Seres Therapeutics and Nestlé Health Science Announce U.S. Commercial Availability of VOWST™, the First and Only FDA-Approved Microbiota-Based Oral Therapeutic for Prevention of Recurrence of C. Difficile Infection

June 5, 2023

– VOWST is now available by prescription in the U.S. for adult patients following antibiotic treatment for recurrent CDI –

– VOWST Voyage™ Support Program to help reduce out-of-pocket patient costs for eligible patients and facilitate treatment start –

CAMBRIDGE, Mass. & HOBOKEN, N.J.--(BUSINESS WIRE)--Jun. 5, 2023-- Seres Therapeutics, Inc. (Nasdaq: MCRB) and Nestlé Health Science today announced that VOWST™ (fecal microbiota spores, live-brpk) is now commercially available for patients. VOWST, formerly called SER-109, is the first and only U.S. Food and Drug Administration (FDA)-approved 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.

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"The commercial availability of VOWST provides a new oral dosing option that has demonstrated efficacy in the prevention of further recurrences of rCDI, including those who have experienced a first recurrence. We look forward to helping patients who have this potentially life-threatening disease," said Eric Shaff, President and Chief Executive Officer at Seres.

"At Nestlé Health Science, we are leveraging our strong existing infrastructure, including our gastrointestinal sales force and payer access team, to commercialize VOWST and provide this product to those who need it most," said Greg Behar, Chief Executive Officer, Nestlé Health Science. "Since the approval of VOWST, our teams have engaged with healthcare professionals and are committed to facilitating patient access."

"As a treating physician, I am pleased to now have the ability to prescribe VOWST, a 3-day oral regimen, to eligible patients in my practice," said Carl Crawford M.D., Assistant Professor of Clinical Medicine at Weill Cornell Medical College. "Recurrent *C. difficile* infection is a challenging and debilitating disease, and VOWST has potential to make a meaningful impact to this patient community."

VOWST Voyage™
Seres Therapeutics and Nestlé Health Science are committed to broad access for appropriate patients. The VOWST Voyage Support Program offers a range of resources and programs designed to help eligible patients prescribed VOWST access and initiate treatment. The program includes the VOWST Co-Pay Savings Program for eligible, commercially insured patients to help reduce their out-of-pocket costs.

Information on the VOWST Voyage Support Program is available at VowstHCP.com or by calling 888-356-5444.

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 morbidity and 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.[2]

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 evaluating SER-155 in a Phase 1b study in patients receiving allogeneic hematopoietic stem cell transplantation. The Company is also conducting research to inform further development of microbiome therapeutics for ulcerative colitis. 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 commercial success of VOWST, our ability to supply VOWST to the market, the success of the VOWST Voyage program 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC), on May 9, 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

1. U.S. Bureau of Labor Statistics. CPI Inflation Calculator. U.S. Bureau of Labor Statistics. Published 2022. https://www.bls.gov/data/inflation_calculator.htm. *CPI inflation adjusted to March 2023.*
2. Rodrigues R, Barber GE, Ananthakrishnan AN. A Comprehensive Study of Costs Associated With Recurrent *Clostridium difficile* Infection. *Infect Control Hosp Epidemiol.* 2016;38:196-202. DOI: 10.1017/ice.2016.246

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