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(SKB), now GlaxoSmithKline, which was approved by the Food and Drug Administration (FDA) in December 1998 but was withdrawn from the market in 2002 due to low demand.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

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