

CEPI awards up to US\$23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine

Oslo, Norway, and Saint-Herblain, France, July 25, 2019—Valneva SE (“Valneva”), a biotech company developing and commercializing vaccines for infectious diseases with major unmet needs, and the Coalition for Epidemic Preparedness Innovations (CEPI) hereby announce a new partnering agreement. With support from the European Union’s (EU’s) Horizon 2020 programme, CEPI will provide Valneva up to US\$23.4 million for vaccine manufacturing and late-stage clinical development of a single-dose, live-attenuated vaccine (VLA1553) against Chikungunya. In line with CEPI’s commitment to equitable access, the funding will underwrite a partnership effort to accelerate regulatory approval of Valneva’s single-dose Chikungunya vaccine for use in regions where outbreaks occur and support WHO prequalification to facilitate broader access in lower and middle income countries.

Valneva will also maintain a stockpile of the vaccine candidate and work to transfer the secondary manufacturing of the drug product to partners for lower and middle income countries—where outbreaks of Chikungunya have occurred—to improve access to the vaccine for at-risk populations.

The investment is part of CEPI’s third call for proposals, launched earlier this year with support from the EU’s Horizon 2020 research and innovation programme under grant agreement N^o. 857934.¹ Since the launch of this call in January 2019, over US\$66 million has been invested in two Chikungunya vaccine candidates and two RVF vaccine candidates.

Chikungunya virus was first identified in Tanzania in 1952, with sporadic outbreaks of the disease reported subsequently across Africa and Asia.^{2,3} In 2004, the disease began to spread quickly, causing large-scale outbreaks around the world. Since the re-emergence of the virus, the total number of cases has been estimated at over 3.4 million in 43 countries.⁴ As such, the World Health Organization (WHO) has highlighted Chikungunya as a major public health risk.⁵

Chikungunya is spread by the bites of infected female *Aedes* mosquitoes and causes fever, severe joint pain, muscle pain, headache, nausea, fatigue and rash. Joint pain is often debilitating and can persist for weeks to years.⁶

¹ https://cepi.net/news_cepi/cepi-launches-call-for-proposals-to-develop-vaccines-against-rift-valley-fever-and-chikungunya-viruses/

² <https://www.who.int/news-room/fact-sheets/detail/chikungunya>

³ https://academic.oup.com/jid/article/214/suppl_5/S441/2632641

⁴ <https://cmr.asm.org/content/31/1/e00104-16>

⁵ <https://www.who.int/blueprint/priority-diseases/en/>

⁶ <https://jvi.asm.org/content/jvi/88/20/11644.full.pdf>

Climate change could further amplify the threat posed by Chikungunya. As the climate warms, more areas across the world will become habitable for the mosquito vectors that transmit the virus, thereby increasing the size of the human population at risk of infection. For example, in 2007, an outbreak of Chikungunya virus infections was declared for the first time in Europe with more than 200 human cases reported in Italy.⁷ Since 2014, in the USA, local-transmission of the virus has been reported in Florida, Puerto Rico, and the U.S. Virgin Islands.⁸

Dr Richard Hatchett, CEO of CEPI said:

“Millions of people have been affected by Chikungunya and, today, over a billion people live in areas where Chikungunya outbreaks occur. Despite the large outbreaks and significant consequences of this disease, there is currently no specific antiviral drug treatment nor are any vaccines licenced for human use against this virus. Through our partnership with Valneva, we hope to speed up the development of a Chikungunya vaccine, ensure that the people most affected by this virus can benefit from this product, and by doing so help to alleviate the burden of this debilitating disease.”

Thomas Lingelbach, CEO of Valneva said:

“Valneva is delighted to announce this partnership with CEPI. Chikungunya infection is a major unmet medical need and we believe that our single-shot vaccine is uniquely positioned to provide optimal protection in all outbreak situations for people living in areas where Chikungunya occurs and also for travelers to these regions. We continue to invest heavily in the program and look forward to working with CEPI on the project. We plan to enter the pivotal study phase of our vaccine as soon as possible in close alignment with the US FDA, with the aim of an accelerated approval.”

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About CEPI

CEPI is an innovative partnership between public, private, philanthropic, and civil organisations launched in Davos in 2017 to develop vaccines to stop future epidemics. CEPI has received multi-year funding from Norway, Germany, Japan, Canada, Australia, and the Bill & Melinda Gates Foundation, and Wellcome. CEPI has also received single-year investments from the Government of Belgium and the United Kingdom. The European Union provides financial support for relevant projects through their Horizon 2020 programme as well as through the European and Developing Countries Clinical Trials Partnership. CEPI has reached over US\$750 million of its \$1 billion funding target. Since its launch in January 2017, CEPI has announced three calls for proposals. The first call was for candidate vaccines against Lassa

⁷<https://ecdc.europa.eu/en/chikungunya/threats-and-outbreaks/chikungunya-fever-eueea>

⁸<https://www.cdc.gov/chikungunya/geo/united-states.html>



virus, Middle East Respiratory Syndrome coronavirus (MERS-CoV), and Nipah virus. The second call was for the development of platforms that can be used for rapid vaccine development against unknown pathogens. The third call is for candidate vaccines against Chikungunya and Rift Valley fever viruses. To date, CEPI has committed to investing over \$413 million in vaccine development. This includes 18 vaccine candidates against its priority pathogens (six against Lassa virus, five against MERS-CoV, three against Nipah virus, two against Chikungunya, two against Rift Valley fever) and three vaccine platforms to develop vaccines against Disease X. To assess the effectiveness of these platforms 7 additional vaccine candidates are being developed (two against influenza, one against Marburg virus, two against Rabies virus, one against Respiratory Syncytial Virus, and one against yellow fever).

Learn more at CEPI.net. Follow us at [@CEPIvaccines](https://twitter.com/CEPIvaccines).

About Valneva

Valneva is a biotech company developing and commercializing vaccines for infectious diseases with major unmet needs. Valneva's portfolio includes two commercial vaccines for travelers: IXIARO®/JESPECT® indicated for the prevention of Japanese encephalitis and DUKORAL® indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by ETEC. The Company has various vaccines in development including a unique vaccine against Lyme disease. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the US with approximately 480 employees. More information is available at www.valneva.com.

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