



DVC Case Study

CHEMICAL DEFENSE: CSC DEVELOPS TREATMENT TO PROTECT ARMED FORCES FROM NERVE AGENT ATTACKS

BioScavenger treats exposure to nerve agents because it "scavenges" the nerve agents in the bloodstream before they have a chance to cause any ill effects.

DynPort Vaccine Company LLC, a CSC company, has developed products to protect against biowarfare agents since 1997. DVC is now breaking new ground by developing a treatment for chemical agent attacks. The treatment, nicknamed "BioScavenger," uses human plasma-derived butyrylcholinesterase to counteract the effects of chemical nerve agents such as sarin, soman and VX.

DVC, a biopharmaceutical company dedicated to the development and licensure of safe and efficacious biodefense vaccines for the U.S. Department of Defense and civilian populations, has comprehensive experience in the advanced development of biodefense biologics, including live attenuated vaccines, recombinant vaccines, therapeutics, therapeutic polyclonal antibodies and alternative vaccine delivery systems.

MIT, BAXTER AND CSC: TEAMING TO DEVELOP A TREATMENT

The client for this contract is the Department of Defense (DoD) Medical Identification and Treatment Systems (MITS) Joint Product Management Office. MITS manages the development and fielding of products used to diagnose and treat chemical and biological agent warfare exposure in the U.S. military personnel.

MITS products range from specific hardware devices that will enable medical personnel to diagnose specific biological warfare agent exposure, to drugs that will prevent or mitigate the actions of chemical or biological agents.

DVC teamed with Baxter Healthcare Corporation to take proof-of-concept studies conducted by the DoD forward into advanced development. The DVC team currently handles project management and the Phase 1 clinical trial. Baxter is performing manufacturing, regulatory interactions with the U.S. Food and Drug Administration (FDA) and nonclinical testing.

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Answers for Success



BEATING CHEMICAL AGENT ATTACKS

The treatment, called BioScavenger, works in a different manner than a vaccine. Vaccines trigger an immune response, while a chemical agent treatment must inhibit the chemical. BioScavenger treats exposure to nerve agents because it "scavenges" the nerve agents in the bloodstream before they have a chance to cause any ill effects. In untreated individuals, certain nerve agents act by binding to proteins involved in the transmission of impulses between nerves, and between nerves and muscles. This results in the failure of critical bodily functions, leading to severe debilitation and death. In treated individuals who have been exposed to the nerve agents, BioScavenger attaches to the nerve agents before they can attach to the proteins involved in the nerve-to-nerve and nerve-to-muscle impulses. It is able to do so because it is very similar in form and function to the proteins involved in nerve impulse transmission. Timely administration of BioScavenger therefore limits or prevents the effects of the nerve agent by removing them from the bloodstream.

PROVIDING A TREATMENT FOR THE DEPARTMENT OF DEFENSE

While BioScavenger works differently from the vaccines that DVC develops, the FDA approval process is similar. After process development and initial production, BioScavenger went through nonclinical testing to show that the treatment was safe before it could be tested in humans. After nonclinical testing, an Investigational New Drug application was filed with the FDA, and clinical studies began.

A DEVELOPMENT WINDSPRINT

The DVC team is on a very aggressive schedule developing and testing BioScavenger. Phase 1 clinical trials were completed in April 2008 and the clinical study reports are currently being developed. Following the Phase 1 clinical trial, DVC hopes to obtain additional funding to advance the product to licensure. Once the treatment has gained licensure, it will be used to protect military personnel who may be exposed to nerve agents or who have suffered an attack.

In addition to DOD use, once approved the FDA, BioScavenger could potentially be used as treatment in the civilian population in the case of a chemical terrorist attack or to help protect first responders.

This product is currently under clinical investigation and has not been licensed by the FDA.