Emergent BioSolutions Secures $51.9 Million Contract Modification Award for CNJ-016® [Vaccinia Immune Globulin Intravenous (Human)] (VIGIV) as part of U.S. Biodefense Preparedness Efforts

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GAITHERSBURG, Md., July 08, 2025 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) today announced a contract modification has been secured to deliver CNJ-016® [Vaccinia Immune Globulin Intravenous (Human)] (VIGIV) to the Administration for Strategic Preparedness and Response (ASPR), part of the U. S. Department of Health and Human Services (HHS), for smallpox preparedness. ASPR exercised an option from its existing 10-year contract (75A50119C00037) for additional doses of VIGIV, a treatment for complications due to smallpox vaccination.

“Securing this contract modification for VIGIV treatment underscores Emergent’s ongoing partnership with the U.S. government to support its overall smallpox preparedness strategy,” said Paul Williams, senior vice president, head of products business, global government & public affairs at Emergent. “We are proud to fulfill our mission to protect and save lives and stand ready to provide our diverse medical countermeasures through our North American supply chain and capabilities for stockpiling to help address public health threats in the United States and around the world.”

This contract modification award follows Emergent’s recently announced BAT® [Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) – (Equine)] contract amendment with ASPR under contract 75A50119C00075.

Indication and Select Important Safety Information for CNJ-016® [Vaccinia Immune Globulin Intravenous (Human)] (VIGIV)

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. *(See full prescribing information for complete boxed warning)*

VIGIV is an Immune Globulin (Human), 5% Liquid, indicated for the treatment of complications due to vaccinia vaccination including eczema vaccinatum, progressive vaccinia, severe generalized vaccinia, vaccinia infections in individuals who have skin conditions, and aberrant infections induced by vaccinia virus (except in cases of isolated keratitis). VIGIV is not indicated for postvaccinial encephalitis.

VIGIV is contraindicated in isolated vaccinia keratitis, individuals with a history of anaphylactic or severe systemic reaction to human globulins, and IgA-deficient patients with antibodies against IgA and a history of IgA hypersensitivity.

Warnings and Precautions

- Hypersensitivity to human immune globulin (acute anaphylaxis)
- Acute renal dysfunction/failure
- 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

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

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

Indication and Select Important Safety Information for 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.

Warnings and Precautions
Hypersensitivity reactions including anaphylaxis. Prepare for monitoring and management of allergic reactions during and after BAT infusion. *Delayed allergic reactions (serum sickness)*. Patient monitoring is recommended. *Infusion reactions*. Monitor and slow or interrupt infusion and administer treatment based on the severity of the reaction. *Interference with non-glucose specific blood sugar testing systems*. Use glucose-specific testing systems. *Transmissible Infectious Agents*. BAT is made from equine plasma and may contain infectious agents (e.g., viruses).

Adverse Reactions

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 save lives. For over 25 years, we've been at work preparing those entrusted with protecting public health. We deliver protective and life-saving solutions for health threats like smallpox, mpox, botulism, Ebola, anthrax and opioid overdose emergencies. To learn more about how we help prepare communities around the world for today's health challenges and tomorrow's threats, 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 CNJ-016® and BAT® 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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