April 9, 2013

Onconova Announces Presentation of Positive Data of Oral Rigosertib in Advanced Head and Neck Cancer at AACR 2013 Annual Meeting

Oral Rigosertib Progresses to Phase 2 Clinical Trial in Squamous Cell Head and Neck Cancers

April 9, 2013 – NEWTOWN, PA: Onconova Therapeutics, Inc., a development-stage pharmaceutical company focused on discovering and developing novel small molecule drug products to treat cancer, today announced that tolerability and favorable anti-tumor activity data from a Phase 1 trial evaluating oral rigosertib, a dual pathway inhibitor, in patients with advanced solid tumors including refractory metastatic head and neck cancer were presented today at the American Association for Cancer Research (AACR) Annual Meeting. The presentation was made by Antonio Jimeno, MD, PhD, of the University of Colorado School of Medicine and Director of the University's Head and Neck Cancer Medical Oncology Program.

The oral presentation by Dr. Jimeno entitled, "Phase 1 and molecular correlates study of oral rigosertib in patients with refractory metastatic head and neck cancer and advanced solid tumors," reported on the safety and activity of rigosertib in 48 patients. The objectives of this study were to define dose limiting toxicity, to characterize the pharmacokinetic (PK) profile, and to identify anti-tumor activity. Oral rigosertib was generally well tolerated. Notably, two of the six metastatic head and neck squamous cell carcinoma patients, with disease refractory to previous platinum-based therapy, showed anti-tumor responses. These responses included a confirmed complete response (CR) as well as a confirmed partial response (PR). These patients have received single-agent oral rigosertib for 98 and 48 weeks, respectively.

"The encouraging data reported today at AACR, describing the tolerability and clinical activity of oral rigosertib in advanced head and neck cancer, have driven the initiation of an 80-patient, multi-institutional nationwide Phase 2 trial in this patient population. Additionally, two Phase 2 trials, supported by proof of activity in earlier Phase 1 trials, are currently exploring utility of oral rigosertib in transfusion-dependent lower-risk MDS patients," commented François Wilhelm, MD, PhD, Chief Medical Officer of Onconova. "We believe that these findings provide clinical support for further investigation of oral rigosertib as a treatment for advanced solid tumors, including metastatic head and neck cancer."

Rigosertib has been extensively studied in clinical trials conducted in the U.S., Europe, Japan and India, in patients with solid tumors and blood cancers, with more than 850 patients enrolled in Phase 1, 2 and 3 trials, including a pivotal randomized Phase 3 trial conducted under a special protocol assessment (SPA) for patients with higher-risk myelodysplastic syndromes (MDS) previously treated with hypomethylating agents. Rigosertib, a patented new chemical entity, has received orphan designation for MDS and pancreatic cancer. For more information on rigosertib, please visit www.onconova.com or www.clinicaltrials.gov.

AACR 2013 Presentations Relating to Rigosertib

Tuesday, April 9th, 2013
Time: 10:30 AM - 12:30 PM
Session Title: Clinical Trials
Location: Salon C, East Hall, Washington Convention Center

Abstract #LB-198
"Phase 1 and molecular correlates study of oral rigosertib in patients with refractory metastatic head and neck cancer and advanced solid tumors."

About Rigosertib

Rigosertib is an inhibitor of two important cellular signaling pathways, phosphoinositide 3-kinase, or PI3K, and polo-like kinase, or PLK, both of which are frequently activated in cancer cells. Rigosertib is being developed in oral and intravenous forms as a treatment for both solid and hematological malignancies. Onconova is evaluating intravenous rigosertib in a Phase 3 trial of adult patients with myelodysplastic syndromes whose disease has failed azacitidine or decitabine therapy, and a Phase 3 trial for first-line treatment in combination with gemcitabine for patients with metastatic pancreatic cancer who had not previously received any chemotherapy. The oral form of rigosertib is currently being studied in Phase 2 trials in patients with transfusion-dependent lower-risk myelodysplastic syndromes and in patients with head and neck cancer.

About Onconova Therapeutics, Inc.

Onconova Therapeutics is a development-stage pharmaceutical company focused on discovering and developing novel small molecule drug products to treat cancer. Onconova's portfolio of drug development candidates is based on its proprietary library of targeted anti-cancer agents which are designed to work against specific molecular and cellular pathways that promote cancer while causing minimal damage to normal cells. The Company's most advanced product candidate, rigosertib, is in a Phase 3 trial of adult patients with myelodysplastic syndromes whose disease has failed azacitidine or decitabine therapy with additional trials being conducted in other indications. For more information, please visit http://www.onconova.com.

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