

# Dealdoc

Contract service and supply agreement for smallpox antivirals using ST-246

SIGA Technologies

Department of Health and Human Services

Oct 13 2010

## Contract service and supply agreement for smallpox antivirals using ST-246

Companies: SIGA Technologies

Department of Health and Human Services

Announcement date: Oct 13 2010

**Deal value, US\$m:** 2800.0 : sum of contract value

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- Contract

### **Details**

Announcement date:
Oct 13 2010
Biotech
Government
Therapy areas:
Infectives » Viral
Biodefense
Vaccines

Deal components: Contract service Supply

Stages of development: Marketed

Geographic focus: North America » United States

## **Financials**

**Deal value, US\$m:** 2800.0 : sum of contract value **Upfront, US\$m:** 500.0 : initial contract value

Milestones, US\$m: 2300.0 : additional revenues if all options exercised

## **Termsheet**

HHS to make an award to SIGA of a contract to deliver 1.7 million courses of its smallpox antiviral for the Strategic National Stockpile

The contract is based ST-246® drug

The award relates to a Request for Proposal issued by HHS's Biomedical Advanced Research and Development Authority (RFP-BARDA-09-35).

The base contract, if finalized, is expected to generate revenues of approximately \$500 million, and the entire contract, if all options are exercised, is expected to generate revenues of approximately \$2.8 billion.

### **Press Release**

16 May 2011

Protest Filed Against BARDA Over Smallpox Antiviral Biodefense Contract BARDA to Defend Its Decision

Contract Work Suspended During Protest

NEW YORK, May 15, 2011 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (Nasdaq:SIGA), a company specializing in the development of pharmaceutical agents to fight biowarfare pathogens, announced today that the Biomedical Advanced Research and Development Authority (BARDA) of the United States Department of Health and Human Services (HHS) has informed SIGA that Chimerix, Inc. has filed a post-award

protest against BARDA with respect to the Government's contract with SIGA to deliver smallpox antiviral ST-246® to the Strategic National Stockpile. Work under the contract will be suspended until further notice pursuant to the applicable protest rules. SIGA's previous HHS contracts for advanced development of ST-246® for therapeutic use, intravenous formulation of the drug and post-exposure prophylaxis are unaffected by the protest, as is SIGA's work on commercial-scale validation of the oral adult formulation.

Chimerix filed its protest with the U.S. Government Accountability Office (GAO), which has the authority to decide protests concerning the procedures under which a contract is awarded. BARDA has indicated to SIGA that the Government intends to defend its decision to contract with SIGA. GAO protests are generally resolved in no more than 100 days.

Dr. Eric A. Rose, SIGA's Chairman and Chief Executive Officer, commented, "We are undaunted by what we believe will be a brief delay in starting work on this important bioterrorism defense contract and will make every effort to deliver our smallpox antiviral drug to the Strategic National Stockpile as soon as possible. SIGA is uniquely positioned to assist the Government in its efforts to protect our nation against the threat of smallpox, and we are confident that the Government's decision to award this contract to SIGA will be upheld as entirely proper."

SIGA's groundbreaking drug, ST-246®, is an oral therapeutic agent active against orthopoxviruses including smallpox. While no longer present naturally in the environment, smallpox is considered a formidable bioterrorism threat, and there is currently no FDA-approved treatment for symptomatic individuals. ST-246® works by blocking the ability of the virus to spread to other cells, preventing it from causing disease. The FDA has designated ST-246® for "fast-track" status, creating a path for expedited FDA review and eventual regulatory approval.

Further information concerning ST-246® and the BARDA contract are available in the separate press releases issued by SIGA and BARDA on May 13, 2011.

About SIGA Technologies, Inc.

In the United States and around the world, populations face a serious but unmet need for drugs to protect against potentially catastrophic emerging viral pathogens and biological weapons of mass destruction. SIGA Technologies, Inc. is a pharmaceutical company specializing in the development and commercialization of therapeutic solutions for some of the most lethal disease-causing pathogens in the world, including smallpox, Ebola, dengue, Lassa fever and other dangerous viruses. Our business is to discover, develop and commercialize drugs to prevent and treat these high-priority threats. Our mission is to disarm dreaded viral diseases and create robust, modern biodefense countermeasures. For more information about SIGA, please visit SIGA's web site at www.siga.com.

#### 13 October 2010

SIGA SELECTED FOR THE PROCUREMENT OF SMALLPOX ANTIVIRAL DRUG FOR THE STRATEGIC NATIONAL STOCKPILE AND RESPONDS TO SMALL BUSINESS SIZE PROTEST

New York, New York, October 13, 2010 -- SIGA Technologies, Inc. (NASDAQ: SIGA), a company specializing in the development of pharmaceutical agents to combat bio-warfare pathogens, announced today that the U.S. Department of Health and Human Services (HHS) has announced HHS's intention to make an award to SIGA of a contract to deliver 1.7 million courses of its smallpox antiviral for the Strategic National Stockpile, pending resolution of issues relating to SIGA's status with the Small Business Administration. The award relates to a Request for Proposal issued by HHS's Biomedical Advanced Research and Development Authority (RFP-BARDA-09-35). The base contract, if finalized, is expected to generate revenues of approximately \$500 million, and the entire contract, if all options are exercised, is expected to generate revenues of approximately \$2.8 billion.

The Small Business Administration issues noted above derive from HHS notification to SIGA that Chimerix, Inc. (Chimerix) has filed a small business size protest against SIGA after receiving pre-award notice from HHS that Chimerix was an unsuccessful bidder. HHS designated the proposed contract as a small business set-aside at the time of the original solicitation in March 2009. SIGA intends to respond promptly to the Small Business Administration concerning Chimerix's protest.

Dr. Eric A. Rose, SIGA's Chairman and Chief Executive Officer, stated, "We are very proud that HHS has selected our groundbreaking drug, ST-246®, for this important acquisition and believe that SIGA appropriately qualified as a small business concern for this procurement."

Details of HHS's March 11, 2009 request for proposal and subsequent amendments can be found on the Federal Business Opportunities website at www.fbo.gov/index?s=opportunity&mode=form&id=61e7acbe316f2c52bfe0cc8c4b4852fd&tab=core&\_cview=1. SIGA expects the proposed contract to be executed following resolution of the Chimerix protest; however, there can be no assurance concerning the outcome of the small business size protest.

About SIGA Technologies, Inc.

SIGA Technologies is applying viral and bacterial genomics and sophisticated computational modeling in the design and development of novel products for the prevention and treatment of serious infectious diseases, with an emphasis on products for biological warfare defense. SIGA believes that it is a leader in the development of pharmaceutical agents to fight potential bio-warfare pathogens. SIGA has antiviral programs targeting smallpox and other Category A pathogens, including arenaviruses (Lassa fever, Junin, Machupo, Guanarito, Sabia, and lymphocytic choriomeningitis), dengue virus, and the filoviruses (Ebola and Marburg). For more information about SIGA, please visit SIGA's web site at

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# Filing Data

Not available.

# Contract

Not available.