Emergent BioSolutions Confirms Approximately $400 million in Orders in 2024 & 2025 to Support Smallpox and Mpox Preparedness Efforts

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- $185+ million in incremental orders for ACAM2000® and VIGIV to be delivered in 2024 and 2025

GAITHERSBURG, Md., Sept. 25, 2024 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) today announced it has secured approximately $400 million in orders in 2024 and 2025 associated with its vaccinia, smallpox and mpox product portfolio. This includes the previously disclosed U.S. government contract modification to procure ACAM2000®, (Smallpox and Mpox (Vaccinia) Vaccine, Live), as well as CNJ-016® [Vaccinia Immune Globulin Intravenous (Human)] (VIGIV) contract options exercised in 2023 and 2024. To date in 2024, customer orders of nearly $210 million have been delivered for ACAM2000® and VIGIV. For the remainder of 2024 and into 2025, Emergent is confirmed to deliver an incremental $185+ million in ACAM2000® and VIGIV orders.

“Emergent continues to be a trusted partner to supply medical countermeasures for biodefense and global health preparedness, and these incremental orders demonstrate our ongoing leadership to help address serious viral threats like smallpox and mpox,” said Joe Papa, president and CEO of Emergent. “As a leader in public health preparedness for 25 years, we recognize that the world is increasingly dangerous, and we believe our products, services and overall capabilities are critical to safeguarding communities against potential public health outbreaks.”

Emergent is actively involved in playing its part in addressing the ongoing mpox outbreak. In August, the U.S. Food and Drug Administration approved an update for ACAM2000® to include prevention of mpox disease in individuals determined to be at high risk for mpox infection in its label, in addition to the previously approved smallpox indication.

Shortly after achieving this regulatory milestone, Emergent announced that it submitted an Expression of Interest for ACAM2000® vaccine to be assessed for Emergency Use Listing (EUL) with the World Health Organization (WHO). This was in response to the WHO’s invitation for mpox vaccine manufacturers to submit dossiers for EUL evaluation. Emergent is currently in discussions with the WHO surrounding next steps for a potential EUL or Prequalification submission for ACAM2000®. The EUL/Prequalification process is part of the WHO’s broader efforts to support the mpox outbreak response and is a prerequisite of the recent and related UNICEF emergency tender.

In furtherance of its commitment to support mpox response efforts, Emergent has donated 50,000 doses of ACAM2000® for potential deployment across impacted countries across the African continent.

About ACAM2000®, (Smallpox and Mpox (Vaccinia) Vaccine, Live)
ACAM2000® is indicated in the U.S. for active immunization for the prevention of smallpox and mpox disease in individuals determined to be at high risk for smallpox and mpox 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 severe or fatal smallpox or mpox infection.

Additionally, there are warnings and precautions for myocarditis, pericarditis, encephalitis, encephalomyelitis, encephalopathy, progressive vaccinia, generalized vaccinia, severe vaccinial skin infections, erythema multiforme major (including Stevens-Johnson Syndrome), eczema vaccinatum resulting in permanent sequelae or death, accidental eye infection (ocular vaccinia), which can cause ocular complications that may lead to blindness, and fetal death. These may occur following either primary vaccination or revaccination with live vaccinia virus vaccines, including ACAM2000®. These risks are increased in certain individuals and may result in severe disability, permanent neurological sequalae and/or death.

Please see the full Prescribing Information for ACAM2000®, (Smallpox and Mpox (Vaccinia) Vaccine, Live) Vaccine for full Boxed Warning and additional safety information.

About CNJ-016® [Vaccinia Immune Globulin Intravenous (Human)] (VIGIV)
(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 of complications due to vaccinia vaccination. VIGIV is 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 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 communication 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 supply and expected timing for delivery of the ACAM2000® and VIGIV, Emergent's ability to increase inventories of ACAM2000 ® and VIGIV to meet requested levels within specified time frames, if needed, the discussions with the WHO regarding Emergent's EUL or Prequalification submission for ACAM2000 ®, and the WHO's assessment of such submission and related UNICEF emergency tender, are forward-looking statements. We generally identify forward-looking statements by using words like "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "future," "goal," "intend," "may," "plan," "position," "possible," "potential," "predict," "project," "should," "target," "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 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 statements. Any forward-looking statement speaks only as of the date of this communication and, except as required by law, we do not undertake any obligation to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause our actual results to differ materially from those indicated by any forward-looking statements. Readers should consider this cautionary statement, as well as the risk factors and other disclosures included in our periodic reports filed with the Securities and Exchange Commission, when evaluating our forward-looking statements.

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