Seres Therapeutics Presents Late-Breaking Phase 3 Data on Investigational Microbiome Therapeutic SER-109 in Recurrent C. Difficile Infection at American College of Gastroenterology 2021 Annual Scientific Meeting

October 26, 2021

– Study shows that SER-109 reduced the risk of recurrent C. difficile infection in patients with risk factors for recurrence, including acid-reducing medications –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 26, 2021-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, today announced late-breaking data from its Phase 3 ECOSPOR III study evaluating SER-109, an investigational oral microbiome therapeutic for recurrent *C. difficile* infection (rCDI). New data from an exploratory analysis demonstrate SER-109 reduced the risk of rCDI compared to placebo in patients with risk factors for recurrence, including those taking acid-reducing medications such as proton pump inhibitors (PPIs) and H2 blockers (40.7% of patients). These data, presented by Louis Korman, M.D. on October 26 from 3:25-3:35 PM PT at the American College of Gastroenterology 2021 Annual Scientific Meeting in Las Vegas, may assist healthcare providers in their clinical decision-making on the use of PPIs and H2 blockers in patients at risk for recurrent CDI.

“Those living with gastrointestinal issues are faced with limited treatment options to help address some of the debilitating symptoms they face each day. While many turn to acid-reducing medicines, previous studies have shown that this can result in a higher risk of recurrent *C. difficile* infection,” said Lisa von Moltke, M.D., Chief Medical Officer at Seres. “We were pleased to see that with the administration of SER-109, subjects in the study experienced a lower CDI recurrence rate regardless of their risk factors, including the use of acid-reducing medications—a highly prevalent characteristic in this study population.”

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 over 24 weeks (21% vs. 47%, respectively). SER-109 was observed to be well tolerated in the study, with no treatment-related serious adverse events observed in the active arm and an adverse event profile comparable to placebo.

“As a clinician treating people living with recurrent *C. difficile* infection, I recognize the serious and often debilitating impact it has on their lives. I’m further encouraged by these new findings as they show that SER-109 has the potential to be broadly effective, including in patients known to be at higher risk of experiencing a recurrence of *C. difficile* infection,” said Louis Korman, M.D., Director, Chevy Chase Clinical Research, Principal Investigator of the SER-109 Phase 3 trial and presenting author.

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

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 potential of microbiome therapeutics to treat and prevent disease, the timing and results of our clinical studies, 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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