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Onconova Announces Results of Interim Analysis of Metastatic Pancreatic Cancer Study

NEWTOWN, Pa., Dec. 17, 2013 (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 discontinuation of the Phase 3 ONTRAC study of intravenous (IV) rigosertib plus gemcitabine in front-line metastatic pancreatic cancer. Upon completion of a planned interim analysis, the Data Safety Monitoring Board (DSMB) determined that the combination of rigosertib and gemcitabine is unlikely to demonstrate a statistically significant improvement in overall survival compared to gemcitabine alone. There were no safety concerns raised in the DSMB review of the study.

The ONTRAC study is a randomized, multi-center, controlled Phase 3 trial of the safety and efficacy of gemcitabine alone and IV rigosertib combined with gemcitabine in patients with previously untreated metastatic pancreatic cancer. The study employed an adaptive design that allowed for an interim review of data to assess the rationale for continuing the evaluation of rigosertib plus gemcitabine in this patient population.

"We are very disappointed by these results, especially for patients with metastatic pancreatic cancer, given the lack of meaningful treatment options," said Ramesh Kumar, Ph.D., President and Chief Executive Officer of Onconova. "We would like to thank the patients and investigators for their participation in this trial."

A detailed analysis of the efficacy and safety results will be conducted and presented at a future scientific meeting. Any alternative trials for this patient population may be explored upon complete analysis of this information.

About Rigosertib

Rigosertib is small molecule inhibitor of two important cellular signaling pathways, phosphoinositide 3-kinase, or PI3K, and polo-like kinase, or PLK, both of which are frequently overactive in cancer cells. Due to this dual effect of inhibiting the PI3K and PLK pathways, rigosertib has shown activity in a variety of cancer types including both solid tumors and hematological malignancies. Clinical trials with both intravenous and oral formulations of rigosertib have been conducted at leading institutions in the U.S. and abroad. To date, more than 1,000 patients with solid tumors and hematological diseases have received rigosertib.

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 in clinical trials, and several candidates are in pre-clinical stages. For more information, please visit <http://www.onconova.com>.

CONTACT: Onconova Therapeutics

Benjamin Hoffman, 267-759-3680

bhoffman@onconova.us

or

Media:

MacDougall Biomedical Communications

Chris Erdman, 781-235-3060

chris@macbiocom.com