Sources Sought Notice (SNN)

Antimicrobial Resistance Project BioShield
BARDA Antibiotic for Treatment of Hospital-Acquired and Ventilator-Associated Bacterial Pneumonia or Bloodstream Infections Caused by Drug-Resistant Bacteria or Biothreat Pathogens
SSN No.: BARDA-CBRN-11042024

PURPOSE

The Center for the Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS), is issuing this Sources Sought Notice (SSN) to collect feedback from current and prospective antibiotic development partners. Information obtained from this SSN will serve as continued market research for potential future acquisitions and programs. The information collected in response to this SSN is intended to strengthen BARDA's understanding of the current and future marketplace. This notice seeks information from Other than Small Businesses (OTSB) and Small Businesses (SB) regarding their qualifications, experience, and capabilities.

THIS IS STRICTLY FOR MARKET RESEARCH.

AUTHORITY

The Office of Contracts, Management and Acquisitions (CMA) is issuing this SSN on behalf of BARDA pursuant to FAR paragraphs 5.205(c), 15.201(e) and FAR parts 10, 19. Information collected in response to this SSN will enhance BARDA's ability to establish potential vendor source files and listings as well as lawfully execute the preparedness mission efficiently.

BACKGROUND

Within the Federal Government, ASPR/BARDA is tasked with protecting the civilian population from the adverse health effects resulting from intentional or unintentional release and exposure to CBRN threats, pandemic influenza, and emerging infectious diseases; this includes secondary bacterial infections caused by antibiotic-resistant bacteria. Development and procurement of antibiotics that overcome known and emerging forms of resistance will enhance the USG's emergency preparedness.

The subject of this Sources Sought Notice is to gain information regarding antibiotics in development for the treatment of hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) and bloodstream infections (BSI) caused by drug-resistant bacterial infections. Proposed antibiotics may also be developed for post-exposure prophylaxis and/or treatment of biothreat pathogens (*Yersinia pestis, Francella tularensis, Burkholderia pseudomallei*, and *Bacillus anthracis*).

DESCRIPTION

BARDA is issuing this SSN to assist in understanding the landscape of antibiotics in development for the treatment of HABP/VABP and BSI, as well as PEP and/or treatment of biothreat pathogens. For the purpose of this SSN, BARDA is seeking:

- Antibiotic programs that already have or expect to hold their end-of-Phase 2 meeting with the FDA by May 1, 2025, with an intended indication for the treatment of HABP/VABP
- Antibiotic programs that already have or expect to hold their end-of-Phase 2 meeting with the FDA by May 1, 2025, with an intended indication for the treatment of BSI.
- Antibiotic programs that already have or expect to hold their end-of-Phase 2 meeting with the FDA by May 1, 2025, with an intended indication for the treatment of HABP/VABP or BSI that could also

be developed for a biothreat indication.
- Antibiotics that are approved for HABP/VABP and/or BSI that have sufficient data to warrant development for a biothreat indication.

Respondents are asked to provide the following information:

1. Overview of the antibiotic candidate:
    a. Pathogens targeted.
    b. Clinical indication(s) sought or approval date (if applicable)
    c. Commercial formulation (IV, PO)
    d. FDA correspondences and future FDA meeting plans
        i. If targeting a biothreat pathogen, summary of discussions with the FDA on the biothreat development program to achieve an sNDA
    e. Status of the IP
    f. Proposed timeline for sNDA or NDA submission

2. Overview of nonclinical studies and status:
    a. In vitro and in vivo efficacy
    b. In vitro activity against pathogens with key resistant phenotypes
    c. In vivo pharmacology/pharmacodynamics and ADME studies
    d. Toxicology and safety data

3. Overview of clinical development status:
    a. Phase 1 trial(s)
        i. Trial design and endpoints
        ii. Safety data summary
        iii. Final CSR – date completed and summary of data.
    b. Phase 2 trial(s)
        i. Trial design and endpoints summary
        ii. Enrollment target and date completed (or target completion)
        iii. Interim analysis – date completed (or target completion) and summary of data (if available)
        iv. Final CSR – date completed (or target completion) and summary of data (if available)
    c. Phase 3 trial(s)
        i. Trial design and endpoints summary
        ii. Enrollment target and date completed (or target completion)
        iii. Interim analysis – date completed (or target completion) and summary of data (if available)
        iv. Final CSR – date completed (or target completion) and summary of data (if available)
    d. Black Box Warnings or anticipation of a Black Box Warning with a risk-benefit assessment to justify the products use during a public health emergency.

4. Manufacturing:
    a. Registration/primary batches – summary of the current status and plans, with timelines
    b. Process validation – summary of current status and plans, with timelines
    c. Stability testing – summary of stability data for drug substance (DS) and drug product (DP) and plans to achieve 5 years of product shelf-life for the DS and DP
    d. Summary of current demonstrated and planned manufacturing scale
    e. Status of contract manufacturing organization (CMO), including location, and whether any

US domestic capacity currently exists for both DS and fill/finish of DP. If US domestic capacity does not yet exist, provide a timeline and summary of the approach to onshore both DS manufacturing and fill-finish of DP.

5. Procurement:
    a. If procured, the USG-owned product must be able to be 1) delivered as final drug product (FDP) to the ASPR/SNS or; 2) maintained as FDP by the sponsor as vendor-managed inventory. Provide a summary of how the Respondent would meet both of these requirements should BARDA procure the antibiotic for stockpiling.

6. Commercialization Plan:
    a. A summary of the commercialization strategy for the proposed product and a corporate sustainability strategy.

Respondents are asked to provide only the most pertinent information, data, and materials necessary to adequately convey a declaration of capability in line with this notice. Responses should be limited to 15 single-sided pages or less. Content that is more than the stated limit per section will not be reviewed. Respondents are asked to state whether they are registered as a small business. Responses shall be sent electronically to erin.greninger@hhs.gov and audrey.glover@hhs.gov **for receipt by Noon, EST on November 29, 2025**. Any questions, comments, or concerns regarding this notice shall be sent to erin.greninger@hhs.gov or audrey.glover@hhs.gov.

DISCLAIMER AND IMPORTANT NOTES

This notice is issued solely for information and planning purposes and does not obligate the US Government to award a contract. No entitlement to payment of direct or indirect costs or charges by the US Government will arise because of the submission of the requested information. No reimbursement will be made for any costs associated with providing information in response to this announcement and any follow-up information requests. The US Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the US Government to determine the organization's qualifications to perform the work. Respondents are advised that the US Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published on SAM.gov under Contract Opportunities in accordance with FAR part 5. However, responses to this notice will not be considered adequate responses to a solicitation.

CONFIDENTIALITY

Respondents shall mark confidential, privileged, proprietary, trade-secret, copyrighted information, data, and materials with appropriate restrictive legends. ASPR/BARDA will presume that any unmarked information, data, and materials were furnished with an "unlimited rights" license, as FAR subpart 27.4 defines that term, and ASPR/BARDA assumes no liability for the disclosure, use, or reproduction of the information, data, and materials. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation.