



THE EBOLA RESPONSE AND THE PERMITTING EXPERIENCE

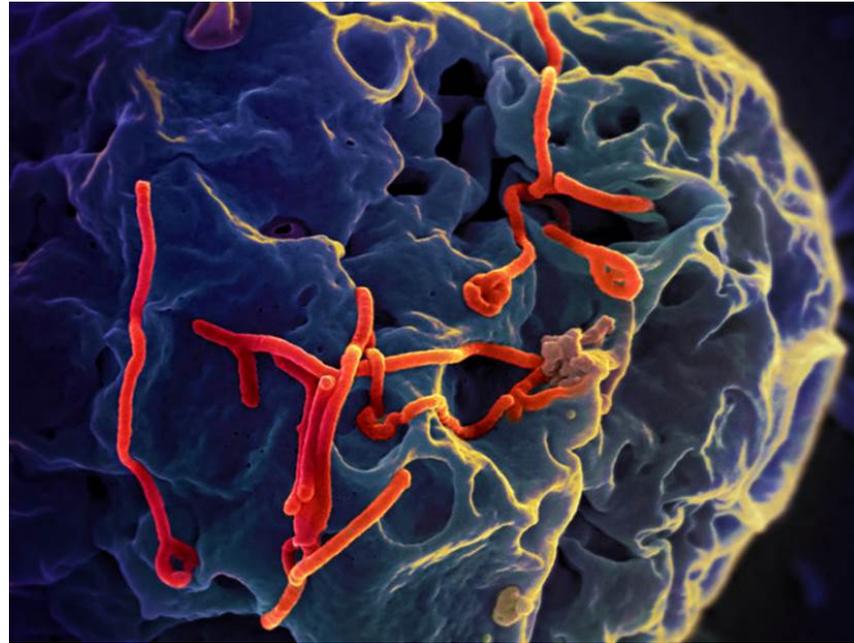
Thomas Warf

September 16, 2015

3rd Annual Import/Export Permit Webcast

Resilient People. Healthy Communities. A Nation Prepared.

BARDA's Ebola Response



BARDA's Ebola Response is Global

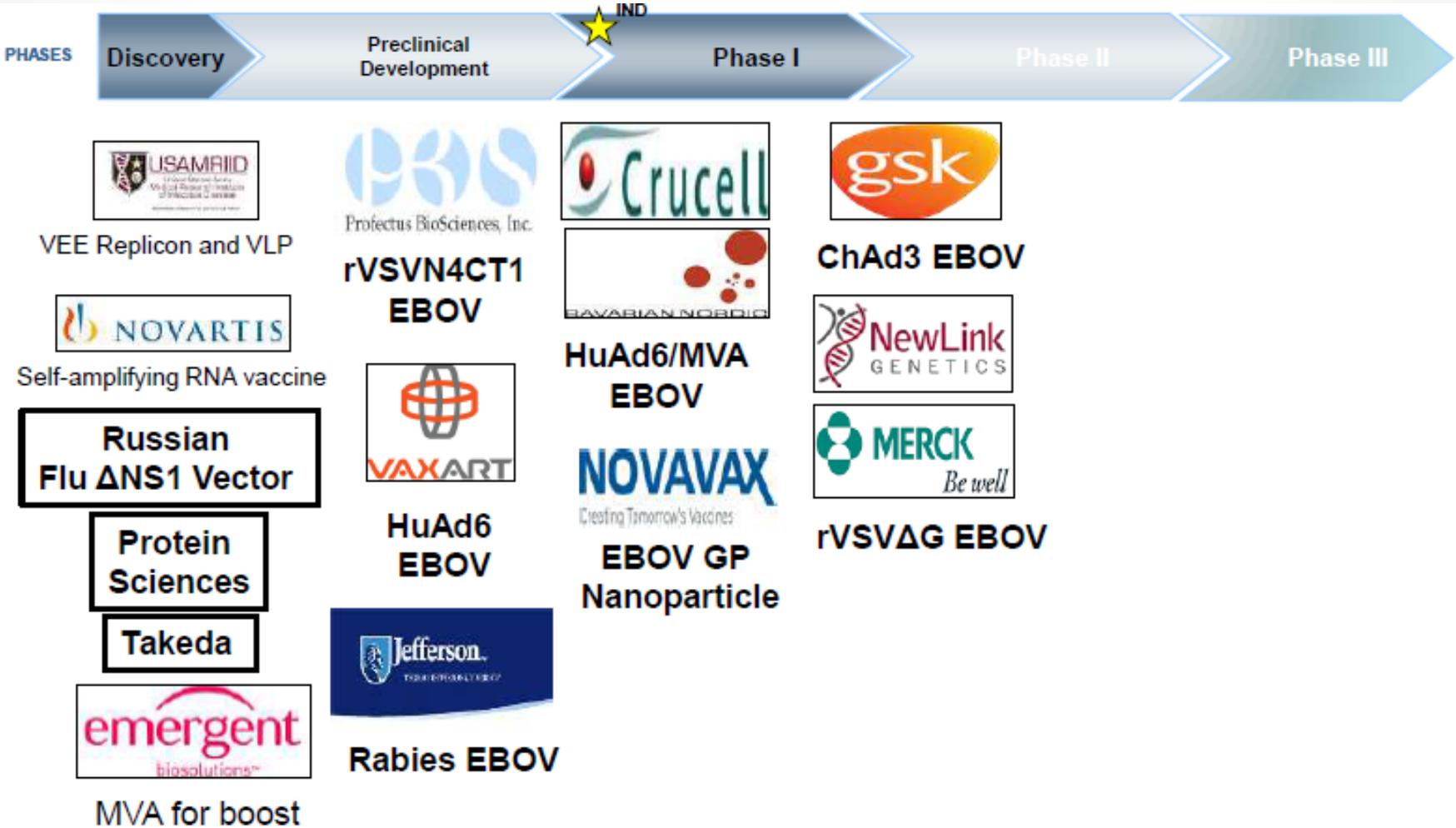


Coordination Partners

- Development
 - NIH
 - DoD
 - BARDA
 - FDA
 - PHAC
 - Industry partners (multiple)
- Evaluation
 - NIH
 - DoD
 - CDC/OID/NCIRD
 - FDA
 - BARDA
 - WHO
 - NGOs
 - Industry partners (multiple)
 - US Treatment Centers/Hospitals
 - Liberia, Sierra Leone, and Guinea regulatory authorities



Ebola Vaccine Landscape



Vaccines – General Considerations

- Pre-exposure prophylaxis (GUP – General Use)
 - Number of doses (prime/boost if necessary)
 - Time to protective immunogenicity
 - Duration of “immunity”
 - Possibility that vaccine will only reduce disease severity (increase survival)
- Post-exposure prophylaxis (PEP)
 - Window of opportunity
 - Dosing relative to GUP for efficacy



rVSVΔG (NewLink)

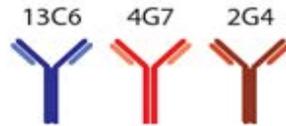
- BioProtection Systems
- VSV with Ebola Zaire GP exchanged for native GP
- IND
- Single dose
- NHP – 100% / GUP (at one week); 50% / PEP (day of exposure)
- Single dose administered for lab accident



Therapeutics



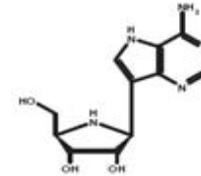
ZMAPP



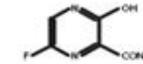
TOYAMA CHEMICAL CO., LTD.
FUJIFILM FUJIFILM Group



BCX4430



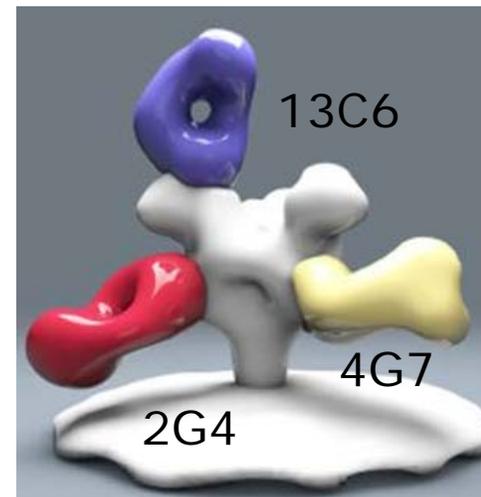
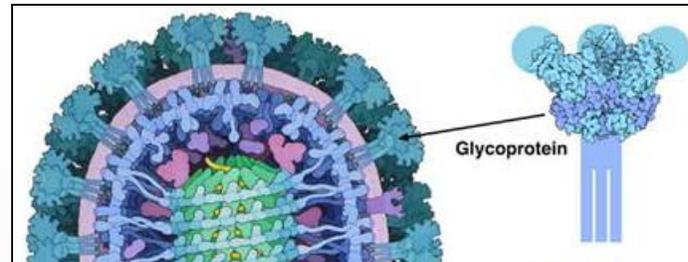
T-705



	ZMAPP	BCX4430	T-705
Companies	LeafBio, Mapp Biopharmaceuticals	Biocryst	Medivector, Toyama Chemical

Therapeutic – mAbs Produced in Tobacco Plants

- ZMapp™ is currently being manufactured under partnership with Leaf/Mapp Bio
 - Manufactured in tobacco plants
 - Three monoclonal antibodies that bind to the Ebola glycoprotein
 - Campaign one is complete – filling week of Dec 8
 - Campaign two is ongoing
 - Total of six campaigns at this scale
 - Product will become available in December and every month after for 5 months
 - Working with DoD and NIAID to support IND enabling studies for evaluation in Phase 1 and Phase 2 in early 2015



Import/Export

Emory University Hospital

Walter Reed Army Institute of Research

University of Nebraska Medical Center

