FDA approves vaccine for cholera

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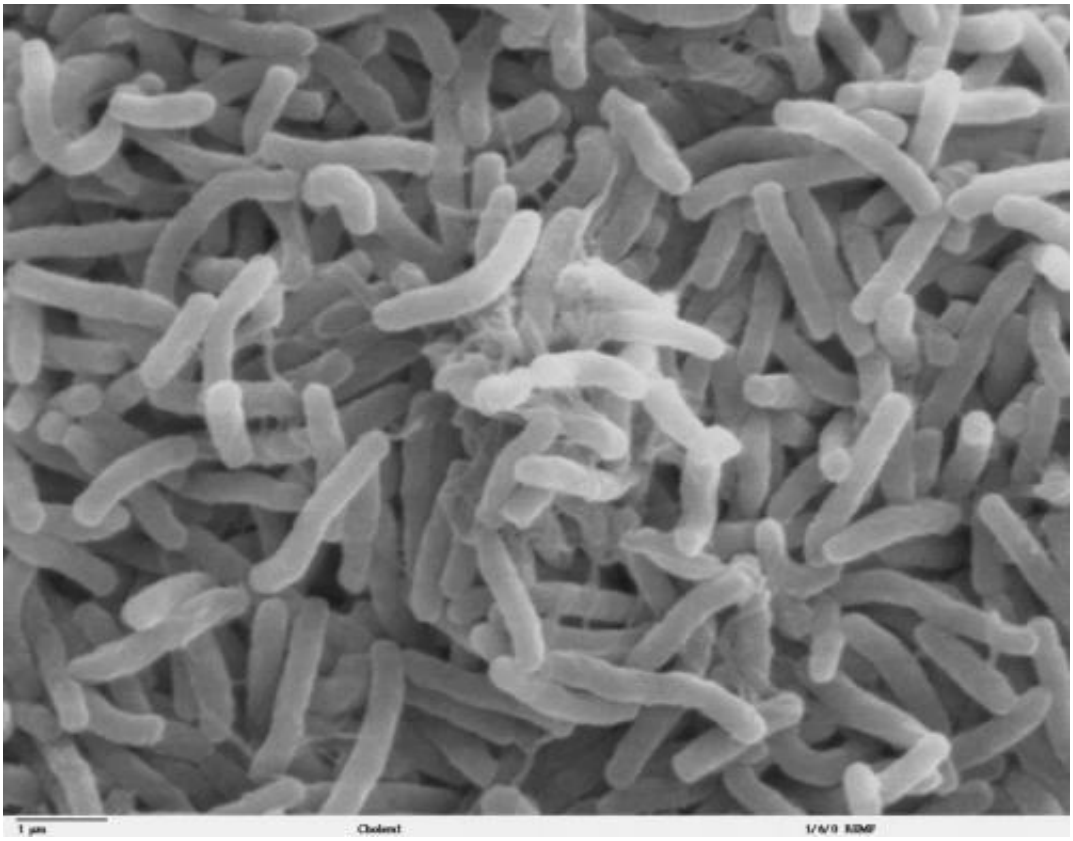

Scanning electron microscope image of Vibrio cholerae bacteria, which infect the digestive system. Credit: Ronald Taylor, Tom Kirn, Louisa Howard/Wikipedia

In a milestone years in the making, a vaccine to prevent cholera, invented and developed by researchers at the University of Maryland School of Medicine's Center for Vaccine Development, was approved today by the U.S. Food and Drug Administration (FDA).

The vaccine, Vaxchora, is the only approved vaccine in the U.S. for protection against cholera. Its licensure allows for use in people traveling to regions in which cholera is common, including travelers, humanitarian aid workers, and the military.

PaxVax, a global biotechnology company based in California, received marketing approval from the FDA for Vaxchora, a single-dose oral, live attenuated cholera vaccine that is indicated for use in adults 18 to 64 years of age. Vaxchora is the only vaccine available in the U.S. for protection against cholera and the only single-dose vaccine for cholera currently licensed anywhere in the world.

The vaccine was invented in the 1980s at Center for Vaccine Development (CVD). Since 2009, CVD researchers have worked closely with PaxVax to develop the vaccine and secure FDA licensure approval.

"This important FDA decision is the culmination of years of dedicated work by many researchers," said Myron M. Levine, the Simon and Bessie Grollman Distinguished Professor at the University of Maryland School of Medicine (UM SOM). "For travelers to the many parts of the world where cholera transmission is occurring and poses a potential risk, this vaccine helps protect them from this disease. It is a wonderful example of how public-private partnerships can develop medicines from bench to bedside." Dr. Levine is co-inventor of the vaccine, along with James B. Kaper, Professor in the UM SOM Department of Microbiology and Immunology.

Cholera is an acute intestinal diarrheal infection acquired by ingesting contaminated food or water. Globally, cholera cases have increased steadily since 2005 and, millions of people are affected by this disease each year. Cholera can cause severe dehydration and death in less than 24 hours, if left untreated. While some cholera cases are rarely acquired in the U.S. from ingestion of uncooked seafood from the Gulf of

Mexico, the vast majority of cases of domestic cholera cases occur in travelers to areas with epidemic or endemic cholera (for example, parts of Africa, Asia, or the Caribbean). A report from the U.S. Centers for Disease Control and Prevention suggests that the true number of cholera cases in the U.S. is at least 30 times higher than observed by national surveillance systems. The currently recommended intervention to prevent infection is to avoid contaminated water and food. But studies have shown that 98 percent of travelers do not follow these precautions.

Vaxchora is expected to be commercially available later this year. The FDA approval is based on results from a phase 1 safety and immunogenicity trial, a phase 3 efficacy trial, and a phase 3 trial to test manufacturing consistency. The first two of these trials were led by Wilbur H. Chen, associate professor of medicine at UM SOM, and chief of the CVD's Adult Clinical Studies section. The pivotal efficacy trial, which demonstrated protection from cholera of more than 90 percent at 10 days and 80 percent at 3 months after vaccination, is the first instance the FDA has based the decision to approve a product on a human experimental challenge model. Therefore, the licensure of Vaxchora marks a significant regulatory milestone. The most common adverse reactions to Vaxchora in the clinical trials were tiredness, headache, abdominal pain, nausea/vomiting, lack of appetite and diarrhea.

Cholera is chiefly a disease of poverty, poor sanitation, and lack of access to safe drinking water, so the global health burden of cholera rests on those populations residing in vulnerable developing countries. The World Health Organization estimates the burden of cholera to be between 1.4 and 4.3 million cases per year globally. Dr. Chen said that the next steps for this cholera vaccine are to explore formulations that could be developed into successful strategies to prevent and control cholera in countries where cholera is common. These future activities would involve immunizing young children in developing countries; this group has the highest risk of dying from cholera.

"The FDA approval of a new vaccine for a disease for which there has been no vaccine available is an extremely rare event. The approval of Vaxchora is an important milestone for PaxVax and we are proud to provide the only vaccine against cholera available in the U.S.," said Nima Farzan, chief executive officer and president of PaxVax. "We worked closely with the FDA on the development of Vaxchora and credit the agency's priority review program for accelerating the availability of this novel vaccine. In line with our social mission, we have also begun development programs focused on bringing this vaccine to additional populations such as children and people living in countries affected by cholera."

Provided by University of Maryland School of Medicine