

Chemical Biological Medical Systems-Propylaxis

INVESTMENT COMPONENT

Modernization

Recapitalization

Maintenance



MISSION

Delivers safe, effective, and robust medical products that protect U.S. forces against validated CBRN threats. CBMS applies government and industry best practices to develop or acquire Food and Drug Administration (FDA)-approved products within rigorously managed cost, schedule and performance constraints.

DESCRIPTION

Chemical Biological Medical Systems-Propylaxis consists of the following components:

Anthrax Vaccine Absorbed (AVA):

The Anthrax Vaccine Absorbed is the only FDA-licensed anthrax vaccine in the United States that provides cutaneous, gastrointestinal, and aerosol infection by battlefield exposure to *Bacillus anthracis*.

Recombinant Plague Vaccine (rF1V):

The Recombinant Plague Vaccine is a highly purified polypeptide produced from non-sporeforming bacterial cells transfected with a recombinant vector from *Yersinia pestis* to prevent pneumonic plague.

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

The Recombinant Botulinum Bivalent Vaccine is comprised of nontoxic botulinum toxin heavy chain (Hc) fragments of serotypes A and B formulated with an aluminum hydroxide adjuvant and delivered intramuscularly prior to potential exposure to botulinum toxins.

Bioscavenger (BSCAV):

The Bioscavenger program fills an urgent capability gap in 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 Smallpox Vaccine System 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.

SYSTEM INTERDEPENDENCIES

None

PROGRAM STATUS

- **1QFY11:** rF1V manufacture scale-up and validation ongoing
- **1QFY11:** BSCAV In Process Review
- **3QFY11:** Plague Vaccine completes Phase 2b clinical trial volunteer vaccinations
- **4QFY11:** rF1V large-scale manufacturing validation
- **4QFY11:** rBV A/B large-scale manufacturing process validation complete
- **Current:** Smallpox and AVA in sustainment

PROJECTED ACTIVITIES

- **1QFY12:** rBV A/B consistency lot manufacturing begins
- **1QFY12:** BSCAV Milestone Decision
- **2QFY12:** rBV A/B Milestone C Decision
- **3QFY12:** rF1V manufacturing process validation complete
- **4QFY12:** rF1V Phase 3 clinical trial begins

ACQUISITION PHASE

Technology Development

Engineering and Manufacturing Development

Production and Deployment

Operations and Support

Chemical Biological Medical Systems-Prophylaxis

FOREIGN MILITARY SALES

None

CONTRACTORS

AVA:

Emergent BioSolutions (Bioport)
(Lansing, MI)

rF1V:

DynPort Vaccine (Frederick, MD)

rBV A/B:

DynPort Vaccine (Frederick, MD)

BSCAV:

To be determined

SVS:

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

