



March 3, 2016

## **Onconova Therapeutics, Inc. Receives Notice of Termination for Convenience from Baxalta**

### **Rights to Commercialize Rigosertib in Europe to Revert to Onconova**

NEWTOWN, Pa., March 03, 2016 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ:ONTX), a clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, received notice today from Baxalta US Inc. of Baxalta's termination of the September 2012 development and license agreement between Baxalta and Onconova for rigosertib, Onconova's lead development candidate. Onconova, following prior consultation with Baxalta, began enrolling the first of approximately 225 patients in December 2015 for the INSPIRE trial for IV rigosertib as a treatment for higher-risk myelodysplastic syndromes (HR-MDS) after failure of hypomethylating agent (HMA) therapy.

In accordance with the terms of the Baxalta agreement, upon termination, the rights that Onconova has licensed to Baxalta, in particular the exclusive right to commercialize rigosertib for specified indications in Europe, will revert to Onconova at no cost to Onconova.

Dr. Ramesh Kumar, Onconova's President and CEO, stated that "Onconova is deeply disappointed by the timing of Baxalta's decision, given that patient enrollment in this pivotal trial for patients with short life spans and no alternative available therapies commenced only three months ago." Baxalta stated in its termination letter that its continuing support for the INSPIRE trial did "not align with Baxalta's strategic priorities" and, on that basis, Baxalta terminated the agreement for convenience, effective August 30, 2016.

The INSPIRE trial is a global, 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, or failed to respond to, or relapsed after previous treatment with HMAs. For these patients who have failed treatment with an HMA, there is a significant unmet medical need because there is no alternative available therapy. The INSPIRE trial is now enrolling higher-risk MDS patients who have failed all approved therapies, at multiple U.S. sites, and the Company is initiating additional clinical centers in the U.S. and abroad.

Until the August 30, 2016 termination date, Baxalta is obligated to provide various financial contributions, including 50 percent of the clinical trial costs for the INSPIRE trial up to a specified cap. Onconova is currently in discussions with Baxalta regarding the amount of financial support sufficient to complete the INSPIRE trial that was commenced in December following consultation with Baxalta.

### **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>.

### **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 for rigosertib are being conducted at MDS Centers of Excellence 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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