



ANTIVIRAL AND ANTITOXINS PROGRAM

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CBRN Antiviral and Antitoxin Portfolio Overview



Anthrax Antitoxin	Elusys Therapeutics, Inc.	emergent biosolutions™
Botulism Antitoxin		emergent biosolutions™
Smallpox Antiviral	CHIMERIX, INC.	SIGA
Filovirus Antiviral	Mapp Biopharmaceutical	BIOCRYST PHARMACEUTICALS, INC.
		REGENERON
		Mapp Biopharmaceutical



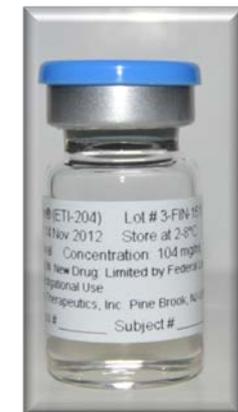


Anthrax Antitoxin Program

Objective: Develop safe and effective anthrax antitoxins to treat inhalational anthrax

Approved products:

- Raxibacumab (Emergent, Formerly GSK) – November 2012
- AIG IV (Anthrasil) (Emergent) – March 2015
- Obiltoxaximab (Anthim[®]) (Elusys) – March 2016



Achieved licensure, procurement for the Strategic National Stockpile



Botulism Antitoxin Program

Objective: Develop safe and effective botulism antitoxin(s) to treat botulism intoxication – all seven serotypes

Approved product

- BAT[®] (Emergent) - March 2013

Achieved licensure, procurement for the Strategic National Stockpile



<http://wjtv.com/2016/06/13/botulism-outbreak-at-yazoo-city-federal-prison/>

<http://www.chicagotribune.com/news/nationworld/ct-botulism-outbreak-nacho-cheese-20170526-story.html>





Antitoxin Program Future Strategy

- Complete post marketing commitments/requirement for licensed products
- Sustainment and risk mitigation
- Consider next-generation botulism and anthrax antitoxin products

BAA Area of Interest #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: Develop safe and effective treatment options (multiple antiviral drugs with different mechanisms of actions) for individuals with smallpox disease

Two ongoing programs:

- ST-246/TPOXX (SIGA) – late stage development
- CMX-001/Brincidofovir (Chimerix)– late stage development

Achieved procurement for the Strategic National Stockpile with TPOXX





Smallpox Antiviral Program Future Strategy

- Address the desire for a second antiviral in the SNS with a different mechanism of action
 - Animal models can assess new candidates
- Address special populations
- Maintain stockpile for preparedness

BAA Area of Interest #2.3

Development of antibody treatments and other therapeutic agents against smallpox. Programs must have evidence for antiviral activity against orthopoxviruses. Programs at higher TRL levels will be given priority.



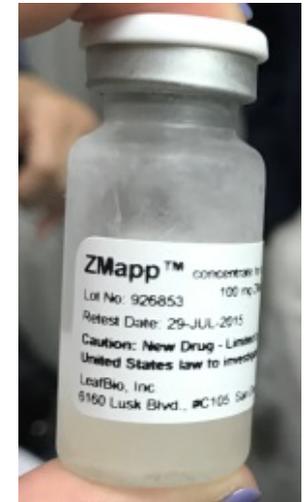


Filovirus Antiviral Program

Objectives: Develop safe and effective treatment options for individuals with viral hemorrhagic fever caused by filovirus infection

Ongoing programs:

- Zaire ebolavirus therapeutics
 - ZMapp™ (Mapp)
 - REGN 3470/71/79 (Regeneron)
 - Galidesivir/BCX4430 (BioCryst): collaboration with NIAID
- Sudan ebolavirus and Marburg virus therapeutics
 - MBP134 (mAb cocktail) (Mapp)
 - MBP091 (single mAb) (Mapp)





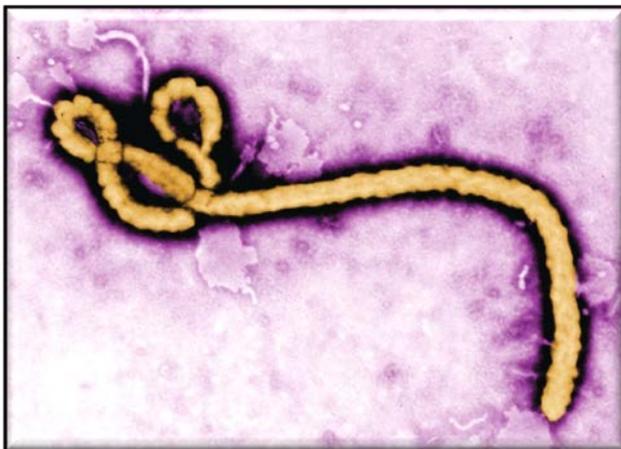
Filovirus Antiviral Program

ORIGINAL ARTICLE

A Randomized, Controlled Trial of ZMapp for Ebola Virus Infection

The PREVAIL II Writing Group, for the Multi-National PREVAIL II Study Team*

N Engl J Med 2016; 375:1448-1456



Zmapp™ continues to be available in West Africa and the US under an expanded access protocol





Filovirus Antiviral Program Future Strategy

- Continue late stage development of filovirus therapeutics candidates towards licensure
 - Licensure/approval under Animal Rule, but no accepted FDA animal model. Establishing regulatory animal models for filovirus
- Project BioShield contracts establish initial preparedness for Ebola therapeutics
- Advance development of Marburg and Sudan therapeutic candidates

BAA Area of Interest #2.2:

Development of antibody treatments and other therapeutic agents for viral hemorrhagic fevers viruses. Programs must be at TRL-5 with a lead candidate identified





Online Resources

<https://www.medicalcountermeasures.gov/home.aspx>

- Portal to BARDA: Register to request a **TechWatch** meeting

<https://www.fbo.gov/> (“FedBizOpps”)

- Official announcements and info for all government contract solicitations

<https://www.usajobs.gov/>

- Join the team!

<https://www.phe.gov/about/BARDA/Pages/default.aspx>

- Program description, information, news, announcements

