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$_{50}$ 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$_{50}$ 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**
  - Program description, information, news, announcements
- **www.medicalcountermeasures.gov**
  - Portal to BARDA
  - Register, request a meeting
  - Tech Watch
- **www.fedbizopps.gov**
  - Official announcements and detailed information about all government contract solicitations