Incentivizing Antibacterial Research and Development

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Acting Branch Chief Antibacterial MCM Program
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BARDA’s Innovation Partners

Discovery & Hit to Lead

Preclinical Development

Phase I

Phase II

Phase III

Licensure & Post Marketing Commitments

Production

Delivery/Access

CARB-X

Project BioShield

BARDA

NIH

GARDP

Our Goal

Reduce the morbidity and mortality caused by antimicrobial resistant bacterial infections following a CBRN incident, influenza pandemic, emerging infectious disease outbreak, or any other public health emergency

- Incentivizing industry efforts by providing financial support
- Accelerating product development by providing partners with access to internal core services
- Reducing technical risk during product development by providing SME support during all phases and in all areas of drug development
- Facilitating interactions with interagency partners interested in providing additional support and R&D services to product sponsors
Our Priorities

**Drug Class**
- Unprecedented
  - Novel Target
  - Novel Chemistry
- Precedented
  - Reduced AR
- Nontraditional Therapies
  - mAbs, phage, host-based
- Prevention/interdiction
  - Vaccines
  - Microbiome

**Biothreat**
- B. pseudomallei
- B. mallei
- F. tularensis
- Y. pestis
- B. Anthracis
- MDR B. Anthracis
- Genetically engineered biothreats

**Antibiotic Resistance**
- CR Enterobacteriaceae
- MDR A. baumannii
- MDR P. aeruginosa
- ESBL Enterobacteriaceae
- C. difficile
- DR N. gonorrhoea
- VR Enterococcus
- MR S. aureus
- DR S. pneumoniae

**ConOps**
- HABP/VABP
- CABP
- BSI
- Oral delivery

[www.fbo.gov](http://www.fbo.gov)  BAA-18-100-SOL-00003
Our Partners

The Medicines Company
SD LLC
## BARDA’s Antibacterial Pipeline

<table>
<thead>
<tr>
<th>SPONSOR</th>
<th>COMPOUND</th>
<th>DEVELOPMENT STAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rempex/Melinta (formerly MDCO)</td>
<td>Vabomere</td>
<td>BL/BLI Combination cUTI/AP, CRE (Biothreat Relevance: melioidosis &amp; glanders)</td>
</tr>
<tr>
<td>Achaogen</td>
<td>Zemdri</td>
<td>Next-Generation Aminoglycoside cUTI/AP, CRE (Biothreat Relevance: plague &amp; tularemia)</td>
</tr>
<tr>
<td>CUBRC/Tetraphase</td>
<td>Xerava</td>
<td>Fully Synthetic Tetracycline cIAI, MDR (Biothreat Relevance: anthrax, plague, &amp; tularemia)</td>
</tr>
<tr>
<td>Melinta (formerly Cempra)</td>
<td>Solithromycin</td>
<td>Next-Generation Fluoroketolide CABP, GC (Biothreat Relevance: anthrax, &amp; tularemia)</td>
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<tr>
<td>AtoxBio</td>
<td>Reltecmid</td>
<td>Host-Directed Immune Modulator NSTI</td>
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<tr>
<td>Basilea</td>
<td>Ceftobiprole</td>
<td>Cephalosporin ABSSI, SAB, CABP (Biothreat Relevance: plague, &amp; tularemia)</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>Gepotidacin</td>
<td>Topo II Inhibitor CABP, GC, uUTI (Biothreat Relevance: plague, tularemia, &amp; anthrax)</td>
</tr>
<tr>
<td>Pfizer</td>
<td>Aztreonam-Avibactam</td>
<td>BL/BLI Combination cIAI, HAP/VAP, MDR gram neg pathogens (Biothreat Relevance: plague)</td>
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<tr>
<td>Hoffman-La Roche</td>
<td>Nacubactam</td>
<td>Broad Spectrum BLI</td>
</tr>
<tr>
<td>Spero</td>
<td>Tebipenem</td>
<td>Oral BL cUTI (Biothreat Relevance: anthrax, melioidosis, &amp; plague)</td>
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<tr>
<td>Summit</td>
<td>Ridinilazole</td>
<td>Novel 1st in Class Oral Antibiotic C. Diff</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>GSK-680</td>
<td>Topo II Inhibitor cUTI, cIAI, HABP/VABP</td>
</tr>
<tr>
<td>Achaogen</td>
<td>C-Scape</td>
<td>Oral BL/BLI Combination cUTI/AP (Biothreat Relevance: plague &amp; tularemia)</td>
</tr>
<tr>
<td>MDCO</td>
<td>ORlvance</td>
<td>Broad Spectrum BLI</td>
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<td>MDCO</td>
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<td>Broad Spectrum BLI</td>
</tr>
<tr>
<td>MDCO</td>
<td>Novel Polymyxin</td>
<td>Polymyxin</td>
</tr>
</tbody>
</table>

*Saving Lives. Protecting Americans.*
Successes From the Past Year

- **VABOMERE™**
  - Treats complicated urinary tract infections and kidney infections

- **ZEMDRI™**
  - (plazomicin) Injection
  - Treats complicated urinary tract infections and kidney infections

- **XERAVA™**
  - (eravacycline) for injection
  - Treats complicated intra-abdominal infections

BARDA Broad Agency Announcement

BAA-18-100-SOL-00003
Area of Interest #3: Antimicrobial Therapeutics

Develop and test antibacterial products that are in development for post-exposure prophylaxis (PEP) and treatment efficacy against one or more of the following biodefense threat agents: *Bacillus anthracis*, *Yersinia pestis*, *Francisella tularensis*, *Burkholderia mallei*, and *Burkholderia pseudomallei*.

Develop new small molecule drugs that treat or prevent resistant bacterial infections either alone or in combination with other therapeutics.

Develop non-traditional antibacterial therapeutics that treat or prevent resistant infections.

Products should possess activity against one or more of the pathogens categorized as serious, urgent, or concerning threats in the September 2013 CDC Report.

https://www.fbo.gov/ ("FedBizOpps")
Qualities that Strengthen a Proposal

Candidates demonstrating substantial improvements over existing antimicrobial products are of greatest interest including novel first in class compounds with unprecedented mechanisms of action and candidates with in an existing class.

- Is the product differentiated from existing products?
- Does product address an unmet medical need?
- Does the product fill a portfolio gap? (Drug class, pathogen spectrum, indication, etc.)

Greater technological advancement of the candidate: the more advanced the more competitive.

Regulatory feasibility: FDA correspondence regarding the development plan:
- Is the development approach sound?

Special populations

Cost sharing

CARB-X & BARDA’s Antibacterial Pipeline

Investing $192 million in FY 2018 through Novel Public Private Partnerships to support a Portfolio of Antibacterial Products to repopulate the Antibacterial Pipeline

Total number of products supported

45

Updated Sept 18, 2018 (Diagnostics product not shown)
Continue our momentum

1. Continue Support
   - Development of dual use therapeutics
   - Biothreat pathogens
   - MDR “Urgent & Serious” pathogens

2. New Partnerships
   - Novel candidates
   - Non-traditional therapeutic
   - Leveraging outreach
   - Challenging indications & formulations

3. Utilize
   - PBS to acquire innovative products that address biothreats

How to contact BARDA

- **Portal to BARDA: Register to request a TechWatch meeting!**
  
  - [medicalcountermeasures.gov/home.aspx](http://medicalcountermeasures.gov/home.aspx)

- **Official announcements and info for all government contract solicitations**
  
  - [www.fbo.gov/](http://www.fbo.gov/)  
    - (“FedBizOpps”)  

- **Program description, information, news, announcements**
  
  - [https://www.phe.gov/about/BARDA/Pages/default.aspx](https://www.phe.gov/about/BARDA/Pages/default.aspx)

- **DRIVE questions**
  
  - [www.drive.hhs.gov](http://www.drive.hhs.gov)

- **Join the team!**
  
  - [https://www.usajobs.gov/](https://www.usajobs.gov/)

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