Seres Therapeutics, Inc. Announces FDA Orphan Drug Designation for SER-109 for the Prevention of Recurrent Clostridium difficile Infection in Adults

August 21, 2015

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 21, 2015-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics platform company, announced today that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to SER-109, an oral therapeutic currently in a Phase 2 clinical trial for the prevention of recurrent *Clostridium difficile* infection (CDI) in adults. SER-109 is being investigated as a new therapeutic modality to treat recurrent CDI by correcting a dysbiosis of the human microbiome, which is an underlying cause of the condition.

CDI is one of the U.S. Centers for Disease Control's top three most urgent antibiotic-resistant bacterial threats. It is the leading cause of hospital-acquired infection in the U.S., and is responsible for the deaths of approximately 29,000 Americans each year. Recurrent CDI affects between 85,000 and 110,000 people in the U.S. annually

"Receiving orphan drug designation from the FDA for SER-109 is another step on our path to bringing this important new medicine to patients in dire need of an effective, durable treatment. Moreover, it signifies a landmark event, as it marks the first microbiome drug to achieve this regulatory milestone, and is also rarely given for infectious disease indications," said Roger Pomerantz, M.D., Chairman, President and CEO of Seres. "SER-109 is intended to re-introduce essential bacteria that restore the body's natural resistance to CDI by re-establishing the ecology of the colonic microbiome. Because we're focused on treating the underlying cause of the disease, we believe we have the potential to break the cycle of recurrent CDI and have a significant impact for patients. We're extremely pleased that we continue to make both clinical and regulatory progress, well positioning us to advance this radically new approach to address such a difficult and devastating infectious disease."

Antibiotics are currently the only FDA-approved treatment option for recurrent CDI. Exposure to antibiotics is the greatest risk factor for acquiring CDI and their use to treat CDI may induce or prolong an imbalance of the microbiome, which is comprised of trillions of bacteria and other organisms that inhabit or live on our bodies. When in balance, these organisms play critical, beneficial roles in a wide range of biological processes, including resistance to infection by pathogens such as the *Clostridium difficile* bacterium, education and regulation of the immune system, and regulation of energy metabolism. In a dysbiotic state, the microbiome cannot carry out some of these roles, which leads to the onset and progression of various diseases and conditions. In a single dose of four capsules, SER-109 re-introduces an ecology of purified bacterial spores which restore the microbome to a healthy state, able to once again carry out key biological functions, including resistance to *Clostridium difficile*.

Results from a Phase 1b/2 study of SER-109 in recurrent CDI patients showed that 87 percent of patients achieved efficacy endpoint per protocol, and 97 percent of patients achieved a clinical cure, which was defined as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing.

Seres is currently conducting a multicenter, randomized, placebo-controlled Phase 2 clinical study to assess the efficacy and safety of SER-109 in preventing recurrent CDI. The primary outcome measure is the absence of CDI through eight weeks following administration of SER-109 compared to placebo. We expect the results from this study to be available in the middle of 2016.

The FDA Orphan Drug Designation program provides a special status to drugs and biologics intended to treat, diagnose or prevent rare diseases and conditions that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 people but are not expected to recover the costs of developing and marketing the product in the U.S. The designation provides Seres with certain benefits, including a seven-year marketing exclusivity period for this indication upon approval of SER-109, tax credits for clinical research expenses incurred in the U.S., and an exemption from FDA application user fees.

In addition to Orphan Designation, in June 2015, SER-109 was granted Breakthrough Therapy Designation by the FDA, which is intended to expedite the development and review of therapeutics for serious conditions that may demonstrate a substantial improvement over existing therapies, based on preliminary clinical evidence.

About SER-109

SER-109 is the lead Ecobiotic® microbiome therapeutic in clinical testing for the treatment of recurrent *Clostridium difficile* infection (CDI). SER-109 was developed utilizing the Seres Microbiome Therapeutics™ platform that provides deep insight into the ecologies of disease and then identifies microbial compositions that can catalyze a shift to a healthier state. CDI is a rapidly growing problem associated with antibiotic use. Approximately 85,000 to 110,000 CDI patients in the U.S. have more than one recurrence each year.

About Seres Therapeutics, Inc.

Seres Therapeutics, Inc. 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.

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, without

limitation, statements regarding the progress of the clinical development of SER-109, the treatment potential of SER-109, the ability of SER-109 to restore the microbiome, and the timing of the results from studies of SER-109.

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 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; managing our growth could result in difficulties; 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 in the near future; unfavorable or lacking analyst research or reports; and we may be 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 (the "SEC") on August 10, 2015, 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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