients with Myelodysplastic Syndromes (MDS)," may be accessed by visiting "Posters" in the Investors and Media section of Onconova's website at <a href="https://www.onconova.com">www.onconova.com</a>.

### 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 <a href="http://www.onconova.com">http://www.onconova.com</a>.

#### **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 Pl3K. The 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.

### **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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