Antivirals & Antitoxins Program

David Boucher, PhD
Project Officer, CBRN Antivirals and Antitoxins
October 29, 2018
BARDA Chemical Biological Radiological & Nuclear Portfolio at a Glance: Antivirals & Antitoxins Branch

**Discovery**
- Filovirus Antiviral
- Smallpox Antiviral

**Preclinical Development**
- Filovirus Antiviral
- Smallpox Antiviral

**Phase I**
- Filovirus Antiviral

**Phase II**
- Smallpox Antiviral
- CHIMERIX

**Phase III**
- Anthrax Antitoxin
- Botulism Antitoxin
- Smallpox Antiviral

**Licensure**
- NDA/BLA

**Production & Delivery**
- IND
- Preclinical Development
- Discovery
Anthrax Antitoxin Program

OBJECTIVE

Develop safe and effective anthrax antitoxins to treat inhalational anthrax

Approved Products:

**Raxibacumab**
(Emergent, formerly GSK & HGS)

**AIG IV (Anthrasil)**
(Emergent, formerly Cangene)

**Obiltoxaximab (Anthim®)**
(Elusys)

All three products are in the Strategic National Stockpile and available for deployment

Anthrax Antitoxins: Program Strategy and Opportunities

Continuing Efforts

• Coordinate with industry and ASPR/SNS to ensure medical countermeasure preparedness
• Extend shelf-life and improve concept of operations of existing products
• Support completion of post-marketing commitments

Program Objectives

• Further diversify the portfolio and, in turn, our response capabilities

Opportunities

• BARDA BAA, AOI #2.1, solicits TRL-6 or greater candidates that meet one or more of the following requirements:
  • Are peptides, small molecules or novel compounds;
  • Have a unique mechanism of action;
  • Provide a transformational change in operational use;
  • Provide a transformational change in Total Life Cycle Costs
Botulinum Antitoxin Program

OBJECTIVE
Develop safe and effective botulism antitoxins to treat botulism intoxication caused by serotypes A-G

Approved Products:
hBAT *Emergent, formerly Cangene*)

hBAT is in the Strategic National Stockpile and available for deployment
Botulinum Antitoxins:
Program Strategy and Opportunities

Continuing Efforts

• Coordinate with industry and ASPR/SNS to ensure medical countermeasure preparedness
• Support post-marketing commitments

Program Objectives

• Further diversify the portfolio and, in turn, our response capabilities

Opportunities

• BARDA BAA, AOI #2.2, solicits candidates that meet one or more of the following requirements:
  • Are mAbs, peptides, small molecules or novel compounds;
  • Have a unique mechanism of action;
  • Provide a transformational change in operational use;
  • Provide a transformational change in Total Life Cycle Costs
  • Candidates at TRL-5 are preferred; however, earlier candidates can be considered based on program impact
Smallpox Antiviral Program

OBJECTIVE
Develop safe and effective treatment options (multiple antiviral drugs with different mechanisms of action) for individuals with smallpox disease

Approved Products:
- JUL 2018
- ST-246/TPOXX (SIGA)

Ongoing Program:
- CMX-001/Brincidofovir (Chimerix)

ST-246/TPOXX is in the Strategic National Stockpile and available for deployment
Smallpox Antivirals: Program Strategy and Opportunities

Continuing Efforts

• Coordinate with industry and ASPR/SNS to ensure medical countermeasure preparedness
• Extend shelf-life and improve concept of operations of existing products
• Support completion of post-marketing commitments

Program Objectives

• Further diversify the portfolio and, in turn, our response capabilities

Opportunities

• BARDA BAA, AOI #2.3, solicits candidates with evidence of antiviral activity against orthopoxviruses.
  • Candidates at TRL-5 are preferred; however, earlier candidates can be considered based on program impact
Filovirus Antiviral Program (Ebola Zaire)

OBJECTIVE
Develop safe and effective treatment options for individuals with viral hemorrhagic fever caused by filovirus infection

ARD Program
Galidesivir/BCX4430 (BioCryst)

PBS Program
ZMapp (Mapp Biopharmaceutical)

PBS Program
REGN-EB3 (Regeneron)

Both ZMapp and REGN-EB3 are being made available under EAP/MEURI
Filovirus Antiviral Program (Sudan and Marburg)

OBJECTIVE
Develop safe and effective treatment options for individuals with viral hemorrhagic fever caused by filovirus infection

Manufacturing material that could be used as part of a response to outbreaks/high-risk exposures for which there are no available MCMs is a priority

“Innovation” ARD Program
MBP091 (Mapp Biopharmaceutical)
  • Targets the Marburg virus
MBP134 (Mapp Biopharmaceutical)
  • Targets the Sudan virus

ARD Program
MBP134 (Mapp Biopharmaceutical)
Filovirus Antiviral Program Strategy & Opportunities

Continuing Efforts

- Advance PBS Programs to licensure and continue to make those products available when needed
- Continue to support field use of filovirus therapeutics through EAP, RCT & MEURI

Program Objectives

- Further diversify the Zaire portfolio
- Build the Sudan and Marburg portfolios

Opportunities

- BARDA BAA, AOI #2.2, solicits candidates at TRL-5 or higher and, for Ebola Zaire, meet one or more of the following requirements:
  - Are single mAbs, peptides, small molecules or novel compounds;
  - Have a unique mechanism of action;
  - Provide a transformational change in operational use;
  - Provide a transformational change in Total Life Cycle Costs
# BARDA’s Antivirals & Antitoxins Team

## Medical Countermeasures Program
- Chia-Wei Tsai, *Branch Chief*
- David Boucher
- Clay Hughes
- Malen Link
- Michael Merchlinsky
- Kimberly Sciarretta
- David Simon
- Danielle Turley
- Carol Diaz-Diaz, *ORISE Fellow*

## Subject Matter Experts
- Clinical Development
- Pharmaceutical Countermeasure Infrastructure
- Non-clinical Development
- Regulatory & Quality Assurance

## Contracts Management & Acquisitions
- Jason Bell
- Brooke Bernold
- Wendell Conyers
- Erin Greninger
- Phil Hastings
- Francine Hemphill
- Ethan Muller
- Oke Obi
- Matthew Rose
How to contact BARDA

- **Medical Countermeasures.gov**
  - Portal to BARDA: Register to request a TechWatch meeting!

- **www.fbo.gov/ (FedBizOpps)**
  - Official announcements and info for all government contract solicitations

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

- **www.drive.hhs.gov**
  - DRIVe questions

- **https://www.usajobs.gov/**
  - Join the team!