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Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries

Saint-Herblain (France), Sao Paulo, (Brazil), January 25, 2021 – Valneva SE ("Valneva" or "the Company"), a specialty vaccine company focused on prevention of infectious diseases with significant unmet medical need, and Instituto Butantan, producer of immunobiologic products, today announced the signing of definitive agreements for the development, manufacturing and marketing of Valneva's single-shot chikungunya vaccine, VLA1553, in Low and Middle Income Countries (LMICs). This finalization follows the signing of a binding term sheet in May 2020[1]. The collaboration falls within the framework of the $23.4 million funding agreement Valneva signed with the Coalition for Epidemic Preparedness Innovations (CEPI) in July 2019[2].

Under the collaboration, Valneva will transfer its chikungunya vaccine technology to Instituto Butantan, who will develop, manufacture and commercialize the vaccine in LMICs. In addition, Instituto Butantan will provide certain clinical and Phase 4 observational studies that Valneva will use to meet regulatory requirements. The agreement includes small upfront and technology transfer milestones.

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, "The dreadful impact of the COVID-19 pandemic on the world has underlined the importance of vaccines to combat public health crises. Chikungunya outbreaks have impacted over 120 countries and affected millions, yet no vaccine or treatment is currently available to prevent this debilitating disease. We look forward to working with Instituto Butantan to help address this urgent public health need and speed up the development of a chikungunya vaccine in LMICs, which are high outbreak risk areas."

Dr. Dimas Covas, Director of Instituto Butantan added, "Within the concept of the relevance of qualified partnerships for complementary actions with an impact on society, the relationship established between the Butantan Institute and Valneva is extremely significant and auspicious. It is a partnership that allows the development and national production of an immunizer highly relevant to the Brazilian public health system and which will allow the prevention of thousands of annual cases of Chikungunya virus infections and their consequences."

Dr Melanie Saville, Director of Vaccine Development at CEPI, said: "Over the past 15-20 years, we have seen the expansion of Chikungunya outbreaks around the world—particularly affecting people living in low- and middle-income countries (LMICs). Chikungunya is a truly debilitating disease, causing symptoms which can last for months and the risk of permanent disability from long-term complications. This agreement will accelerate the development and manufacturing of this vaccine candidate for LMICs, in keeping with CEPI's core commitment to enable equitable access to vaccines."

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[1] *Valneva to Partner with Instituto Butantan on Single-Shot Chikungunya Vaccine for Low- and Middle-Income Countries*

[2] *CEPI awards up to US$23.4 million to Valneva for late-stage development of a single-dose chikungunya vaccine*

About Chikungunya

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), a *Togaviridae* virus, transmitted by *Aedes* mosquitoes. Infection leads to symptomatic disease in 72-92% of humans after 4 to 7 days following the mosquito bite. While mortality with CHIKV is low, morbidity is high. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea and rash. 4.1%-78.6% of infections develop into chronic arthralgia (> 3 months). Chikungunya virus often causes sudden large outbreaks with high attack rates, affecting one-third to three-quarters of the population in areas where the virus is circulating. The highest risk areas of infection for travelers are places where chikungunya virus-carrying mosquitos are endemic, including the Americas, parts of Africa, and Southeast Asia. As of September 2020, there have been more than 3 million reported cases in the Americas[3] and the economic impact is considered to be significant (e.g. Colombia outbreak 2014: $73.6 million[4]). The medical and economic burden is expected to grow as the CHIKV primary mosquito vectors continue to further spread geographically. There are no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat.

About VLA1553

VLA1553 is a live-attenuated, single dose vaccine candidate for protection against chikungunya disease and currently tested in clinical Phase 3. VLA1553 has been designed by deleting a part of the chikungunya virus genome. As a live-attenuated vaccine, VLA1553 is particularly well suited to target long-lasting protection.

Valneva is the first company to advance a chikungunya vaccine candidate into Phase 3. The sponsor of the first chikungunya vaccine Biologics License Application (BLA) to be approved in the U.S. will be eligible to receive a Priority Review Voucher (PRV) [5].

VLA1553 would expand Valneva's existing travel vaccine portfolio and as such, Valneva intends to commercialize this vaccine leveraging its existing manufacturing and commercial operations. The global market for vaccines against chikungunya is estimated to exceed $500 million annually by 2032[6].

VLA1553 Phase 1 data in 120 volunteers were published in The Lancet Infectious Diseases[7]. The vaccine was well tolerated at the dose level selected for Phase 3. No vaccine-related serious adverse events were reported during 12 months of follow-up. Neutralizing antibodies were developed in 100% of volunteers within 14 days after a single vaccination and were maintained up to one year. Based on these encouraging results, pivotal Phase 3 testing was initiated in September 2020 for the program which was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) and PRIME designation by the European Medicines Agency (EMA).

About Phase 3 study VLA1553-301

VLA1553-301 Phase 3 study was initiated in September 2020. It is a prospective, double-blinded, multicenter, randomized, pivotal Phase 3 study comprising approximately 4,000 participants aged 18 years or above. Lyophilized VLA1553 or placebo will be administered as a single intramuscular immunization. The primary objective of the study is to evaluate the

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[3] *PAHO/WHO data: Number of reported cases of chikungunya fever in the Americas. https://www.paho.org/data/index.php/en/mnu-topics/chikv-en/550-chikv-weekly-en.html. Last accessed 13 Oct 2020.*
[4] *Cardona-Ospina et al. 2015, Trans R Soc Trip Med Hyg 109:793-802.*
[5] *https://priorityreviewvoucher.org/*
[6] *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*
[7] *Wressnigg et al. 2020, Lancet ID;20(10):1193-1203.*

immunogenicity and safety of the final dose of VLA1553 28 days following a single immunization. Safety data collection and immunogenicity will continue to be assessed until Month 6; further long-term follow up is planned.
Additional information, including a detailed description of the study design, eligibility criteria and investigator sites, is available at ClinicalTrials.gov (Identifier: NCT04546724).

About Valneva SE
Valneva SE is a specialty vaccine company focused on prevention of infectious diseases with significant unmet medical need. The Company has several vaccines in development including unique vaccines against Lyme disease, COVID-19 and chikungunya. 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. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the U.S. with over 500 employees.

About Instituto Butantan
Instituto Butantan is the main producer of immunobiological products and vaccines in Brazil. Instituto Butantan carries out scientific missions domestically and abroad through the Pan American Health Organization, the World Health Organization, UNICEF and the United Nations. The Institute collaborates with other agencies of the São Paulo State Secretariat of Health and the Brazilian Ministry of Health for the improvement of overall health in Brazil. It acts in partnership with various universities and entities such as the Bill & Melinda Gates Foundation for the achievement of its institutional objectives. For more information please visit the Institute website at www.butantan.gov.br or contact the press office at (+55 11) 2627-9606 / 9428 or email to imprensa@butantan.gov.br

About CEPI
CEPI is an innovative partnership between public, private, philanthropic, and civil organizations, launched at Davos in 2017, to develop vaccines to stop future epidemics. Before the emergence of COVID-19 CEPI's priority diseases included Ebola virus, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever and Chikungunya virus. CEPI also invested in platform technologies that can be used for rapid vaccine and immunoprophylactic development against unknown pathogens (Disease X).
CEPI has moved with great urgency and in coordination with WHO in response to the emergence of COVID-19. CEPI has initiated 9 partnerships to develop vaccines against the novel coronavirus. The programmes will leverage rapid response platforms already supported by CEPI as well as new partnerships. The aim is to advance COVID-19 vaccine candidates into clinical testing as quickly as possible.
CEPI, alongside Gavi and the World Health Organisation, co-leads the vaccines pillar of the ACT Accelerator – known as COVAX – which is working to develop, distribute and deploy COVID-19 vaccines to the world. Learn more at **http://www.cepi.net**. Follow us at **@CEPIvaccines**.

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Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing and completion of research, development and clinical trials for product candidates, the ability to manufacture, market, commercialize and achieve market acceptance for product candidates, the ability to protect intellectual property and operate the business without infringing on the intellectual property rights of others, estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements and needs for additional financing. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this press release, those results or developments of Valneva may not be indicative of their in the future. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based largely on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, and the ability to obtain or maintain patent or other proprietary intellectual property protection. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. Valneva is providing the information in these materials as of this press release, and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.