



Emergent BioSolutions Secures \$17 Million Contract Modification for Oral Suspension TEMBEXA® (brincidofovir), a Smallpox Antiviral, and Strengthens Overall U.S. Supply Chain

September 15, 2025

GAITHERSBURG, Md., Sept. 15, 2025 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) today announced it has received a \$17 million contract modification from the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), to supply TEMBEXA® (brincidofovir) oral suspension. This follows the U.S. Food and Drug Administration's (FDA) recent approval of the manufacturing scale-up of TEMBEXA® oral suspension. Oral suspension formulation is an important option for patients who may have trouble swallowing due to age or medical status.

"Our newly secured contract modification and ongoing collaboration with BARDA and its procurement of TEMBEXA® (brincidofovir) oral suspension formulation reinforces the critical need for a continuous supply of countermeasures to help address smallpox disease among vulnerable patient populations during a potential outbreak," said Paul Williams, senior vice president, head of products business, global government & public affairs at Emergent. "We are proud of our efforts to increase manufacturing scale to respond to customers' immediate needs by strengthening our U.S. manufacturing and supply chain process and serving as a trusted partner supporting the U.S. government to address this serious national health security threat."

This newly exercised contract modification (CLIN0004B) to supply TEMBEXA® builds upon the [previously announced options](#) (CLIN0004A and CLIN0005A) from September 2024, and are all under Emergent's existing 10-year contract. This project has been funded in whole or in part with federal funds from the U.S. Department of Health and Human Services; Administration for Strategic Preparedness and Response; the Biomedical Advanced Research and Development Authority 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.

Indication

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: (1) TEMBEXA is not indicated for the treatment of diseases other than human smallpox disease. (2) The effectiveness of TEMBEXA for 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. (3) TEMBEXA efficacy may be reduced in immunocompromised patients based on studies in immune deficient animals.

Select Important Safety Information

Boxed Warning: 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.

Warnings and Precautions: *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 co-administered 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.

Adverse Reactions: The most common adverse reactions (occurring in at least 2% of TEMBEXA-treated subjects) were diarrhea, nausea, vomiting, and abdominal pain.

To report Suspected Adverse Reactions, contact Emergent BioSolutions at 1-877-246-8472 or medicalinformation@ebsi.com

Please see the [Prescribing Information](#) for TEMBEXA for full 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 Emergent's ability to increase manufacturing scale of TEMBEXA® to respond to customer needs, 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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