Seres Therapeutics Initiates SER-109 Phase 3 Study in Patients with Multiply Recurrent C. difficile Infection

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- Based on recent FDA interactions, the new SER-109 Clinical Study is to be designated a Phase 3 Trial -

- SER-109 Phase 3 Trial is the first pivotal trial in the emerging field of microbiome-based oral therapeutics -

- Phase 3 Trial initiation triggers a $20 million milestone payment from Nestlé Health Science -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 12, 2017-- Seres Therapeutics, Inc. (NASDAQ:MCRB) today announced the initiation of its Phase 3 SER-109 clinical study (ECOSPOR III) in patients with multiply recurrent *C. difficile* infection. Based on recent interactions with the U.S. Food and Drug Administration (FDA), ECOSPOR III will now be designated a Phase 3 trial and the company expects that this single pivotal study may support SER-109 registration and approval.

"We are extremely pleased to be able to initiate the SER-109 Phase 3 ECOSPOR III study. If ECOSPOR III is successful, we believe this study could serve as the basis for SER-109 approval. Our goal is to have SER-109 approved as the first microbiome drug in this new field of medicine, and the first for patients with multiply recurrent *C. difficile* infection, an area of very high unmet need for patients in the U.S. and around the world," said Roger J. Pomerantz, M.D., President, CEO and Chairman of Seres.

The ECOSPOR III Phase 3 study design incorporates direct learnings from prior SER-109 development efforts, as well as helpful feedback obtained from the FDA and study investigators. The study is expected to enroll approximately 320 patients with multiply recurrent *C. difficile* infection, randomized 1:1 to either SER-109 or placebo. The study is sized to contribute to an adequate safety database that may support product licensure. ECOSPOR III will utilize more than 100 clinical sites across the U.S. and Canada. The study's primary endpoint will compare the reduction of *C. difficile* recurrence rates in subjects who receive SER-109 verses placebo at up to eight weeks after dosing.

The initiation of the SER-109 Phase 3 ECOSPOR III study triggers a $20 million milestone payment under the company's previously announced development and commercialization collaboration agreement with Nestlé Health Science. In partnership with Nestlé Health Science, Seres plans to accelerate interactions with European regulatory agencies in the coming months to establish a path toward SER-109 product approval across Europe.

About SER-109 and *C. difficile* Infection

SER-109, an oral capsule, is Seres' lead Ecobiotic® microbiome therapeutic for the treatment of multiply recurrent *C. difficile* infection. SER-109 is a biologically sourced consortium of bacterial spores designed to catalyze a shift in a dysbiotic gastrointestinal microbiome to a healthier state. The FDA has granted SER-109 both Breakthrough Therapy and Orphan Drug Designations.

C. difficile infection is one of the top three most urgent antibiotic-resistant bacterial threats in the United States according to the Centers for Disease Control. *C. difficile* is a leading cause of hospital acquired infection in the U.S. and is responsible for the death of approximately 29,000 Americans each year.

About Seres Therapeutics

Seres Therapeutics is a leading microbiome therapeutics platform company developing a novel class of biological drugs that are designed to treat disease by restoring the function of a dysbiotic microbiome, where the natural state of bacterial diversity and function is imbalanced. A Phase 3 clinical study with its lead program, SER-109, is ongoing in patients with multiply recurrent *C. difficile* infection. Seres' second clinical candidate, SER-287, is being evaluated in a Phase 1b study in patients with mild-to-moderate ulcerative colitis, and the study has completed enrollment. Seres is also developing SER-262, the first ever synthetic microbiome therapeutic candidate, in a Phase 1b study in patients with primary *C. difficile* infection. For more information, please visit www.serestherapeutics.com. Follow us on Twitter @SeresTx.

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, which may not be available; our limited operating history; the unpredictable nature of our early stage development efforts for marketable drugs; the unproven approach to therapeutic intervention of our microbiome therapeutics; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; potential delays in enrollment of patients which could affect the receipt of necessary regulatory approvals; potential delays in regulatory approval, which would impact the ability to commercialize our product candidates and affect our ability to generate revenue; any fast track or Breakthrough Therapy designation may not lead to faster development, regulatory approval or marketing approval; our possible inability to receive orphan drug designation should we choose to seek it; our reliance on third parties to conduct our clinical trials and the potential for those third parties to not perform satisfactorily; our reliance on third parties to manufacture our product candidates, which may delay, prevent or impair our development and commercialization efforts; our lack of experience in manufacturing our product candidates; the potential failure of our product candidates to be accepted on the market by the medical community; our lack of experience selling, marketing and distributing products and our lack of internal capability to do so; failure to compete successfully against other drug companies; potential competition from biosimilars; failure

to obtain marketing approval internationally; post-marketing restrictions or withdrawal from the market; anti-kickback, fraud, abuse, and other healthcare laws and regulations exposing us to potential criminal sanctions; recently enacted or future legislation; compliance with environmental, health, and safety laws and regulations; protection of our proprietary technology; protection of the confidentiality of our trade secrets; changes in United States patent law; potential lawsuits for infringement of third-party intellectual property; our patents being found invalid or unenforceable; compliance with patent regulations; claims challenging the inventorship or ownership of our patents and other intellectual property; claims asserting that we or our employees misappropriated a third-party's intellectual property or otherwise claiming ownership of what we regard as our intellectual property; adequate protection of our trademarks; ability to attract and retain key executives; difficulties managing our growth; risks associated with international operations; potential system failures; the price of our common stock may fluctuate substantially; our executive officers, directors, and principal stockholders have the ability to control all matters submitted to the stockholders; a significant portion of our total outstanding shares are eligible to be sold into the market; unfavorable or lacking analyst research or reports; and that we are currently subject to securities class action litigation. 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 May 4, 2017 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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