Emergent BioSolutions Initiates Phase 1 Study Evaluating Lassa Virus Vaccine Candidate

September 6, 2022

GAITHERSBURG, Md., Sept. 06, 2022 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) today announced that it has dosed the first participant in its Phase 1 study evaluating the safety and immunogenicity of EBS-LASV, a recombinant VSV-vectored Lassa virus vaccine candidate being developed for prevention of disease caused by Lassa virus infection. Emergent and CEPI (the Coalition for Epidemic Preparedness Innovations) are co-funding this program.

“Over the last 24 years, Emergent’s mission to protect and enhance life and commitment to help mitigate public health threats have remained unchanged,” said Kelly Warfield, Ph.D., SVP for research and development at Emergent BioSolutions. “We are proud to deploy our product development and partnering capabilities to address emerging infectious diseases like Lassa fever, for which there is currently no approved vaccine or therapeutic, and to advance our pipeline for patients.”

This Phase 1 study, a randomized, placebo-controlled, dose-escalation study, will evaluate the safety and immunogenicity of Emergent’s rVSV-vectored Lassa virus vaccine in approximately 36 healthy adults at the Navrongo Health Research Centre and Kintampo Health Research Centre in Ghana. View the clinical trial registry.

“There have been a series of exciting developments within the Lassa R&D field in recent years and today’s announcement from Emergent is another key milestone moment as we progress towards developing and deploying tools that can help protect vulnerable populations across West Africa—and possible wider areas —against this potentially fatal threat,” explained CEPI’s Executive Director of Vaccine R&D, Dr. Melanie Saville. “This is particularly important as Lassa cases continue to be reported across the region, while health systems also battle other worrisome infectious disease outbreaks.”

About Lassa Virus

An estimated 100,000 to 300,000 cases of Lassa virus infection occur each year,[1] although the true disease burden is unknown. Lassa virus—a single-stranded RNA virus belonging to the family *Arenaviridae* —can cause the acute viral hemorrhagic illness known as Lassa fever. First described in the 1950s, the virus was identified in 1969 after two missionary nurses died from the disease in the Nigerian town of Lassa.[2] The virus is spread to humans via contact with food or household items that have been contaminated with urine or feces from infected *Mastomys* rats. Person-to-person transmission occurs in both community and healthcare settings, where the virus can spread via contaminated medical equipment.[3] Sexual transmission of Lassa virus has also been reported.[4]

About 80% of people who become infected have no symptoms. One in five infections results in severe disease, where the virus affects several organs such as the liver, spleen and kidneys.[5] The virus is endemic in Benin, Ghana, Guinea, Liberia, Mali, Sierra Leone, and Nigeria, but probably exists in other West African countries as well. There is currently no approved vaccine or therapeutic that protects against or treats Lassa fever.[6] There have been outbreaks of Lassa fever in Liberia, Nigeria, and Sierra Leone.[7]

About EBS-LASV vaccine development

The VesiculoVax™ vaccine delivery platform is the result of basic research funding provided by theU.S. Department of Health and Human Services, National Institutes of Health (NIH), and National Institute of Allergy and Infectious Diseases (NIAID) initially to Yale University and subsequently to Profectus (Auro Vaccines). In 2018, Emergent acquired development rights to the Profectus Lassa vaccine candidate now named EBS-LASV. CEPI is co-funding development of EBS-LASV as a monovalent vaccine to protect against Lassa fever, as part of its plan to reduce the threat of future known and novel epidemic and pandemic threats. Its goal, as part of the plan, is to support the development of a Lassa vaccine towards licensure. To push forward this aim, CEPI has also initiated *Enable*, the largest-ever Lassa fever epidemiological study to increase knowledge of the true Lassa disease burden across West Africa and better inform the design of future late-stage Lassa vaccine trials.

Emergent supports CEPI’s commitment to global equitable access for delivering a safe and effective LASV vaccine candidate to populations that need it at a price that public service agencies find affordable. Emergent has also agreed to rapidly share all data and results arising from its CEPI-supported project in Open Access journals/website where possible.

About Emergent BioSolutions

At Emergent, our mission is to protect and enhance life. For over 20 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, Twitter, and Instagram.

Safe Harbor Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements regarding our ability to fill the need for a Lassa virus vaccine and the safety and immunogenicity of the product candidate are forward-looking statements. The reader 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, which speak only as of the date of this press release.

There are a number of important factors that could cause the company's actual results to differ materially from those indicated by such forward-looking statements, including the success of the planned development program; the timing of and ability to obtain regulatory approvals for the product candidate; and our commercialization, marketing and manufacturing capabilities. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Readers should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.

[1] US CDC. Lassa fever: fact sheet. https://www.cdc.gov/vhf/lassa/pdf/factsheet.pdf (accessed August 4, 2022)

[2] Gov.UK. Lassa fever: origins, reservoirs, transmission and guidelines https://www.gov.uk/guidance/lassa-fever-origins-reservoirs-transmission-and-guidelines (accessed August 4, 2022)

[3] WHO. Lassa fever: fact sheet. http://www.who.int/en/news-room/fact-sheets/detail/lassa-fever (accessed August 4, 2022)

[4] Gov.UK. Lassa fever: origins, reservoirs, transmission and guidelines https://www.gov.uk/guidance/lassa-fever-origins-reservoirs-transmission-and-guidelines (accessed August 4, 2022)

[5] WHO. Lassa fever: fact sheet. http://www.who.int/en/news-room/fact-sheets/detail/lassa-fever (accessed August 4, 2022)

[6] WHO. Lassa fever: fact sheet. http://www.who.int/en/news-room/fact-sheets/detail/lassa-fever (accessed August 4, 2022)

[7] WHO. Weekly bulletin on outbreaks and other emergencies. http://apps.who.int/iris/bitstream/handle/10665/272981/OEW26-2329062018.pdf (accessed August 4, 2022)

Investor Contact
Robert Burrows
Vice President, Investor Relations
burrowsr@ebsi.com
(240) 413-1917

Media Contact
Matt Hartwig
Senior Director, Media Relations
mediarelations@ebsi.com

EMERGENT

Source: Emergent BioSolutions