



Emergent BioSolutions Responds to Mpox Public Health Emergency as Cases Surge in Africa

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- Active engagement with the World Health Organization, U.S. government and other global health leaders on critical efforts to prevent mpox disease transmission
- 50,000 doses of ACAM2000[®], (Smallpox (Vaccinia) Vaccine, Live) will be donated to Direct Relief for potential deployment across often difficult-to-reach locations, and as informed by local and regional health authorities

GAITHERSBURG, Md., Aug. 19, 2024 (GLOBE NEWSWIRE) -- Emergent BioSolutions (NYSE: EBS) today announced it is proactively working with the World Health Organization (WHO) and the U.S. government to partner and help address the current mpox outbreak across Central Africa, and has pledged to donate 50,000 doses of its ACAM2000[®], (Smallpox (Vaccinia) Vaccine, Live), through [Direct Relief](#), a humanitarian relief organization with a long history of providing vital medicines to the Democratic Republic of the Congo (DRC), as well as the other impacted countries of Burundi, Kenya, Rwanda, and Uganda. These efforts are in response to the WHO's Director-General's August 14 [statement](#) declaring that the upsurge of mpox in the DRC and a growing number of countries in Africa constitutes a public health emergency of international concern (PHEIC) under the International Health Regulations (2005) (IHR).

"Africa CDC estimated they will need 10 million doses to control the epidemic in the continent," said Dr. Raina McIntyre, Professor of Global Biosecurity, NHMRC L3 Research Fellow, Head, Biosecurity Program, Kirby Institute, University of New South Wales Sydney. "It is unlikely there will be enough supply of 3rd generation vaccines to control the epidemic in Africa, given demand in other countries."

In October 2023, [Emergent filed a supplemental Biologics License Application](#) (sBLA) to the U.S. Food and Drug Administration (FDA) seeking an expanded indication for ACAM2000[®] vaccine to include immunization against mpox virus. The sBLA, which has an FDA target for review completion in the third quarter 2024, includes previously available human safety data and data from a well-controlled animal study in which ACAM2000[®] vaccine has been shown to be effective in protecting against mpox virus exposure. ACAM2000[®] is a single-dose vaccine administered via a bifurcated needle that is dipped into the vaccine solution and the skin is pricked several times in the upper arm with a droplet of the vaccine.

Accordingly, Emergent has also responded to the WHO invitation for manufacturers of mpox vaccines to submit an Expression of Interest for the WHO's assessment of ACAM2000[®] vaccine to be added as an Emergency Use Listing (EUL), which is a WHO risk-based procedure for assessing and listing unlicensed medical products in various countries with the aim of expediting the availability of these products needed in public health emergency situations like the current mpox outbreak.

"As the WHO has declared, the mpox outbreak is a public health emergency of international concern, and Emergent is ready to scale up response efforts and partner with U.S. and global public health leaders," said Joe Papa, president and CEO, Emergent BioSolutions. "For years, Emergent has supplied ACAM2000[®] to the U.S. and allied governments in support of preparedness and stockpiling initiatives. Currently, we have additional product already in inventory, with the ability to increase supply by approximately 40 million doses, if and potentially when needed. In the meantime, 50,000 doses of ACAM2000[®] vaccine will be donated to help control the outbreak across the African continent."

Mpox is a disease caused by infection with the mpox virus. Mpox virus is part of the same family of viruses as variola virus, the virus that causes smallpox. In 2022, the world experienced a global outbreak of clade II mpox, associated with West Africa, which led to more than 95,000 cases across 115 non-endemic countries.

Clade I is endemic to Central Africa and is characterized by more severe clinical outcomes and a higher case fatality rate. The recently identified clade Ib variant, exhibiting enhanced transmissibility through close contact, has led to an increase in cases, particularly in Central Africa, and a sizable impact on children and families. [According to the WHO](#), clade I mpox tends to cause a higher number of severe infections and have a higher mortality rate than clade II mpox.

Papa continued, "The increasing outbreaks of mpox around the world should raise concerns and spur ongoing efforts to produce and stockpile vaccines and treatments to address all orthopox viruses, including mpox and smallpox."

In 1980, the WHO officially declared smallpox eradicated; however, the threat of reemergence by intentional introduction (e.g., bioterrorism) persists and minimal immunity in populations today against mpox exists. Vaccines like ACAM2000[®] formed the basis of one of the most successfully integrated public health responses in the eradication of smallpox.

ACAM2000[®], (Smallpox (Vaccinia) Vaccine, Live)

ACAM2000[®] is the primary smallpox vaccine designated for use in a bioterrorism emergency, with doses having been supplied to the U.S. Strategic National Stockpile. ACAM2000[®] is also licensed in Canada, Australia and Singapore and is currently stockpiled both in the U.S. and internationally.

ACAM2000[®] is indicated for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection.

The labeling for ACAM2000[®] contains a contraindication for individuals with severe immunodeficiency. Severe localized or systemic infection with vaccinia (progressive vaccinia) may occur in persons with weakened immune systems. Individuals with severe immunodeficiency who are not expected to benefit from the vaccine should not receive ACAM2000[®]. The risk for experiencing severe vaccination complications must be weighed against the risk for experiencing a potentially fatal smallpox infection.

Additionally, there are warnings and precautions for myocarditis, pericarditis, 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, ocular complications, blindness and fetal death. These have occurred following either primary vaccination or revaccination with live vaccinia virus smallpox vaccines. These risks are increased in certain individuals and may result in severe disability, permanent neurological sequelae and/or death.

Please see full [Prescribing Information](#) for full Boxed Warning and additional safety information.

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 plan to protect or enhance 1 billion lives by 2030, visit our [website](#) and follow us on [LinkedIn](#), [X](#), [Instagram](#), [Apple Podcasts](#) and [Spotify](#).

Safe Harbor Statement

This communication 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 expected timing for delivery of the ACAM2000[®] vaccine and for the completion of the FDA review of the sBLA, and Emergent's ability to increase inventories of ACAM2000[®] vaccine to meet requested levels within specified time frames, if needed, 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 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 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 communication 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 our 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 Securities and Exchange Commission, when evaluating our forward-looking statements.

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