



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



Therapeutic Biologics Portfolio

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BARDA Industry Day

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Therapeutic Areas of Interest



- Anthrax antitoxins
- Botulinum antitoxins
- Ebola virus
- Marburg virus



Toxin Threats



- Three antitoxins in strategic National Stockpile (out of five total CBRN countermeasures)
- One procurement requirement met (botulism)
- One procurement recommendation met (anthrax)
- Two novel products approved under FDA Animal Rule (hBAT and raxibacumab)
- Focus shifted to sustainment of existing preparedness



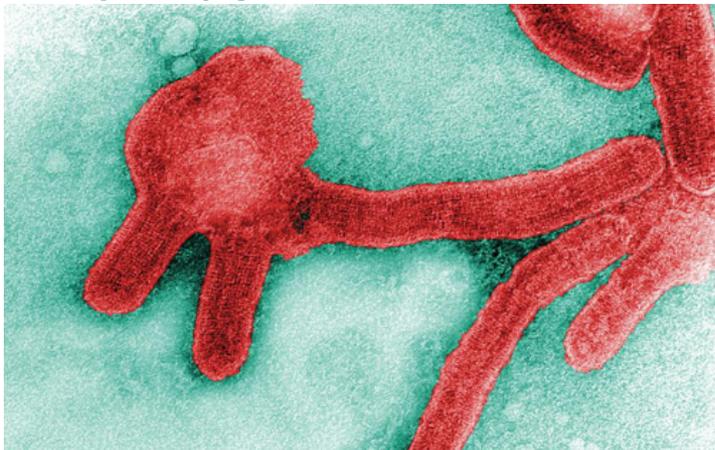
Viral Hemorrhagic Fever (VHF) Threats

- Ebola and Marburg viruses, causative agents of viral hemorrhagic fevers, are some of the most virulent pathogens known
- Mortality rates approach 90%, current Ebola outbreak 60%
- Natural reservoir is unknown



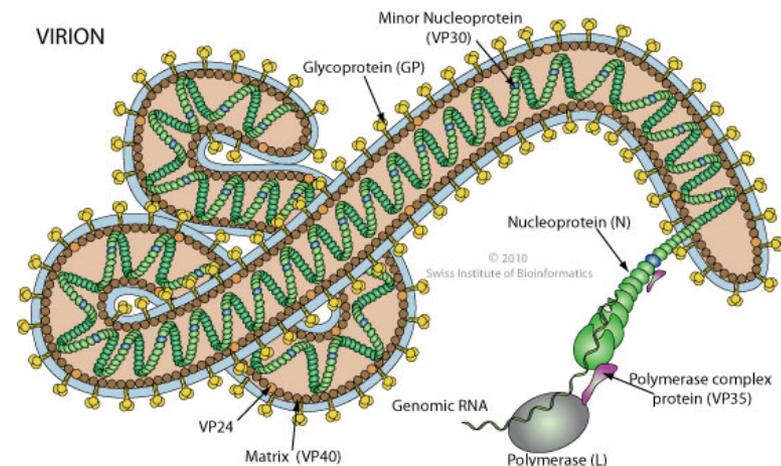
VHF Threats (cont'd)

- Disease characterized by a sudden onset of fever, headache, myalgias, gastrointestinal symptoms, and severe coagulopathy
- Caused by four families of viruses: arenavirus, bunyavirus, flavivirus, and filovirus
- Material Threat Determination (MTD) currently limited to filovirus



BARDA VHF Approach

- Integrated project team to address MCMs, animal models, and diagnostics
- Close cooperation with existing filovirus efforts outside BARDA (e.g., NIAID and DoD)
- Multiple MCM candidates to increase chance of success
- Potentially more than one MCM needed for successful treatment
- Pathogen and host targets
 - Current focus is on therapeutics that target the pathogen
 - Immunomodulators





VHF Portfolio



- Call for white papers
 - BAA 13-100-SOL-00013 available at FedBizOpps.gov
 - Area 2.3 Development of antibody treatments and other therapeutic agents for viral hemorrhagic fevers viruses. Programs must be at TRL-5 or higher with a lead candidate identified.
- Proof of concept data required (NHP model)
 - Time after exposure or therapeutic trigger
- Seeking access to products for testing and evaluation of therapeutic value and synergy with other products in animal models



Interacting with BARDA



- www.phemce.gov
 - Program description, information, and announcements
- www.medicalcountermeasures.gov
 - Portal to BARDA
 - Request a meeting or register for conferences
- www.fedbizopps.gov
 - Official announcements and detailed information about all USG contract solicitations
- stephen.morris@hhs.gov
 - Help and clarification