NEWS RELEASE

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Johnson City, TN

Existing Radiation Countermeasures Inadequate! Development of Rx100 Promises Change!

Recent events in Japan have caused the world to focus on unintended radiation exposure. Exposure to radiation can be a cause for concern – especially if radiation levels reach or exceed 1 Gy. Radiation targets rapidly proliferating cells of the body. Cells of the hematopoietic system (bone marrow) and the gastrointestinal (GI) tract are two such cell types. Damage to these cells initiates programmed cell death (apoptosis).

First responders, healthcare professionals, and citizens lack sufficient medications to prevent cellular damage and death due to exposure to significant levels of whole-body irradiation. Agents that protect from radiation exposure are divided into three categories: 1) Agents that must be administered before cellular exposure to ionizing radiation or "radioprotectants;" 2) Agents that can be administered after exposure and which will forestall the cascade of events leading to radiation-induced damage or "radiomitigants;" and 3) Agents that can facilitate or promote endogenous recovery from radiation-induced damage or "regenerators."

To date, the FDA has approved a few radioprotectants. These include:

- Prophylactic potassium iodide to protect the thyroid from exposure to excess I^{132}.
- Laxatives and chelating agents (i.e. diethylene triamine pentaacetic acid ("DTPA"), etc., to decrease exposure by binding and promoting urinary excretion.
- Absorbing agents such as Prussian Blue to limit GI absorption or high oral doses of calcium to compete with intestinal absorption of milk contaminated with strontium^{90}.

There are a small handful of agents presently under development as radiomitigants. These include Rx100. Although under development, this product shows significant promise because of its ability to be administered up to **72 hrs.[1] after exposure** to high levels of radiation – making it arguably the most potent such compound under development. Rx100 protects against damage to both the bone marrow as well as the critical cells of the small intestine.

Testing of Rx100 has demonstrated its unique properties in comparison to other drug candidates in the pipeline. Of significance is the fact that Rx100: a) is a small molecule, b) is essentially nontoxic at therapeutic doses, c) has a long shelf life, d) is nonimmunogenic, e) and provides effective treatment of ARS when administered up to 72 hours after exposure to lethal, whole-body radiation.

Dr. W. Shannon McCool, RxBio's CEO, points out that: "Rx100 is unique among radioprotectants / radiomitigators in that it boosts natural mechanisms that promote and sustain cell survival in almost every cell type and at the same time inhibits the cascade leading to programmed cell death (apoptosis). Thus, Rx100 augments the good and shuts down the bad. While other products shut down essential cellular signaling mechanisms involved in radiation-induced cellular injury and tend to lack specificity and/or may be toxic, Rx100 is a specific activator of natural, nontoxic, protective mechanisms of cell survival and antiapoptosis. Among its actions, Rx100 protects critical stem cells. Rx100 can be

[1] Based on studies to date in rodents.

formulated for a wide range of patient types—from infants to the elderly – and can be administered either orally or subcutaneously."

In addition, Dr. Gabor Tigyi, RxBio's CSO, comments that: "Rx100 is a potent protector of the GI tract. This drug provides significant protection to the gut from radiation as well as other toxic substances such as cholera toxin. Among its actions, Rx100 maintains the mucosal barrier of the GI tract. It prevents severe diarrhea and the entry of bacterial toxins into the blood stream – both potentially severe side effects." RxBio has recently presented it's initial NHP data at the BARDA meeting that took place in January, 2011, in Washington. That data demonstrated significant protection of the all-important GI tract.

Agencies of the Federal Government continue their interest and support in this promising new compound and its unique approach and mechanism. Representatives of both BARDA and NIAID have requested meetings with representatives of the company to accelerate development of Rx100. NIAID has additionally expressed interest in follow-on compounds, Rx101 and EDL2000. While Rx101 is related to Rx100, EDL2000 is completely unique, is also a small molecule, is extremely safe, and can be given orally, parenterally, and/or topically.

For further information on Rx100 or RxBio, **contact: W. Shannon McCool, D.Ph., RxBio, Inc., P.O. Box 5389, 1325 Sunset Drive, Johnson City, TN 37602-5389; phone: (423) 928-3330; fax: (423) 282-6602; email: smccool@rxbio.com.**