Emergent BioSolutions Receives Approval from Singapore Health Sciences Authority for Expanded Indication of ACAM2000® (Smallpox and Mpox (Vaccinia) Vaccine, Live) to Include Mpox

April 30, 2026

GAITHERSBURG, Md., April 30, 2026 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) today announced 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.

The expanded indication in Singapore is supported by existing human safety data and data from a well-controlled animal study in which ACAM2000® vaccine was shown to be effective in protecting against mpox virus exposure. This regulatory milestone expands the authorized use of ACAM2000® in Singapore to support public health preparedness and response efforts.

"The Singapore HSA approval of ACAM2000® for immunization against mpox in high-risk individuals demonstrates the strength and breadth of Emergent's medical countermeasures portfolio," said Simon Lowry, chief medical officer of Emergent. "We are committed to working with international regulatory authorities as part of our broader vision to become the leader in delivering protective and life-saving solutions to communities around the world."

ACAM2000® is a single-dose vaccine administered percutaneously via a bifurcated needle dipped into the vaccine solution and used to prick the skin several times in the upper arm with a droplet of the vaccine. The vaccine was first approved by the HSA in 2009 for active immunization for the prevention of smallpox disease in individuals determined to be at high risk for smallpox infection. With this expanded indication, the vaccine is now also approved for active immunization for the prevention of mpox disease in adults determined to be at high risk for mpox infection, for use during mpox outbreaks associated with severe or life-threatening disease where alternative vaccines are unavailable or contraindicated. Mpox is an infectious disease endemic to central and west Africa caused by the double-stranded DNA mpox virus.

About ACAM2000® (Smallpox and Mpox (Vaccinia) Vaccine, Live)

US FDA-Approved Indication and Important Safety Information

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 and mpox infection.

Select 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 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, have occurred following either primary vaccination or revaccination with ACAM2000® or other live vaccinia virus vaccines that were used historically. These risks are increased in certain individuals and may result in severe disability, permanent neurological sequelae and/or death.

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 & Precautions: Myocarditis and/or pericarditis, ischemic heart disease and non-ischemic dilated cardiomyopathy; encephalitis, encephalomyelitis, encephalopathy, progressive vaccinia (vaccinia necrosum), generalized vaccinia, severe vaccinial skin infections, erythema multiforme major (including Stevens-Johnson syndrome), eczema vaccinatum, fetal vaccinia, and fetal death; accidental eye infection (ocular vaccinia) that may lead to blindness.

Adverse Reactions: Inoculation site signs and symptoms, lymphadenitis, and constitutional symptoms, such as malaise, fatigue, fever, myalgia, and headache.

To report Suspected Adverse Reactions, contact Emergent BioSolutions at 1-877-246-8472 (U.S.), 1-800-768-2304 (Canada), or medicalinformation@ebsi.com; or VAERS at 1-800-822-7967 and https://vaers.hhs.gov.

Please see the full US Prescribing Information for ACAM2000® for complete Boxed Warning and safety information. Singapore Prescribing Information will be available on the corporate website as soon as available.

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," "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 statements 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 statements. Any forward-looking statement speaks only as of the date of this press release, 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 the company'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 and other disclosures included in our periodic reports filed with the U.S. Securities and Exchange Commission, when evaluating our forward-looking statements.

Investor Contact:
Richard S. Lindahl
Executive Vice President, CFO
lindahlr@ebsi.com

Media Contact:
Assal Hellmer
Vice President, Communications
mediarelations@ebsi.com

EMERGENT

Source: Emergent BioSolutions