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**Onconova Therapeutics Announces Initiation of Phase I Clinical Testing for Ex-RAD™, a Radioprotective Drug**

- *Collaborative Publication with the U.S Department of Defense Scientists on Novel Mechanism of Action*
- *\$5 Million in Additional Funds Awarded for the Program*
- *Onconova to Present at JPMorgan Healthcare Conference*

**JANUARY 23, 2009 – LAWRENCEVILLE, NJ** – Onconova Therapeutics, Inc. announced today the successful completion of the first dose cohort of a Phase I clinical trial of its novel radioprotective drug ON 01210.Na (Ex-RAD™). A first-in-class radiation protection drug for both prophylactic and therapeutic applications, ON 01210.Na is a modulator of DNA repair pathways and has been shown to enhance survival in animal models of radiation injury. The drug is being developed under the FDA's Animal Rule which outlines the approval pathway for drugs indicated for protection against harmful agents, including radiation.

The Phase I clinical trial was initiated to evaluate the safety, tolerability and pharmacokinetics of ON 01210.Na in healthy volunteers. Data from this initial trial will be used to design larger studies to provide safety profile for approval purposes.

Currently there are no FDA approved drug products for protection against lethal effects of harmful radiation. Radiation exposure can occur in a variety of scenarios, including nuclear weapons, accidental exposure in power plants, in nuclear submarines and via intentional terrorist activity as well as during extended space travel. Radiation affects the whole body, and in particular the hematological (blood) and the gastrointestinal (GI) systems. A radioprotective drug that can be deployed as a preventative (prophylactic) agent has to be capable of mitigating or reversing the deleterious effects of radiation while meeting a very high threshold of safety and tolerability. The departments of Defense, Homeland Security (Project Bioshield), Health & Human Services, and other governmental agencies have recognized the urgent need to provide solutions to this potential vulnerability and have established programs for developing, procuring, stockpiling and deploying novel protective agents.

Ex-RAD™ (ON 01210.Na) is a small molecule, synthetic compound derived from a proprietary chemical library developed by Dr. E. Premkumar Reddy, the scientific founder of Onconova, and Director of Fels Institute for Cancer Research & Molecular Biology at Temple University. Ex-RAD™ can be administered either by a subcutaneous injection or by mouth (oral formulation is under development). The novel mechanism of action of this drug permits its use both as a prophylactic and a therapeutic for radiation protection.

“This program is the result of a successful collaboration between our scientists and the researchers at the Armed Forces Radiobiology Research Institute (AFRRI), a Department of Defense (DoD) organization whose mission includes research on the prevention and treatment of radiation injuries. AFRRI’s experience and expertise in this field, led by Col. Patricia Lillis-Hearne, Director, combined with the drug development capabilities within Onconova have made it possible to bring this drug to the clinical stage,” said Dr. Manoj Maniar, Senior Vice President, Product Development, of Onconova.

The novel mechanism of action of Ex-RAD™ was elucidated by the scientists from AFRRI led by Dr. Sree Kumar with the collaborative efforts from Onconova. The results of their studies carried out under a Cooperative Research and Development Agreement (CRADA) among The Uniformed Services University of the Health Sciences, (which includes AFRRI), an institution of higher learning within the DoD, an agency of the United States Government; The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., a private, not-for-profit organization that supports medical research and education at the university and the military medical community; and Onconova, will be published on-line in January in Radiation Research, a peer-reviewed journal of the Radiation Research Society of America.

Onconova has successfully combined its internal resources and technologies with targeted Government funding for this program. Under the recently completed “Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009”, \$5 Million in additional funding was provided for the "Ex-RAD Radiation Protection Program" development by DoD. The total funding for this program from grants and budget allocation exceeds \$10 Million to date and these funds have allowed Onconova to develop Ex-RAD™, while at the same time advancing a portfolio of novel anticancer compounds; two of which, ON 01910.Na and ON 013105, are currently in various stages of clinical testing in the U.S. and abroad.

“The Ex-RAD™ program fully illustrates the broad-based potential of Onconova’s chemical library and biological capabilities. The ability to combine resources from a Government laboratory and funding, with our discovery and development engine, has positioned us to provide a potential solution to an unmet need of national interest. The benefits of this program span military and public safety as well as many medical needs.”, said Mr. Michael Hoffman, Chairman of Onconova.

#### **About ON 01210.Na**

ON 01210.Na, is a novel, synthetic, low molecular weight compound with a demonstrated protection of DNA, bone marrow stem cells, gastrointestinal crypt cells, and amelioration of

cytopenia from radiation. The compound significantly enhances survival rates, when administered prophylactically or therapeutically, in model in vivo systems of Acute Radiation Syndrome.

### **Onconova's Product-Pipeline**

Onconova is developing therapeutic candidates directed at critical targets involved in signal transduction, cell-cycle and DNA repair. These candidates are derived from the Company's proprietary library of new chemical entities and non-ATP competitive chemotypes. In addition to Ex-RAD™, the company is developing ON 01910.Na, a novel broad spectrum anticancer agent, now in Phase II trials. Other promising programs include regulators of Cyclin D, ON 013105 (in Phase I), and inhibitors of JAK and Bcr-abl pathways.

### **About Onconova Therapeutics, Inc.**

Onconova, with offices in Newtown, PA and Lawrenceville, NJ, discovers and develops novel, small molecule therapeutic agents for cancer, radiation protection and hematological disorders. Employing a proprietary chemical library platform, Onconova has discovered non-ATP competitive kinase inhibitors directed at validated and novel targets, and is developing a new immunoconjugate technology (comprising potent active compounds and proprietary linkers) that arm monoclonal antibodies for cancer therapy. All of the Company's products and technologies are being developed internally.

For more information on Onconova Therapeutics, Inc., please visit [www.onconova.com](http://www.onconova.com).

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