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Onconova and Cellworks Announce Presentation of Rigosertib Predictive Signature for Clinical Response in Myelodysplastic Syndromes (MDS) at 2016 ASH Annual Meeting

Computational Subgroup Analysis of Phase 3 ONTIME Trial Provides Insights into Clinical Response to Rigosertib in Higher-risk MDS

NEWTOWN, Pa. and SAN JOSE, Calif., Dec. 06, 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 and Cellworks, a customized therapy design company that improves clinical outcomes and creates value for pharma, payers and physicians, today announced the presentation of their collaborative effort to identify higher-risk MDS (HR-MDS) patients that are likely to respond to rigosertib at the 2016 ASH Annual Meeting in San Diego California, taking place December 3-6, 2016.

The presentation by Dr. Guillermo Garcia-Manero from the MD Anderson Cancer Center, lead investigator from the ONTME trial, used Cellworks' proprietary bio-simulation platform to retrospectively correlate clinical benefit to IV rigosertib treatment in the Phase 3 ONTIME study in HR-MDS patients with molecular and cytogenetic data. This computer simulation led to the characterization of certain biological pathways that predict response to IV rigosertib in HR-MDS patients. Notably, patients with these predictive biological pathways also shared common cytogenetic abnormalities — trisomy of chromosomes 8 and 21 — that correlated with positive clinical outcome in ONTIME.

"This retrospective analysis of ONTIME has helped identify biological factors related to clinical outcomes to treatment with IV rigosertib," stated Guillermo Garcia-Manero, MD, Chief of the Section of Myelodysplastic Syndromes at The University of Texas MD Anderson Cancer Center, and lead author of the study. "These results confirm prior studies where patients with certain cytogenetic abnormalities were sensitive to IV rigosertib. These data also reinforce the clinical strategy of the ongoing Phase 3 INSPIRE trial to target only the highest-risk MDS patients with rigosertib."

"We are excited by this use of our proprietary bio-simulation platform to predict response to novel therapeutics in a heterogeneous disease like HR-MDS," commented Yatin Mundkur, CEO of Cellworks. "Among other applications, the Cellworks platform is intended to inform the design of Phase 2 and 3 clinical trials by establishing and validating inclusion criteria. In this case, we are pleased that this analysis has validated enrollment criteria for Onconova's Phase 3 INSPIRE trial."

The poster entitled "Computational Analysis of Genomic Abnormalities from a Phase 3 Trial of Rigosertib in Higher-Risk MDS: Simulation of a Predictive Signature for Clinical Response," was presented on December 5, 2016 at the ASH Annual Meeting in San Diego, California. A copy of the poster is available by visiting the Scientific Presentations section under the Investors & Media tab of Onconova's website.

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. The Company's most advanced product candidate, 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 and PI3 kinases. 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. In addition to rigosertib, two other candidates are in the clinical stage, and several candidates are in pre-clinical stages. For more information, please visit http://www.onconova.com.

About IV Rigosertib

The intravenous form of rigosertib has been employed in Phase 1, 2, and 3 clinical trial involving more than 800 patients, and is currently being evaluated in the randomized Phase 3 global INSPIRE trial as 2nd-line treatment for patients with higher-risk MDS, after failure of hypomethylating agent, or HMA, therapy. This formulation is suited for patients with advanced disease and provides long duration of exposure and ensures adequate dosing under a controlled setting.

About INSPIRE

The **IN**ternational **S**tudy of **P**hase III **I**V **R**igos**E**rtib, 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. 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).

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," "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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