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Onconova Enrolls First Patient in Europe for Phase 3 INSPIRE Trial of Rigosertib in Higher-Risk Myelodysplastic Syndromes

More than 10 European and U.S. Sites Activated

NEWTOWN, Pa., March 21, 2016 (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 enrollment of the first European patient in Salzburg, Austria for the Phase 3 INSPIRE trial for IV rigosertib as a treatment for higher-risk myelodysplastic syndromes (HR-MDS) following failure of hypomethylating agent (HMA) therapy. The first patient in this global trial was enrolled at the MD Anderson Cancer Center in December 2015.

"We are excited to expand enrollment for this important trial to Europe," said Dr. Steven Fruchtman, Chief Medical Officer of Onconova. "The recent publication in *Lancet Oncology* of results of the ONTIME study provides support for the present trial and highlights the urgent unmet medical needs of patients following failure of front-line treatment with HMAs. There are no approved therapies for HR-MDS patients whose disease has failed treatment with an HMA, and the clinical community is looking for novel drugs to address this treatment gap."

The INSPIRE trial is a multi-center, randomized controlled Phase 3 study to assess the efficacy and safety of IV rigosertib in HR-MDS patients who had progressed on, or failed to respond to, or relapsed, following previous treatment with HMAs. The trial will enroll approximately 225 patients randomized at a 2:1 ratio into two treatment arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. The primary endpoint of INSPIRE is overall survival and an interim analysis is anticipated.

The INSPIRE trial is actively screening patients at multiple sites in the United States and Europe, and additional sites are being initiated globally. Onconova's collaboration partner in Japan and Korea, Symbio Pharmaceuticals, Ltd., intends to begin enrolling patients in Japan shortly.

[About INSPIRE](#)

The **International Study of Phase III IV Rigosertib**, or INSPIRE, is based on guidance received from the U.S. Food and Drug Administration and European Medicines Agency and derives from the findings of the ONTIME Phase 3 trial. INSPIRE is a multi-center, randomized controlled study to assess the efficacy and safety of IV rigosertib in HR-MDS patients who had progressed on, failed to respond to, or relapsed after previous treatment with an HMA within the first nine months of initiation of HMA treatment. This time frame optimizes the opportunity to respond to treatment with an HMA prior to declaring treatment failure, as per NCCN Guidelines.¹ The trial will enroll approximately 225 patients randomized at a 2:1 ratio into two treatment arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. The primary endpoint of INSPIRE is overall survival and an interim analysis is anticipated. Full details of the INSPIRE trial, such as inclusion and exclusion criteria, as well as secondary endpoints, can be found on clinicaltrials.gov (NCT02562443).

[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 PI3K. 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.

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>.

References

¹National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Myelodysplastic Syndromes. Version 1.2016.

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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