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# Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15

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+ Lyme disease is the fastest growing vector-borne infectious disease in the United States, according to the CDC;
+ Currently, there is no vaccine available to protect humans against Lyme disease and VLA15 is the only candidate in clinical development;
+ Valneva recently completed Phase I subject enrollment and expects to announce first results in Q1 2018;
+ The Company aims to accelerate VLA15's development and plans to initiate a Phase II trial in Q1 2018;
+ Fast track designation may offer a faster way to market approval through frequent interactions with the FDA

Lyon (France), July 24, 2017 – Valneva SE ("Valneva" or "the Company"), a fully integrated, commercial stage biotech company focused on developing innovative lifesaving vaccines, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for its Lyme disease vaccine candidate VLA15.

Fast Track designation is granted by the FDA to products that are under development for serious conditions and have the potential to fulfill an unmet medical need. It is designed to facilitate the clinical development and expedite the review of new drugs and vaccines with the intention to accelerate the availability of promising products on the market

**Thomas Lingelbach, President and CEO of Valneva commented**, "Lyme disease affects an increasing number of people each year, many of whom have to live with long-term sequelae that are not only extremely difficult to treat but also represent a heavy health economic burden. We feel privileged to advance the only active clinical stage Lyme vaccine candidate to date and are looking forward to working closely with the FDA and other authorities to facilitate the development towards approval."

Valneva recently completed subject enrollment for the ongoing Phase I study of its Lyme disease vaccine candidate. The study is being conducted at three sites – two in the U.S. and one in Europe (Belgium) – combining approximately 180 subjects aged between 18 and 40 years. The primary objective of the observer-blind, partially randomized, dose escalation study is to evaluate the vaccine candidate´s safety and tolerability profile at different dose levels and formulations.

Immunogenicity, measured by observing IgG antibodies2 against the six most prevalent serotypes of Lyme borreliosis in the US and Europe present in the vaccine, will also be monitored for different dose groups and formulations at different time-points.

Given the steady increase in the incidence of the disease and its spread to new territories, Valneva is committed to accelerate the development of VLA15 as a novel prevention against such a highpriority medical need. As such, the company plans to initiate Phase II as early as the first quarter of 2018.

Pre-clinical data showed that Valneva's vaccine candidate had the potential to provide protection against the majority of Borrelia species pathogenic for humans3 .

**About Lyme disease**
Lyme disease (LD), also known as Lyme borreliosis, is an infectious disease caused by Borrelia bacteria which are transmitted to humans by infected ticks. 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. When treatment for LD is delayed or inadequate, infection with Borrelia can lead to serious complications involving the joints, heart and central nervous system. Each year, an estimated 300,000 US citizens4 and 85,000 Europeans5 develop Lyme disease. It was diagnosed as a separate condition for the first time in 1975 in Old Lyme, Connecticut.

**About VLA15**
VLA15 is a new hexavalent, protein subunit-based vaccine candidate targeting the Outer Surface Protein A (OspA) of Borrelia, the most dominant protein expressed by the bacteria when present in a tick. By targeting the most prevalent serotypes of Borrelia and blocking the transmission of these Lyme-causing bacteria from the tick to the host, the vaccine has the potential to protect from Borrelia infection in the U.S., Europe, and potentially worldwide. The target indication for Valneva's vaccine candidate is the active prophylactic immunization against Lyme disease in children and adults. The global market for a vaccine against Lyme disease is estimated at approximately €700 - €800 million annually6 .

**About Valneva SE**
Valneva is a fully integrated, commercial stage biotech company focused on developing innovative lifesaving vaccines.

Immunoglobulin G antibodies (IgG) are found in all body fluids. They are the smallest but most common antibody (75% to 80%) of all the antibodies in the body. IgG antibodies are essential in fighting bacterial and viral infections.
http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0113294.
http://www.cdc.gov/lyme/stats/graphs.html.
Estimation from available national data based on WHO Europe Lyme Report; ECDC tick-borne-diseases meeting-report.
Company estimate based on independent market studies.

The Company seeks financial returns through focused R&D investments in promising product candidates and growing financial contributions from commercial products, striving towards financial self-sustainability.

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 proprietary vaccines in development including candidates against Clostridium difficile and Lyme Borreliosis. A variety of partnerships with leading pharmaceutical companies complement the Company's value proposition and include vaccines being developed using Valneva's innovative and validated technology platforms (EB66® vaccine production cell line, IC31® adjuvant). Valneva shares are tradable on Euronext-Paris, the Vienna stock exchange and Deutsche Börse's electronic platform Xetra® . The Company has operations in France, Austria, Great Britain, Sweden, Canada and the US with over 400 employees. More information is available at www.valneva.com.

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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 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 4/4 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 in this press release will in fact be realized. Valneva is providing the information in these materials as of the date of this press release, and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise