Seres Therapeutics Announces Completion of Rolling BLA Submission to FDA for Investigational Microbiome Therapeutic SER-109 for Recurrent C. Difficile Infection

September 7, 2022

– Investigational therapeutic SER-109 has the potential to become the first-ever FDA-approved oral microbiome therapeutic –

– Anticipated product launch in the first half of 2023 –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 7, 2022-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, today announced it has completed the rolling submission process for its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for SER-109 for the prevention of recurrent *C. difficile* infection (rCDI). SER-109 is an entirely new treatment modality that shows promise to improve the current standard of care for rCDI.

"Completing this BLA submission marks a key milestone for Seres and, more importantly, a potential turning point for the treatment of nearly 170,000 cases of recurrent *C. difficile* infection each year in the United States alone," said Lisa von Moltke, MD, Chief Medical Officer at Seres. "We look forward to continuing to work with the FDA on the review of this BLA so that, if approved, we can bring this therapeutic candidate to patients as quickly as possible with our collaborator, Aimmune Therapeutics, a Nestlé Health Science Company."

SER-109 has FDA Breakthrough Therapy designation, which provides the potential for priority review of the BLA. If granted, Seres anticipates the potential approval and launch of SER-109 in the first half of 2023, with SER-109 potentially becoming the first ever FDA-approved oral microbiome therapeutic.

"After well over a decade of research, Seres has established strong leadership in the development of microbiome therapeutics with a promising pipeline," said Eric Shaff, President and Chief Executive Officer at Seres. "We are conducting key pre-commercialization activities, including market education with appropriate health care professionals as well as payer engagement, and we continue to scale up manufacturing operations to produce SER-109 commercial supply in preparation for launch."

The submission is supported by the results of two Phase 3 studies: ECOSPOR III (NCT03183128) and ECOSPOR IV (NCT03183141). The ECOSPOR III study was a multicenter, randomized, placebo-controlled study, results of which were published in the *New England Journal of Medicine*. ECOSPOR III achieved its primary endpoint demonstrating that SER-109 was superior to placebo in reducing CDI recurrence at eight weeks, with a sustained clinical response rate of approximately 88% at eight weeks post-treatment, compared to 60% in the placebo arm. In June 2022, Seres shared confirmatory results from the ECOSPOR IV open-label extension study, where the overall safety profile observed through 24 weeks indicated that SER-109 was well tolerated, consistent with the safety profile observed in the placebo-controlled ECOSPOR III study. Further, ECOSPOR IV subjects treated with SER-109 demonstrated a recurrence rate of 8.7% at eight weeks, which indicates a 91.3% sustained clinical response.

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 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.

Building upon the proven mechanisms of SER-109 within Infection Protection, Seres is currently evaluating SER-155 in a Phase 1b study in individuals undergoing allogeneic hematopoietic stem cell transplantation and at elevated risk of life-threatening infections. Seres is also advancing additional preclinical stage programs targeting Infection Protection and combating the slow pandemic of antimicrobial resistant infections more broadly.

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 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 therapeutic; the timing of a BLA acceptance and potential product launch; the potential market for SER-109; the anticipated indication of SER-109; our manufacturing capabilities; 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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