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Onconova Therapeutics Announces Submission of Investigational New Drug Application for Pivotal Phase 3 Trial for IV Rigosertib in Higher-Risk Myelodysplastic Syndromes

Key Milestone in Positioning Rigosertib on Approval Track for HR-MDS

Pivotal Phase 3 Trial Expected to Begin in Second Half of 2015

NEWTOWN, Pa., Aug. 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 the submission of an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) for IV rigosertib as a treatment for higher-risk myelodysplastic syndromes (HR-MDS) after failure of hypomethylating agent (HMA) therapy. Upon clearance, the IND enables Onconova to initiate a randomized, controlled pivotal Phase 3 trial in patients with HR-MDS that have failed prior HMA therapy.

"We are pleased to achieve this important milestone, which positions rigosertib back on an approval track in HR-MDS," said Ramesh Kumar, Ph.D., President and CEO of Onconova. "We plan to submit Clinical Trial Applications (CTAs) in several European countries shortly. Onconova anticipates initiating enrollment in the new Phase 3 study in the second half of 2015."

The pivotal trial, designated 04-30 or "INSPIRE", will enroll HR-MDS patients under 80 years of age who had progressed on, or failed to respond to, previous treatment with HMAs within the first nine months of initiation of HMA treatment, and had their last dose of HMA therapy within six months prior to enrollment in the trial. The primary endpoint of this study will be overall survival, and an interim analysis is anticipated. This randomized trial of approximately 225 patients will be conducted at about 100 sites globally. Enrollment in this trial is expected to begin later this year, though the ability to conduct the trial as planned will require additional financing.

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.

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 our 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 our clinical trials and regulatory approval of protocols, and 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.

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