

CEPI Awards Contract Worth up to \$36 Million to Profectus BioSciences and Emergent BioSolutions to Develop Lassa Virus Vaccine

OSLO (Norway), BALTIMORE and GAITHERSBURG, Md (USA), August 16, 2018— CEPI (the Coalition for Epidemic Preparedness Innovations) today announced a new collaboration with Profectus BioSciences, Inc. and Emergent BioSolutions Inc. (NYSE: EBS) under which they will receive up to USD\$36 million to advance the development and manufacture of a vaccine against the Lassa virus—an estimated 100,000 to 300,000 cases of Lassa virus infection occur each year.¹

Under the terms of the Framework Partnering Agreement for the collaboration among the three parties, Profectus will receive development funding from CEPI for advancing its Lassa virus vaccine. CEPI will provide \$4.3 million to support the first phase of the project, with options to invest up to a total of \$36 million over five years, including procurement of the vaccine for stockpiling purposes. Emergent will provide technical and manufacturing support for the CEPI-funded program. Through a separate agreement with Profectus, Emergent has an exclusive option to license and to assume control of development activities for the Lassa-virus vaccine from Profectus. The global non-profit organization PATH will also be working with the consortium under a separate agreement with CEPI to work on clinical development. This is CEPI's second award to the collaboration following an award in May, 2018, for the development of a Nipah virus vaccine.

Lassa virus infection—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 *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 that protects against Lassa virus.⁶

¹ US CDC. Lassa fever: fact sheet. <https://www.cdc.gov/vhf/lassa/pdf/factsheet.pdf> (accessed July 10, 2018)

² Gov.UK. Lassa fever: origins, reservoirs, transmission and guidelines <https://www.gov.uk/guidance/lassa-fever-origins-reservoirs-transmission-and-guidelines> (accessed July 10, 2018)

³ WHO. Lassa fever: fact sheet. <http://www.who.int/en/news-room/fact-sheets/detail/lassa-fever> (accessed July 10, 2018)

⁴ Gov.UK. Lassa fever: origins, reservoirs, transmission and guidelines <https://www.gov.uk/guidance/lassa-fever-origins-reservoirs-transmission-and-guidelines> (accessed July 10, 2018)

⁵ WHO. Lassa fever: fact sheet. <http://www.who.int/en/news-room/fact-sheets/detail/lassa-fever> (accessed July 10, 2018)

⁶ WHO. Lassa fever: fact sheet. <http://www.who.int/en/news-room/fact-sheets/detail/lassa-fever> (accessed July 10, 2018)

This year has seen outbreaks of Lassa virus in Liberia, Nigeria, Sierra Leone, and South Sudan,⁷ with Nigeria facing its largest ever outbreak of the disease.⁸

Dr. Richard Hatchett, CEO of CEPI, said:

“With 472 confirmed cases to date and 121 deaths,⁹ 2018 has seen Nigeria battle its largest documented outbreak of Lassa virus on record. Lassa fever continues to be a threat to public health in many parts of West Africa and has clearly demonstrated its potential to cause severe epidemics. In view of its epidemic potential, the World Health Organization has identified Lassa virus as a priority pathogen that needs further research and development. But despite the urgent need, no approved vaccine against the virus is currently available.

CEPI’s investment of up to \$36 million, over a five-year period, adds another Lassa vaccine candidate to CEPI’s growing portfolio and demonstrates our commitment to addressing this terrible disease.”

Thomas Lynch, Chair and CEO of Profectus BioSciences, said:

“Profectus is pleased to partner with CEPI, Emergent, and PATH in the development of our VesiculoVax™-vectored vaccine to protect against Lassa fever. Jointly we can address the substantial unmet medical need of those living in, or travelling to, areas where Lassa virus is endemic.”

Daniel J. Abdun-Nabi, CEO of Emergent BioSolutions, said:

“Through our collaboration with Profectus, CEPI, and PATH, Emergent is pleased to be part of the solution to provide medical countermeasures for emerging infectious diseases where there are none currently such as for Lassa fever. Our Center for Innovation in Advanced Development and Manufacturing is designed for surge manufacturing during public health emergencies, when they count the most.”

About CEPI

CEPI is an innovative partnership between public, private, philanthropic and civil organizations founded in Davos in 2017 to develop vaccines to stop future epidemics. To date, CEPI has received multi-year funding from Norway, Germany, Japan, the Bill & Melinda Gates Foundation, and Wellcome. CEPI has also received single-year investments from the governments of Australia, Belgium, and Canada. It has reached \$630 million of its target \$1 billion funding target. The European Commission has announced a contribution in kind of €250 million that will support relevant projects through EC mechanisms. Since its launch in January 2017, CEPI has announced two Calls for Proposals. The first was for candidate vaccines against MERS-COV, Nipah and Lassa viruses. The second was for the development of platforms that can be used for rapid vaccine development against unknown pathogens. Learn more at CEPI.net. Follow us at [@CEPIvaccines](https://twitter.com/CEPIvaccines).

⁷ WHO. Weekly bulletin on outbreaks and other emergencies.

<http://apps.who.int/iris/bitstream/handle/10665/272981/OEW26-2329062018.pdf> (accessed July 10, 2018)

⁸ WHO. Nigeria battles its largest Lassa fever outbreak on record. <https://www.afro.who.int/news/nigeria-battles-its-largest-lassa-fever-outbreak-record> (accessed July 10, 2018)

⁹ Nigeria Centre for Disease Control. Situation report, week 27.

file:///C:/Users/sh64/Downloads/An%20update%20of%20Lassa%20fever%20outbreak%20in%20Nigeria_290718_30.pdf



About Profectus BioSciences, Inc.

Profectus BioSciences, Inc. is a clinical-stage vaccine platform company developing novel vaccines for the prevention and treatment of infectious diseases and associated cancers. Profectus' vaccines are based on the company's proprietary vaccine delivery platforms to provide protection against emerging infectious diseases of public health and biodefense importance such as Ebola, Marburg, Chikungunya, Zika, the equine encephalitis viruses, and respiratory syncytial virus; and therapeutically targeting virally infected cells and cancers associated with hepatitis B virus (HBV), human papilloma virus (HPV), herpes simplex virus type 2 (HSV-2), and human immunodeficiency virus (HIV). For more information, please visit www.profectusbiosciences.com.

About Emergent BioSolutions Inc.

Emergent BioSolutions Inc. is a global life sciences company seeking to protect and enhance life by focusing on providing specialty products for civilian and military populations that address accidental, intentional, and naturally occurring public health threats. Through our work, we envision protecting and enhancing 50 million lives with our products by 2025. Additional information about the company may be found at www.emergentbiosolutions.com. Find us on LinkedIn and follow us on Twitter @emergentbiosolu and Instagram @life_at_emergent.

About the Lassa vaccine development

The VesiculoVax™ vaccine delivery platform is the result of basic research funding provided by the US 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. Currently, Federal funds from NIH/NIAID under Contract No. HHSN272201700077C are funding development of a multi-valent vaccine to provide simultaneous protection against Ebola, Marburg, and Lassa viruses. The NIH/NIAID and CEPI programs for Lassa-vaccine development are complementary and mutually supportive. NIAID conducts and supports research—at the NIH, throughout the US, and worldwide—to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing, and treating these illnesses.

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