CBRN VACCINE PROGRAMS

Daniel Wolfe, Ph.D.
Health Scientist, Vaccine Branch
CBRN Division

BARDA Industry Day
November 7, 2017
Smallpox and Anthrax Programs

- Mature vaccine programs; licensed products and stockpile capabilities exist
- Program emphasis is enhancing and sustaining the capability
  - Operational use and logistics
    - Extended shelf life
    - Reduction of doses needed for protection
  - Protecting special populations
Viral Hemorrhagic Fever Program

- Ebola (*Zaire ebolavirus*) vaccine program matured rapidly through public and private investments
  - Multiple vaccines in Phase 2 and 3 clinical trials
  - Two Project BioShield awards
- Unmet needs remain for *Sudan ebolavirus* and *Marburg virus*
Smallpox Vaccine Program

Overarching Strategy
Maintain preparedness levels and address the needs of special populations (immunocompromised individuals) during a smallpox emergency

Problem: Current formulations have limited stability; limited capabilities for immunocompromised individuals

• Near-term objectives:
  1. Maintain stockpile of IMVAMUNE with transition to lyophilized formulation
  2. Complete activities for licensure of liquid frozen and lyophilized IMVAMUNE

• Future objectives:
  1. Transition lyophilized IMVAMUNE to SNS for maintenance

Note: No additional vaccine development programs are planned for smallpox
Anthrax Vaccine Program

Overarching Strategy
Expand BioThrax utility and pursue licensure of next generation vaccine(s) that provide equivalent protection with fewer doses

Problem: Current Anthrax vaccine requires 3 doses; only for 18-65 year olds
- Near-term objectives
  1. Enhance utility of BioThrax and AV7909
  2. Evaluate Protective Antigen-based candidates
- Future objectives
  1. Achieve licensure of AV7909
  2. Assess potential single-dose vaccines

Note: Future investments will only include single-dose vaccines but no proposals will be sought at this time
Enhance protective capabilities for Ebola while establishing a portfolio of Sudan and Marburg candidates to be evaluated in clinical studies

Problem: No licensed vaccines are available; pipeline is limited for Sudan and Marburg

- Near-term objectives
  1. Achieve licensure for Ebola vaccine(s)
  2. Establish a portfolio of Sudan and Marburg vaccines

- Future objectives
  1. Evaluate utility of monovalent versus multivalent approaches
  2. Down-select Sudan/Marburg candidates to continue towards licensure
Future Directions

Key Gaps and Potential Paths Forward

1. Address existing gaps in VHF requirements (Sudan and Marburg) including:
   a) Candidate development
   b) Animal models
   c) Critical assays

2. Enhance the utility of current vaccines; operational use, special populations, etc.

3. Identify opportunities in which vaccines can be used to target antimicrobial resistant threats:
   a) Reduce morbidity and mortality
   b) Reduce the prevalence of resistant serotypes/strains
   c) Reduce the need for antibiotics

Note: Monitor FedBizOpps (Federal Business Opportunities) for issuance of new BAAs or amendments to current BAA
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

ASPR: Saving Lives...Protecting America