# Seres Therapeutics and Nestlé Health Science Announce FDA Approval of VOWST™ (fecal microbiota spores, live-brpk) for Prevention of Recurrence of *C. difficil*e Infection in Adults Following Antibacterial Treatment for Recurrent CDI

*– First and only FDA-approved orally administered microbiota-based therapeutic, validating Seres' microbiome platform –*

*– Phase 3 ECOSPOR III study demonstrated that 88% of treated individuals were recurrence-free at 8 weeks –*

*– Opportunity to address prevention of recurrence of C. difficile infection in adults with rCDI, including first recurrence, following antibacterial treatment –*

*– VOWST product availability expected in June –*

*– Conference call at 8:30 a.m. ET tomorrow –*

**CAMBRIDGE, Mass. and HOBOKEN, N.J., April 26, 2023** — Seres Therapeutics, Inc. (Nasdaq: MCRB) and Nestlé Health Science today announced the U.S. Food and Drug Administration (FDA) approval of VOWST™ (fecal microbiota spores, live-brpk), formerly called SER-109, an orally administered microbiota-based therapeutic to prevent recurrence of *C. difficile* Infection (CDI) in adults following antibacterial treatment for recurrent CDI (rCDI). VOWST is not indicated for the treatment of CDI.

"Since being founded by Flagship Pioneering over a decade ago, Seres has led the development of microbiome therapeutics, and today's FDA approval of VOWST as the first orally administered microbiota-based therapeutic for the prevention of recurrent *C. difficile* infection marks a tremendous milestone for the patient community, and for Seres. We are deeply grateful to the patients, caregivers, clinical investigators, and employees who contributed to the discovery, development, and approval of VOWST," said Eric Shaff, President and Chief Executive Officer at Seres. "With VOWST, we and Nestlé Health Science have the opportunity to prevent recurrence in a broad group of adult rCDI patients, including those who have experienced a first recurrence."

"Our strategic collaboration with Seres is part of Nestlé Health Science's ongoing commitment to advancements in the gastrointestinal space to address unmet patient needs," said Greg Behar, Chief Executive Officer, Nestlé Health Science. "Our teams have vast experience in gastrointestinal disorders and are poised to engage with healthcare professionals to start addressing this critical need for patients. We expect VOWST to be available in June and look forward to helping patients."

Recurrent CDI represents significant unmet need and is a leading cause of hospital-acquired infection that can result in severe illness and death.[1] Based on data from the U.S. Centers for Disease Control and Prevention (CDC), the companies estimate 156,000 episodes in the U.S. in 2023.

"Recurrent *C. difficile* infection is a highly debilitating and life-threatening disease, and antibiotics alone do not address the underlying cause of rCDI, dysbiosis of the gut microbiome," said Carl Crawford M.D., Assistant Professor of Clinical Medicine at Weill Cornell Medical College. "The approval of VOWST provides an important new oral treatment option for this disease, and I am pleased to now be able to offer this medicine to recurrent CDI patients."

"Recurrent *C. difficile* infection significantly impacts patients' quality of life, both physically and emotionally, leaving many living in tremendous fear of future recurrences. Patients have been waiting for new treatment options that address a key concern: prevention of an additional CDI recurrence," said Christian John Lillis, Executive Director at Peggy Lillis Foundation for *C. diff* Education and Advocacy.

**VOWST Phase 3 Study Data**

The FDA approval of VOWST was supported by a robust Phase 3 development program that included the ECOSPOR III and ECOSPOR IV studies. VOWST was previously granted Breakthrough Therapy and Orphan Drug Designations by the FDA.

ECOSPOR III was a multicenter, randomized, placebo-controlled study in individuals with rCDI, the results of which were published in the *New England Journal of Medicine*.[2] The study's primary objective was to demonstrate the reduction of CDI recurrence with VOWST. In ECOSPOR III, VOWST was shown to reduce CDI recurrence at eight weeks, with approximately 88% of individuals recurrence-free at eight weeks post-treatment, compared to 60% in participants who received placebo.[2] In addition, at six months post-treatment, 79% of the VOWST group were demonstrated to be recurrence-free, compared to 53% in the placebo group.[3] No treatment-related serious adverse events were observed in the active arm and the frequency of treatment-related adverse events was similar between the VOWST and placebo arms. The most common adverse reactions through eight weeks in VOWST treated participants versus placebo were solicited events of abdominal distention (31.1% VOWST versus 29.3% placebo), fatigue (22.2% VOWST versus 21.7% placebo), constipation (14.4% VOWST versus 10.9% placebo), chills (11.1% versus 7.6% placebo), and unsolicited event of diarrhea (10.0% versus 4.3% placebo).[4]

ECOSPOR IV was an open-label, single arm study evaluating VOWST in 263 adult participants with rCDI. Study results were published in the *JAMA Network Open*.[5] The ECOSPOR IV study results contributed to the VOWST safety database and supported product approval.

Seres and Nestlé Health Science are committed to helping appropriate patients who have been prescribed VOWST obtain access. Additional details about VOWST access programs will be available at launch.

**Joint Commercialization Agreement**

In July 2021, Seres and Nestlé Health Science entered into an agreement to jointly commercialize VOWST in the U.S. and Canada. Nestlé Health Science is leveraging its global pharmaceutical business and assuming the role of lead commercialization party, including the utilization of its existing infrastructure, gastrointestinal sales force and payer access team.

Seres is due to receive a $125 million milestone payment from Nestlé Health Science associated with the FDA approval of VOWST. Upon VOWST commercialization, each company will be entitled to share equally in commercial profits and losses.

**Conference Call Information**

Seres' management will host a conference call tomorrow, April 27, 2023, at 8:30 a.m. ET. Accompanying slides will be posted on the Seres website prior to the call. To access the conference call, please dial 773-305-6867 (domestic) or 866-400-0049 (international) and reference Conference ID 1937506. To join the live webcast, please visit the "Investors and News" section of the Seres website at www.serestherapeutics.com.

A webcast replay will be available on the Seres website beginning approximately two hours after the event and will be archived for at least 21 days.

**INDICATION AND IMPORTANT SAFETY INFORMATION FOR VOWST**

**INDICATION**

VOWST is indicated to prevent the recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI).

Limitation of Use: VOWST is not indicated for treatment of CDI.

**IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS**

**Transmissible infectious agents:** Because VOWST is manufactured from human fecal matter, it may carry a risk of transmitting infectious agents. Report any infection that is suspected to have been transmitted by VOWST to Aimmune Therapeutics, Inc. at 1-833-246-2566.

**Potential presence of food allergens:** VOWST may contain food allergens. The potential to cause adverse reactions due to food allergens is unknown.

**ADVERSE REACTIONS**

The most common adverse reactions (reported in ≥5% of participants) were abdominal distension (31.1%), fatigue (22.2%), constipation (14.4%), chills (11.1%), and diarrhea (10.0%).

To report SUSPECTED ADVERSE REACTIONS, contact Aimmune Therapeutics at 1-833-AIM-2KNO (1-833-246-2566), or the FDA at 1-800-FDA-1088, or visit www.fda.gov/MedWatch.

**DRUG INTERACTIONS**
Do not administer antibacterials concurrently with VOWST.

**Please see Full Prescribing Information and Patient Information**

**About Recurrent *C. difficile* Infection (rCDI)**
Recurrent *C. difficile* infection is a gastrointestinal infection caused by *C. difficile* bacteria. rCDI is linked to dysbiosis of the gastrointestinal microbiome and is associated with increased mortality. CDI has been characterized as an Urgent Health Threat by the Centers for Disease Control and Prevention (CDC). rCDI results in a substantial burden on the healthcare system[1] with the average rCDI-related annual costs per patient at approximately $43K.[6]

**About Seres Therapeutics**
Seres Therapeutics, Inc. (Nasdaq: MCRB) is a commercial-stage company developing novel microbiome therapeutics for serious diseases. Seres' lead program, VOWST™, obtained U.S. FDA approval in April 2023 as the first orally administered microbiota-based therapeutic to prevent recurrence of *C. difficile* infection (CDI) in adults following antibacterial treatment for recurrent CDI and is being commercialized in collaboration with Nestlé Health Science. Seres is also developing a novel class of multifunctional fermented bacterial consortia designed to functionally interact with host cells and tissues to treat disease. For more information, please visit www.serestherapeutics.com.

**About Nestlé Health Science**
Nestlé Health Science, a leader in the science of nutrition, is a globally managed business unit of Nestlé. We are committed to redefining the management of health, offering an extensive portfolio of science-based consumer health, medical nutrition, pharmaceutical therapies, and vitamin and supplement brands. Our extensive research network provides the foundation for products that empower healthier lives through nutrition. Headquartered in Switzerland, we have more than 12,000 employees around the world, with products available in more than 140 countries. For more information, please visit www.nestlehealthscience.us.

**Forward-Looking Statements**
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including the timing of commercial launch, the availability of VOWST, the commercial success of VOWST; and other statements which are not historical fact.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding; our limited operating history; the impact of the COVID-19 pandemic; our unproven approach to therapeutic intervention; our reliance on third parties and collaborators to conduct our clinical trials, manufacture our product candidates and develop and commercialize our product candidates, if approved; the unknown degree and competing factors of market acceptance for VOWST; the competition we will face; our ability to protect our intellectual property; and our ability to retain key personnel and to manage our growth. These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC), on March 7, 2023, and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

**References:**


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