August 27, 2015

Onconova Therapeutics Files European Clinical Trial Applications for Global Phase 3 Trial for IV Rigosertib in Higher-Risk Myelodysplastic Syndromes

Trial Expected to Begin in Second Half of 2015

NEWTOWN, Pa., Aug. 27, 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 it has filed Clinical Trial Applications (CTAs) with the United Kingdom, German and Austrian regulatory agencies for IV rigosertib as a treatment in higher-risk myelodysplastic syndromes (HR-MDS) patients after failure of a hypomethylating agent (HMA) therapy. Upon clearance of the CTAs and the recently updated U.S. IND submission, Onconova intends to initiate a single randomized controlled pivotal Phase 3 trial, designated 04-30 or "INSPIRE", in patients with HR-MDS whose prior therapy with an HMA has failed. Additional filings in other European countries and in Japan are expected to follow shortly.

"These filings follow our recent updated IND submission to the U.S. FDA," said Ramesh Kumar, Ph.D., President and CEO of Onconova. "Together, acceptance of these regulatory filings will allow Onconova to initiate a single global pivotal trial for IV rigosertib in HR-MDS. We anticipate enrollment in the new Phase 3 study will begin in the second half of 2015."

Per a development and licensing agreement with Baxalta (formerly the BioScience business of Baxter International Inc.), which grants Baxalta commercialization rights to rigosertib in the European Union and other countries in Europe, the company has elected to and Baxalta will fulfill its obligation under the agreement to pay for half of the costs for the trial of rigosertib in HR-MDS up to a specified cap.

Onconova has partnered with SymBio Pharmaceuticals, Ltd. for clinical development of rigosertib in Japan and Korea. SymBio plans to participate in the global Phase 3 trial by enrolling patients in Japan, which should accelerate the timing of regulatory filings in Japan and Korea.

"We completed a Phase 1 trial for oral rigosertib (SyB C-1101) in relapsed or refractory MDS last June and expect to complete the ongoing Phase 1 trial for IV rigosertib (SyB L-1101) in the treatment of relapsed or refractory HR-MDS patients this October. After consulting with the PMDA (Japanese Pharmaceuticals and Medical Devices Agency), it is our plan to participate in the global 04-30 trial, and to begin enrolling patients in Japan for this unmet medical need in HR-MDS," added Mr. Fuminori Yoshida, President and CEO of SymBio.

"Onconova is appreciative of the continued collaborations with Baxalta and SymBio to advance the INSPIRE Trial," continued Dr. Kumar. "We look forward to working closely with our partners in the development of IV rigosertib in HR-MDS in Europe and in Japan."

The INSPIRE Trial will enroll HR-MDS patients who had progressed on, or failed to respond to, previous treatment with an HMA. The primary endpoint of this study is 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.

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 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.

CONTACT: Onconova Therapeutics
Benjamin Hoffman, 267-759-3036
bhoffman@onconova.us