New England Journal of Medicine Publishes Data from ECOSPOR III Phase 3 Study Evaluating Investigational Microbiome Therapeutic SER-109 in Recurrent C. Difficile Infection

January 19, 2022

– SER-109 achieved statistically significant and clinically meaningful improvements in key primary and secondary efficacy measures compared with placebo –

– SER-109 was well tolerated, with a safety profile comparable to placebo –

– Company expects to finalize Biologics License Application (BLA) filing in mid-2022 –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 19, 2022-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, today announced the publication in the *New England Journal of Medicine* (NEJM) of data from its Phase 3 ECOSPOR III study evaluating SER-109, an investigational oral microbiome therapeutic for the treatment of recurrent *C. difficile* infection (rCDI). The publication highlights data that found SER-109 to be superior to placebo in reducing CDI recurrence, with 88% of SER-109 patients achieving a sustained clinical response compared to 60% on placebo. SER-109 was also found to be well tolerated, with a side effect profile comparable to placebo and no serious drug-related adverse events observed. Seres expects to finalize a BLA submission for SER-109 with the U.S. Food and Drug Administration (FDA) in mid-2022.

"The publication of these data in the *New England Journal of Medicine* underscores the potential of SER-109 and its ability to provide safe, effective treatment to prevent recurrent *C. difficile* infection – of which there are 170,000 annual cases in the U.S.," said Lisa von Moltke, M.D., Chief Medical Officer at Seres. "These robust findings reinforce our belief that microbiome therapeutics have the potential to transform the way we treat serious diseases and help maximize opportunities in infection prevention based upon the proven mechanism of SER-109."

The SER-109 ECOSPOR III Phase 3 study (ClinicalTrials.gov identifier: NCT03183128) was a multicenter, randomized, placebo-controlled study. Previously reported topline data demonstrated that the study achieved its primary endpoint where SER-109 was superior to placebo in reducing CDI recurrence at eight weeks, reflecting 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.

"Recurrent *C. difficile* infection can have a serious and debilitating impact on patients' lives, and there are currently very few treatment options available. As a clinician, I am excited by the data presented in this publication and the potential for an effective, safe and orally administered microbiome therapeutic that could alter the devastating impacts of this disease," said Paul Feuerstadt, MD, FACG, AGAF, Yale University School of Medicine and lead author. "SER-109 is an entirely new treatment modality that shows promise to change the current standard of care."

The published manuscript, titled "SER-109, an oral investigational microbiome therapeutic for patients with recurrent *Clostridioides difficile* infection," is available online and will appear in the January issue of the *New England Journal of Medicine* (N Engl J Med 2022;386(3):220-229).

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 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 to reduce the recurrence of *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 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 November 10, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20220119005871/en/

PR Contact
Kristin Ainsworth
kainsworth@serestherapeutics.com

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

Source: Seres Therapeutics, Inc.