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Valneva: Renowned Vaccinologist Dr. Stanley Plotkin to Present at R&D Investor Day in New York City on July 9th

Live webcast beginning at 8:30am EDT / 2:30pm CEST

Saint-Herblain (France), July 3, 2019 – Valneva SE ("Valneva" or "the Company"), a biotech company developing and commercializing vaccines for infectious diseases with major unmet medical needs, today announced that renowned vaccinologist Dr. Stanley A. Plotkin, MD will present on Lyme disease and chikungunya at its Research & Development (R&D) Investor Day on Tuesday, July 9th, 2019 in New York City, from 8:30a.m. to 11:00a.m. Eastern Daylight Time (EDT).

Dr. Plotkin serves as a consultant to the vaccine industry and is an emeritus professor at both the Wistar Institute and University of Pennsylvania. He developed the rubella vaccine, which is now used worldwide, and has played a pivotal role in both the development and application of various other vaccines including: polio, rabies, varicella, rotavirus and cytomegalovirus. He is the author of more than 600 research papers and has edited several books including, *Vaccines*. Dr. Plotkin has served as the senior assistant surgeon with the Epidemic Intelligence Service, U.S. Public Health Service, director of the division of infectious diseases at Children's Hospital of Philadelphia, associate chairman of the department of paediatrics, University of Pennsylvania and Medical Director at Sanofi Pasteur for seven years. Due to his personal interest in a Lyme vaccine, Dr. Plotkin does not receive remuneration or any benefits from Valneva. Furthermore, Dr. Plotkin does not hold any stock or stock options in the Company.

As previously announced, Valneva's Chief Executive Officer Thomas Lingelbach and Chief Medical Officer Wolfgang Bender, MD, PhD, will give a full update on the Company's two leading vaccine clinical development programs, VLA15 (Lyme disease) and VLA1553 (chikungunya).

Valneva's vaccine candidate VLA15 is the only Lyme disease vaccine in clinical development worldwide, while the Company's unique chikungunya vaccine candidate, VLA1553, has potential single-shot long-term efficacy.

R&D Day Event Details

The event will be held on Tuesday, July 9th at the Parker Hotel in New York City. Doors will open at 7:45a.m. for registration and breakfast, and the event will end around 11:00a.m. Please RSVP in advance if you plan to attend, as space is limited. For those who are unable to attend in person, a live webcast and replay will be accessible via the link here.

For further information please visit www.valneva.com or email the Investor Relations team at investors@valneva.com.

About Lyme Disease

Lyme disease is a systemic infection caused by *Borrelia* bacteria transmitted to humans by infected *Ixodes* ticks[1]. It is considered the most common vector borne illness in the Northern Hemisphere. According to the US Centers for Disease Control and Prevention (CDC), approximately 300,000 Americans[2] are diagnosed with Lyme disease each year with at least a further 200,000 cases in Europe[3]. Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called *Erythema migrans* or more unspecific symptoms like fatigue, fever, headache, mild stiff neck, arthralgia or myalgia) are often overlooked or misinterpreted. Left untreated, the disease can disseminate and cause more serious complications affecting the joints (arthritis), the heart (carditis) or the nervous system. The medical need for vaccination against Lyme disease is steadily increasing as the disease footprint widens[4].

About VLA15

Valneva's vaccine candidate, VLA15, is currently the only active vaccine program in clinical development against Lyme disease. The program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017[5] .

Valneva reported final Phase 1 data demonstrating VLA15's favorable safety profile and immunogenicity in all doses and formulations tested, with good OspA-specific IgG antibody responses against all OspA serotypes. In addition, VLA15 elicited an excellent anamnestic response following a booster vaccination in a time window of 12 to 15 months after initial primary immunization[6]. As part of the ongoing Phase 2, two higher, alum-adjuvanted formulations have been selected for further development[7].

VLA15 is a multivalent, protein subunit vaccine that targets the outer surface protein A (OspA) of *Borrelia*. It is designed for prophylactic, active immunization against Lyme disease aiming for protection against the majority of human pathogenic *Borrelia* species in Europe and the US. VLA15 is designed to confer protection by raising antibodies that prevent *Borrelia* from migrating from ticks to humans after a bite. The safety profile is expected to be similar to other lipidated protein based vaccines that are approved for active immunization in adults and children.

The target population includes individuals at risk above 2 years of age living in endemic areas, people planning to travel to endemic areas to pursue outdoor activities and people at risk who have a history of Lyme disease (as infection with Borrelia does not confer protective immunity against all pathogenic Borrelia species). Vaccination with OspA was proven to work in the 1990s and VLA15 pre-clinical data showed that the vaccine has the potential to provide protection against the majority of the *Borrelia* species pathogenic for humans[8].

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

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[1] *Stanek et al. 2012, The Lancet 379:461–473*

[2] *As estimated by the CDC, https://www.cdc.gov/lyme/stats/humancases.html.*

[3] *Estimated from available national data. Number largely underestimated based on WHO Europe Lyme Report as case reporting is highly inconsistent in Europe and many LB infections go undiagnosed; ECDC tick-borne-diseases-meeting-report*

[4] *New Scientist, Lyme disease is set to explode and we still don't have a vaccine; March 29, 2017 https://www.newscientist.com/article/mg23431195-800-lyme-disease-is-set-to-explode-and-you-cant-protect-yourself/*

[5] *https://www.valneva.com/en/investors-media/news/2017#270*

[6] https://www.valneva.com/en/investors-media/news/2019#309

[7] https://www.valneva.com/en/investors-media/news/2019#319

[8] *http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0113294.*

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 have been reported (case fatality rates of 0.1% to 4.9% from epidemics)[9] 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[10] and the economic impact is considered to be significant (e.g. Colombia outbreak 2014: $73.6m[11]). 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 monovalent, single dose, live-attenuated vaccine candidate for protection against chikungunya and was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in December 2018[12]. 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 at up to €500 million annually[13].

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[14].

In pre-clinical development, a single-vaccine shot was shown to be highly immunogenic in vaccinated Non-Human Primates (NHP) (*cynomolgus* macaques) and showed no signs of viremia after challenge[15]. In NHPs, VLA1553 induced a strong, long lasting (more than 300 days) neutralizing antibody response comparable to wild-type CHIKV infections, combined with a good safety profile.

About Valneva SE

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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[9] WHO, PAHO
[10] PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)
[11] Cardona-Ospina et al., Trans R Soc Trip Med Hyg 2015
[12] Valneva PR: Valneva Awarded FDA Fast Track Designation for Chikungunya vaccine candidate
[13] Company estimate support by an independent market study
[14] Hallengärd et al. 2013 J. Virology 88: 2858-2866
[15] Roques et al. 2017JCI Insight 2 (6): e83527

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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.