W911SR-24-S-HDTX

REQUEST FOR INFORMATION

HOST-DIRECTED THERAPEUTICS FOR PROPHYLAXIS, POST-EXPOSURE PROPHYLAXIS AND TREATMENT OF EXPOSURE TO VIRUSES, BACTERIA AND TOXINS

Objective:

This is a Request for Information (RFI) for planning purposes only. It is not to be construed as a commitment by the Government nor will the Government pay for the information solicited.

JPM CBRN Medical is hosting an Industry Day 29 October 2024 at the United States Patent and Trademark Office (USPTO) in Alexandria, VA. This event will provide Industry the chance to hear from US Government agencies on current and future work in the arena of Host Directed Therapeutics. Presentations will be given by JPEO CBRND, BARDA, and JSTO. The following day, 30 October, selected companies can present their product to USG representatives. Those companies will be selected based on responses to this RFI.

No solicitation document exists or is guaranteed to be issued as a result of this RFI or in person presentation. The Joint Project Manager for Chemical, Biological, Radiological, and Nuclear Medical (JPM CBRN Medical) and the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND) is seeking information on the available capabilities and willingness of private entities (academic, non-profit, and commercial) to collaborate with the Government in the areas listed below.

Background:

The Department of Defense's (DOD) Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) is performing market-based research and is requesting information from product developers who develop medical countermeasures to protect and/or treat the warfighter who may be infected with or exposed to biological agents. The JPEO-CBRND is interested in late-stage development of host-directed therapeutics or repurposing of United States Food and Drug Administration (FDA) licensed therapeutics that are threat-agnostic with the potential for activity across viral families, bacterial species or toxin families.

Requirements:

All submissions must be no more than (3) three total pages and must follow the white paper template attached to this announcement. The rubric showing the priorities for the review is also included. All instructions and submissions will be at https://usg.valideval.com/teams/hdtx_2024/signup.

Performance Objectives:

The candidate(s) should have demonstrated activity alone or in combination with direct-acting licensed therapeutics or other licensed therapeutics for another indication with plans to repurpose the therapeutic to prevent or treat disease caused by viruses, bacteria and toxins. The agents of high priority to the DOD include: Alphaviruses, Filoviruses, Bunyaviruses, Arenaviruses, Coronaviruses Yersinia pestis; Francisella tularensis; Burkholderia pseudomallei; Burkholderia mallei; Bacillus anthracis; Botulinum

neurotoxins (BoNT), Ricin toxin, Conotoxins and Marine toxins. The candidate may have evidence supporting broader threat-agnostic relevance for preventing or treating disease caused by agents beyond the DOD priority list that may additionally pose a risk to the warfighter and result in future public health emergencies. The ideal candidate would be a small molecule with enhanced stability that can be easily administered by either ingestion, inhalation or intramuscular injection. Development and clinical testing of vaccines will not be considered in this request.

The products shall meet or exceed the quality standards established by current Good Manufacturing Practices (cGMP), Good Laboratory Practices (GLP), Good Clinical Practices (GCP) and FDA and/or International Conference on Harmonisation (ICH) and International Organization for Standardization (ISO) standards during the course of development.

Administration:

The Government will retain comments and information received in response to this RFI. Proprietary information should be identified as Company Proprietary. Do not use Government security classification markings. All written responses must be received by COB on 30 August 2024 1700 EDST. Responses should submitted online at https://usg.valideval.com/teams/hdtx_2024/signup. Material that is advertisement only in nature is not desired. If a solicitation is subsequently released based on the responses to this RFI, the first choice for an acquisition vehicle, if appropriate, will be an Other Transaction Agreement (OTA) issued either bilaterally via publicly posted Request for Prototype Proposal (RPP), and/or an RPP issued under the Medical CBRN Defense Consortium (MCDC). Respondents not already members of the MCDC are encouraged to join at www.medcbrn.org. Respondents may also inquire about the MCDC at mcdc@ati.org. In addition, respondents are encouraged to view the Medical Countermeasures Broad Agency Announcement (BAA) in SAM.gov, keywords “CBRND BAA”.