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Seres Therapeutics Presents Late-Breaking Data from SER-109 Phase 3 ECOSPOR III Study in Recurrent *C. Difficile* Infection at IDWeek2021

October 2, 2021

– In ECOSPOR III, investigational microbiome therapy SER-109 was associated with greater reduction of antimicrobial resistance genes in patients with recurrent CDI compared to placebo –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 2, 2021-- [Seres Therapeutics, Inc.](https://www.seres-therapeutics.com) (Nasdaq: MCRB), a leading microbiome therapeutics company, today announced late-breaking data from its Phase 3 ECOSPOR III study evaluating SER-109, an investigational oral microbiome therapeutic for recurrent *C. difficile* infection (rCDI). SER-109 was associated with significantly greater reduction of antimicrobial resistance genes (ARGs) compared to placebo, with the reduction observed both rapidly (by Week 1) and sustained through Week 8 of the study. These data, presented by Timothy Straub on October 2 at the IDWeek 2021 Virtual Conference, support a potential role for microbiome therapeutics in rapid decolonization of antibiotic resistant bacteria.

“As the GI microbiome is the first-line of defense against colonization with antimicrobial resistant bacteria, this exploratory analysis is critical to understanding the potential of SER-109 and our microbiome pipeline more broadly,” said Lisa von Moltke, M.D., Chief Medical Officer at Seres. “As one of the most urgent bacterial threats in the U.S. and a leading cause of hospital-acquired infection, providing patients with safer and more effective treatment options is at the forefront of our mission as we work to potentially bring the first-ever FDA-approved microbiome therapeutic to those suffering from *C. difficile*.”

The SER-109 ECOSPOR III Phase 3 study ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03183128) identifier: NCT03183128) was a multicenter, randomized, placebo-controlled study. Previously reported topline data indicated that the study achieved its primary endpoint at eight weeks and demonstrated a sustained clinical response rate of approximately 88% at eight weeks post-treatment. SER-109 resulted in a 27% absolute reduction of recurrence of CDI compared to placebo at eight weeks post-treatment, which is a relative risk reduction of 68%. In May 2021, Seres [presented](#) 24-week clinical data from the study that demonstrated significantly reduced recurrence rates compared to placebo over 24 weeks (21.3% vs. 47.3%, respectively). SER-109 was observed to be well tolerated, with no treatment-related serious adverse events observed in the active arm and an adverse event profile comparable to placebo. Seres expects to file a Biologics License Application (BLA) with the U.S. Food and Drug Administration in mid-2022.

The data is available to registered attendees on the virtual platform throughout the duration of the IDWeek Conference at www.IDWeek.org.

About SER-109

SER-109 is an oral microbiome therapeutic candidate consisting of a consortium of highly purified Firmicutes spores, which normally live in the healthy microbiome. SER-109 is designed to prevent further recurrences of CDI in patients with a history of multiple infections 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 U.S. FDA has granted SER-109 Breakthrough Therapy designation and Orphan Drug designation for the treatment 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 for the treatment of recurrent *C. difficile* infection and has potential to become a first-in-class FDA-approved microbiome therapeutic. Seres is evaluating SER-301 in a Phase 1b study in patients with ulcerative colitis and SER-155 in a Phase 1b study to address gastrointestinal infections, bacteremia and graft-versus-host disease. For more information, please visit www.seres-therapeutics.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 potential role for microbiome therapeutics in the decolonization of antibiotic resistant bacteria, the potential approval of SER-109 and its status as a first-in-class therapeutic, the timing of a BLA filing, the ultimate safety profile of SER-109, the potential of microbiome therapeutics to treat and prevent disease, the timing and results of our clinical studies, the ultimate safety and efficacy data for our products, 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, 2021, 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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