Seres Therapeutics and Nestlé Health Science Present Late-Breaking Data on VOWST™, a Microbiota-Based Oral Therapeutic for Prevention of Recurrence of C. Difficile Infection in Adults, at ASM Microbe 2023

June 17, 2023

– Post-hoc analysis results with VOWST highlight the importance of gut microbiome diversity as a critical component of a treatment regimen to reduce the risk of recurrent C. difficile infection in rCDI patients, regardless of the number of prior recurrences –

CAMBRIDGE, Mass. & HOBOKEN, N.J.--(BUSINESS WIRE)--Jun. 17, 2023-- Seres Therapeutics, Inc. (Nasdaq: MCRB) and Nestlé Health Science today announced the presentation of a post-hoc analysis from the Phase 3 development program for VOWST™ (fecal microbiota spores, live-brpk), 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). The analysis was featured as a late-breaker Emerging Science presentation at American Society of Microbiology (ASM) Microbe 2023 being held in Houston, TX (June 15-19).

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20230617404809/en/

The presentation highlighted post-hoc gastrointestinal microbiome analyses of recurrent *C. diff* patients enrolled in the ECOSPOR III and ECOSPOR IV Phase 3 studies, including those with a first recurrence and multiple recurrences. Results showed that at baseline (pre-treatment), individuals experiencing a first recurrence or multiple recurrences exhibited a similarly low degree of gut microbiome diversity. Following treatment with VOWST, both first recurrence and multiple recurrence patient groups had a significant increase in microbiome diversity as well as increased levels of secondary bile acids, a metabolites shown to inhibit growth of *C. difficile* bacteria.[1]

"Results from this post-hoc analysis of the ECOSPOR III and ECOSPOR IV Phase 3 studies show that whether recurrent *C. difficile* infection patients have experienced either a first recurrence or multiple recurrences, patients exhibit a similar level of loss of microbiome diversity," said Lisa von Moltke, M.D., Chief Medical Officer at Seres. "Following treatment with VOWST, we observed an early robust increase in microbiome diversity in both patient groups within one week."

Recurrent CDI represents significant unmet need and is a leading cause of hospital-acquired infection that can result in severe illness and death.[2] 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.

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[3] 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 opportunity for VOWST, the impact microbiome diversity on rCDI patient management, and 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. Theriot CM, Bowman AA, Young VB. Antibiotic-Induced Alterations of the Gut Microbiota Alter Secondary Bile Acid Production and Allow for Clostridium difficile Spore Germination and Outgrowth in the Large Intestine. mSphere. 2016;1(1):e00045-15
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
3. 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.*

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