# DxTerity Diagnostics Awarded Up to $150 Million BARDA Contract for Advanced Development and Delivery of REDI-Dx® High Throughput Radiation Biodosimetry Test

(Los Angeles, CA) – DxTerity Diagnostics announced today that it has signed a multi-year contract with the Biomedical Advanced Research and Development Authority (BARDA), which is a division of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, for the Advanced Development and Delivery of its REDI-Dx® High Throughput Radiation Biodosimetry Test. The total contract is valued at up to $150.1 million.

Following a large scale emergency involving radiation, the REDI-Dx test system is designed for determining individualized levels of absorbed radiation from a blood sample. The test measures the relative expression of a panel of 18 genes, and then uses a proprietary algorithm to estimate absorbed dose. Although there are devices available that can be used to measure levels of external radiation, there is no FDA approved test that can be used to determine the amount of radiation that a person has absorbed. This information is critical for determining the appropriate treatment for an individual.

The contract consists of a base 2-year period of performance worth more than $22.4 million to complete the clinical studies and regulatory filings required to obtain full FDA approval for the test system and associated DxCollect® Blood Collection Tubes. The initial contract also includes working with BARDA to obtain Emergency Use Authorization (EUA) for REDI-Dx, and delivery of 40,000 tests and blood collection tubes to the Strategic National Stockpile. Subsequent contract options include the delivery of materials sufficient to maintain a 400,000 test stockpile through 2026

DxTerity expects REDI-Dx to be approved for EUA by the FDA in early 2017, followed by the initial delivery of 40,000 tests and collection tubes in Q2 2017. The company plans to submit for full FDA approval in early 2018.

Dr. Bob Terbrueggen, Founder and CEO of DxTerity, states, "we are honored that BARDA has selected DxTerity to help fulfill this critical unmet need for public safety and preparedness. The REDI-Dx test system is the result of a multi-year collaboration with Duke University, the University of Arizona, Thermo Fisher Scientific, and BARDA, as well as patients and scientists at leading institutions around the US that have provided clinical samples."

Duke Cancer Institute Researchers Dr. Holly Dressman, Ph.D., Dr. Joseph E. Lucas, Ph.D., and John Chute, M.D., first discovered the gene signature that forms the basis of REDI-Dx in 2007 while comparing blood-based gene expression in healthy patients to patients who had undergone full-body radiation. In 2009, Duke partnered with DxTerity and the University of Arizona with funding from BARDA to develop a low cost, high throughput test based upon this gene signature. Thermo Fisher Scientific was subsequently added to the collaboration, enabling the delivery on their large existing install base of clinical sequencing instruments.

Duke Cancer Institute's gene signature research and DxTerity's genomic testing system have other potential applications in clinical medicine. They could provide a method to evaluate a cancer patient's tolerance for radiation treatment and to predict radiation-induced side effects in various types of cancers. The DxTerity platform is also being used to develop low-cost tests for rheumatoid arthritis as well as other autoimmune diseases.

Terbrueggen continues, "the award of the BARDA contract represents a very significant milestone for DxTerity. It provides important validation of the DxDirect® platform and it validates the development process that DxTerity uses to collaborate with academic and industrial partners to turn genomic discoveries into high quality, FDA approved genomic tests."

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