Update: Emergent BioSolutions Awarded $250+ Million in Contract Modifications to Supply U.S. Government with Four Critical Medical Countermeasure Products

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GAITHERSBURG, Md., July 02, 2024 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) today announced it has received more than $250 million in contract modifications from the Administration for Strategic Preparedness and Response (ASPR) at the United States Department of Health and Human Services (HHS), to deliver millions of doses of four medical countermeasures (MCMs). These contract modifications will help ensure continued supply/stockpiling of critical MCMs to address biological threats and emergencies against anthrax, smallpox and botulism.

The four awards include:

- A contract modification valued at $30.0 million to supply CYFENDUS® (Anthrax Vaccine Adsorbed, Adjuvanted) this year. Previously known as AV7909, CYFENDUS® is a two-dose anthrax vaccine for post-exposure prophylaxis use in individuals 18 years of age and older. This new procurement funding is from Emergent's existing 10-year contract with the Biomedical Advanced Research and Development Authority (BARDA) under contract (HHSO100201600030C).
- A contract modification valued at $99.9 million to supply ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) this year. ACAM2000® is licensed for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection. This is under Emergent's existing 10-year contract with ASPR (75A50119C00071).
- Two new contract options totaling $122.9 million have been awarded to supply ASPR with VIGIV® [Vaccinia Immune Globulin Intravenous (Human)] drug product, and BAT® [Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) – (Equine)] drug substance and delivery of drug production this year and into early 2025. VIGIV® is used for treatment of complications to smallpox vaccination, while BAT® is indicated for the treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients. Both are under Emergent's existing 10-year contracts with ASPR (75A50119C00037 and 75A50119C00075, respectively).

"Securing multiple contract modifications with the U.S. government for our medical countermeasure products affirms that Emergent is a trusted biodefense partner, and also demonstrates the strength and sustainment of our product portfolio," said Paul Williams, senior vice president, products head at Emergent. "As part of our longstanding public-private partnership, we stand ready to continue fulfilling preparedness priorities and stockpiling efforts in the U.S. and abroad."

Emergent specializes in developing, manufacturing, and supplying MCMs for military and civilian populations. The types and quantities of products that should be maintained in a stockpile will depend on the population requiring protection, the products available for meeting the threat, as well as government resources and priorities.

About CYFENDUS® (Anthrax Vaccine Adsorbed, Adjuvanted)

Indication

CYFENDUS® (Anthrax Vaccine Adsorbed, Adjuvanted) is a vaccine indicated for post-exposure prophylaxis of anthrax disease following suspected or confirmed exposure to *Bacillus anthracis* in persons 18 through 65 years of age when given with recommended antibacterial drugs.

The efficacy of CYFENDUS® vaccine for post-exposure prophylaxis (PEP) is based solely on studies in animal models of inhalational anthrax.

Important Safety Information

Contraindication: Do not take CYFENDUS® vaccine if you are allergic to CYFENDUS® vaccine, BioThrax® (Anthrax Vaccine Adsorbed) or any ingredient of the vaccine.

Allergic reactions: Appropriate medical treatment and supervision must be available after receiving CYFENDUS® vaccine to manage possible serious allergic reactions. Get medical help right away if you have any symptoms of a serious allergic reaction.

Altered Immunocompetence: Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response to CYFENDUS® vaccine.

Pregnancy: CYFENDUS® vaccine can cause fetal harm when administered to a pregnant individual. Before getting CYFENDUS® vaccine, tell your healthcare provider if you may be pregnant, plan to get pregnant soon, or are nursing a baby.

Adverse reactions: The most common adverse reactions reported were tenderness, pain, warmth, itching, swelling, redness, bruising, arm motion limitations, muscle aches, tiredness, headache, and fever.

U.S. Prescribing Information
The full Prescribing Information for CYFENDUS® vaccine can be found here.

About ACAM2000® (Smallpox (Vaccinia) Vaccine, Live)
ACAM2000® is the primary smallpox vaccine designated for use in a bioterrorism emergency, with doses having been supplied to the U.S. Strategic National Stockpile. ACAM2000® 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 vaccinial 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 sequalae and/or death.

Please see full Prescribing Information for full Boxed Warning and additional safety information.

About VIGIV® [Vaccinia Immune Globulin Intravenous (Human)]
(See full prescribing information for complete boxed warning)

WARNING: INTERACTIONS WITH GLUCOSE MONITORING SYSTEMS
Blood glucose measurement in patients receiving Vaccinia Immune Globulin Intravenous (Human) (VIGIV) must be done with a glucose-specific method (monitor and test strips) to avoid interference by maltose contained in VIGIV. Maltose in IGIV products may give falsely high blood glucose levels in certain types of blood glucose testing systems (for example those based on the GDH-PQQ or glucose-dye-oxidoreductase methods) resulting in inappropriate administration of insulin and life-threatening hypoglycemia. Cases of true hypoglycemia may go untreated if the hypoglycemic state is masked by falsely elevated glucose readings.

Carefully review the product information of the blood glucose testing system, including that of the test strips, to determine if the system is appropriate for use with maltose-containing parenteral products.

VIGIV (vaccinia immune globulin intravenous, human) is an Immune Globulin (Human), 5% Liquid, indicated for the treatment and/or modification of the following conditions: eczema vaccinatum; progressive vaccinia; severe generalized vaccinia; vaccinia infections in individuals who have skin conditions such as burns, impetigo, varicella-zoster, or poison ivy; or in individuals who have eczematous skin lesions because of either the activity or extensiveness of such lesions; and aberrant infections induced by vaccinia virus that include its accidental implantation in eyes (except in cases of isolated keratitis), mouth, or other areas where vaccinia infection would constitute a special hazard.
VIGIV is not considered to be effective in the treatment of postvaccinial encephalitis.

VIGIV is contraindicated in: isolated vaccinia keratitis; Individuals with a history of anaphylaxis or prior severe systemic reaction associated with the parenteral administration of this or other human immune globulin preparations; IgA-deficient patients with antibodies against IgA and a history of IgA hypersensitivity, as it contains trace amounts of IgA (40 mcg/mL).

Warnings and Precautions for VIGIV include:

- Hypersensitivity to human immune globulin (acute anaphylaxis)
- Acute renal dysfunction/failure. Use VIGIV with caution in patients with pre-existing renal insufficiency and in patients at increased risk of developing renal insufficiency.
- Thrombosis may occur with immune globulin products, including VIGIV. For patients at risk of thrombosis, administer VIGIV at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.
- Hemolysis or hemolytic anemia
- Aseptic meningitis syndrome (AMS)
- Noncardiogenic pulmonary edema [Transfusion-Related Acute Lung Injury (TRALI)]
- Transmission of infectious agents from human plasma
- Monitor renal function and urine output in patients at risk of renal failure; check baseline blood viscosity in patients at risk of hyperviscosity; and conduct confirmatory tests if hemolysis or TRALI is suspected.
- Blood glucose monitoring

There is no human or animal data for use of VIGIV during pregnancy. VIGIV should only be given to pregnant and nursing women if the potential benefits outweigh the potential risks. It is not known whether VIGIV is excreted in human milk. The safety and efficacy of VIGIV has not been established in pediatric and geriatric populations.

The most frequently reported adverse reactions to VIGIV treatment in clinical trials (>10%) include: headache, nausea, rigors, and dizziness.

Please see full Prescribing Information for VIGIV for additional safety information.

About BAT® [Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) – (Equine)]

BAT® is a mixture of immune globulin fragments indicated for the treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients. The effectiveness of BAT is based solely on efficacy studies

conducted in animal models of botulism.

The Warnings and Precautions for BAT include:

- Severe hypersensitivity reactions, including anaphylaxis, as well as delayed allergic reactions, including serum sickness may occur following BAT administration. Prepare for monitoring and management of allergic reactions.
- Infusion reactions. These reactions may be related to the infusion rate of BAT.
- Interference with blood glucose testing. Because BAT contains maltose, interference with non-glucose specific blood sugar testing systems can occur. Use glucose-specific testing systems.
- Transmissible infections agents. BAT is made from equine plasma and may contain infectious agents, e.g. viruses.

There is no human or animal data for use of BAT during pregnancy. BAT should only be given to pregnant and nursing women if the potential benefits outweigh the potential risks. It is not known whether BAT is excreted in human milk. The safety and efficacy of BAT has not been established in pediatric and geriatric populations. Only limited safety data exists for pediatric populations.

The most common adverse reactions observed in ≥5% of healthy volunteers in clinical trials were headache, nausea, pruritus, and urticaria. The most common adverse reactions reported in ≥1% of patients in a clinical study were pyrexia, rash, chills, nausea, and edema. One serious adverse reaction of hemodynamic instability was observed in one patient in the clinical study.

Please see full Prescribing Information for BAT for additional safety information.

About Emergent BioSolutions
At Emergent, our mission is to protect and enhance life. For 25 years, we've been at work defending people from things we hope will never happen—so we are prepared just in case they ever do. We provide solutions for complex and urgent public health threats through a portfolio of vaccines and therapeutics that we develop and manufacture for governments and consumers. We also offer a range of integrated contract development and manufacturing services for pharmaceutical and biotechnology customers. To learn more about how we plan to protect or enhance 1 billion lives by 2030, visit our website and follow us on LinkedIn, X, Instagram, Apple Podcasts and Spotify.

Safe Harbor Statement
This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including statements regarding the development, availability, and government procurement of ACAM2000® vaccine, CYFENDUS® vaccine, BAT® and VIGIV® are forward-looking statements. We generally identify forward-looking statements by using words like "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "should," "will," "would," and similar expressions or variations thereof, or the negative thereof, but these terms are not the exclusive means of identifying such statements. Forward-looking statements are based on our current intentions, beliefs, and expectations regarding future events based on information that is currently available. We cannot guarantee that any forward-looking statement will be accurate. Readers should realize that if underlying assumptions prove inaccurate or if known or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Readers 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. Readers should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the U.S. Securities and Exchange Commission, when evaluating our forward-looking statements.

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