

LYME DISEASE



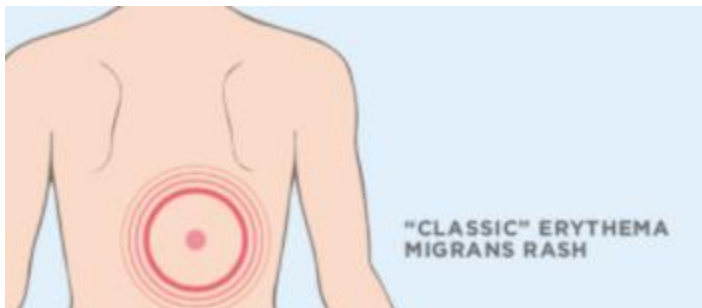
WHAT IS LYME DISEASE?

Lyme disease is the most common vector-borne illness in the Northern Hemisphere[1],[2]. It is caused by *Borrelia* bacteria transmitted to humans by infected *Ixodes* ticks[3]. In most cases, the tick must be attached to the human body for 36 to 48 hours before the bacteria can be transmitted.



SYMPTOMS, DIAGNOSIS & TREATMENT

Early symptoms of Lyme disease include the "classic" bullseye rash, called erythema migrans, that develops in 70-80% of cases and is often accompanied by non-specific symptoms of fatigue, fever, headache, mild stiff neck, arthralgia or myalgia. In many cases the erythema migrans rash is overlooked, making diagnosis difficult.



Left untreated, the disease can spread and cause more serious complications affecting the joints (arthritis), the heart or the nervous system.

Immediate treatment with antibiotics is successful in most cases and patients usually recover without complications. However, there are numerous undiagnosed cases causing serious and permanent symptoms.

PREVENTION

Today, preventing Lyme disease means preventing tick bites[4], but personal protective measures are underutilized[5] and pest management efforts have only had limited success in controlling ticks and the associated diseases[6]. Currently there is no Lyme disease vaccine available to protect humans from this devastating illness and the medical need for vaccination against Lyme is steadily increasing as the disease footprint widens[7].

FACTS & FIGURES

300,000

Americans are diagnosed with Lyme disease each year[1].

\$712m - \$1.3b

Each year the U.S. healthcare system spends between \$712m and \$1.3b on Lyme disease[8].

200,000

Europeans are diagnosed with Lyme disease each year[2].

\$3,000

Each year the U.S. healthcare system spends \$3,000 per Lyme disease patient[8].

VALNEVA'S VACCINE CANDIDATE - VLA15

VLA15 is currently the only active vaccine program in clinical development against Lyme disease.

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 North America. VLA15 is designed to confer protection by raising antibodies that prevent *Borrelia* from migrating from ticks to humans after a bite.

The target population for VLA15 includes individuals at risk above two 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).

The VLA15 program was granted Fast Track designation by the FDA in July 2017[9].

VLA15 is in Phase 2 clinical development with a clear path to commercialization:

- The overall Phase 2 objectives for VLA15 are to determine the optimal dosage level and vaccination schedule for use in Phase 3 pivotal field efficacy studies, based on immunogenicity and safety data.
- Valneva expects to announce initial Phase 2 data (primary endpoint) in mid-2020.
- VLA15 demonstrated a favorable safety profile and high immunogenicity in a Phase 1 clinical study. The Phase 1 clinical trial conducted in 179 volunteers[10] showed no safety concerns associated with the vaccine in any treatment group[11]. VLA15 was immunogenic in all doses and formulations tested.

References

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