Emergent BioSolutions Announces the Execution of Contract Options Valued at $67.4 Million to Procure Additional TEMBEXA® (brincidofovir) to Support National Preparedness Efforts

September 26, 2024

GAITHERSBURG, Md., Sept. 26, 2024 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) ("Emergent") today announced that two contract options have been secured to procure additional treatment courses of TEMBEXA® (brincidofovir) to sustain the U.S. government's national preparedness posture against human smallpox. TEMBEXA® is indicated for the treatment of human smallpox disease in adult and pediatric patients, including neonates. The order is valued at $67.4 million and executes procurement options CLIN0004A and CLIN0005A under Emergent's existing 10-year contract.

"This announcement highlights the strength of the longstanding partnership between Emergent and the U.S. government to meet the country's preparedness needs," said Paul Williams, senior vice president, products business, Emergent. We look forward to continuing to deliver TEMBEXA® to support smallpox preparedness."

The existing contract includes optional procurement CLINs that can be exercised throughout the 10-year contract period of performance with a maximum potential value of $568 million. The exercise of CLIN0004A and CLIN0005A commits funding through 2027 and will help ensure continued supply of TEMBEXA® to address the threat of smallpox.

This project has been funded in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA) under contract number 75A50122C00047.

About TEMBEXA®

TEMBEXA® is an oral antiviral approved by the FDA in June 2021 for the treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates. TEMBEXA® is formulated as 100 mg tablets and 10 mg/mL oral suspension dosed once weekly for two weeks. The oral suspension formulation is particularly important for patients who have difficulty swallowing due to age or medical status.

Important Information about TEMBEXA® (brincidofovir)

TEMBEXA® is an orthopoxvirus nucleotide analog DNA polymerase inhibitor and is indicated for the treatment of human smallpox disease in adult and pediatric patients, including neonates.

Limitations of Use: TEMBEXA® is not indicated for the treatment of diseases other than human smallpox disease. The effectiveness of TEMBEXA® for the treatment of smallpox disease has not been determined in humans because adequate and well-controlled field trials have not been feasible and inducing smallpox disease in humans to study the drug's efficacy is not ethical. TEMBEXA ® efficacy may be reduced in immunocompromised patients based on studies in immune deficient animals.

TEMBEXA® has a BOXED WARNING for increased risk for mortality when used for longer duration. An increased incidence of mortality was seen in TEMBEXA®-treated subjects compared to placebo-treated subjects in a 24-week clinical trial when TEMBEXA® was evaluated in another disease.

The Warnings and Precautions for TEMBEXA® include:

- Elevations in Hepatic Transaminases and Bilirubin: May cause increases in serum transaminases (ALT or AST) and serum bilirubin. Monitor liver laboratory parameters before and during treatment.
- Diarrhea and Other Gastrointestinal Adverse Events: Diarrhea and additional gastrointestinal adverse events including nausea, vomiting, and abdominal pain may occur. Monitor patients, provide supportive care, and if necessary, do not give the second and final dose of TEMBEXA®.
- Coadministration with Related Products: TEMBEXA® should not be coadministered with intravenous cidofovir.
- Embryo-fetal Toxicity: May cause fetal harm. Advise individuals of childbearing potential of the potential risk to the fetus and to use effective contraception.
- Carcinogenicity: TEMBEXA® should be considered a potential human carcinogen. Do not crush or divide TEMBEXA® tablets.
- Male Infertility: Based on testicular toxicity in animal studies, TEMBEXA® may irreversibly impair fertility in individuals of reproductive potential.

Common adverse reactions (occurring in at least 2% of TEMBEXA®-treated subjects) were diarrhea, nausea, vomiting, and abdominal pain.

Please read full Prescribing Information for TEMBEXA® for additional safety information here.

About Smallpox

Smallpox is a highly contagious disease caused by the variola virus. Historically, smallpox was one of the deadliest diseases in history with a case fatality rate of approximately 30 percent. Despite successful eradication of smallpox in the 1970s, there is considerable concern that variola virus could reappear, either through accidental release or as a weapon of bioterrorism. According to the U.S. Centers for Disease Control and Prevention, variola virus is ranked in the highest risk category for bioterrorism agents (Category A) due to its ease of transmission, high mortality rate, and potential to cause public panic and social disruption. Based on a recent report – The Department of Health and Human Services Fiscal Year 2023 Public Health

and Social Services Emergency Fund Justification of Estimates for Appropriations Committee – smallpox remains a threat of high concern to both the domestic and international community.

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 help protect public health, 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 exercise by BARDA of any optional future procurements under the contract (75A50122C00047) to supply TEMBEXA® to the U.S. government, 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 Emergent's current intentions, beliefs, and expectations regarding future events. Emergent 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 Emergent's 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, Emergent does 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 Emergent's 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 identified in Emergent's periodic reports filed with the U.S. Securities and Exchange Commission when evaluating Emergent's forward-looking statements.

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