Seres Therapeutics Announces U.S. Food and Drug Administration Correspondence Following Positive SER-109 Phase 3 Study Results

September 11, 2020

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 11, 2020-- Seres Therapeutics, Inc. (Nasdaq: MCRB) today announced that it has obtained correspondence from the Office of Vaccines Research and Review of the U.S. Food and Drug Administration (FDA) regarding the Company's plans to submit a Biologics License Application (BLA) to support product approval of SER-109 for recurrent *C. difficile* infection (CDI). After obtaining highly statistically significant topline Phase 3 ECOSPOR III SER-109 study results in recurrent CDI, Seres requested a Breakthrough Therapy Designation meeting with the FDA. In response to the meeting request, the FDA reaffirmed its prior guidance regarding the efficacy requirements to support a SER-109 BLA submission, which were exceeded by the recent positive SER-109 Phase 3 study results, reaffirmed its prior guidance that at least 300 patients will be required for the safety database, and indicated there was not a reason for a meeting at this time.

Seres is using its SER-109 open-label study, which also admits patients with a single recurrence of CDI as previously discussed with the FDA, to expand the SER-109 safety database. Seres is taking various measures to expedite open-label study enrollment, including increasing the number of SER-109 clinical study sites across the U.S. and Canada. Seres also anticipates that the quarantine of material used for unapproved Fecal Microbiota Transplantation (FMT) by a national provider will accelerate SER-109 open-label study enrollment.

"Our SER-109 ECOSPOR III Phase 3 study results at eight weeks demonstrated an impressive 30.2% absolute reduction in CDI recurrence, an 88.9% SER-109 sustained clinical response, and a highly favorable safety profile. We believe SER-109 has the potential to transform the outcomes for patients living with recurrent CDI. We are very pleased that the FDA has reaffirmed the efficacy requirements for a BLA filing, and we expect that our Phase 3 data will provide the efficacy basis for product approval," said Eric D. Shaff, President and Chief Executive Officer of Seres. "Patients suffering from recurrent CDI have no attractive treatment options today, and some resort to unapproved FMT, which is unproven and is documented to transmit infectious diseases. There is an urgent need for a new effective and safe therapeutic option for this disease."

Mr. Shaff continued: "Seres is committed to serving patients with recurrent CDI, a devastating and often fatal disease, and we are working expeditiously to bring SER-109 forward to patients in need. Our team is diligently executing our open-label study, activating many new clinical sites in the process, and we expect to expand the SER-109 safety database so that we can file a BLA as soon as possible. We also plan to seek continued FDA dialogue to discuss a rapid path to product approval."

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). SER-109 is comprised of a highly purified consortia of commensal bacteria in spore form and designed to be 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 timing, content, and outcome of any potential meetings with the FDA, the potential approval of SER-109 by the FDA, the results from ECOSPOR III providing an efficacy basis for a BLA submission, the ability of SER-109 to transform the treatment of CDI or be a much-needed effective oral treatment option for recurrent CDI, the potential requirements by the FDA for additional safety data, the initiation of additional clinical sites in the open-label study of SER-109, the speed of patient enrollment in the open-label study, including the potential impact from the quarantine of material used for FMT, the development of an adequate safety database, 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.

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