Structural Vaccines to Prevent Lyme Disease

Technology Readiness Level 4: Validated in Laboratory

Lead Investigator

Sunil Thomas, PhD
Research Professor
Lankenau Institute for Medical Research

Unmet Need

There is currently no vaccine against Lyme disease, a common infection caused by the spirochete *Borrelia burgdorferi*. This infection, which is transferred to humans by infected deer ticks, is seen commonly in North America and other continents where large deer populations exist. In the U.S., the CDC has estimated that up to 476,000 cases of Lyme disease were diagnosed in 2019, although less than 10% that number are reported to CDC. *Borrelia* infections, which are on the rise the last decade, are highly morbid if not diagnosed early. An initial vaccine generated by GSK in the 1990s was withdrawn from the market recently, immediately creating an unmet need to fill.

Opportunity

A specific set of antigenic peptides encoded by the *Borrelia* genome that offer superior uses to diagnose and prevent *Borrelia* infection. For diagnosis, these peptides enable new blood tests to detect *Borrelia* infection. For prevention, these peptides form the basis for a multivalent structural vaccine that effectively generates the potent immunity desired to prevent or clear *Borrelia* infections. These peptides are not derived from the *Borrelia* gene encoding the outer membrane protein OspA, which has been controversial as a vaccine target. As such, they offer novel agents to create a vaccine.

Unique Attributes

The primary attribute of this invention is the specific set of amino acid sequences comprising the *Borrelia* peptide antigens defined at LIMR. The sequences that have been identified demonstrate antigenic character as immune-recognized epitopes in humans. As the basis for a multivalent structural vaccine, these antigenic peptides may offer lower risk compared to the previous approved vaccine, based on the lack of all features deemed controversial. Specifically, the present invention includes (1) no infective agent, (2) no anti-*Borrelia* antibodies, and (3) no sequences from the *Borrelia* OspA protein on which the previous vaccine was based.

Clinical Applications

Use of the defined antigenic peptides as a foundation to create:

- The first diagnostic blood test for *Borrelia*. At present, Lyme disease is diagnosed upon PCR-based measurements of blood-borne *Borrelia* DNA rather than the pathogen itself.

Continued on back

- A second-generation vaccine for Lyme disease. The invention bypasses previous controversies surrounding the initial vaccine now withdrawn from the market.

Stage of Development

Technology Readiness Level 4: Validated in Lab

- For use in diagnostic applications, the technology is at a pre-501(K) development stage.
- For use in vaccine applications, the technology is at a pre-IND development stage.
- In a pilot retrospective study of blood specimens from individuals diagnosed with Lyme disease, the LIMR antigenic peptides were shown to be recognized specifically by natural antibodies that arise in these patients (as compared to non-infected individuals). This first clinical study offers an early-stage proof of concept to use the defined antigenic peptides in vaccine development.

Intellectual Property

US Patent Application No. 20220160856A1 published in May 2022 ("Methods and Compositions for the Diagnosis, Prophylaxis and Treatment of Lyme Disease").

Licensing Opportunities

- Exclusive rights to the invention for creating a second-generation vaccine against Lyme disease.
- Non-exclusive rights to the invention to create a diagnostic test for blood-borne *Borrelia* infection.

Reference

Thomas S. (2022). Structure-Based Design of Diagnostics and Vaccines for Lyme Disease. Methods Mol Biol. 2410: 411-422.

INSTITUTIONAL CONTACT

George C. Prendergast, PhD
+1 484.476.8475
prendergast@limr.org

L2C PARTNERS CONTACT

Merle Gilmore, MBA
+1 610.662.0940
Gilmore@l2cpartners.com

Alex Toglia, MS
+1 610.937.1067
toglia@l2cpartners.com