Seres Therapeutics Announces FDA Acceptance of Biologics License Application for Investigational Microbiome Therapeutic SER-109 for Recurrent C. Difficile Infection for Priority Review

October 26, 2022

– If approved, SER-109 expected to be the first-ever FDA-approved oral microbiome therapeutic –

– PDUFA target action date is April 26, 2023, with anticipated launch soon thereafter –

– FDA advised that they are not currently planning to hold an Advisory Committee Meeting to discuss the SER-109 application –

– Company to hold commercial investor event on December 8, 2022 –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 26, 2022-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, today announced the U.S. Food and Drug Administration (FDA) has accepted for review a Biologics License Application (BLA) for investigational oral microbiome therapeutic SER-109 for the prevention of recurrent *C. difficile* infection (rCDI). The application has been granted Priority Review designation with a Prescription Drug User Fee Act (PDUFA) action date of April 26, 2023. The FDA advised that they are not currently planning to hold an Advisory Committee Meeting to discuss the SER-109 application.

"We are delighted by the FDA's BLA acceptance for priority review, as we believe that SER-109 has the potential to fundamentally transform the management of rCDI," said Lisa von Moltke, M.D., Chief Medical Officer at Seres. "We are working closely with the FDA to bring forth this entirely new treatment modality alongside our collaborator, Aimmune Therapeutics, Inc., a Nestlé Health Science Company."

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

"We are working as quickly as possible to bring this first-ever oral microbiome therapeutic to patients most in need, if approved," said Eric Shaff, President and Chief Executive Officer at Seres. "Today's milestone is the result of tremendous hard work and perseverance by our team, and we look forward to collaborating with the FDA through the ongoing review process."

The application is supported by the results of a completed Phase 3 development program including ECOSPOR III (NCT03183128) and ECOSPOR IV (NCT03183141):

- **ECOSPOR III (SERES-012):** A multicenter, randomized, placebo-controlled study that enrolled 182 adults with rCDI. Results published in the *New England Journal of Medicine* in January showed that 88% of subjects in the SER-109 group were free from *C. difficile* recurrence at eight weeks post-treatment, compared to 60% in the placebo group. At 24 weeks post-treatment, 79% of the SER-109 group were still free from *C. difficile* recurrence, compared to 53% in the placebo group, reinforcing the durable relief. SER-109 was observed to be well tolerated with no drug-related serious adverse events.

- **ECOSPOR IV (SERES-013):** An open-label extension study of ECOSPOR III and open-label program for evaluating SER-109 in 263 adult subjects with rCDI at the commercial dose to fulfill FDA requirements for the SER-109 safety database. The study duration for both cohorts was approximately 27 weeks, including a three-week screening period, an eight-week primary efficacy period, and a 16-week follow-up period. Topline results indicated that the safety profile was well-tolerated and there was a 91% sustained clinical response at eight weeks in the overall population. At 24 weeks post-treatment, 86% of subjects treated with SER-109 experienced sustained clinical response.

In July 2021, Seres entered into an agreement with Nestlé Health Science to jointly commercialize SER-109 in the U.S. and potentially Canada. Under the terms of the agreement, Nestlé Health Science will utilize 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.

Seres plans to host a SER-109 investor event, including participation by Aimmune, focused on the rCDI market opportunity and launch preparations on December 8, 2022. Additional details will be provided at a later date.

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 reduce the recurrence 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 potential approval of SER-109 and its status as a first-in-class oral therapeutic; 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 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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PR
Kristin Ainsworth
kainsworth@serestherapeutics.com

IR
Carlo Tanzi, Ph.D.
ctanzi@serestherapeutics.com

Source: Seres Therapeutics, Inc.