Seres Therapeutics to Present SER-109 Phase 3 ECOSPOR III Study Results at American College of Gastroenterology Annual Scientific Meeting

October 12, 2020

- New data demonstrate a sustained patient benefit following SER-109 administration with a highly statistically significant 31.1% absolute reduction in the rate of C. difficile infection recurrence over 12 weeks, compared to placebo –

- Additional new findings show similar SER-109 efficacy across stratified age groups and prior antibiotic treatment regimen cohorts –

- Well tolerated, with a safety profile comparable to placebo –

- SER-109 open label study enrolling individuals with recurrent C. difficile infection –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 12, 2020-- Seres Therapeutics, Inc. (Nasdaq: MCRB) today announced the presentation of previously announced positive Phase 3 results from the ECOSPOR III trial of SER-109 at the Virtual American College of Gastroenterology (ACG) Annual Scientific Meeting taking place October 23-28, 2020. New data to be presented in Seres' late-breaker oral presentation show that SER-109 led to a sustained highly statistically significant absolute reduction in *C. difficile* infection recurrence at 12 weeks post-treatment when compared to placebo. Additionally, new findings demonstrate that SER-109 administration resulted in similar efficacy when stratified by age groups (i.e., > or <65 years) or prior antibiotic received (i.e., vancomycin or fidaxomicin).

The ECOSPOR III study (ClinicalTrials.gov identifier: NCT03183128) is a multicenter, randomized, placebo-controlled study that enrolled 182 patients with multiply recurrent *C. difficile* infection (CDI). Patients were randomized 1:1 to receive either SER-109 or placebo, after standard of care antibiotic treatment.

Previously reported topline data from ECOSPOR III showed that SER-109 met the study's primary endpoint with a 30.2% absolute reduction of recurrence of CDI compared to placebo at 8 weeks post-treatment.

New data show that at 12 weeks post-treatment the rate of recurrence in the SER-109 arm was 16.7%, compared to a rate of 47.8% in the placebo arm, representing an absolute risk reduction of 31.1% (relative risk 0.35; 95% CI 0.21-0.58; p-value <0.001), consistent with the results seen at eight weeks.

"These new SER-109 Phase 3 data extend the dramatic topline findings previously reported. The results demonstrate the remarkable efficacy levels are sustained over a twelve-week period, and similar treatment benefits are seen in both younger and older patients. In addition, the data show consistent patient benefits regardless of the baseline antibiotic treatment," said Bret Lashner, M.D., FACG, Professor of Medicine, Cleveland Clinic. "SER-109 has the potential to lead a paradigm shift in the clinical management of patients suffering from recurrent *C. difficile* infection."

Seres is sponsoring an ongoing SER-109 open label study in patients with recurrent CDI (ClinicalTrials.gov identifier: NCT03183128). Please inquire for additional information at serescdiffstudy.com.

Presentation details are shown below, and abstracts have been made available by ACG on their ACG2020 conference website.

> **Title:** "8- and 12-week Efficacy and Safety Data from ECOSPOR-III a Phase 3 Double-blind, Placebo-Controlled Randomized Trial of SER-109, an Investigational Microbiome Therapeutic for the Treatment of Patients with Recurrent Clostridioides difficile Infection (rCDI)"
>
> **Presenter:** Bret Lashner, M.D., FACG, Professor of Medicine, Cleveland Clinic

About SER-109

SER-109 is an investigational, oral, biologically-sourced microbiome therapeutic that is designed to reduce recurrence of *C. difficile* infection (CDI), enabling patients to achieve a sustained clinical response by breaking the vicious cycle of CDI recurrence and restoring the diversity of the gastrointestinal microbiome. SER-109 is a consortium of purified Firmicute bacteria in spore form, manufactured by fractionating targeted bacteria from the stool of healthy human donors with further steps to inactivate potential pathogens. The FDA has granted SER-109 Breakthrough Therapy designation and Orphan Drug designation for the treatment of recurrent CDI.

SER-109 is fundamentally distinct from fecal microbiota transplantation (FMT) and FMT-like products. SER-109 is comprised of a highly purified consortia of commensal bacteria in spore form, manufactured in accordance with Current Good Manufacturing Practice (cGMP) conditions using stringent standards to ensure product quality and consistency. To support product safety, Seres utilizes a unique manufacturing process designed to inactivate numerous potential pathogens, including species of non-spore bacteria, such as *Escherichia coli*, and viruses such as SARS-CoV-2.

About *C. difficile* Infection (CDI) and Current Treatments

C. difficile infection (CDI) is one of the top three most urgent antibiotic-resistant bacterial threats in the U.S., according to the Centers for Disease Control, and is a leading cause of hospital-acquired infection in the U.S. It is responsible for the deaths of approximately 20,000 Americans each year. CDI is associated with debilitating diarrhea, which significantly impacts quality of life in every functional domain. Since the discovery of *C. difficile* more

than four decades ago, vancomycin has been the drug most commonly used for patient management. Current approaches provide only modest improvements in sustained clinical response rates, leaving behind a significant pool of patients with recurrent disease. Unapproved FMT, used in cases that are not responsive to approved drugs, remains poorly characterized clinically and has been associated with serious safety concerns, including the transmission of bacterial pathogens and the potential transmission of viruses such as SARS-CoV-2, the virus that causes COVID-19. The recent quarantine and shipping hold of FMT material from a major stool bank highlights the urgent need for an approved effective and safe treatment for recurrent CDI.

About Seres Therapeutics

Seres Therapeutics, Inc., (Nasdaq: MCRB) is a leading microbiome therapeutics platform 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' SER-287 program has obtained Fast Track and Orphan Drug designations from the FDA and is being evaluated in a Phase 2b study in patients with active mild-to-moderate ulcerative colitis. Seres is developing SER-401 in a Phase 1b study in patients with metastatic melanoma, SER-301 for ulcerative colitis and SER-155 to prevent mortality due to 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 ability of SER-109 to transform the treatment of CDI or be a much-needed effective oral treatment option for recurrent CDI, inferences related to the currently-observed efficacy and safety profile of SER-109, and other statements that are not historical facts.

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; our unproven approach to therapeutic intervention; the lengthy, expensive, and uncertain process of clinical drug development; our reliance on third parties to manufacture, develop, and commercialize our product candidates, if approved; the ability to develop and commercialize our product candidates, if approved; the potential impact of the COVID-19 pandemic; our ability to retain key personnel and to manage our growth; and that our management and principal stockholders have the ability to control or significantly influence our business. 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 July 28, 2020 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/20201012005201/en/

PR Contact
Lisa Raffensperger
lisa@tenbridgecommunications.com

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

Source: Seres Therapeutics, Inc.