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Onconova Completes Enrollment in ONTIME Pivotal Phase 3 Study of Rigosertib in Patients with High-risk Myelodysplastic Syndromes

May 9, 2013 – NEWTOWN, PA: Onconova Therapeutics, Inc., a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule drug candidates to treat cancer, announced it has reached its enrollment goal of 270 for its pivotal Phase 3 ONTIME trial of rigosertib in patients with myelodysplastic syndromes (MDS) who have failed prior therapy with hypomethylating agents.

“The completion of enrollment of the ONTIME trial is a significant milestone in our development of rigosertib,” said Ramesh Kumar, Chief Executive Officer of Onconova. “Currently, treatment options for high-risk MDS patients who fail hypomethylating agents are limited and their prognosis is poor. We are developing rigosertib as a second-line therapy for this patient population. We are grateful for the support that we have received from patients, investigators and the Leukemia and Lymphoma Society for the ONTIME trial. We expect to present top-line survival results from this study either in the fourth quarter of 2013 or the first quarter of 2014.”

About the ONTIME Study
ONTIME is a randomized controlled study to evaluate rigosertib in patients with MDS who have failed treatment with hypomethylating agents (such as azacitidine and decitabine), have excess blasts, and have at least one cytopenia. There is currently no approved drug for this group of patients and the current standard treatment consists of best supportive care, which is treatment intended to manage disease-related symptoms. In the ONTIME trial, both groups of patients received best supportive care and the active treatment group of patients also received rigosertib. The study employs a 2:1 randomization. The primary objective of ONTIME is overall survival. Secondary objectives include evaluation of bone marrow, cytogenetic and blood profiles, quality of life scores and time to transition to acute myelogenous leukemia. This 270-patient randomized trial is being conducted in the U.S. and five EU countries under a Special Protocol Assessment from the FDA and under Scientific Advice from the European Medicines Agency.

About Rigosertib
Rigosertib is an inhibitor of two important cellular signaling pathways, phosphoinositide 3-kinase (PI3K) and polo-like kinase (PLK), both of which are frequently activated in cancer cells. Rigosertib is being developed in intravenous and oral forms as a treatment for both solid and hematological malignancies. In addition to the ONTIME trial, Onconova is evaluating intravenous rigosertib in a Phase 3 trial (ONTRAC) for first-line treatment in combination with gemcitabine for patients with metastatic pancreatic cancer who have not previously received any chemotherapy. The oral form of rigosertib is currently being studied in Phase 2 trials in patients with transfusion-dependent low-risk MDS and in patients with head and neck cancers. Rigosertib has been granted orphan drug status for MDS in both the United States and Europe as well as orphan drug status for pancreatic cancer in the United States. Rigosertib is being developed in partnership with Baxter International (commercialization rights in Europe) and SymBio Pharmaceuticals (Japan and Korea). Onconova has retained all other territories for commercialization.

About Onconova Therapeutics, Inc.
Onconova Therapeutics is a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule drug candidates to treat cancer. Onconova's portfolio of drug development candidates is derived from a proprietary library of targeted anti-cancer agents designed to work against specific cellular pathways that promote cancer without causing harm to normal cells. For more information, please visit http://www.onconova.com.

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