Emergent BioSolutions Supports New Clinical Trial Evaluating the Safety and Efficacy of Brincidofovir in Treating Mpox Virus Across Africa

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- PANTHER to conduct clinical trial under the leadership of Africa Centres for Disease Control and Prevention

GAITHERSBURG, Md., Nov. 06, 2024 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) today announced that brincidofovir (brand name TEMBEXA®) will be included in a clinical trial conducted and sponsored by PANTHER, under the leadership of the Africa Centres for Disease Control and Prevention (Africa CDC), as part of the 'MpOx Study in Africa' (MOSA). The study will evaluate the safety and efficacy of brincidofovir in treating mpox virus in a randomized double-blind placebo-controlled trial.

"We applaud Africa CDC and PANTHER for the launch of the 'MpOx Study in Africa' (MOSA), an important step in advancing research for brincidofovir, and are proud to support the trial with our brincidofovir antiviral treatment," said Joe Papa, president and CEO, Emergent BioSolutions. "Emergent is committed to working with partners around the world to study and produce vaccines and treatments to address all orthopoxviruses, including mpox and smallpox."

Brincidofovir is an antiviral medical countermeasure that is part of Emergent's product portfolio. There are currently no therapeutics approved by the FDA to treat patients infected by mpox virus who are at risk of severe complications. While brincidofovir treatment is available to be used for mpox in the U.S. under emergency Investigational New Drug protocol, it has not yet been evaluated in any randomized double-blind placebo-controlled studies for mpox.

On August 13, Africa CDC declared mpox a public health emergency of continental security, which was followed by a statement from World Health Organization's Director-General 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 under the International Health Regulations (2005).

About the clinical trial: The study MOSA (MpOx Study in Africa) is a pan-African, double-blind, platform adaptive trial assessing treatments for patients diagnosed with mpox virus. Inclusion criteria are children, adults with mucosal lesions or PLWHIV. It is sponsored by PANTHER 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.* The trial is scheduled to begin in the coming weeks in the Democratic Republic of Congo and neighboring countries.

Please read full Prescribing Information for TEMBEXA® for additional safety information here.

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 help protect public health, 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 the any future procurements to supply brincidofovir (brand name TEMBEXA®), 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 Emergent's current intentions, beliefs, and expectations regarding future events. Emergent 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 Emergent's 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, Emergent does not undertake to update any forward-looking statement to reflect new information, events or circumstances. There are a number of important factors that could cause Emergent'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 identified in Emergent's periodic reports filed with the U.S. Securities and Exchange Commission when evaluating Emergent's forward-looking statements.

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