



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



Filovirus MCM Portfolio

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BARDA Industry Day

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- Ebola and Marburg viruses, causative agents of viral hemorrhagic fevers, are some of the most virulent pathogens known
- Mortality rates approach 90%
- 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
- Threat determination currently limited to filovirus





PHEMCE MCM Requirements



Marburg and Ebola viruses

- Treatment and post-exposure prophylaxis
- No requirement for vaccines or pre-exposure prophylaxis
- Combination of products may be necessary



Integrated Filovirus Therapeutic Pipeline (September 2013)



- ★ Inhibikase; Gleevec repurposing
- ★ Novartis; SMIPs toolbox
- ◆ USAMRIID/Zaliscus; screen of FDA approved drugs for filovirus activity
- ◆ USAMRIID; IgG Marburg and Ebola
- ◆ Drexel; Glucosidase inhibitors Ebola
 - ◆ Tekmira; Ebola, siRNA platform
 - ◆ Sarepta; Marburg, phosphorodiamidate morpholino oligomers platform
- ◆ Biocryst, RNA polymerase inhibitor, Ebola and Marburg
 - ◆ Mapp; monoclonals against Ebola Zaire (NIAID & DTRA funded)
- ◆ Unither; glycosidase inhibitor, Ebola
- ★ Univ. Washington (Gale) IRF-3 pathway activators for Ebola
- ★ Defyrus, IFN alpha Ad5 vector (Canadian funding)
- ◇ PHAC, Zmab antibody cocktail (Canadian funding)

NIH Funded

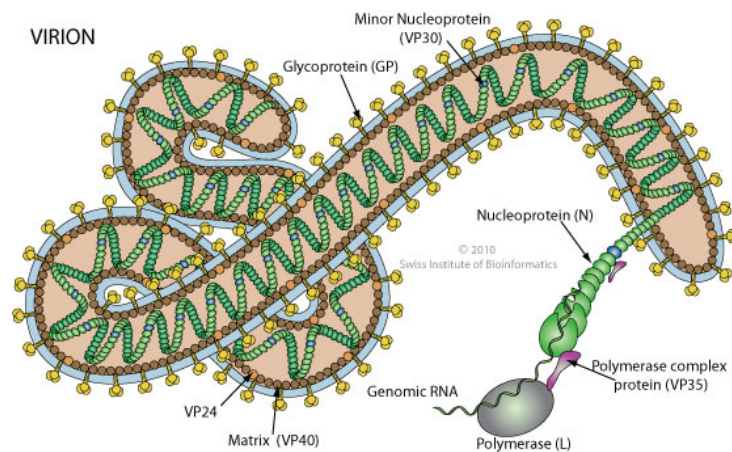
DoD Funded

★ = Host target

◇ = Viral target

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
- More than one MCM needed for successful treatment
- Pathogen and host targets, 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
 - 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