# Seres Therapeutics Presents Data Supporting its Microbiome Pipeline at IDWeek 2021, Including Data from SER-109 Phase 3 ECOSPOR III Study in Recurrent C. Difficile Infection

September 29, 2021

*– Data presented highlights significant impact of SER-109 on health-related quality of life (HRQoL) and reduction of recurrence regardless of risk factors –*

*– Preclinical assessments support the ability of SER-155 to decolonize antibiotic-resistant pathogens, potentially reducing the risk of subsequent infection –*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 29, 2021-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, today announced data from its Phase 3 ECOSPOR III study evaluating SER-109, an investigational oral microbiome therapy for recurrent *C. difficile* infection (rCDI), will be presented at the IDWeek 2021 Virtual Conference (Sept. 29-Oct. 3). The Company will be presenting seven posters and oral presentations related to SER-109 and *C. difficile*, including a late-breaker, as well as an oral presentation on SER-155, an investigational cultivated microbiome therapeutic entering clinical development designed to reduce the risk of gastrointestinal antibiotic-resistant bacterial infections, bacteremia and graft-versus-host-disease (GvHD) in immunocompromised patients.

Notably, exploratory analyses of SER-109 data revealed that SER-109 was associated with improved overall and mental health scores compared to baseline regardless of clinical outcome, as measured by CDiff32 (presenting author: Kevin Garey, PharmD, M.S.). Another poster highlights that despite more than half of the patient population in ECOSPOR III having at least one co-morbidity, SER-109 was observed to significantly reduce the incidence of recurrence compared to placebo in these patients. SER-109 was observed to reduce CDI recurrence among patients at risk for recurrence because of age, gender, proton pump inhibitor use, and/or co-morbidities such as diabetes, cardiac disease and malignancy, in comparison to placebo (presenting author: Stuart Cohen, M.D.).

“The data we’re presenting at IDWeek 2021 further validates the strength of our investigational microbiome pipeline as we urgently work to address the unmet treatment needs for both recurrent *C. difficile* infection and immunocompromised patients,” said Lisa von Moltke, M.D., Chief Medical Officer at Seres. “We believe microbiome therapeutics have the potential to target multiple disease pathways and offer new, potentially transformative treatment options for patients in need.”

The oral presentation by Elizabeth Halvorsen, Ph.D. on SER-155, an investigational cultivated microbiome therapeutic, will highlight preclinical data showing that SER-155 can decolonize antibiotic-resistant pathogens (VRE: vancomycin-resistant *Enterococcus faecium* and CRE: carbapenem-resistant *Klebsiella pneumoniae*); potentially reducing the risk of subsequent infection.

In addition, Seres is presenting the following SER-109-related posters and a late-breaker presentation at IDWeek 2021:

- SER-109, an Investigational Microbiome Therapeutic, Reduces Abundance of Antimicrobial Resistance Genes in Patients with Recurrent *Clostridioides difficile* Infection (rCDI) after Standard-of-Care Antibiotics, Saturday, October 2, 1:15 PM – 3:00 PM ET, Presenting Author: Timothy Straub (late-breaker)
- Manufacturing Processes of SER-109, a Purified Investigational Microbiome Therapeutic, Reduce Risk of Transmission of Emerging and Undetected Infections in Donor Stool, Presenting Author: Christopher McChalicher
- Diagnostic Testing Among Patients with Suspected Recurrent *Clostridioides difficile* Infection (rCDI) in ECOSPOR III a Phase 3 Clinical Trial: Implications for Clinical Practices vs Clinical Trials, Presenting Author: Matthew Sims
- Time to Recurrence of *Clostridioides difficile* Infection (rCDI) is Rapid Following Completion of Standard of Care Antibiotics: Results from ECOSPOR-III, a Phase 3 Double-Blind, Placebo-Controlled Randomized Trial of SER-109, an Investigational Microbiome Therapeutic, Presenting Author: Thomas Louie
- The Burden of Illness Associated with Recurrent *Clostridioides difficile* Infection: A Claims-based Analysis, Presenting Author: Rachel Black

In addition, Paul Feuerstadt, M.D. will be providing a sponsored talk on Friday, October 1 at 2:00-2:45 PM ET, entitled “Perspectives on the Pathogenesis of Recurrent *Clostridioides difficile* Infection: Insights into Microbiome Science.”

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 SER-155**

SER-155, an oral consortium of cultivated bacteria, is a microbiome therapeutic candidate intended to advance into clinical development. SER-155 is designed using microbiome biomarker data from human clinical data, human cell-based assays, and *in vivo* disease models, with the aim to decrease infection and translocation of antibiotic-resistant bacteria in the gastrointestinal tract and modulate host immune responses to decrease GvHD. The rationale for this program is based in part on published clinical evidence from Seres' collaborators at Memorial Sloan Kettering Cancer Center showing that allogeneic hematopoietic stem-cell transplantation (HSCT) patients with decreased diversity of commensal microbes are significantly more likely to die due to infection and/or GvHD. SER-155 was developed using Seres' reverse translational discovery platform to reduce morbidity and mortality due to gastrointestinal infections, bacteremia and GvHD in immunocompromised patients, including in patients receiving allogeneic HSCT or solid organ transplants.

**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.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 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 ultimate market for SER-109, the potential for microbiome therapeutics to improve the outcome of immunocompromised patients, the ability of SER-109 to improve rCDI patients' quality of life, the potential of microbiome therapeutics to treat and prevent disease, the timing and results of our clinical studies, the benefits of our collaborations, 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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