BARDA’s Broad Spectrum Antimicrobial (BSA) Program

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BARDA Principles at Work

- Exists to address the medical consequences of biothreats, pandemic influenza and emerging infectious diseases, including antimicrobial resistance.
- Works with our federal partners to transition medical countermeasures from early development into advanced development towards ultimate FDA approval.
- Has established public-private partnerships with industry; sharing in development costs.
- Established a network of core services to assist developers in non-clinical, clinical, manufacturing, and fill/finish activities.
- Provides subject matter expertise in all aspects of product development.
- Make sure that safe and effective products are available if needed during an incident or public health emergency.
BARDA Created a Robust & Productive MCM Development Pipeline

• More than 150 MCM product candidates in development since 2004 (aggregate)
BARDA’s MCMs Have Been Approved by the FDA

Cell-based Influenza Vaccine

Recombinant-based Influenza Vaccine

Protein Sciences Corp.

H1N1 & H5N1 Vaccine w/ Adjuvant

GlaxoSmithKline

Anthrax Antitoxin

HGS/GSK

Influenza IV Antiviral Drug

Botulinum Antitoxin

Cangene

Next-Gen Portable Ventilators

Covidien

Flu/RSV POC Diagnostic

3M/Focus
The BARDA Model

• The BARDA model works to address market failures
  — Products FDA approved/cleared for biothreats and pandemic influenza
  — Products stockpiled for emergency use
• This model is being successfully applied to antimicrobial resistance
  — Utilization of novel public:private partnerships to incentivize antibiotic research and development
  — 4 products in Phase III clinical development
  — 2 products have hit endpoints in Phase III trials

## Current BARDA Program Investments

### BARDA’s BSA Supported Product Pipeline

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Compound</th>
<th>Development</th>
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</thead>
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<tr>
<td>Achaogen</td>
<td>Plazomicin (ACHN-490)</td>
<td><strong>Preclinical</strong> Next-generation aminoglycoside: Broad Spectrum plague, tularemia and carbapenem resistant Enterobacteriaceae (CRE)</td>
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<tr>
<td>CUBRC/Tetraphase</td>
<td>Eravacycline (TP-434)</td>
<td><strong>Preclinical</strong> A novel fully synthetic tetracycline: Broad Spectrum plague, tularemia, complicated intra-abdominal and urinary tract infections (cIAI, cUTI)</td>
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<tr>
<td>Cempra</td>
<td>Solithromycin (CEM-101)</td>
<td><strong>Preclinical</strong> Next-generation fluoroketolide: Broad Spectrum anthrax, tularemia, gonorrhea and community-acquired bacterial pneumonia (CABP)</td>
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<tr>
<td>Basilea</td>
<td>BAL30072</td>
<td><strong>Phase I</strong> A novel sulfactam: Broad Spectrum MDR Gram negative infections, melioidosis, glanders</td>
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<tr>
<td>Rempex</td>
<td>Carbavance™ (meropenem/RPX7009)</td>
<td><strong>Phase II</strong> Carbapenem/β-lactamase inhibitor: Broad Spectrum CRE, cUTI, hospital-acquired pneumonia/ventilator-associated pneumonia (HAP)/(VAP), melioidosis, glanders</td>
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<tr>
<td>GSK</td>
<td>A portfolio approach</td>
<td><strong>Phase III</strong> Broad Spectrum Antibiotic Portfolio A partnership to fund multiple compounds to combat antibiotic resistance at various stages of development</td>
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**Disclaimer:** The above projects are supported by BARDA’s BSA Program utilizing non-dilutive funding via a contract and/or agreement. The stage of development is approximate as of July 2014 (please refer to the sponsors site for updated information). The table represents the compounds most advanced commercial indication being pursued by the developer.
BARDA’s Portfolio Partnership for Antibacterial Drug Development

• Established 5 year $200M public:private partnership in May 2013

• Utilizes HHS’s first use of Other Transactional Authority

• Supports the development of multiple antibiotic candidates

• Allows for activities and resources to be adjusted fluidly to adapt to technical risk and programmatic priorities

• Governance is through a BARDA:GSK Joint Oversight Committee

• Partnership model we want to replicate going forward
BARDA BSA Program Budget Projections

• Current Funding for FY15: $79M

• Requested Funding in FY16 budget: $192M

• Additional Funding would support:
  – 2-3 Diagnostics Programs
  – 2-3 Additional Partnerships to support development of novel antimicrobial therapies
  – Emphasis on utilizing Other Transactional Authority as a means to form innovative partnerships with industry
BARDA’s Broad Spectrum Antimicrobial Program

• Summary:
  – BARDA’s antimicrobial program will continue to support the development of novel antimicrobials and diagnostics to address the growing public health threat of antimicrobial resistance and biothreat pathogens
  – Limited expansion of current program projected at current funding levels