## Vowst™ (fecal microbiota spores, live-brpk) – New orphan drug approval

- On April 26, 2023, the FDA announced the approval of Seres Therapeutics' Vowst (fecal microbiota spores, live-brpk), to prevent the recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI).
    - Vowst is not indicated for treatment of CDI.
- The human intestinal tract contains millions of microorganisms, often referred to as the "gut flora," or "gut microbiome." Certain situations, such as taking antibiotics to treat an infection, may change the balance of microorganisms in the gut, allowing *C. difficile* to multiply and release toxins causing diarrhea, abdominal pain, and fever, and in severe cases, organ failure and death. After recovering from CDI, individuals may get the infection again, a condition known as rCDI.
    - CDI is one of the most common healthcare-associated infections in the U.S. and is associated with 15,000 to 30,000 deaths annually.
    - The administration of fecal microbiota is thought to facilitate restoration of the gut flora to prevent further episodes of CDI.
- Vowst is the first orally administered fecal microbiota product for the prevention of rCDI.
- The efficacy of Vowst was evaluated in a randomized, placebo-controlled study in 182 patients with a confirmed diagnosis of rCDI. Patients were randomized to receive Vowst or placebo. The primary efficacy endpoint was CDI recurrence through 8 weeks after completion of treatment. Recurrence was defined as ≥ 3 unformed stools per day for 2 consecutive days with continued diarrhea until antibacterial treatment was initiated, a positive *C. difficile* test on a stool sample determined by a toxin assay, and assessment by the investigator that the clinical condition of the participant warranted antibacterial treatment.
    - Through 8 weeks after treatment, CDI recurrence in Vowst-treated participants (12.4%) was lower compared to that in placebo-treated participants (39.8%) (relative risk 0.32, 95% CI: 0.18, 0.58).
- Warnings and precautions for Vowst include risk of transmitting infectious agents and potential presence of food allergens.
- The most common adverse reactions (≥ 5%) with Vowst use were abdominal distention, fatigue, constipation, chills, and diarrhea.
- The recommended dose of Vowst is four capsules taken orally once a day for three consecutive days.
    - Vowst should be administered 2 to 4 days after the completion of antibacterial treatment for rCDI.
    - Refer to the Vowst drug label for complete administration instructions.

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- Seres Therapeutics plans to launch Vowst in June 2023. Vowst will be available as a capsule (single dose is 4 capsules).