

Chemical Biological Medical Systems–Prophylaxis

INVESTMENT COMPONENT

Modernization

Recapitalization

Maintenance



MISSION

Provides the warfighter with safe, robust, and affordable medical countermeasures against a broad spectrum of chemical, biological, radiological, and nuclear (CBRN) threats.

DESCRIPTION

Chemical Biological Medical Systems–Prophylaxis consists of the following components:

Anthrax Vaccine Absorbed (AVA):

The Anthrax Vaccine Absorbed is the only Food and Drug Administration (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 II (BSCAV II):

The Bioscavenger program fills an urgent capability gap in the warfighter's defense against nerve agents by development of a nerve agent prophylactic by rendering protective equipment, in theory, unnecessary. Bioscavenger Increment II consists of Protexia®, recombinant human butyrylcholinesterase produced in the milk of transgenic goats and modified with polyethylene glycol.

Smallpox Vaccine System (SVS):

The Smallpox Vaccine System (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.

SYSTEM INTERDEPENDENCIES

None

PROGRAM STATUS

- **1QFY09:** Plague Vaccine Phase 2a clinical study complete; Plague Vaccine manufacture scale-up and validation initiated; rBV Phase 1b clinical study complete; rBV Phase 2 clinical study initiated
- **1QFY10:** Bioscavenger Phase 1 clinical study complete; Bioscavenger large-scale manufacturing, process qualification, and validation begins
- **3QFY10:** Plague Vaccine Phase 2b clinical study begins
- **4QFY10:** rBV Phase 2 clinical study complete
- **Current:** Smallpox and AVA in Sustainment

PROJECTED ACTIVITIES

- **4QFY11:** rBV A/B large-scale manufacturing process validation complete
- **2QFY13:** rBV A/B Milestone C decision

ACQUISITION PHASE

Technology Development

Engineering & Manufacturing Development

Production & Deployment

Operations & Support

Chemical Biological Medical Systems—Prophylaxis

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 II:

PharmAthene (Annapolis, MD)

SVS:

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

