

National Institute for Allergy and Infectious Diseases (NIAID) awards contract to RxBio, Inc., for Accelerated Development of Radiation/Nuclear Medical Countermeasures

RxBio, Inc., (RxBio) has been awarded \$4.5 million over 3 years, if options are exercised, for continued development of Rx100 as a Medical Countermeasure for Acute Radiation Syndrome. RxBio is an early stage, privately-held, company founded upon novel science initially developed at the University of Tennessee Health Science Center (UTHSC) and licensed by RxBio. Resultant product development has been made possible by a combination of federally and privately funded work. Only a select number of companies are funded by the Radiation and Nuclear Countermeasures Program (RNCP) of the National Institute for Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), based on highly competitive applications. NIH selected RxBio's unique drug candidate Rx100 for inclusion in its RNCP awards.

Rx100 is first being developed as a field-rugged, shelf-stable formulation for emergency use as a radiation countermeasure. Rx100 is an advanced drug candidate for the treatment of gastrointestinal acute radiation syndrome (GI-ARS) before or after exposure.

"RxBio is enthusiastic about continuing our partnership with NIAID in the development of Rx100 as a Radiation Medical Countermeasure. This contract award proves instrumental in continuing the development of Rx100 and coincides nicely with our development of Rx100 for other indications" stated RxBio's President and CEO, W. Shannon McCool. "GI-ARS continues to lack a suitable FDA-approved treatment, and Rx100 may fill this gap," says McCool.

About Acute Radiation Injury

GI-ARS occurs when an individual is exposed to high doses of radiation, and death can occur within a few weeks of exposure. There are no FDA-approved or stockpiled products designed for treatment of GI-ARS. RxBio has developed a small molecule designated Rx100, which significantly protects and treats the gut when exposed to otherwise lethal doses of ionizing radiation, resulting in a significant rate of survival in animal models.

About Rx100

Rx100 is a first-in-class small molecule analog of the growth factor-like lipid mediator lysophosphatidic acid (LPA). Rx100 is being developed as an experimental treatment for several conditions disrupting gut and barrier function that includes gastrointestinal injury from radiation, gastric erosions caused by anti-inflammatory non-steroidal drugs, and severe toxin-induced infectious diarrheas. Rx100 is a slow-metabolizing-LPA mimic that significantly reduces mortality from otherwise lethal doses of ionizing radiation – even when administered 24 h after radiation exposure – in animal models. Studies to date have been conducted in two animal species – with one predicting efficacy in humans as required by the Animal Rule. The growth-factor-like actions of Rx100, including its cellular mechanism of action, have been well-explored and involve inhibition of apoptosis and promotion of cell regeneration, and DNA repair in tissue-specific stem and progenitor cells.

RxBio's most recent NIAID contract award continues the advanced development toward achieving FDA approval. This project is funded in whole or in part with federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272201800052C.