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

Saint-Herblain (France), Sao Paulo, (Brazil), May 5, 2020 – Valneva SE ("Valneva" or "the Company"), a specialty vaccine company, and Instituto Butantan, producer of immunobiologic products, today announced the signing of a binding term sheet for the development, manufacturing and marketing of Valneva's single-shot chikungunya vaccine, VLA1553, in Low and Middle Income Countries (LMICs). The collaboration falls within the framework of the $23.4 million in funding Valneva received from the Coalition for Epidemic Preparedness Innovations (CEPI) in July 2019[1]. The definitive agreements are expected to be finalized in the next six months.

After the signing of the definitive agreements, 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 will include small upfront and technology transfer milestones.

Valneva held its End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in February 2020 and is now preparing to initiate Phase 3 clinical studies in the U.S. later this year.

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, "Although millions of people have been affected by chikungunya, there is currently no vaccine and no effective treatment available against this debilitating disease. We look forward to working with Instituto Butantan to help address this current public health crisis and speed up the development of a chikungunya vaccine in LMICs, which are high outbreak areas."

Dr. Dimas Covas, Director of Instituto Butantan added, "The burden of chikungunya virus disease resides not only in the two million deaths worldwide since 2005, but also in the chronification of its symptoms, which constitutes a long term public health problem. By tackling the challenge of developing, manufacturing and marketing Valneva's chikungunya vaccine, Instituto Butantan will further strengthen its commitment to improving public health in low and middle income countries."

About Chikungunya
Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), a *Togaviridae* virus, transmitted by *Aedes* mosquitoes. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea and rash, potentially developing into long-term, serious health impairments. Chikungunya virus causes clinical illness in 72-92% of infected humans around 4 to 7 days after an infected mosquito bite. Complications resulting from the disease include visual, neurological, heart and gastrointestinal manifestations; fatalities

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

have been reported (case fatality rates of 0.1% to 4.9% from epidemics)[2] in elderly patients at higher risk. Chikungunya outbreaks have been reported in Asia, Africa, the Americas and recently (2017) in Europe. As of 2017, there have been more than one million reported cases in the Americas[3] and the economic impact is considered to be significant (e.g., 2014 Colombia outbreak: $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 Valneva's vaccine candidate VLA1553

VLA1553 is a monovalent, single dose, live-attenuated vaccine candidate for protection against chikungunya. It was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in December 2018[5].

The vaccine candidate is designed for prophylactic, active, single-dose immunization against chikungunya in humans over one year old. The vaccine targets long-lasting protection and an anticipated safety profile similar to licensed vaccines for active immunization in adults and children. The target population segments are travelers, military personnel and individuals at risk living in endemic regions. The global market for vaccines against chikungunya is estimated to exceed $500 million annually[6], including a traveler vaccine market potential of ~$250 million. VLA1553 is based on an infectious clone (CHIKV LR2006-OPY1) attenuated by deleting a major part of the gene encoding the non-structural replicase complex protein nsP3, aiming for protection against various chikungunya virus outbreak phylogroups and strains[7].

About Valneva SE

Valneva is a specialty vaccine company focused on prevention against 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 unique vaccines against Lyme disease and chikungunya. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the U.S. with over 500 employees. For more information, visit www.valneva.com and follow the company on LinkedIn.

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

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[2] WHO, PAHO
[3] PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)
[4] Cardona-Ospina et al. 2015, Trans R Soc Trip Med Hyg 109:793-802.
[5] Valneva Awarded FDA Fast Track Designation for Chikungunya vaccine candidate
[6] Company estimate supported by an independent market study
[7] Hallengärd et al. 2013, J. Virology 88:2858-2866.

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 organisations, launched at the World Economic Forum at Davos in 2017, to develop vaccines to stop future epidemics. CEPI's priority diseases include Ebola virus, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever and Chikungunya virus. CEPI also invests in platform technologies that can be used for rapid vaccine and immunoprophylactic development against unknown pathogens (i.e., 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 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's commitment to access
As COVID-19 demonstrates, infectious diseases utterly ignore political borders. We cannot prevent or stop a global infectious disease threat without equitable access to globally fair allocation of vaccines. CEPI is wholly committed to equitable access. This commitment drives every aspect of our work. CEPI's support for equitable access is key to our success as a global health organisation. Equitable access to epidemic vaccines—in the context of an outbreak—means that appropriate vaccines are first available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay.

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.