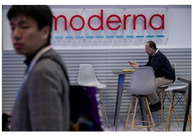
Explosion in tick diseases spurs race for treatment, prevention



A sign for Moderna is seen at the Las Vegas Convention Center during the Consumer Electronics Show on Jan. 10. 2024, in Las Vegas. (Brendan Smialowski/AFP via Getty Images/TNS)

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Bloomberg News

Drugmakers are pushing to develop effective defenses against Lyme disease as intensifying tick seasons continue to put more people at risk, with trials focused on vaccines and on drugs designed to block the pests' ability to infect.

Companies including Pfizer Inc. and Moderna Inc. have stepped up efforts 24 years after the only Lyme vaccine approved in the U.S. was pulled off the market — and as people find it increasingly difficult to avoid the blood-feeding arachnids that can make them sick.

One answer is a new vaccine, the target for Pfizer and its partner Valneva SE, as well as Moderna. Another approach is to offer short-term protection with drugs that neutralize the threat from tick bites, such as with an antibody shot being tested by Tonix Pharmaceuticals and a pill from Tarsus Pharmaceuticals.

There's urgency to find something efficient and marketable before another surge in tick bites, said Thomas Daniels, director of Fordham University's Louis Calder Center, which conducts tick-disease surveillance.

"It's difficult not to worry about the future in terms of exposure to tick-borne pathogens," he said. "Tick diseases have spread remarkably quickly in the past 20 or 30 years."

The Pfizer-Valneva vaccine effort is the farthest along, with results from a late-stage clinical trial made public in March. European authorities have started a regulatory review.

The U.S. tick season typically kicks off in April and runs through the fall.

Larger habitats and longer active seasons, fueled in part by warmer temperatures, have contributed to increases in infections. This year's cycle was severe. The U.S. Centers for Disease Control and Prevention reported emergency room visits for tick bites in August were at their highest level for the month since 2019.

Before GSK Plc's short-lived vaccine was approved in 1998 by the U.S. Food and Drug Administration, about 16,000 cases of Lyme were reported in the U.S. each year. Now, according to the CDC, some 476,000 people are diagnosed and treated annually.

The federal government has recognized the threat. The Department of Health and Human Services wants to cut Lyme cases 25% by 2035 and said last month it was awarding about $3 million to test novel ways to curtail ticks. President Donald Trump recently ordered agencies to reduce the number of ticks in Washington DC by 50% by 2028 through non-chemical methods.

It's unclear what demand would be for a Lyme vaccine. In March, when Pfizer and Valneva reported their trial results, RBC Capital Markets estimated peak sales might reach $525 million.

The phase-three trial found their vaccine cut the risk of Lyme disease by 73%. While that was less than anticipated by investors, the companies said they're confident about the potential. The vaccine works by stimulating human antibodies that can neutralize Lyme-causing bacteria inside a tick.

Pfizer said it couldn't specify a timeline for seeking approval from the FDA. "We're working toward that," a spokesperson said.

The European Medicines Agency started its regulatory review for the EU in August.

Another shot

At Moderna, development continues on two vaccine candidates that are years away from final-stage trials. Both use the molecule mRNA to instruct human cells to produce an immune response to fight the bacteria. A company spokesperson declined to comment on a timetable.

Tonix and Tarsus are working on protections for people to employ before embarking on activities that increase exposure, such as hiking, or for those who live in tick-dense areas, like Lyme, Connecticut, where the disease was first identified.

For the Tonix monoclonal antibody shot, which has finished an early-stage trial, a two-dose regimen may work for at least six months, according to the company. It's designed to send antibodies into the bloodstream to kill Lyme-causing bacteria inside a feeding tick. The next clinical trial is expected to begin in early 2027.

"Because we're not counting on the body's immune response to make an immune response, we're just providing it, we think we have a better chance than vaccines — or at least as good a chance," said Seth Lederman, Tonix's chief executive officer.

Tarsus's pill is built to target and kill ticks after they've landed but before they have time to do harm. It deploys a version of the molecule lotilaner that works in pets.

"We saw that that class of medicines had been used to prevent Lyme in animals," said Tarsus CEO Bobby Azamian. "So we thought, why not do this in humans?"

Lotilaner is the active ingredient in Elanco Animal Health Inc.'s Credelio line of flea-and-tick drugs, approved by FDA for use on dogs. Tarsus has a license agreement with Elanco to develop lotilaner as a medicine for people. The company began a phase-two trial in April and expects results in the first half of 2027.

Other pathogens

Lyme, carried by blacklegged ticks, is the most commonly reported vector-borne disease in the U.S. It can be difficult to diagnose. And some people suffer long-term health problems, like arthritis and chronic fatigue, even after antibiotic treatment.

Blacklegged ticks, also called deer ticks, can transmit other pathogens, including babesiosis, anaplasmosis and the Powassan virus. A study in New York's Dutchess County found roughly 10% of ticks carried two or more pathogens, with Lyme and babesiosis coinfections increasing.

"The coinfection in particular is undesirable," said Shannon LaDeau, a disease ecologist at the Cary Institute of Ecosystem Studies and the study's lead author. "Because if you're infected by two, it's increasingly probable that they're not going to respond to the same medication or treatment."

Treatments for babesiosis haven't kept pace with ticks' growing reach. 60 Degrees Pharmaceuticals Inc. is testing the effectiveness of the malaria drug tafenoquine. "Here we have a disease, babesiosis, that's like malaria, that affects Americans all up and down the East Coast, and we're still treating them with a standard of care that's like the 1930s," said Geoffrey Dow, 60 Degrees' CEO.

The conditions that have fueled the spread of blacklegged ticks show little signs of easing. Warmer winters have helped them and their hosts thrive, while suburban development and rebounding deer numbers have created more spaces for interactions with humans.

"Tick populations are higher and more people that didn't used to be at risk are at risk now, because the ticks are in their neighborhoods," said Thomas Mather, a professor of public health entomology at the University of Rhode Island.

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With assistance from Robert Langreth and Madison Muller.