

# NIH Grants 1.9 Million for Vaccine to Prevent Lyme

West Virginia University researchers received a \$1.9 million grant from the National Institute of Allergy and Infectious Diseases, an institution of the National Institute of Health (NIH), for a vaccine to prevent humans from contracting Lyme disease.



Mariette Barbier, assistant professor in the School of Medicine's Department of Microbiology, Immunology and Cell Biology, is leading the five-year project, along with Timothy Driscoll, assistant professor of biology in the Eberly College of Arts and Sciences, and Heath Damron, assistant professor and director of the WVU Vaccine Development Center.

Barbier and her team will try to develop a vaccine effective against the various species of *Borrelia* (the Lyme disease bacteria). They will be using RNA sequencing to examine how pathogens respond in both infected ticks and mice, and identify relevant antigens during infection.

Driscoll will be studying the proteins made by *Borrelia* during the black-legged ticks life cycle. "In vaccine development, what we try to do is identify those proteins and target them in hopes of clearing the pathogen out, killing it, essentially. If a protein is essential for survival, it makes it harder for the pathogen to change it and evade the immune system," says Driscoll.

Barbier has studied bacterial pathogens, including *Pseudomonas aeruginosa*, which requires iron to grow and infect their host.

“We figured out which antigens could be used to formulate a vaccine, and found the Achilles heel to the bacteria to use against it,” Barbier said. “We focused on one system, which is the iron acquisition system of *Pseudomonas*.” Since *Borrelia* does not require iron, she is driven to find what would be required of *Borrelia*.

Barbier said. “If it doesn’t use iron, what else can we use against it? By bringing in the expertise of others, we’re going to crack the problem.”

**Read more about the project here** ([eurekalert.org](http://eurekalert.org))

**Click here for Project Info on NIH site**

**Read about another recent NIH-funded Lyme Vaccine study here**

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## **NIH awards \$3.5 Million for Novel Lyme Disease Vaccine Study**

With a new \$3.5 million grant from the National Institutes of Health (NIH), Utpal Pal, PhD, professor in Veterinary Medicine at the University of Maryland (UMD) will be partnering with Matthias Schnell, director of the Jefferson Vaccine Center at Thomas Jefferson University to develop a novel “next-generation” Lyme disease vaccine.



Pal, a tick immunobiologist, and Schnell, whose lab studies

rabies virus as a platform for vaccination, will adapt the rabies virus platform to fight Lyme disease. The inactivated rabies virus, which helps the body produce antibodies to fight rabies, will be repurposed to produce other types of proteins that can fight *Borrelia burgdorferi*, the Lyme disease bacteria, a technique found effective for other viral vaccinations.

This study will test the four already identified vaccine candidate proteins, as well as the three major types of rabies vaccine platforms— using live attenuated virus, inactivated virus, and the shell of a virus with viral proteins on the outside but no virus inside to trick the body. Pal is also studying both *Borrelia* proteins and the tick proteins that keep the *Borrelia* alive so it can be transmitted to humans.

**Read more about this project here – (prweb.com)**

**Click here for Project Info on NIH site**

**Utpal Pal, PhD lectured at LDA's 2018 Annual Scientific Conference – *Immune Evasion of Lyme Disease Agents***

**Read about Pal's previous research – UMD Research Isolates *Bb* Protein that Disables Immune System**

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**Lyme Vaccine Candidate:**

# Valneva Announces Phase 2 Study Results



Valneva announced that the vaccine candidate against Lyme disease, VLA15-201, showed positive initial results meeting its endpoints in the Phase 2 study. They stated in the July 22, 2020 press release that “compared to Phase 1, the higher doses used in this trial elicited higher antibody responses across all serotypes.” Of particular note was the the immunological response found in older adults (50-65 years), one of the main target groups for a Lyme vaccine. The vaccine candidate is described as “generally safe across all dose and age groups tested”, finding no Serious Adverse Events (SAEs) associated with VLA15. This is an important finding given the history of vaccines and serious concerns that have been generated regarding patient safety and vaccines in the Lyme community.

VLA15 is the only active Lyme disease vaccine candidate in clinical development today, covering six serotypes of Lyme disease prevalent in North America and Europe. It was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017. In a few months, Valneva expects to report top-line results for the second Phase 2 study, VLA15-202. Valneva and Pfizer are collaborating for development and commercialization of VLA15.

**Read full July 22, 2020 press release here**

**Read Valneva vaccine history and Lyme Disease Association’s concerns here:**

<https://lymediseaseassociation.org/news/lyme-disease-vaccine-collaboration-announced/>

<https://lymediseaseassociation.org/about-lyme/controversy/vaccine/new-vaccine-in-the-news/>

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# Lyme Disease Vaccine Collaboration Announced



## Press Release Summary

Specialty vaccine company Valneva SE and Pfizer Inc. announced a collaboration to develop VLA15, Valneva's Lyme disease vaccine candidate, which is currently in Phase 2 clinical studies.

According to a Pfizer press release, VLA15 is the only active Lyme disease vaccine program in clinical development today. The program covers six serotypes of Lyme disease that are prevalent in North America and Europe. The vaccine's mechanism targets the outer surface protein A (OspA) of *Borrelia burgdorferi* (*Bb*), the bacteria that causes Lyme disease. OspA is one of the most dominant surface proteins expressed by *Bb* when present in a tick.

Pfizer states that VLA15 has demonstrated strong immunogenicity and safety data in pre-clinical and Phase 1 studies. In July 2017, the program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA).

Valneva expects to report on results from the first Phase 2 studies by mid-2020.

“We look forward to working closely with Valneva to continue advancing the VLA15 program and potentially bring a new solution to patients for this significant unmet need,” said Nanette Cocero, Global President, Pfizer Vaccines.

### **Comments From the Lyme Disease Association**

The Lyme Disease Association President, Pat Smith, had this to say about the announcement: “A safe and effective vaccine for Lyme disease has been a goal for many decades. Unfortunately, many stakeholders, especially some vaccine recipients and providers who were then giving the vaccine, felt there were problems associated with the past Lyme vaccine, perhaps connected to its Osp A base. There are still many unanswered questions about what really happened, and like much that happens with Lyme disease, decades later, we still do not have those answers. The prudent thing for the government and/or vaccine developers to have done would have been to hold public meetings regarding a new Lyme vaccine with all interested stakeholders to hear concerns and answer questions about the development of a new Osp A-based vaccine and what research was done to address the previous concerns and any newly arisen concerns.

In general, much research on Lyme disease has still not been done. In fact, ~46 years into Lyme disease, it ranks below leprosy in the number of clinical trials done in infectious diseases (Goswami et al., 2013). Those who have questioned the safety and efficacy and approval process of the past vaccine have been publicly accused of bringing that vaccine down. When the opportunity for dialogue which engages the Lyme community and all stakeholders has not been offered as part of the approval process, it creates an atmosphere of distrust among those whose trust is necessary to accept a new Lyme disease vaccine.”

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## Links for You

Read Pfizer's VLA15 press release.

Read articles on the history of Lyme disease vaccines.

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# New Lyme Vaccine in Clinical Trials: Update!



An article on a new vaccine for Lyme disease, "New Effort for Lyme Disease Vaccine Draws Early Fire," by Sumathi Reddy, appeared in the Wall Street Journal on July 9, 2018. The article, which includes a quote by LDA

President, Pat Smith, reports that a European company, Valneva SE, is in clinical trials for a vaccine for Lyme disease, which has been fast tracked by the FDA. **(see 4/28/19 update at end of article)**

A company official estimates it will take at least five years before it becomes commercially available. The vaccine is similar to Lymerix, by Smith Klein Beecham (SKB), now GlaxoSmithKline, which was approved by the Food and Drug Administration (FDA) in December 1998 but was withdrawn from the market in 2002 due to low demand.

"We don't feel that there has been enough research done to answer the questions as to what occurred with the prior

vaccine,” says Patricia Smith, president of the Lyme Disease Association Inc., a New Jersey-based national nonprofit group, which raises money for Lyme research, education and patient support. “The vaccine that is now in development is something with the same base. There were a lot of patients that thought they were harmed from that vaccine. It’s very problematic.”

Check out the history of Lymerix and efforts by the LDA and others to get the facts behind the vaccine and its withdrawal—individuals who took the vaccine who spoke at the FDA on the problems they felt were related to the vaccine; class-action lawsuits that alleged it caused serious side effects; and a meeting requested by LDA at the FDA where LDA brought in a vaccine expert and physicians who were seeing patients with problems they felt were connected to receiving the vaccine.

**Update on Lyme vaccine 4-28-19** On July 2017, Valneva received from the Food & Drug Administration (FDA) a Fast Track Designation for VLA15. On April 4, 2018, Valneva presented Phase 1 interim results of the vaccine at the World Vaccine Congress in DC. In December of 2018, Valneva announced the initiation of Phase 2 Clinical Trial Development to determine the optimal dosage level and schedule for use in Phase 3 field efficacy studies, based on immunogenicity & safety data.

**[Click here for a history of the LDA’s involvement with the FDA and the Lymerix vaccine](#)**

**[Click here to read full Wall Street Journal article](#)**

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# **The LYMERix™ Story: FDA Approval to Market Withdrawal □ Learning from History**

This is a piece on the Lymerix Vaccine controversy, written by Patricia V. Smith, President, Lyme Disease Association, Inc., in 2013 and published on LDA website.

**2013 version published on LDA website**

It was published in the **Lyme Times Special Issue Sept. 2018**  
*The LYMERix™ Story: FDA Approval to Market Withdrawal – Learning from History*

**2018 version published in Lyme Times**

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## **Philadelphia Inquirer on Lyme Vaccine and Attorney's Op-Ed**

The Philadelphia Inquirer published an article regarding the development of a vaccine for Lyme disease, October 2013. The article is titled, *"It's Time to Develop a Vaccine for Lyme Disease, Doctor Says"* by Ilene Raymond Rush. We are providing a response to that article by Stephen A. Sheller, founding partner of Sheller, P.C., a national whistleblower, plaintiff's product liability, personal injury class action law firm based in Philadelphia. His book including his work on Lyme Disease, *A Nation Betrayed*, is soon to be released.

**Click here for the article in Philadelphia Inquirer**

[Click here for the Op-Ed](#)

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# **Neurological Complications of Vaccination with Outer Surface Protein A (OspA). Marks DH1**

Int J Risk Saf Med. 2011;23(2):89-96. doi: 10.3233/JRS-2011-0527.

<https://www.ncbi.nlm.nih.gov/pubmed/21673416>

## **Abstract**

A wide range of neurological complications have been reported via the medical literature and the VAERS system after vaccination with recombinant outer surface protein A (OspA) of *Borrelia*. To explore this issue, 24 patients reporting neurological adverse events (AE) after vaccination with Lymerix, out of a group of 94 patients reporting adverse events after Lymerix vaccination, were examined for causation. Five reports of cerebral ischemia, two transient Ischemic attacks, five demyelinating events, two optic neuritis, two reports of transverse myelitis, and one non-specific demyelinating condition are evaluated in this paper. Caution is raised on not actively looking for neurologic AE, and for not considering causation when the incidence rate is too low to raise a calculable difference to natural occurrence.

PMID:

21673416

DOI:

10.3233/JRS-2011-0527

[Indexed for MEDLINE]

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# Neuropathy and Cognitive Impairment Following Vaccination with the OspA Protein of *Borrelia burgdorferi*

J Peripher Nerv Syst. 2004 Sep;9(3):165-7.

Latov N<sup>1</sup>, Wu AT, Chin RL, Sander HW, Alaedini A, Brannagan TH 3rd.

<https://www.ncbi.nlm.nih.gov/pubmed/15363064>

## Abstract

Neurological syndromes that follow vaccination or infection are often attributed to autoimmune mechanisms. We report six patients who developed neuropathy or cognitive impairment, within several days to 2 months, following vaccination with the OspA antigen of *Borrelia burgdorferi*. Two of the patients developed cognitive impairment, one chronic inflammatory demyelinating polyneuropathy (CIDP), one multifocal motor neuropathy, one both cognitive impairment and CIDP, and one cognitive impairment and sensory axonal neuropathy. The patients with cognitive impairment had T2 hyperintense white

matter lesions on magnetic resonance imaging. The similarity between the neurological sequelae observed in the OspA-vaccinated patients and those with chronic Lyme disease suggests a possible role for immune mechanisms in some of the manifestations of chronic Lyme disease that are resistant to antibiotic treatment.

PMID:

15363064

DOI:

10.1111/j.1085-9489.2004.09306.x

[Indexed for MEDLINE]

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# **Conflicts of Interest in Lyme Disease: Treatment, Laboratory Testing, and Vaccination**

Published in April, 2001, *Conflicts of Interest in Lyme Disease: Treatment, Laboratory Testing, and Vaccination* by Lyme Disease Association, Inc. The Lyme vaccine is discussed on p.40-70.

**[Click here to read report](#)**