

EMERGENT

Enrollment Starts in Africa CDC-Led MpOx Therapeutic Study (MOSA)

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ADDIS ABABA, Ethiopia and KINSHASA, Democratic Republic of the Congo and WASHINGTON and PARIS, Jan. 16, 2025 (GLOBE NEWSWIRE) -- Africa CDC's support for the MOSA, a pan-African randomized platform adaptive trial for the MpOx Study, adding to the initial EU funding, has enabled the enrollment of the first patients at Mbandaka Hospital in Equateur Province, Democratic Republic of Congo (DRC). These patients have been randomized in this pivotal clinical trial, marking a critical step in addressing the Mpox health threat. As Clade Ib cases emerge outside Africa and Clade I and II cases continue to be reported across the continent, Africa CDC, INRB, and PANTHER are leading efforts to test promising therapeutic options to combat this persistent health threat.

Declared a Public Health Emergency of Continental Security on August 13, 2024, Mpox remains a significant health threat across Africa, particularly among vulnerable populations such as women, children, and individuals living with HIV. Despite the pressing need, no therapeutic has been approved to treat Mpox in the United States or Africa. Recent results from the PALM 007 and STOMP studies showed that tecovirimat did not show the expected effect on lesion resolution, underscoring the need for additional therapeutic options.

The MOSA trial demonstrates Africa's leadership in addressing this urgent healthcare gap. The study will evaluate different antivirals, either alone or in combination. It will start by evaluating the safety and efficacy of brincidofovir. Brincidofovir is an antiviral from the global life sciences company Emergent BioSolutions. In the United States it is available under a single-patient emergency use Investigational New Drug (IND) for Mpox. The safety and efficacy of brincidofovir to treat Mpox in humans has not been established in double-blind, placebo-controlled studies for Mpox. In the MpOx Study, patients will receive either brincidofovir or a matching placebo in a liquid oral formulation, administered once-a-week, for 2 weeks.

A first interim analysis is expected by the end of Q1 2025.

"Africa is not just responding to the Mpox outbreak; we are leading the charge in finding solutions by spearheading research and development for Mpox therapeutics," said Africa CDC Director General, Dr. Jean Kaseya. "The MpOx Study represents a groundbreaking step toward developing a treatment. This effort goes beyond research—it's about African ownership and leadership in addressing our continent's health challenges through vital, innovative research."

Sponsored by PANTHER, a key research partner of Africa CDC, the MOSA trial builds upon initial funding provided by the European Union's Horizon Europe program. The study protocol was reviewed through the AVAREF collaborative process in 2023, ensuring it meets the highest ethical and scientific standards. The innovative study design includes pre-planned interim analyses, allowing for rapid decision-making should early signs of either futility or success be observed.

"This milestone highlights the vital role of research preparedness and response. Funded initially by Horizon Europe as part of the emergency response to the mpox outbreak in 2022, I am delighted to see MOSA trial fully operational now to advance treatments for mpox." Marc Lemaître, European Commission, Director-General for Research and Innovation.

"We are proud of this important milestone illustrating PANTHER's mission in addressing continental epidemic priorities," said Prof. Samba Ousmane Sow, Director General of the Centre for Vaccine Development in Mali (CVD-Mali) and President of the Board of PANTHER. "We hope to contribute to Africa CDC's response to the current crisis while also deriving concrete lessons to better prepare for future ones."

As Africa continues to report rising Mpox cases, particularly in the DRC, the MOSA trial seeks to provide critical data on potential treatment options. The study will recruit both children and adults, focusing on those most at risk of severe outcomes, especially in remote areas.

"We look forward to advancing MOSA, another critical research project that complements ongoing studies on transmission, vaccines and social sciences," said Prof. Placide Mbala, Principal Investigator for the study in the DRC and Head of the Department of Epidemiology and Global Health at INRB.

"Mpox continues to be a global threat to public health, creating a need for treatments and vaccines," said Simon Lowry, M.D., chief medical officer, head of research and development, Emergent. "We applaud Africa CDC and PANTHER for their work progressing the 'MpOx Study in Africa' (MOSA) and advancing research for brincidofovir."

The U.S. FDA Prescribing Information for TEMBEXA® (brincidofovir) is provided for additional safety information [here](#).

About the Pandemic Preparedness Platform for Health and Emerging Infections Response (PANTHER)

PANTHER is the first African-led pandemic preparedness platform for health and emerging infection response. Bringing together leading African and global researchers and public health teams, it aims to create regional hubs and clinical research platforms to support preparedness and rapid response to emerging infectious diseases globally, particularly in Africa.

For more information, visit <https://pantherhealth.org>.

PANTHER is sponsoring MOSA as part of the MPX-RESPONSE Project that has received funding from the European Union's Horizon Europe Research and Innovation programme under grant agreement 101115188



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About Africa Centres for Disease Control and Prevention (Africa CDC)

The Africa Centres for Disease Control and Prevention (Africa CDC) is a public health agency of the African Union. It is autonomous and supports member states in strengthening health systems. It also helps improve disease surveillance, emergency response, and disease control.

Learn more at: <http://www.africacdc.org> and connect with us on [LinkedIn](#), [Twitter](#), [Facebook](#) and [YouTube](#).

About Emergent BioSolutions

At Emergent, our mission is to protect and enhance life. For over 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](#).

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