



Seres Therapeutics' ECOSPOR III Study Data on SER-109 Published in Journal of the American Medical Association

October 19, 2022

– Summarized data from the study's secondary endpoints show investigational oral microbiome therapeutic rapidly and durably lowered risk of recurrent *C. difficile* infection –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 19, 2022-- [Seres Therapeutics, Inc.](#) (Nasdaq: MCRB), a leading microbiome therapeutics company, today announced the publication of Phase 3 clinical data in the [Journal of the American Medical Association](#) (JAMA), highlighting that the clinical benefits of investigational therapeutic SER-109 for preventing recurrent *C. difficile* infection (rCDI) were apparent as early as two weeks post-treatment and sustained for at least 24 weeks.

With nearly 170,000 cases in the U.S. each year, rCDI is one of the top three most urgent bacterial threats in the country, according to the Centers for Disease Control and Prevention, and is a leading cause of hospital-acquired infection. SER-109 is an investigational microbiome therapeutic composed of purified Firmicutes spores designed to reduce recurrence of rCDI, which shows promise to improve the current standard of care for this debilitating disease.

"We are honored to see these important findings published in such a well-regarded medical research journal," said Lisa von Moltke, M.D., Chief Medical Officer at Seres and publication co-author. "Recurrent *C. difficile* infection can be difficult to treat, and these findings further suggest that repopulating the GI tract with key protective bacteria via oral delivery has the potential to dramatically reduce the risk of recurrence."

The JAMA paper summarizes data from the secondary endpoints of the multicenter, double-blind ECOSPOR III trial ([NCT03183128](#)), which enrolled 182 participants with a history of rCDI and randomly assigned them to receive either SER-109 or placebo. At each of the 4-, 12- and 24-week secondary endpoints, significantly fewer participants in the SER-109 group experienced a CDI recurrence, compared to the placebo group, building on the positive 8-week primary endpoint data published earlier this year in the [New England Journal of Medicine](#).

While comorbidities were common among study participants in both arms of the study, SER-109 was well-tolerated with no serious treatment-related adverse events observed over the course of the 24-week study period.

The published manuscript, titled, "Extended Follow-up of Microbiome Therapeutic SER-109 Through 24 Weeks for Recurrent *Clostridioides difficile* Infection in a Randomized Clinical Trial" is [available online](#).

A Biologics License Application (BLA) for SER-109 has been submitted to the U.S. Food and Drug Administration (FDA) and Seres anticipates product approval and commercial launch in the first half of 2023.

About SER-109

SER-109 is an oral microbiome therapeutic candidate consisting of a consortium of highly purified Firmicutes spores, which normally live in a healthy microbiome. SER-109 is designed to prevent further recurrences of CDI by modulating the disrupted microbiome to a state that resists *C. difficile* colonization and growth. The SER-109 manufacturing purification process is designed to remove unwanted microbes, thereby reducing the risk of pathogen transmission beyond donor screening alone. The FDA has granted SER-109 Breakthrough Therapy designation and Orphan Drug designation for the prevention of rCDI.

About Seres Therapeutics

Seres Therapeutics, Inc. (Nasdaq: MCRB) is a leading microbiome therapeutics company developing a novel class of multifunctional bacterial consortia that are designed to functionally interact with host cells and tissues to treat disease. Seres' SER-109 program achieved the first-ever positive pivotal clinical results for a targeted microbiome drug candidate and has obtained Breakthrough Therapy and Orphan Drug designations from the FDA. The SER-109 program is being advanced to prevent further recurrences of *C. difficile* infection and has potential to become a first-in-class oral FDA-approved microbiome therapeutic. Seres is evaluating SER-155 in a Phase 1b study in patients receiving allogeneic hematopoietic stem cell transplantation to reduce incidences of gastrointestinal infections, bloodstream infections and graft-versus-host disease as well as additional preclinical stage programs targeting Infection Protection in medically compromised patients. The Company is also conducting research to inform further development of microbiome therapeutics for ulcerative colitis.

For more information, please visit www.serestherapeutics.com.

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 ultimate efficacy and safety profile of SER-109; the potential approval of SER-109; the timing of potential product approval and launch; the potential market for SER-109; the anticipated indication of SER-109; the potential for SER-109 to improve the standard of care for rCDI; 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; the lengthy, expensive and uncertain process of clinical drug development; 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; 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, or SEC, on August 3, 2022, 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.

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