The Connecticut Agricultural Experiment Station

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PRESS RELEASE

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CAES Announces Field Trials Show Impact of a non-GMO Rodent-Targeted Oral Bait Vaccine in Preventing Lyme Disease Transmission

New Haven, CT - The Connecticut Agricultural Experiment Station (CAES) and US Biologic, Inc. announced today the publication of field trials showing the effectiveness of the delivery of an orally-delivered anti-Lyme vaccine targeting the major wildlife source of Lyme disease, the white-footed mouse.

The journal article, "Field Evaluation of a Novel Oral Reservoir-Targeted Vaccine Against *Borrelia burgdorferi* Utilizing an Inactivated Whole-Cell Bacterial Antigen Expression Vehicle" has been published in the peer-reviewed publication, *Experimental and Applied Acarology*.

The field trials were conducted over three years in the residential area of Redding, Connecticut. During that time, the authors observed significant drops in the numbers of mice infected with *Borrelia burgdorferi*, the bacterium that causes Lyme disease, and its infection in blacklegged ticks (*Ixodes scapularis*, the major vector associated with the disease) feeding on mice when comparing homes where the vaccine was and was not applied.

Specifically, the authors noted that, after one year of deployment, treated sites showed a 13X greater decrease in infection compared to control sites (i.e., 26% drop versus 2% drop). “Fewer infected ticks mean less infection in the field overall,” says Stafford, “So the decrease would be greater year-over-year that the vaccine is applied."

“Along with fewer infected mice, we observed a second effect also seen in previous laboratory-based studies,” notes Scott Williams, PhD, Agricultural Scientist at the CAES and a co-author of the study. “The vaccine causes the generation of antibodies in the mice. Previously infected ticks will ingest those antibodies when feeding on mice and be ‘cleared’ of infection. So, feeding ticks are a ‘xenodiagnostic marker’ of vaccine impact.” According to Williams, when non-infected mice consume vaccine-coated pellets, they are protected from infection with *Borrelia burgdorferi*. “Non-infected ticks, therefore, cannot pass the disease to other animals, including humans” he says.

“Lyme disease is, according to the CDC, one of the most challenging healthcare problems today,” says lead author Kirby C. Stafford, III, PhD, Connecticut’s state entomologist and Chief Scientist at the Center for Vector Biology &

Zoonotic Diseases located at the Connecticut Agricultural Experiment Station (CAES); "329,000 U.S. citizens are estimated to contract Lyme disease each year, and, according to the U.S. Department of Health & Human Services, the disease costs the U.S. between $50B-$100B".

"Several studies have shown the impact of an orally delivered vaccine," notes US Biologic's Chief Science Officer, Jolieke G. van Oosterwijk, MSc, PhD, one of the journal article's co-authors. "However, these vaccines were considered GMOs. The significant scientific advancement of this form of the vaccine is that it is 'inactivated', or killed, which makes it, by definition, a non-GMO." According to van Oosterwijk, "This feature facilitates global acceptance by public agencies and private homeowners."

The vaccine is currently undergoing the USDA regulatory process for commercial licensure.

The research program was supported, in part, by U.S. Hatch Act funds, the Centers for Disease Control and Prevention (CK000182-03), and US Biologic.

White-footed mouse, *Peromyscus leucopus*, with larval blacklegged ticks (visible on the ears)
(Photo by Kirby Stafford, CAES)

About The Connecticut Agricultural Experiment Station

The Connecticut Agricultural Experiment Station (CAES), established in 1875, is the first agricultural experiment station in the United States. The main mission of the CAES is research. Programs also exist to educate the public and to transfer new findings to people trying to solve agricultural, public health, and environmental problems. The CAES is also a member of the Northeast Regional Center for Excellence in Vector-Borne Diseases supported by the Centers for Disease Control and Prevention (CDC). (portal.ct.gov/caes)

About US Biologic

US Biologic is a social innovation company that "Delivers Disease Prevention."® The company's proprietary oral-delivery system is changing global disease prevention, allowing safe, effective, and cost-efficient delivery of a variety of preventative therapeutics (vaccine and medicine) to wildlife, companion animals, and food animals. US Biologic works with world-renowned experts, placing their proven technologies into its oral-delivery system and then commercializes those new products by providing necessary funding, regulatory support, manufacturing, and distribution expertise. (usbiologic.com)

Journal Reference

Stafford III, K. C., S. C. Williams, J. G. van Oosterwijk, M. A. Linske, S. Zatechka, L. M. Richer, G. Molaei, C. Przybyszewski, and S. K. Wikel. 2020. Field evaluation of a novel oral reservoir-targeted vaccine against *Borrelia burgdorferi* utilizing an inactivated whole-cell bacterial antigen expression vehicle. Experimental and Applied Acarology. https://doi.org/10.1007/s10493-019-00458-1

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