

EMERGENT

Emergent BioSolutions Awarded 10-Year HHS Contract to Deliver ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live) Into the Strategic National Stockpile

September 3, 2019

- Reaffirms ACAM2000 as a key component of the U.S. preparedness stance against the threat of smallpox as a biologic weapon
- Supports the government's continued efforts and long-term strategy to maintain sufficient quantities of smallpox vaccine to provide a response capability to vaccinate every American during a smallpox emergency

GAITHERSBURG, Md., Sept. 03, 2019 (GLOBE NEWSWIRE) -- In support of the U.S. government's policy to maintain a stockpile to be able to protect every American from smallpox, Emergent BioSolutions Inc. (NYSE: EBS) today announced a contract award by the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS) valued at approximately \$2 billion over 10 years for the continued supply of ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live) into the U.S. Strategic National Stockpile (SNS). The actual number of ACAM2000 doses to be procured is dependent on certain timing and tiered-pricing terms that are subject to the discretion of ASPR. ACAM2000 vaccine is the only vaccine licensed by the U.S. Food and Drug Administration (FDA) for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection.

Robert G. Kramer Sr., president and chief executive officer of Emergent BioSolutions, stated, "Emergent applauds the U.S. government's continued focus on national security demonstrated through its long-term stockpiling strategy, which ensures a sustainable supply of critical medical countermeasures such as ACAM2000 vaccine, and its investment in a stable domestic manufacturing infrastructure to help protect the U.S. population against smallpox in the event of an attack. Awarded on the heels of our recently announced contract to supply our Vaccinia Immune Globulin Intravenous or VIGIV therapeutic, this contract solidifies our role as a solutions provider supporting the government's smallpox preparedness efforts and helping fulfill their needs with our smallpox franchise. It is one of the unique ways we live out our mission – to protect and enhance life."

This contract for the procurement of ACAM2000 vaccine consists of a one-year base period of performance, valued at approximately \$170 million, and nine option years. The company expects to deliver into the SNS a majority of the doses under the base year by year end 2019, the effect of which is already included in the company's full year financial forecast, which was recently reaffirmed on August 1. This multiple year contract is intended to support the replacement of the smallpox vaccine stockpile and follows the conclusion of a prior 10-year, \$425 million contract to establish domestic warm-base manufacturing capabilities and procure smallpox vaccines issued by the U.S. government April 1, 2008. ACAM2000 continues to be one of the lowest priced vaccines that the U.S. government procures across all relevant vaccine programs.

Abbey Jenkins, SVP and vaccines business unit head at Emergent, said, "The U.S. government's long-term commitment to smallpox preparedness and the role ACAM2000 vaccine serves have been reinforced in guidance and legislation within the last two decades. As the only smallpox vaccine administered in one dose, ACAM2000 vaccine remains the primary smallpox vaccine for general population use in the event of a smallpox emergency. We are proud of our employees, especially those at our Canton, Massachusetts and Rockville, Maryland locations, who are dedicated to producing this critical countermeasure. Because of their work, Emergent stands ready to continue our partnership with HHS in fulfilling this contract."

Smallpox vaccines have been foundational to the U.S. government's preparedness and response efforts as documented in the Project BioShield Act of 2004 (<https://www.govtrack.us/congress/bills/108/s15/text>) and its predecessor the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (<https://www.congress.gov/bill/107th-congress/house-bill/3448>). In 2015, the Centers for Disease Control and Prevention (CDC) issued clinical guidance for smallpox vaccine use in a post-event scenario (<https://www.cdc.gov/mmwr/pdf/rr/rr6402.pdf>) stating that surveillance and containment activities including vaccination with replication-competent smallpox vaccine such as ACAM2000 will be the primary response strategy for achieving epidemic control. Persons exposed to smallpox virus are at high risk for developing and transmitting smallpox and should be vaccinated with a replication-competent smallpox vaccine unless severely immunodeficient.

Contract 75A50119C00052 is funded by the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services.

About ACAM2000 Vaccine

ACAM2000 vaccine is the primary smallpox vaccine designated for use in a bioterrorism emergency, with almost 269 million doses having been supplied to the U.S. Strategic National Stockpile. ACAM2000 vaccine is also licensed in Australia and Singapore and is currently stockpiled both in the U.S. and internationally.

ACAM2000 is indicated for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection.

The labeling for ACAM2000 contains a contraindication for individuals with severe immunodeficiency. Severe localized or systemic infection with vaccinia (progressive vaccinia) may occur in persons with weakened immune systems. Individuals with severe immunodeficiency who are not expected to benefit from the vaccine should not receive ACAM2000. The risk for experiencing severe vaccination complications must be weighed against the risk for experiencing a potentially fatal smallpox infection.

Additionally, there are warnings and precautions for myocarditis, pericarditis, encephalitis, encephalomyelitis, encephalopathy, generalized vaccinia, severe vaccinia skin infections, erythema multiforme major (including Stevens-Johnson Syndrome), eczema vaccinatum resulting in permanent sequelae or death, ocular complications; blindness and fetal death have occurred following either primary vaccination or revaccination with live vaccinia virus smallpox vaccines. These risks are increased in certain individuals and may result in severe disability, permanent neurological sequelae and/or death.

Please see full [Prescribing Information](#) for full boxed warning and additional safety information.

About Smallpox

Smallpox is a highly contagious disease caused by the variola virus, a member of the Orthopox virus family. According to the CDC, it is one of the most devastating diseases with a mortality rate as high as 30%. Smallpox is classified by the CDC as a Category A bioterrorism agent and the U.S. government continues to invest in countermeasures to protect the nation from this threat. Governments around the world are also taking precautionary measures to be ready to deal with a potential smallpox outbreak.

About Emergent BioSolutions

Emergent BioSolutions Inc. is a global life sciences company seeking to protect and enhance life by focusing on providing specialty products for civilian and military populations that address accidental, deliberate, and naturally occurring public health threats. We aspire to be a Fortune 500 company recognized for protecting and enhancing life, driving innovation, and living our values. Additional information about the company may be found at www.emergentbiosolutions.com. Find us on LinkedIn and follow us on Twitter @emergentbiosolu and Instagram @life_at_emergent.

Safe Harbor Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements regarding the total potential realizable value of the contract, the timing of ACAM2000 deliveries and their impact on the company's full year financial forecast, and any other statements containing the words "believes," "expects," "anticipates," "intends," "plans," "estimates" and similar expressions, are forward-looking statements. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause the company's actual results to differ materially from those indicated by such forward-looking statements, including the availability of funding for our U.S. government grants and contracts, decisions by HHS to exercise options under the contract and our manufacturing capabilities and strategy. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.

Investor Contact:

Robert G. Burrows
Vice President, Investor Relations
240-631-3280
BurrowsR@ebsi.com

Media Contact:

Lynn Kieffer
Vice President, Corporate Communications
240-631-3391
KiefferL@ebsi.com

ⁱ CDC. Clinical Guidance for Smallpox Vaccine Use in a Postevent Vaccination Program. MMWR Recomm Rep 2015;64 (No. 2).



Source: Emergent BioSolutions