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Onconova Therapeutics Announces Presentation of Clinical Proof of Concept of ON 01910.Na in Patients with High Risk Myelodysplastic Syndrome (MDS) at ASH 2009 Annual Meeting

– Additional Data Presented Reveals New Understanding of MOA for ON 01910.Na, a U.S. Patent Protected New Chemical Entity –

– ON 01910.Na Designated an “Orphan Drug” for MDS by the FDA –

DECEMBER 7, 2009, NEWTOWN, PA AND LAWRENCEVILLE, NJ – Onconova Therapeutics, Inc. today announced promising results from two clinical trials in patients with advanced Myelodysplastic Syndrome (MDS) treated with ON 01910.Na. These trials are being conducted at the National Heart, Lung, and Blood Institute (NHLBI) in Bethesda, MD, and St. Vincent’s Comprehensive Cancer Center in New York. In these studies, treatment with ON 01910.Na resulted in significant decrease in blast count (cancer cells) in bone marrow without significant toxicity in these high risk MDS patients. After treatment, MDS patients with cytogenetic abnormalities showed fewer abnormal (aneuploid) cells, and many patients showed improved normal blood cell counts, (i.e., had an improvement in cytopenias). These findings were discussed in an oral presentation (December 6th) and a poster (December 7th) at the Annual Meeting of the American Society of Hematology (ASH) in New Orleans.

ON 01910.Na is a novel, targeted small molecule anti-cancer compound in Phase I and II clinical trials for MDS and solid tumors at several major centers in the U.S. and abroad. More than 190 patients have been treated in these clinical trials.

The positive clinical trial data were presented by Elaine Sloand, M.D., lead investigator for the trial at the National Heart, Lung, and Blood Institute. These studies were conducted, in part, with a “bench to bedside” translational award from the NHLBI and exemplify a mechanism and biomarker aided approach to development of new anti-cancer drugs.

“These findings are very promising and reaffirm our efforts to investigate ON 01910.Na for high risk MDS, which is difficult to treat, and for which few therapeutic options are available,” said Azra Raza, M.D., lead investigator for the trial at St. Vincent’s. Dr. Raza’s studies were also featured in a poster presentation.

“We are very pleased to see progress with our lead compound, for which a broad U.S. patent was issued in October,” said Mr. Michael Hoffman, Chairman of Onconova. “These encouraging results have led to the initiation of MDS trials at three additional sites, Mt. Sinai Medical Center, Stanford University Cancer Center and Moffitt Cancer Center. We anticipate additional clinical findings from ongoing trials of ON 01910.Na in single agent and combination therapy for solid tumor patients.”

ON 01910.Na was recently designated an “orphan drug” for treatment of MDS by the Food and Drug Administration. If ON 01910.Na is approved for the treatment of patients with high-risk MDS in the U.S., orphan drug designation could provide Onconova with potential market exclusivity for seven years. In addition, a drug candidate designated by the FDA as an orphan-drug product may qualify for subsidies on regulatory fees and tax incentives and may be eligible for research grant funding to assist in further clinical development.

Mechanism of Action and Biomarker Findings Presented at ASH

Also presented at the ASH meeting were non-clinical findings that further elucidate how ON 01910.Na causes selective cell death in cancer cells.

In an oral presentation, Patricia Perez-Galan, Ph.D. (NHLBI), described mechanism of action studies using human white blood cells from chronic lymphocytic leukemia (CLL) patients and normal donors. CLL, the most common leukemia in Western countries, is characterized by excess accumulation of B-cells. Incubation with ON 01910.Na killed B-cells from the CLL patients, but not their T-cells, nor T- or B-cells from the normal donors. This study revealed that selective killing of CLL cells by ON 01910.Na involved a dual mechanism: up-regulation of certain apoptotic signals, accompanied by down-regulation of the key PI3K/AKT survival/growth pathway. A clinical trial of ON 01910.Na with CLL patients is now accruing patients at the National Heart, Lung, and Blood Institute (Co-investigators: Drs. Mark Roschewski and Adrian Wiestner).

A poster presented by Dr. Wendy Fantl and Dr. David Soper (Nodality, Inc.) showed results of a mechanism of action study of ON 01910.Na aimed at identification of treatment-related biomarkers. Single Cell Network Profiling (SCNP), a new technology, employs flow cytometry to measure multiple parameters in human blood cells. Following treatment with ON 01910.Na, several critical proteins involved in regulating progression through the G2/M phase of the cell cycle were changed by treatment with ON 01910.Na, leading to death of these cells. These potential biomarkers are being tested in samples from an ongoing clinical trial in MDS patients at Stanford University Cancer Center.

Summary of ASH Presentations Relating to ON 01910.Na

Oral Presentations:

Sunday, December 6:

Session: Myelodysplastic Syndromes: Novel Therapeutics and Clinical Observations Session

Abstract #120:

“ON 01910.Na Suppresses Cyclin D1 Accumulation in Trisomy 8 Myelodysplastic Syndromes Patients While Decreasing Bone Marrow CD34+ Blast Counts and Aneuploid Clone Size”

Elaine M. Sloand, Matthew J. Olnes, Naomi Galili, Aarthi Shenoy, Loretta Pfannes, Francois Wilhelm, Barbara Weinstein, Phillip Scheinberg, Jerome E. Groopman and Azra Raza; National Heart, Lung, and Blood Institute, NIH, Bethesda, MD; St. Vincent's Comprehensive Cancer Center, New York, NY; Onconova Therapeutics, Newtown, PA; Harvard Institutes of Medicine, Beth Israel Deaconess Med. Ctr., Boston, MA;

Monday, December 7:

Session: Molecular Pharmacology, Drug Resistance II Session

Abstract #22045:

“The PI3K Inhibitor ON 01910.Na Inhibits Critical Survival Pathways and Induces Apoptosis in CLL Cells through Induction of NOXA and BIM”

Patricia Perez-Galan, Colby Chapman, Federica Gibellini, Poching Liu, Nalini Raghavachari and Adrian Wiestner; National Heart, Lung, and Blood Institute, NIH, Bethesda, MD, USA.

Poster Presentations:

Monday, December 7:

Session: Myelodysplastic Syndromes Poster III

Poster Board # III-731

Abstract #3815:

“Initial Evaluation of a 48-h Continuous Intravenous Infusion Weekly Regimen of ON 01910.Na in Advanced Myelodysplastic Syndrome (MDS)”

Azra Raza, Naomi Galili, Muhammad Shahzad Ali, Fahad Ali, Alyssa Goodman, Samir Ahmed Qasim and Francois Wilhelm; Saint Vincent's Comprehensive Cancer Center, New York, NY; Onconova Therapeutics, Newtown, PA

Poster Board # III-763

Abstract #3827:

“Single Cell Network Profiling (SCNP) to Evaluate the Mechanism of Action of ON 01910.Na, a Novel Clinical Trial Stage Compound”

David M. Soper, Ying-Wen Huang, Francois Wilhelm, Steve Cosenza, E. Premkumar Reddy, Alessandra Cesano, Peter L. Greenberg and Wendy J. Fantl; Nodality, Inc., South San Francisco, CA; Onconova Therapeutics Inc, Newtown, PA; The Fels Institute for Cancer Research and Molecular Biology at Temple University School of Medicine, PA; Stanford University Cancer Center, Stanford, CA

About Onconova's Product Pipeline

Employing a proprietary chemical library and novel targets, Onconova has advanced three products to the clinical development stage. ON 01910.Na has been tested in more than 190 patients in single agent and combination therapy trials in the US and abroad. These studies have revealed a favorable safety profile and strong indication of activity in single agent trials in solid tumor patients (Jimeno, et. al., *J Clin Oncology*, 2008). In addition, ON 01910.Na exhibits synergy with several classes of chemotherapeutic agents and has potential utility in treating patients with advanced solid tumors. Currently, clinical studies with ON 01910.Na in combination with either Eloxatin® or Gemzar® are underway at leading cancer centers in the USA.

In October 2009 the FDA designated ON 01910.Na as an "Orphan Drug" for treatment of MDS. The US Patent office granted a broad patent to ON 01910.Na (US Patent No. 7,598,232, issue date October 6, 2009).

In addition to ON 01910.Na, Onconova is testing ON 013105 in clinical trials for advanced lymphoma patients, and Ex-RAD™ has completed the first in man Phase I safety trial. Ex-RAD is a radiation protection drug that promotes DNA repair in radiation damaged cells, and is being developed under a funded collaboration with the US Department of Defense.

About Onconova Therapeutics, Inc.

Onconova, based in Newtown, PA and Lawrenceville, NJ, discovers and develops novel patent-protected small molecule therapeutic agents for cancer, radiation protection and hematological disorders. The proprietary chemical library platform has yielded non-ATP competitive kinase inhibitors directed at validated and novel targets, and a new immunoconjugate technology (comprising potent active compounds and proprietary linkers) for arming monoclonal antibodies for cancer therapy. For more information on Onconova Therapeutics, Inc., please visit www.onconova.com.

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