Advancing vaccines for better lives.

“The high incidence of Lyme disease is perhaps the greatest failure of contemporary public health in the United States and perhaps also in Europe, considering that we know the immunologic basis of control but have no licensed vaccine. A new vaccine would protect people of all ages from serious complications of this bacterial infection.”

— STANLEY A. PLOTKIN
Emeritus Professor of the Wistar Institute at the University of Pennsylvania and inventor of the Rubella vaccine

3 As estimated by the CDC: https://www.cdc.gov/lyme/stats/humancases.html
5 www.cdc.gov/lyme/FAQ/index.html
7 www.cdc.gov/Lyme
12 No differences in the safety profile were observed for the adjuvanted groups compared to the non-adjuvanted treatment groups
13 IgG levels were substantially higher after three immunizations (Day 84) compared to after two (Day 56)

For further reference

For further information please contact
VALNEVA communications@valneva.com
**WHAT IS LYME DISEASE?**

Lyme disease is caused by Borrelia bacteria, which are transmitted to humans through the bite of infected blacklegged ticks.

Inadequately treated or not treated in the early stages of infection, Lyme disease can be disabling and lead to very serious complications, including chronic joint pain in the elbows and knees, paralysis of facial muscles, shortness of breath, and heart inflammation.

**WHO IS AT RISK?**

Each year, an estimated 300,000 Americans and 200,000 Europeans contract Lyme disease. In addition, the global footprint of Lyme disease is rapidly expanding putting more and more people at risk every year.

**WHAT IS THE PUBLIC HEALTH IMPACT?**

Lyme disease presents a significant unmet medical need:

— Lyme disease symptoms – apart from the classic “bullseye”-shaped Erythema migrans rash, which is not always present and can be overlooked – are nonspecific and can be misdiagnosed as other conditions.

— Early in the disease, the two-tiered testing system recommended by the CDC may not be capable of detecting all cases.

It is also an extremely costly medical burden. The U.S. health care system spends between $712 million and $1.3 billion a year and $3,000 per patient related to Lyme disease.

**DIAGNOSIS**

Diagnosing the disease is difficult, since people do not associate the most common early symptoms (fever, headache, fatigue and a rash occurring in 70-80% of cases) with Lyme disease.

**TREATMENT**

Immediate treatment with antibiotics is successful in most cases, but there are numerous undiagnosed cases which can lead to serious, permanent symptoms.

**PREVENTION**

Today, preventing Lyme disease means preventing tick bites, but personal protective measures are underutilized and pest management efforts have only had limited success in controlling ticks and the associated diseases.

Currently no Lyme disease vaccine is available for humans, although it has been shown that the disease can be prevented by immunization with an Outer surface protein A (OspA)-based vaccine.

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**VALNEVA’S MULTIVALENT LYME VACCINE CANDIDATE: VLA15**

VLA15 is currently the most advanced active clinical vaccine program of its kind and has the potential to prevent people suffering from this debilitating illness. It is designed to offer protection against the six most common types of Borrelia spirochetes that cause Lyme disease in North America and Europe.

Valneva’s goal with VLA15 is to prevent Lyme disease in adults and children aged two years and older, aiming for protection against the majority of human pathogenic Borrelia species.

VLA15 was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017.

**PHASE 2 STUDY (VLA15-201) INITIATED DECEMBER 2018**

Valneva recently announced the first of two planned, parallel Phase 2 studies of VLA15 to be conducted at trial sites in the U.S. and Europe.

The overall Phase 2 objective is to determine the optimal dosage level and schedule for use in Phase 3 pivotal field efficacy studies, based on immunogenicity and safety data.

Valneva previously released positive interim Phase 1 clinical trial results for VLA15 in March 2018:

— VLA15 met the primary study endpoint, showing a favorable safety profile: no safety concerns were associated with VLA15 in any treatment group.

— VLA15 was also immunogenic in all doses and formulations tested, with good OspA-specific IgG antibody responses against all OspA serotypes.

Valneva expects to announce interim Phase 2 data in 2020.