



*United States Department of*  
**Health & Human Services**  
Office of the Assistant Secretary for Preparedness and Response



# ***Smallpox Vaccines and Antivirals***

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**BARDA Industry Day**  
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*ASPR: Resilient People. Healthy Communities. A Nation Prepared.*

# PHEMCE Smallpox Strategy

- Enough vaccine for every American (300 million doses)
- Primary response – contain the event
- A portion of population is contraindicated

**ACAM2000**



- Individuals with HIV, atopic dermatitis all age ranges including nursing and pregnant mothers
- Enough for 10 M individuals

**MVA**



- Treatment of those symptomatic with disease (1.7 million treatment courses)

**Anti-virals**



- CDC maintains inventory of vaccinia immunoglobulin (VIG)

**Support licensure of MVA and approval of antivirals**



# BARDA Smallpox Strategy



- Develop and provide medical countermeasures (MCMs) for USG response in a smallpox emergency
- MCMs and uses
  - Vaccines to break chain of transmission
    - ACAM2000 (CDC program)
    - APSV (WetVax)
    - MVA
  - Vaccines suitable for special populations
    - MVA
  - Antivirals to treat symptomatic populations
    - ST-246
    - CMX001



# Vaccine Projects



- ACAM2000 (sanofi pasteur; CDC program)
  - Licensed vaccine
    - Tech transfer to new facilities for manufacturing
- IMVAMUNE liquid frozen (Bavarian Nordic)
  - Awarded June 2007 under Project BioShield
  - Deliveries to SNS ongoing under CDC-held pre-EUA
    - HIV, atopic dermatitis (all age ranges and pregnant and nursing women)
  - Phase 3 lot consistency and safety study nearing completion
  - Head-to-head clinical trial with ACAM2000 to support licensure
- MVA freeze-dried (Bavarian Nordic)
  - Awarded 2009 under advanced research and development
  - Phase 2 trial underway
  - Potential long term savings in life-cycle management
    - Longer shelf-life
    - Stored at 2-8°C



# Antiviral Projects



- **SIGA Technologies – ST-246 (tecoviromat)**
  - Awarded February 2011 under Project BioShield
  - Initiated delivery March 2013
  - CDC-held pre-EUA for treatment of individuals symptomatic with smallpox
  - In support of approval
    - Efficacy studies to establish dose in NHP
- **Chimerix – CMX001**
  - Supported under advanced research and development awarded 2011
  - In support of approval
    - Phase 3 study for the prevention of CMV infection in hematopoietic cell transplant patients
    - Phase 2 efficacy for treatment of early stage adenovirus infection
    - Efficacy in RPX model
- **BARDA is working with both sponsors to develop RPX model**



# Resolution of Potential Issues



- Regulatory path
  - IMVAMUNE: CBER workshop September 2011 led to regulatory path for BLA
  - ST-246/CMX001: CDER symposium December 2011 led to path for NDA
- Life-cycle management
  - ARD contract supporting lyophilized formulation of MVA to extend shelf-life and store at 2-8° F
  - ST-246: storage at room temperature, apparent 5-yr stability
  - Potential for cost savings with CMX001 as a commercial product



# Future of Smallpox Program



- Projects are relatively mature
- BARDA does not foresee expanding the program beyond the currently funded projects
  - BARDA continues to perform market surveillance
- Work with our PHEMCE partners to ensure products delivered, or with the potential for delivery, to the SNS are sustainable
- Continue to support licensure or approval of products currently under development