

Chemical Biological Medical Systems (CBMS)–Prophylaxis

INVESTMENT COMPONENT

Modernization

Recapitalization

Maintenance

MISSION

Delivers safe, effective, and robust medical products that protect U.S. forces against validated chemical, biological, radiological, and nuclear (CBRN) threats by applying government and industry best practices to develop or acquire Food and Drug Administration (FDA) approved products.

DESCRIPTION

Chemical Biological Medical Systems (CBMS)–Prophylaxis consists of eight components:

Anthrax Vaccine Absorbed (AVA):

AVA is the only FDA-licensed anthrax vaccine in the United States that provides protection against cutaneous, gastrointestinal and aerosol infection by battlefield exposure to Bacillus anthracis.

Recombinant Plague Vaccine (rF1V):

rF1V is a highly purified polypeptide produced from bacterial cells transfected with a recombinant vector from Yersinia pestis to prevent pneumonic plague.

Recombinant Botulinum Toxin Vaccine A/B (rBV A/B):

rBV A/B is comprised of nontoxic botulinum toxin heavy chain fragments of serotypes A and B formulated with an aluminum hydroxide adjuvant and delivered intramuscularly prior to potential exposure to botulinum toxin.

Bioscavenger (BSCAV):

The BSCAV program fills an urgent capability gap in the warfighter’s defense against nerve agents by development of a nerve agent prophylactic that significantly reduces or eliminates the need for post-exposure antidotal therapy.

Smallpox Vaccine System (SVS):

The SVS Program provides both the ACAM2000™ smallpox vaccine and the Vaccinia Immune Globulin, Intravenous (VIGIV) to vaccinate and

protect the warfighter from potential exposure to smallpox. Both products are FDA approved.

Filovirus Vaccine (Vac Filo):

The Vac Filo program covers an essential capability gap for protecting warfighters against aerosolized filovirus for which there is no current therapeutic. Target filovirus strains include Ebola Sudan, Ebola Zaire, and Marburg.

Ricin Vaccine (Vac Ricin): The Vac Ricin program will develop a vaccine against the A and B chains of this threat agent and validate performance against aerosolized material.

Western, Eastern Venezuelan Equine Encephalitis Vaccine (Vac WEVEE):

The Vac WEVEE program will develop a vaccine against three arboviruses with the goal of a single product protecting against all three threats.

SYSTEM INTERDEPENDENCIES

None

PROGRAM STATUS

- **1QFY12:** rBV A/B consistency lot manufacturing began
- **2QFY12:** Vac Ricin and Vac WEVEE Medical Device Directive (MDD)
- **3QFY12:** BSCAV MDD
- **3QFY12:** rF1V manufacturing process validation completed

PROJECTED ACTIVITIES

- **2QFY13:** Vac Ricin and Vac WEVEE Milestone A
- **3QFY13:** rFV1 Milestone C
- **4QFY13:** rBV A/B Milestone C
- **4QFY13:** rF1V Phase 3 clinical trial begins
- **4QFY13:** rBV A/B Milestone C
- **1QFY15:** rBV rF1V Initial Operational Capability (IOC)

ACQUISITION PHASE

Technology Development

Engineering & Manufacturing Development

Production & Deployment

Operations & Support

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FOREIGN MILITARY SALES

Plague Vaccine:

Canada, United Kingdom

CONTRACTORS

AVA:

Emergent BioSolutions (Bioport)
(Lansing, MI)

rF1V:

DynPort Vaccine (Frederick, MD)

rBV A/B:

DynPort Vaccine (Frederick, MD)

BSCAV:

In source selection

SVS:

Acambis PLC (Cambridge, MA)
Cangene, Corp. (Winnipeg, Manitoba,
Canada)

