Office of Biomedical Advanced Research and Development Authority (BARDA) Division of Research, Innovation & Ventures (DRIVe)

Amendment 002 Issuance for Easy Broad Agency Announcement (EZ-BAA) BAA-22-100-SOL-00003

The purpose of this Amendment is the following:

1) Add the following Areas of Interest (AOI):

AOI #24: REPAIR

2) Clarify an administrative error

INTRODUCTION AND OVERVIEWINFORMATION

A. Development Opportunity Objective:

Under this Amendment, DRIVe is doing the following:

1) Add the following research Area of Interest (AOI):

AOI #24: REPAIR

We are seeking abstract submissions for the following AOI:

AOI #24: REPAIR

Repurposing and **A**dvancing **I**nnovations Against **R**ad/Nuc Threats (**REPAIR**)

Exposure to ionizing radiation can result in a spectrum of injuries known as Acute Radiation Syndrome (ARS). Due to multiple organ involvement, medical countermeasures (MCM) that treat the systemic nature of the injury or multi-organ pathologies are needed. These MCMs need to be effective when given 24 hours or later post-exposure to be consistent with current deployment expectations. Commercially available products should be familiar to end users, as well as be potentially available at multiple points of care such as pharmacies and hospitals. This ensures MCMs are available immediately when and where they are needed, while resources are deployed from stockpiles.

Repurposing existing FDA-approved and late-stage development therapeutics as potential MCMs for radiological and nuclear events could expand treatment options as well as support the concept of pre-deployed MCMs. The clinical data needed to reach these stages of development can also enable development under FDA's Animal Rule. This includes safety data, stage appropriate manufacturing, and a well-defined mechanism of action.

BARDA is seeking abstracts that describe repurposing of therapeutics to be used as MCMs to treat ARS. *Candidate MCMs should either be FDA approved or have successfully completed (met the primary endpoint) their phase 2 trial.*

This Program is focused on repurposing therapeutics for the following:
Cell Death: Development of MCMs to counteract loss of tissue/organ cellularity resulting from exposure to ionizing radiation injury. These treatments should either aim to maintain cellular populations, replenish, or preserve stem/progenitor cell population.

Vascular Injury: Development of MCMS that treat vascular injury by targeting the vascular endothelium and prevent further injury to blood vessels resulting from exposure to ionizing radiation.

Bleeding/Coagulation: Development of MCMs that treat bleeding, restore hemostasis, and/or target the coagulation cascade. Candidates should have a mechanism of action distinct from increasing thrombopoietin or by binding the thrombopoietin receptor.

Ischemia: Development of MCMs to treat hypoxia and facilitate tissue oxygenation resulting from exposure to ionizing radiation injury.

The end goal of this AOI is to support the collection of proof-of-concept data on FDA-approved and late-stage development therapeutics in the context of ionizing radiation exposure in relevant nonclinical models.

To be considered responsive under this AOI, respondents should have the following:

- A drug that is a candidate for repurposing as a MCM against vascular injury, cell death, bleeding or coagulating disorders, or ischemia associated with ARS
- Is FDA-approved or has met its primary endpoint in Phase 2 clinical trial; evidenced by a clinical study report(s)
- A clear rationale as to why the candidate should be efficacious as a post-exposure ARS MCM
- Outline of appropriate facilities (or description of subcontractor or other partner) demonstrating ability to execute radiation exposure experiments

Out of scope:
-Evaluation of MCMs which already have an H-ARS indication.
-Prophylactic administration prior to exposure to ionizing radiation.
-MCMs that do not have a defined MOA and relevant PD markers.
-Evaluation of MCMs outside the context of injuries resulting from a nuclear detonation.

2) Clarify the following administrative error originally published October 18, 2022 posting of the the EZ BAA:

Under Section D.1 "Determination of Interest in the Abstract Submission," we would like to clarify the following typographical error, which is underlined:

"The determination will not be based on the content of the submission and prior communication with BARDA that may have occurred during a market research call will not be considered."

This is hereby deleted and replaced with:

"The determination will only be based on the content of the submission. Prior communication with BARDA that may have occurred during a market research call will not be considered."

B. Eligible Respondents & Scope Parameters:

This Amendment is open to all responsible sources as described in the EZ-BAA. Abstract submissions that do not conform to the requirements outlined in the EZ-BAA may be considered non-responsive and will not be reviewed. In particular, an entity must have an active registration with https://sam.gov at the time of submission to be reviewed. If not, the abstract submission will not be reviewed and will be rejected. Please do not attempt to submit an abstract if your registration is not active in https://sam.gov.

IMPORTANT NOTE: Interested vendors are strongly encouraged to request and schedule a pre-submission call before submitting an abstract. This request should include the project title, key project staff, and a brief description of the proposed project. Please submit the requests to the following:

AOI #24: REPAIR (repair@hhs.gov)

The closing date for abstract submissions for this AOI, unless otherwise extended will be:

Area of Interest	Closing Date for Abstract Submissions
#24	12:00pm ET on February 28, 2023

C. Number of Awards:

Multiple awards are anticipated and are dependent upon the program priorities, scientific/technical merit of abstract submissions, how well the abstract submissions fit within the goals of the AOI, and the availability of funding. The program funding is subject to change based on the Government's discretion.

Funding is limited, so we encourage any interested vendors to reach out to the respective program as soon as possible before submitting an abstract.

D. Amendment Application Process:

This Amendment will follow the same submission process and review procedures as those established under this EZ-BAA, unless otherwise noted. For complete details, please read the EZ-BAA in its entirety along with all amendments.

IMPORTANT NOTE: Respondents who are awarded a contract under each of these AOIs will be required to share any collected, de-identified data in an effort to advance the field and knowledge. Interested Respondents are strongly encouraged to commercialize their technology and algorithms, however note that consistent with BARDA's mission and federal standards, data collected through the use of government funding will be delivered to BARDA for government usage pursuant to applicable regulations and law.