Seres Therapeutics Achieves Enrollment of 300 Subjects with Phase 3 ECOSPOR IV Open-Label Extension Study of SER-109, a Potentially First-in-Class Investigational Microbiome Therapeutic for Recurrent C. difficile Infection

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– Seres expects both the completed Phase 3 study results and the pending open-label study database to finalize a Biologics License Application (BLA) filing in mid-2022 –

– Potential to be first-ever FDA-approved microbiome therapy –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 15, 2021-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, today announced it has achieved enrollment of 300 subjects with the ECOSPOR IV open-label study evaluating SER-109, an investigational oral microbiome therapeutic for recurrent *C. difficile* infection (rCDI). The target enrollment of a minimum of 300 subjects for the SER-109 safety database was reached in conjunction with a prior completed Phase 3 study, ECOSPOR lll. Seres is required by the U.S. Food and Drug Administration (FDA) to demonstrate safety of SER-109 in at least 300 subjects who have received the dose to be commercialized, consistent with standard FDA guidance, with a 24-week follow-up period, to support a Biologics License Application (BLA) submission. Seres plans to close enrollment in the open-label study in the coming weeks and will engage with the FDA on initiation of an expanded access program by the end of the year. Seres intends to seek agreement with the FDA to begin a rolling submission of the BLA for SER-109 in the first half of 2022 and finalize the submission with data from the safety database in mid-2022.

“This is a meaningful milestone for the company as it positions us for a BLA submission that, if approved, could make SER-109 the first-ever FDA-approved microbiome therapeutic,” said Eric Shaff, Chief Executive Officer at Seres. “We are working tirelessly alongside our commercial collaborator, Nestlé Health Science, to bring this potentially revolutionary therapeutic to recurrent *C. difficile* patients, who urgently need safer and more effective treatment options to reduce the likelihood of recurrent disease. We believe SER-109 has the potential to fundamentally transform the management of this very serious disease.”

The SER-109 ECOSPOR III Phase 3 study (ClinicalTrials.gov identifier: NCT03183128) was a multicenter, randomized, placebo-controlled study. Previously reported topline data indicated 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.

“SER-109 has the potential to change the treatment paradigm and meaningfully improve medical outcomes for the more than 170,000 recurrent CDI patients in the U.S. suffering from this deadly disease each year, including over 20,000 deaths annually. Reaching this enrollment milestone is critical to achieving that goal, and we are grateful to these trial participants, their families and healthcare providers for their contributions,” said Lisa von Moltke, M.D., Chief Medical Officer at Seres.

CDI is one of the top three most urgent bacterial threats in the U.S., according to the Centers for Disease Control and Prevention, and is a leading cause of hospital-acquired infection. It is associated with significant morbidity and mortality, with an annual cost to the U.S. healthcare system of approximately $6.3 billion, and the annual cost of a recurrent CDI patient estimated at approximately $34,000.

Seres entered into an agreement with Nestlé Health Science in July 2021 to jointly commercialize SER-109 in the U.S. and Canada. Under the terms of the agreement, Nestlé Health Science will use its global pharmaceutical business Aimmune Therapeutics and will assume the role of lead commercialization party. Seres has received an upfront license payment of $175 million, and will receive an additional $125 million upon FDA approval of SER-109. The agreement also includes sales target milestones which, if achieved, would total up to $225 million. Seres will be responsible for development and pre-commercialization costs in the U.S. Upon commercialization, Seres will be entitled to an amount equal to 50% of the commercial profits.

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.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 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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