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Onconova Announces ONTIME Data Presentations at the 2014 ASH Annual Meeting

Detailed Data From Phase 3 ONTIME Trial Presented on Rigosertib Activity and Biological Plausibility in MDS Subgroups

NEWTOWN, Pa., Dec. 7, 2014 (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 presentation of data from clinical trials of rigosertib in myelodysplastic syndromes (MDS) at the 56th American Society of Hematology (ASH) Annual Meeting in San Francisco, California, December 6-9, 2014.

Three presentations from Dr. Guillermo Garcia-Manero, Dr. Lewis R. Silverman and Dr. Ghulam Mufti provided details of Phase 3 results from the ONTIME study of IV rigosertib in higher risk MDS.

"The ONTIME pivotal trial with IV rigosertib was the first randomized, controlled clinical trial in higher risk MDS patients who had progressed on, failed to respond to, or relapsed after prior therapy with hypomethylating agents (HMAs)," said Guillermo Garcia-Manero, M.D., lead investigator and Chief, Section of Myelodysplastic Syndromes, at the University of Texas MD Anderson Cancer Center. "Although the trial did not achieve its primary endpoint, rigosertib was found to improve overall survival in multiple patient subgroups, which represent a substantial proportion of MDS patients with the highest levels of unmet medical need. This group included patients who had progressed on or failed to respond to previous treatment with hypomethylating agents (primary HMA failures), as well as patients in the Revised International Prognostic Scoring System (IPSS-R) Very High Risk category, and patients with certain karyotypic abnormalities, such as, monosomy 7, del7q and trisomy 8. Patients in these subgroups have a very poor prognosis, and currently there is no approved drug available to treat their disease once they have failed HMA therapy."

As announced previously, a top-line analysis for overall survival in the intent-to-treat (ITT) population from the ONTIME trial demonstrated a 2.3 month increase for rigosertib compared to best supportive care (BSC). The log-rank p-value was 0.33 and the hazard ratio was 0.87, which was quite different from the ratio of medians (0.72), a result of survival curves converging at 15 months. Further analysis revealed rigosertib treatment-related improvements in overall survival for various subgroups that were well balanced between rigosertib and BSC arms. Notably, rigosertib improved overall survival in primary HMA failure patients, representing 64% of all patients in the ONTIME trial. Primary HMA failure patients are those who do not benefit from front-line treatment with HMAs. In this group, with investigator assessment of primary HMA failure, the increase in overall survival was 3.3 months with a hazard ratio of 0.69 (p value = 0.04). In a similar analysis, with blinded centralized assessment for primary HMA failure, a hazard ratio of 0.63 (p value = 0.011) was noted. Additional analysis indicated that MDS patients who were in the IPSS-R Very High Risk category (45% of patients in the study) had a 4.4 month improvement in survival (7.6 months for treatment arm compared to 3.2 months with BSC; HR = 0.56, p value = 0.005). Patients with well-defined cytogenetic abnormalities also experienced a survival benefit with rigosertib treatment (monosomy 7 patients: HR = 0.24, p value = 0.003; del7q patients: HR = 0.38, p value = 0.14; and trisomy 8 patients: HR = 0.34, p value = 0.035).

In addition to IPSS-R and karyotype analyses, mutational sequencing was conducted across 24 myeloid genes. In the trial population samples that were analyzed (n=111), greater than 80% of samples carried mutations, and the frequency of mutation correlated with IPSS-R score and poor prognosis karyotypes. These analyses help establish a foundation for biological plausibility for rigosertib activity in MDS patients with poor prognoses.

Continuous intravenous infusion with rigosertib appeared to be well-tolerated. Median number of cycles was 5.0 and median dose intensity was 92%, with dose reduction observed in 5% of patients. Importantly, no significant compliance or operational issues, related to the administration of rigosertib by ambulatory continuous infusion, were reported.

"We are encouraged by the presentation of these results from the ONTIME study. We are currently in discussions with U.S. and European regulatory agencies concerning the paths for approval of rigosertib in higher risk MDS patients. We will provide development updates following the completion of these discussions," stated Ramesh Kumar, Ph.D., President and CEO of Onconova.

Investor Event and Webcast

Onconova will host a webcast and live investor event on December 12th in New York, NY at 8:30 AM ET to review the clinical data presented at the ASH Annual Meeting. The event will provide access to key opinion leaders working with rigosertib clinical trials in MDS. A status update on our discussions with regulatory agencies will also be provided. A live webcast can be

accessed by visiting "Events & Presentations" in the Investors and Media section of the Company's website at 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 abroad. To date, more than 500 MDS patients have been enrolled in clinical trials with rigosertib. Rigosertib is covered under composition of matter patents issued worldwide. Orphan designation has been granted for rigosertib in MDS in the U.S., Europe, Australia and Japan.

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.

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 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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