Pfizer Launches Final Phase of Testing for Experimental Lyme Disease Vaccine

Pfizer on Monday launched the final phase of testing for an experimental vaccine to "prevent" Lyme disease. The company wants to create a seasonal vaccine that people age 5 and older can get during the months when ticks are most active.

If approved, the vaccine would be the first human vaccine available for Lyme disease in the U.S. in more than two decades after LYMERix, manufactured by GlaxoSmithKline, was withdrawn from the market in 2002, due to lawsuits, safety concerns and dwindling sales.

According to a press release, Pfizer and French partner Valneva are enlisting 6,000 participants ages 5 and older for a late-stage clinical trial that will test the vaccine, VLA15, against the tick-borne illness.

According to ClinicalTrials.gov, "18,000 healthy participants 5 years and older" were recruited for the study. In its press

release, Pfizer did not explain the discrepancy in the number of trial participants.

VLA15 is a "multivalent protein subunit vaccine" targeting "the outer surface protein A (OspA) of Borrelia," the bacteria that causes Lyme disease. The vaccine is supposed to protect against six forms of the protein expressed by the bacterial species present in North America and Europe.

During the Phase 3 clinical trial, participants will receive three doses of VLA15 or a placebo, followed by one booster dose or another placebo.

The study will be held in as many as 50 sites where Lyme disease is "highly endemic," the drugmakers said, including Finland, Germany, the Netherlands, Poland, Sweden and the U.S.

Pending successful completion of the trials, Pfizer may request approval for its vaccine from regulators in the U.S. and Europe in 2025.

"With increasing global rates of Lyme disease, providing a new option for people to help protect themselves from the disease is more important," Annaliesa Anderson, senior vice president and head of vaccine research & development at Pfizer, said in a press release.

Anderson told The Associated Press the company is "really looking at something that's a seasonal vaccine," so people have high antibody levels during the months when ticks are most active.

According to the Centers for Disease Control and Prevention (CDC), about 476,000 people in the U.S. each year are treated for Lyme disease, which is "caused by the bacterium Borrelia burgdorferi and rarely, Borrelia mayonii." It is transmitted to humans through the bite of infected blacklegged ticks.

Typical symptoms of the illness include rashes, fever, chills,

headache, fatigue, muscle and joint aches and swollen lymph nodes.

Lyme disease can be treated effectively and rapidly with antibiotics. If left untreated, it can cause damage to joints, facial palsy or drooping.

About 1 in every 100 cases can result in Lyme carditis, which occurs when Lyme disease bacteria enter the heart tissues. Yet, only 11 fatal cases of Lyme carditis were reported during a 34-year period between 1985 and 2019.

Pfizer data show 'immunity' from Lyme vaccine wanes

In Phase 2 of the study, the companies tested the experimental VLA15 vaccine at two different administration schedules: a two-dose regimen six months apart and a three-dose regimen with follow-up shots administered at two and six months after the initial administration.

Both schedules involved 180 µg doses.

Similar to claims Pfizer made about booster doses of the COVID-19 vaccines, the drugmaker said that while the two-dose regimen of VLA15 demonstrated immunity, a third VLA15 dose "increased the level of antibodies against an outer surface protein."

According to data obtained after the Phase 2 trial, Pfizer's Lyme disease vaccine saw a drop-off in protection after 18 months and vaccine recipients will need a booster, Fierce Biotech reported.

Antibody titers, which can show how one part of the immune system is remembering the shot, "declined thereafter across all groups, remaining above baseline but confirming the need for a booster strategy."

Lyme disease to become profitable market for vaccine makers

The U.S. Food and Drug Administration July 2017 issued biotech company Valneva a fast-track designation that specifically allows for expedited review of "drugs to treat serious conditions and fill an unmet medical need."

Valneva sold the rights to VLA15 to Pfizer for $130 million in 2020, at which time the two companies announced a collaboration for the continued development and commercialization of the vaccine.

Pfizer penned the $308 million deal with Valneva in May 2021. Under the terms of the two companies' agreement, the first dose in the Phase 2 study triggered an additional $10 million payment from Pfizer to Valneva.

Pfizer agreed to make an additional $25 million "milestone payment" to Valneva at the start of Monday's trial.

According to Fierce Biotech, a successful Phase 3 trial "could give Pfizer a clear run at a growing opportunity" and "offers Pfizer the chance to add a growth driver to its mammoth vaccine unit."

VLA15 is the only Lyme disease vaccine candidate in active clinical development, according to Pfizer, however it does not represent the first attempt to develop a Lyme disease vaccine.

Pasteur Mérieux Connaught (now Sanofi Pasteur) developed an OspA Lyme vaccine called ImuLyme and tested it in a large study, but the company never applied for a license to market the vaccine.

Baxter International in 2013 released data about a vaccine for Lyme disease it was developing but sold off its vaccine portfolio. Today, Takeda, the largest drug company in Asia,

owns the vaccine but has not taken it forward.

Merck in 2019 said it was working on a vaccine for Lyme's disease. According to Gregory Poland, the director of the Vaccine Research Group at the Mayo Clinic, every manufacturer that has considered bringing a Lyme disease vaccine to market has determined it's "unlikely" to make a profit. However, this is likely to change as the demand for a Lyme vaccine is "greater than ever before."