News Release

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BARDA funds development of five drugs to protect against radiation

The development of five new drugs to treat injuries associated with acute radiation syndrome will move forward under contracts awarded by the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA).

Acute radiation syndrome is caused by exposure to high doses of damaging (ionizing) radiation. ARS includes injuries to multiple organs, hemorrhaging, infection, and suppression of the immune system's ability to fight organisms that cause infection.

Because no products are licensed to treat any aspect of acute radiation syndrome, BARDA is supporting the development of products to treat bone marrow, gastrointestinal, lung, and skin injury caused by radiation. BARDA expects to expand this list to include products to treat the thermal burns that might be caused by a nuclear detonation.

Today's contracts total $56.3 million for development of products that potentially could treat bone marrow and gastrointestinal injuries from high levels of radiation, such as after denotation of an improvised nuclear device. Bone marrow and gastrointestinal injuries are expected to account for the majority of radiation-related deaths after a nuclear denotation.

The contracts were awarded to Neumedicines Inc. of Pasadena, Calif., RxBio Inc. of Johnson City, Tenn., the University of Arkansas for Medical Sciences of Little Rock, Ark., Araim Pharmaceuticals of Ossining, N.Y., and Cellerant Therapeutics of San Carlos, Calif.

"These contracts support development of products that have the potential to address urgent public health requirements for radiation medical countermeasures while also meeting other unmet medical needs," said BARDA Director Robin Robinson, Ph.D. "For example, they may find day-to-day use in treating the side effects of cancer radiation treatment and chemotherapy. These advanced development contracts demonstrate what can be achieved by repurposing drugs with commercial potential to meet public health emergency requirements, and we would like to encourage other pharmaceutical companies and their collaborators to follow this approach."

Today's $17 million contract with Neumedicines Inc. will evaluate the safety and efficacy of a drug known as recombinant human interleukin-12 (rhuIL-12), or HemaMax, and will further develop manufacturing processes for HemaMax. Under a 2008 contract with BARDA, Neumedicines conducted proof-of-concept studies demonstrating that HemaMax mitigates bone marrow damage caused by damaging radiation. Today's contract builds on that work.

Under a two-year, $15 million contract, RxBio Inc will study the efficacy of its drug Rx100, which may protect against radiation -induced gastrointestinal injury by interrupting programmed cell death, known as apoptosis. Preliminary data suggests that Rx100 can protect or mitigate injury and improve survival if administered up to 72 hours after deadly whole-body radiation exposure. The contract also supports development of manufacturing processes for the drug.

In a two-year, $4.5 million contract, UAMS will evaluate a drug, SOM230, developed by and provided under an agreement with Novartis. Novartis developed SOM230, or pasireotide, to treat a hormone disorder known as Cushing's disease. Preliminary data suggest that the drug also may be useful in treating radiation injuries to the gastrointestinal system. Under the new contract, investigators at UAMS will generate data Novartis needs to submit a new drug application for possible Food and Drug Administration approval to use SOM230 to treat gastrointestinal injuries from radiation exposure. SOM230 appears to protect the intestine by reducing secretions from the pancreas that cross the damaged intestinal wall and exacerbate inflammation in the intestines.

Araim Pharmaceuticals won a two-year, $3.1 million contract to conduct studies of ARA 290 to evaluate whether the drug improves overall survival when the drug is administered 24 hours or longer after exposure to high doses of ionizing radiation. With anti-inflammatory properties and tissue-protective properties, the drug has shown promise in treating stroke, heart disease, and kidney failure. The studies under this contract are the next step in the drug development process and are needed before proceeding to clinical trials and pivotal efficacy studies.

In addition to these new contracts, BARDA today extended a 2010 contract with Cellerant Therapeutics for a second year and an additional $16.7 million. Under the contract, Cellerant will continue studies and manufacturing activities to further develop a new way to treat the illness known as neutropenia, an abnormally low number of white blood cells caused by exposure to high levels of ionizing radiation. Cellerant's drug, called CLT-008, uses a kind of cells called myeloid progenitor cells, which can grow into any kind of blood cell the body needs.

CLT-008 is being developed to support and add to the patient's own progenitor cells, providing protection for patients against life-threatening infections and hemorrhaging while their own bone marrow is recovering. CLT-008 could be used for other blood disorders and complications of cancer in which blood cells and platelets need to be replenished, so it also has promise as supportive therapy for patients receiving bone marrow or fetal cord blood transplants.

Today's awards are part of a rapidly growing BARDA program to develop therapeutics and diagnostics for radiation injury. BARDA is seeking additional proposals for products that potentially could treat or illness and injury from acute radiation syndrome, as well as improved diagnostic tools to measure the radiation dose a person has absorbed after a nuclear denotation or radiation accident. Proposals are accepted through the Broad Agency Announcement BARDA-CBRN-BAA-11-100-SOL-00009 at www.fbo.gov.

BARDA, an agency within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services, provides a comprehensive integrated portfolio approach to the advanced research and development, innovation, acquisition, and manufacturing infrastructure for vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products for public health emergency threats. These threats include chemical, biological, radiological, and nuclear threats, pandemic influenza, and emerging infectious diseases.

For more information about BARDA and the advanced research and development of medical countermeasures visit www.phe.gov and www.medicalcountermeasures.gov. Contract opportunities and awards are announced at www.fbo.gov.

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