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BARDA Provides the Sabin Vaccine Institute with an Additional $20 Million for Further Development of Ebola Sudan and Marburg Vaccines

Sabin and Partner ReiThera Initiate Manufacturing of Clinical Trial Material

WASHINGTON, D.C. and ROME, Italy, May 13, 2020 – The Sabin Vaccine Institute (Sabin) and its partner ReiThera Srl today announced that the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, has exercised the first two options, valued at $20 million, under the 2019 contract to advance the development of vaccines against Ebola Sudan and Marburg viruses through Phase 2 clinical trials. In September 2019, BARDA awarded Sabin a development contract, valued at $128 million, and provided the initial funding award of $20.5 million. This second $20 million award will enable the manufacture and release of clinical vaccine material developed by ReiThera, a specialist in the development and cGMP manufacture of adenoviral vector vaccines. The funding will also support non-clinical studies to evaluate efficacy and immune response.

Ebola Sudan and Marburg are among the world's deadliest viruses, causing hemorrhagic fever with subsequent death in an average of 50 percent of cases.[1,2] A closely related strain, Ebola Zaire, has caused more than 2,200 deaths since 2018 in the Democratic Republic of Congo (DRC),[3] leading the World Health Organization (WHO) to declare it a Public Health Emergency of International Concern.[4] With Ebola Sudan and Marburg's own history of outbreaks and their potential for future devastating outbreaks, preventative measures are overdue to protect civilian populations, military personnel, first responders, health care workers and laboratory workers, both in the United States and abroad, against these emerging infectious diseases.

"As the world has begun to appreciate, the next deadly outbreak is not a question of if, but when. At a time when global health and security are under siege by the novel coronavirus, we are grateful for BARDA's foresight in funding programs like ours that will help guard against future pandemics," said Sabin Chief Executive Officer Amy Finan. "We also greatly value ReiThera's partnership, given their extensive experience developing and manufacturing these vaccines."

"Our team at ReiThera (previously at Okairos) has more than 20 years' experience in developing novel adenoviral vaccine platform technologies targeting a range of serious diseases. We believe our approach makes them particularly suitable to safely and rapidly induce protective immunity ahead of and during outbreaks," said ReiThera's Chief Technology Officer, Stefano Colloca. "We are proud therefore to be a part of this important work with Sabin to prevent and control outbreaks of deadly hemorrhagic fevers by developing vaccines for the millions of people at risk."

Under a 2019 agreement between GSK and Sabin, Sabin exclusively licensed the technology for the candidate vaccines, based on GSK's proprietary ChAd3 platform, and acquired certain patent rights specific to these vaccines. The three candidate vaccines were initially developed collaboratively by the U.S. National Institutes of Health and Okairos, which was acquired by GSK in 2013.

This new funding from BARDA will enable Sabin and ReiThera to advance the investigational Ebola Sudan and Marburg vaccines through Good Manufacturing Practice (GMP) manufacturing and release of ChAd3-MARV and ChAd3-SUDV Phase 2 clinical material under Option 1 and conduct pilot efficacy and immunogenicity studies under Option 2. Additional non-clinical studies, as well as Phase 2 clinical trials in the United States and Africa, may be supported by an additional $87.5 million in funding under this contract.

This project has been funded in whole or in part with federal funds from the U.S. Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract number 75A50119C00055.

Learn more about Sabin's Ebola Sudan and Marburg program.

Citations:

[1] WHO fact sheet, Ebola virus disease, accessed August 28, 2019 – available at: https://www.who.int/news-room/fact-sheets/detail/ebola-virus-disease
[2] WHO fact sheet, Marburg virus disease, accessed August 28, 2019 – available at: https://www.who.int/news-room/fact-sheets/detail/marburg-virus-disease
[3] WHO, Ebola in the Democratic Republic of the Congo – Health Emergency Update, accessed August 28, 2019 – available at: https://www.who.int/emergencies/diseases/ebola/drc-2019
[4] WHO press release, Ebola outbreak in the Democratic Republic of the Congo declared a Public Health Emergency of International Concern, accessed August 28, 2019 – available at: https://www.who.int/news-room/detail/17-07-2019-ebola-outbreak-in-the-democratic-republic-of-the-congo-declared-a-public-health-emergency-of-international-concern

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About the Sabin Vaccine Institute

The Sabin Vaccine Institute, a non-profit organization founded in 1993, is a leading advocate for expanding vaccine access and uptake globally, advancing vaccine research and development, and amplifying vaccine knowledge and innovation. Sabin's R&D strategy focuses on continuing the development of candidate vaccines that have demonstrated early scientific value and target disease primarily impacting the world's most vulnerable populations, but have little commercial value. The Blavatnik Family Foundation and the David E.I. Pyott Foundation provided seed funding to launch Sabin's ChAd3 Ebola program. In past years, Sabin received more than $110 million for vaccine R&D programs from public and philanthropic funding sources, including the Bill & Melinda Gates Foundation, European Commission, Dutch Ministry of Foreign Affairs, Global Health Innovative Technology Fund and the Michelson Medical Research Foundation.

Unlocking the potential of vaccines through partnership, Sabin has built a robust ecosystem of funders, innovators, implementers, practitioners, policy makers and public stakeholders to advance its vision of a future free from preventable diseases. Sabin is committed to finding solutions that last and extending the full benefits of vaccines to all people, regardless of who they are or where they live. At Sabin, we believe in the power of vaccines to change the world. For more information, visit www.sabin.org and follow us on Twitter, @SabinVaccine.

About ReiThera Srl

ReiThera Srl is a biotech company dedicated to the technology development, GMP manufacturing and clinical translation of genetic vaccines and medicinal products for advanced therapies. The company's management and scientific teams have developed a highly innovative technological platform based on simian adeno-vectored vaccines against several infectious diseases, such as RSV and Ebola. ReiThera is led by an experienced management team that has worked together for many years in previous successful enterprises, including Okairos (acquired by GSK), and has a long-standing expertise in scalable processes for viral vector manufacturing, supported by a cGMP facility inclusive of filling suite and quality control laboratories. ReiThera is also part of a pan-European consortium focused on the development and large-scale manufacture of an adeno-viral vector vaccine against COVID-19.

ReiThera has its headquarters, R&D laboratories and GMP facilities in Rome, Italy. For further information see: www.reithera.com

About the GSK-Sabin ChAd3 Transaction

In August 2019, GSK and Sabin entered agreements for Sabin to advance the development of the prophylactic candidate vaccines against Ebola Zaire, Ebola Sudan and Marburg viruses. Under the agreements, Sabin exclusively licensed the technology for all three candidate vaccines and acquired certain patent rights specific to these vaccines. The three candidate vaccines were initially developed collaboratively by the U.S. National Institutes of Health and Okairos, which was acquired by GSK in 2013. The candidate vaccines, based on GSK's proprietary ChAd3 platform, were further developed by GSK, including the Phase 2 development for the Ebola Zaire vaccine. The ChAd3-based vaccines have demonstrated strong safety profiles and encouraging immunogenicity results after being administered to more than 5,000 adults and 600 children in 13 different clinical trials to date.

About Ebola Sudan and Marburg

Ebola Sudan and Marburg are members of the *Filoviridae* virus family and are commonly referred to as filoviruses. Both can cause severe hemorrhagic fever in humans and nonhuman primates. No therapeutic treatment of the hemorrhagic fevers caused by filoviruses has been licensed to date.

Marburg and Ebola viruses are transmitted to humans by infected animals, particularly fruit bats. Once a human is infected, the virus can spread to others through close personal contact or contact with bodily fluids. Isolation of infected people is currently the centerpiece of filovirus control.

Marburg was the first filovirus to be recognized in 1967 when a number of laboratory workers, including some in Marburg, Germany, developed hemorrhagic fever. Ebola was identified in 1976 when two simultaneous outbreaks occurred in northern Zaire (now the DRC) in a village near the Ebola River and southern Sudan. The outbreaks involved what eventually proved to be two different species of Ebola virus; both were named after the nations in which they were discovered.