October 3, 2012

Onconova Presents Positive Clinical Trial Results for Radiation Injury Protector Ex-RAD®

October 3, 2012 – NEWTOWN, PA & PENNINGTON, NJ: Onconova Therapeutics, Inc. today announced positive human safety, tolerability, and pharmacokinetic data from three clinical trials of Ex-RAD (recilisib sodium, ON 01210.Na), a novel radioprotectant being developed as a medical countermeasure for the treatment of acute radiation syndrome (ARS). Ex-RAD and other radioprotection strategies are increasingly important as the threat of accidental and intentional exposure to harmful radiation is becoming a major security concern. These new data were presented on October 3, 2012 at the 58th Annual Radiation Research Society Meeting in San Juan, Puerto Rico.

“The collaborative Ex-RAD program is advancing towards the final stages of development,” said Manoj Maniar, Ph.D., Senior VP of Product Development for Onconova. “The data from these human safety trials are encouraging and support continued development of this novel radiation protector for potential prophylactic and therapeutic indications.”

Dr. Amanda Gillum, Executive Director, Project Management, presented results from two Phase I clinical trials of subcutaneous (SC) Ex-RAD in healthy adult volunteers in a poster presentation entitled “Human safety testing of subcutaneously-administered Ex-RAD® (ON 01210.Na), a small molecule radioprotection agent.”

Subcutaneous (SC) Ex-RAD was studied in two randomized, placebo-controlled Phase I trials in healthy volunteers. In the first trial, 32 volunteers received doses of Ex-RAD ranging from 50 to 300 mg. The second trial, in which 20 volunteers were treated, examined the absorption of drug from various SC sites using a fractionated 2-dose regimen (200 & 400 mg total doses). In both trials, Ex-RAD was rapidly absorbed and found to be well-tolerated, without clinically significant drug-related systemic toxicity. Main adverse events were mild, self-limited injection site reactions, generally subsiding in a few hours. No clinically-significant trends were noted in inflammatory cytokines. High plasma levels of Ex-RAD, proportional to the full dose range, were rapidly achieved following the SC administrations. In the second study, absorption and the total drug exposure was similar, independent of the site of administration.

In a second poster, Dr. Chen Ren, Senior Research Scientist, presented the results from the first Phase I clinical trial of orally-administered Ex-RAD in a presentation entitled “Safety, tolerability and pharmacokinetic behavior of escalating single oral doses of Ex-RAD® (ON 01210.Na) in healthy volunteers.”

In this open-label, single-ascending dose study, three cohorts (3 healthy volunteers/cohort) received 200 to 800 mg oral Ex-RAD solution under fasting conditions. Ex-RAD was rapidly absorbed, well tolerated, and no drug-related systemic side-effects were observed. Ex-RAD displayed excellent oral bioavailability and pharmacodynamically relevant levels were readily achieved, suggesting that oral delivery of Ex-RAD is feasible. Furthermore, drug exposure achieved using the oral administration was ~135% of that observed with a 200-mg SC injection in an earlier clinical study, suggesting that the oral formulation has a higher relative bioavailability. Importantly, this oral formulation would provide a convenient route of administration for first-responders, civilian mass casualties, or at-risk populations who may face exposure to harmful ionizing radiation.

About Ex-RAD

Ex-RAD (recilisib sodium, ON 01210.Na) is a medical countermeasure that protects cells from the harmful effects of ionizing radiation. Ex-RAD is not a free-radical scavenger, chelator, or cell cycle arrestor. Four clinical trials of Ex-RAD have been successfully completed in healthy adults and have demonstrated acceptable tolerability with minimal adverse events in healthy volunteers. Current development efforts for Ex-RAD include both prophylactic (i.e. use prior to exposure to harmful radiation) as well as therapeutic (use after exposure) applications. Ex-RAD is being developed in collaboration with the U.S. Department of Defense under the FDA “Animal Rule,” which permits marketing approval after demonstrating safety in clinical trials in healthy human volunteers and evidence of efficacy in animals when human efficacy studies are not ethical or feasible. The molecule’s novel mode of action involves the enhancement of cellular DNA repair pathways and key elements of the DNA damage cascade in response to harmful radiation. Ex-RAD is available by injection and oral administration for convenient use and rapid distribution.

About Onconova Therapeutics, Inc.

Onconova Therapeutics, based in Newtown, PA and Pennington, NJ, discovers and develops novel small molecule therapeutics directed against targets involved in signal transduction, cell-cycle, and DNA repair. In addition to Ex-RAD, Onconova is developing two other clinical trial-stage products: Rigosertib (ON 01910.Na), a novel targeted anti-cancer compound currently

in a Phase III study for the treatment of a group of rare hematologic malignancies called Myelodysplastic Syndromes (MDS) as well as a Phase II/III study for pancreatic cancer, and ON 013105, a novel anti-cancer agent initially directed to refractory lymphoma, including mantle cell lymphoma. For additional information, please visit http://www.onconova.com.

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