

EMERGENT

Emergent BioSolutions Receives Saudi Food and Drug Authority Approval for ACAM2000® [Smallpox and Mpox (Vaccinia) Vaccine, Live]

May 18, 2026

GAITHERSBURG, Md., May 18, 2026 (GLOBE NEWSWIRE) -- Emergent BioSolutions (NYSE:EBS), a global biodefense company, today announced that the Saudi Food and Drug Authority (SFDA) has approved the registration of ACAM2000® [Smallpox and Mpox (Vaccinia) Vaccine, Live], for the prevention of smallpox and mpox disease in individuals determined to be at high risk for smallpox or mpox infection. This follows Emergent's recent [announcement](#) that Singapore's Health Sciences Authority (HSA) has approved an expanded indication for ACAM2000® [Smallpox and Mpox (Vaccinia) Vaccine, Live] to include prevention of mpox disease in adults determined to be at high risk for mpox infection.

"We are pleased to receive this approval for ACAM2000® from SFDA for immunization against smallpox and mpox in high-risk individuals," said Simon Lowry, chief medical officer of Emergent. "ACAM2000® is the first Emergent product to be licensed by the SFDA and demonstrates the company's intent to collaborate with governments in the Gulf region and around the world as awareness and adoption of biodefense preparedness strategies continues to increase around the world."

Smallpox is considered a credible bioterror threat by experts, and its mortality makes it a potential high-impact threat with health, economic and national security implications.¹ Mpox virus is part of the same family of viruses as variola virus, the virus that causes smallpox. Since the start of the global outbreak of mpox in 2022, there have been more than 137,000 confirmed cases and more than 300 deaths reported globally.²

Emergent specializes in developing, manufacturing and delivering medical countermeasures to governments around the world for national security and health preparedness. These products support how governments respond to emergencies and help protect the public from potential threats like smallpox, mpox, anthrax and botulism.

Indication and Select Important Safety Information for ACAM2000® [Smallpox and Mpox (Vaccinia) Vaccine, Live]

Indication

ACAM2000® is indicated for active immunization for the prevention of smallpox and mpox disease in individuals determined to be at high risk for smallpox or mpox infection.

Important Safety Information

Warning: Serious Complications

Myocarditis and pericarditis (suspect cases observed at a rate of 5.7 per 1000 primary vaccinees (95% CI: 1.9-13.3)), encephalitis, encephalomyelitis, encephalopathy, progressive vaccinia, generalized vaccinia, severe vaccinia 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, have occurred following either primary vaccination or revaccination with ACAM2000® or other live vaccinia virus vaccines that were used historically.

Contraindications

Do not administer ACAM2000® to individuals with severe immunodeficiency. These individuals may include persons who are undergoing bone marrow transplantation or persons with primary or acquired immunodeficiency states who require isolation.

Warnings and Precautions

Serious complications that may follow either primary or revaccination with ACAM2000® include myocarditis and/or pericarditis, ischemic heart disease and non-ischemic dilated cardiomyopathy, encephalitis, encephalomyelitis, encephalopathy, progressive vaccinia (vaccinia necrosum), generalized vaccinia, severe vaccinia skin infections, erythema multiforme major (including Stevens-Johnson syndrome), eczema vaccinatum, fetal at 1-877-246-8472 (U.S.), 1-800-768-2304 (Canada), or medicalinformation@ebsi.com; or VAERS at 1-800-822-7967 or <https://vaers.hhs.gov>. Please see the [full Prescribing Information](#) for ACAM2000® for complete Boxed Warning and 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, 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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¹ [Smallpox as a Weapon for Bioterrorism](#)

² [Mpox 2022 to 2025 Update: A Comprehensive Review on Its Complications, Transmission, Diagnosis, and Treatment](#)

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Source: Emergent BioSolutions