New treatment for recurrence of C. difficile infection approved by FDA

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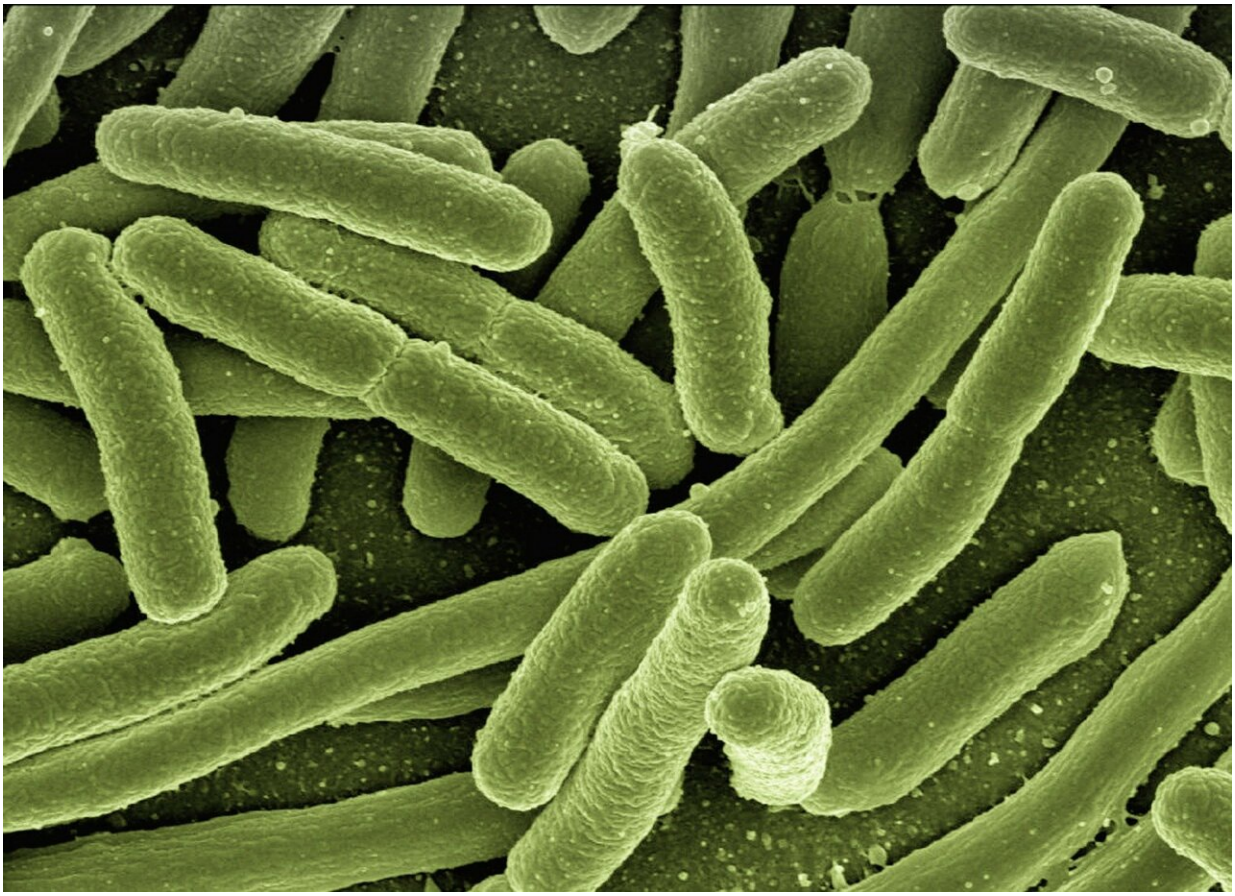

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The U.S. Food and Drug Administration (FDA) has approved VOWST, a microbiota-based therapeutic to prevent recurrence of C. difficile

Infection (CDI) in adults following antibacterial treatment for recurrent CDI (rCDI). The approval was based on clinical trials run by UC Davis Health Chief of Infectious Diseases Stuart Cohen.

The new treatment is the first and only FDA-approved orally administered microbiota-based therapeutic for rCDI.

"Recurrent C. difficile infection is a highly debilitating and life-threatening disease, and antibiotics alone do not address the underlying cause of rCDI," said Cohen. "The approval of VOWST provides an important new oral treatment option for this disease and provides the opportunity to address prevention of recurrence of C. difficile infection in adults with rCDI."

What is recurrent C. difficile infection?

rCDI is a gastrointestinal infection caused by C. difficile bacteria. It is linked to dysbiosis, or imbalance, of the gastrointestinal microbiome. It is a leading cause of hospital-acquired infection that can result in severe illness and death.

Based on data from the U.S. Centers for Disease Control and Prevention (CDC), it is estimated there will be 156,000 episodes of rCDI this year in the United States. The CDC recently characterized the infection as an Urgent Health Threat.

Clinical trials for VOWST

The FDA approval of VOWST was based on clinical data from Phase 3 trials called ECOSPOR III and ECOSPOR IV. They were run by clinical research coordinator Christine Gichigi and overseen by Cohen as a principal investigator.

ECOSPOR III was a randomized, placebo-controlled study in individuals with rCDI that took place at more than 50 health care sites in the U.S. and Canada. In the clinical trial, VOWST was shown to reduce C. difficile Infection recurrence at eight weeks, with approximately 88% of individuals recurrence-free at eight weeks post-treatment, compared to 60% in participants who received a placebo. At six months post-treatment, 79% of the VOWST group were recurrence-free, compared to 53% in the placebo group.

ECOSPOR IV was an open-label study, meaning both providers and patients knew who was getting the treatment. Researchers evaluated VOWST in 263 adult participants with rCDI. Results showed 91% of individuals were recurrence-free at eight weeks post-treatment. At week 24 post-treatment, 86% were recurrence-free.

Provided by UC Davis

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