Seres Therapeutics' Investigational SER-109 ECOSPOR IV Study Data Published in JAMA NETWORK OPEN

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– Clinical data, showing that 91.3% of subjects remained free of C. difficile infection recurrence at 8 weeks, support and extend previous Phase 3 study results –

– SER-109 associated with rapid and steady improvement in HRQOL, an important patient-related outcome, compared with placebo through 8 weeks –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 14, 2023-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, today announced the publication of data from its Phase 3 ECOSPOR IV trial (ClinicalTrials.gov Identifier: NCT03183128) in *JAMA Network Open* that reinforce previously published results from the Phase 3 ECOSPOR III study on the investigational microbiome therapeutic SER-109 for the prevention of recurrent *C. difficile* infection (rCDI). With nearly 156,000 cases in the U.S., rCDI is a leading cause of hospital-acquired infection and places a significant burden on the healthcare system.

The *JAMA Network Open* paper summarizes clinical data from the SER-109 Phase 3 ECOSPOR IV trial, which enrolled 263 participants with a history of rCDI, including individuals that have experienced only a single recurrence of CDI. At the 8- and 24-week primary endpoints, 91.3% and 86.3% of patients remained free of recurrence, respectively, supporting positive data from the SER-109 placebo-controlled ECOSPOR III study published last year in *JAMA*. Similar results were observed in all subgroups, including those with a single recurrence of CDI. While comorbidities were prevalent among study participants, a well-tolerated safety profile was observed in ECOSPOR IV, consistent with the safety-profile observed in ECOSPOR III, with no treatment-related adverse events leading to withdrawal from the study.

"We are proud to see these critical supporting data from the ECOSPOR IV study published in a leading medical research journal. These findings extend our previous results and found that repopulating the GI tract with key protective bacteria via oral delivery can meaningfully reduce the risk of a recurrence of CDI, including in first recurrent patients," said Lisa von Moltke, M.D., Chief Medical Officer at Seres and publication co-author. "Recurrent *C. difficile* infection places a significant burden on patients, providers and the entire healthcare system and we believe that SER-109, if approved, may provide an important new treatment option for this disease."

A Biologics License Application (BLA) for SER-109 has been submitted to the U.S. Food and Drug Administration (FDA) and was accepted for Priority Review, with a Prescription Drug User Fee Act (PDUFA) action date set for April 26, 2023.

The published manuscript, titled, "SER-109, an Investigational Microbiome Therapeutic in Adults with Recurrent *Clostridioides difficile* Infection (rCDI): A 24-Week Open-Label Single-Arm Study (ECOSPOR IV)" was released on January 13, 2023 is available online.

The Company also announced a separate publication from *JAMA Network Open* from January 30, 2023 titled, "Assessment of Quality of Life Among Patients With Recurrent *Clostridioides difficile* Infection Treated with Investigational Oral Microbiome Therapeutic SER-109 Secondary Analysis of a Randomized Clinical Trial." The published data, based on secondary data analysis from the ECOSPOR III Phase 3 study, suggest that SER-109 administration may be associated with a rapid and steady improvement in HRQOL, an important patient-related outcome, compared with placebo through 8 weeks.

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 launch; the potential market for SER-109; the anticipated indication of SER-109; 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 November 2, 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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