



*United States Department of*  
**Health & Human Services**  
Office of the Assistant Secretary for Preparedness and Response



# **Stockpiling of Anthrax Antitoxins**

**BARDA Industry Day**  
**November 12, 2013**

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# USG Antitoxin Requirements



- Department of Homeland Security Material Threat Assessment based on a mass casualty event in a large metropolitan area
- 2009 – USG finalized requirement for anthrax antitoxins
  - In addition to antibiotics and vaccines, a drug is required to treat toxemic effects of anthrax infection
- 2011 – USG revalidated requirement for antitoxins

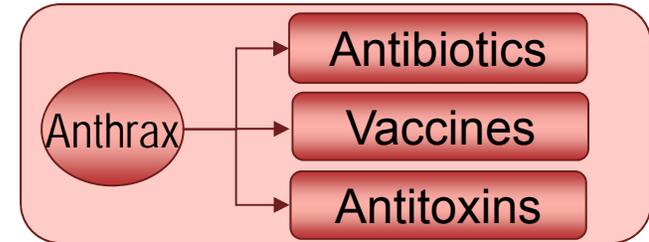


# PHEMCE Anthrax Strategy



- **Vaccines**

- BioThrax® (Anthrax Vaccine Adsorbed)
  - Licensed for general use prophylaxis
  - Use during a declared emergency for post-exposure prophylaxis



- **Antibacterials**

- Two approved for PEP (Ciprofloxacin and doxycycline)
  - Current concepts of operations – 60 days of antibiotics and three doses of vaccine

- **Biologics (antitoxins)**

- Treatment of those symptomatic with disease
  - HGS/GSK – monoclonal
  - Cangene - polyclonal



# Project BioShield Procurements



- Raxibacumab®
  - Human Genome Sciences/GSK
  - Monoclonal antibody directed against protective antigen
  - IV formulation
  - Efficacy modeled in rabbits and NHPs with 200 LD<sub>50</sub> spore challenge
  - Added benefit modeled in “delayed-treatment” rabbit model
  - Safety and PK demonstrated in healthy adults
  - **Licensed under the Animal Rule December 14, 2012**
- Anthrax Immune Globulin (AIG)
  - Cangene
  - Human polyclonal antibody raised against BioThrax®
  - IV formulation
  - Efficacy modeled in rabbits and NHPs with 200 LD<sub>50</sub> spore challenge
  - Added benefit modeled in “delayed-treatment” rabbit model
  - Safety and PK demonstrated in healthy adults





# Trajectory for the Future



- Focus on sustainment and risk mitigation
- Maintain manufacturing capability and inventory
- Complete Post Approval Commitments and Agreements
- Product enhancement to improve shelf-life and reduce life cycle costs
  - Lyophilized formulation for mAb antitoxins
- Investment in next generation small molecule antitoxins needed but not a priority for BARDA



# Interfacing with BARDA



- [www.phe.gov](http://www.phe.gov)
  - Program description, information, news, announcements
- [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)
  - Portal to BARDA
  - Register, request a meeting
  - Tech Watch
- [www.fedbizopps.gov](http://www.fedbizopps.gov)
  - Official announcements and detailed information about all government contract solicitations

