Seres Therapeutics, Inc. Announces First Patient Dosed in Phase 2 Study of SER-109 for the Prevention of Recurrent Clostridium difficile Infection in Adults

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Seres Therapeutics, Inc., a leading microbiome therapeutics platform company, announced today the enrollment and dosing of the first patient in its Phase 2 clinical study of SER-109, an investigational oral microbiome therapeutic for the prevention of recurrent *Clostridium difficile* infection (CDI) in adults. The objective of the Phase 2 study is to further assess the efficacy and safety of SER-109, Seres' leading development candidate.

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"Recurrent CDI is a rapidly growing problem in the U.S., and antibiotics are currently the only FDA-approved treatment option," said Roger Pomerantz, Chairman, President and CEO of Seres. "For many patients, antibiotics may exacerbate the problem by inducing or prolonging an imbalance of the microbiome and creating the conditions that support disease recurrence. We are excited about evaluating the potential of SER-109 to correct the microbiome and address this critical patient need.

"The start of our Phase 2 study is an important milestone for patients, and for Seres. Our earlier studies suggest that SER-109 is a potentially transformative therapeutic for tens of thousands of patients each year, validating our conviction that treating dysbiosis of the microbiome enables us to address the underlying cause of disease and bring about rapid improvements in health."

CDI is one of the top three most urgent antibiotic-resistant bacterial threats in the U.S., according to the Centers for Disease Control. It 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. The incidence of first occurrence is between approximately 640,000 and 820,000 patients per year in the U.S. alone. The risk of recurrence is approximately 25 percent and an additional 8 percent of patients fail to respond to antibiotics after the primary occurrence of CDI; 40 percent or greater after a first recurrence and more than 60 percent for those who have experienced two or more recurrences.

Results from the Phase 1b/2 study of SER-109 in recurrent CDI patients showed that 87 percent of patients met the primary study endpoint 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.

The Phase 2 study is a multicenter, randomized, placebo-controlled study that will evaluate the efficacy and safety of SER-109. The primary outcome measure is the absence of clinically-significant CDI through eight weeks following administration of SER-109 compared to placebo. SER-109 will be administered orally as a single dose, following the standard of care antibiotics for CDI. The study is actively enrolling and will be conducted at approximately 35 centers across the U.S. The read-out from the Phase 2 study is currently expected in the middle of 2016.

About SER-109

SER-109 is the lead Seres 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 health. CDI is a rapidly growing problem associated with antibiotic use. Approximately 85,000 to 110,000 CDI patients in the U.S. are expected to have more than one recurrence.

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.

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