



ANTI-VIRAL AND ANTI-TOXINS PROGRAM

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Anti-toxin Program

- Botulism Anti-toxin
 - Objective: Develop a safe and effective botulism antitoxin(s) to treat botulism intoxication – all seven sero-types
 - BAT approved in March 2013
 - Stockpiling goals achieved
- Anthrax Anti-toxin
 - Objective: Develop safe and effective anthrax antitoxins to treat inhalational anthrax
 - Three approved products:
 - Raxibacumab
 - AIGIV
 - *Obiltoxaximab (Anthim) (Licensed in 2016 March)*
 - Stockpiling preparedness goals achieved



Anti-toxin Program

- Future Focus for Anthrax and Botulism programs
 - Complete post marketing commitments/requirement
 - Sustainment and risk mitigation
- BAA Area of Interest #2.1:
 - 2.1 Development of peptide, small molecule, or other novel compounds, with innovative formulations offering enhanced long-term stability. The candidate must be at TRL-6.



Smallpox Antiviral Program

- Objectives: Provide treatment options (two antiviral drugs with different mechanisms of actions) for individuals symptomatic with smallpox disease.
- Two ongoing programs:
 - ST-246/Tpoxx - PBS
 - CMX-001/Brincidofovir - ARD



Smallpox Antiviral Program

- Future Focus
 - Fulfill requirements
 - Address the need for the second antiviral
 - Complete delivery of entire requirement to the SNS
 - Maintain preparedness
 - Marketplace surveillance utilizing animal models developed in nonclinical program



Filovirus Therapeutics Program

- Objectives: Develop safe and effective products to treat individuals with VHF caused by filovirus infection
- Ongoing programs:
 - EBOLA therapeutics
 - ZMapp (mAb cocktail)
 - Regeneron mAb cocktail
 - BCX4430: adenosine analog (collaboration with NIAID)
 - Marburg therapeutics
 - MR191 (mAb)



Filovirus Therapeutics Program

- Future Focus
 - There are no licensed filovirus therapeutics.
 - There are no Marburg or SEBOV therapeutics in the ARD portfolio and limited candidates in the PHEMCE pipeline.
 - The regulatory path will likely require licensure/approval under the Animal Rule; however, there is currently no accepted FDA animal model for filovirus.
- BAA Area of Interest #2.2:
 - 2.2 Development of antibody treatments and other therapeutic agents for viral hemorrhagic fevers viruses. Program must be at TRL-5 with a lead candidate identified.

