Seres Therapeutics Receives FDA Breakthrough Therapy Designation for Its Lead Product Candidate, SER-109

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Seres Therapeutics, Inc., a leading microbiome therapeutics platform company, today announced that SER-109 (Firmacute Eubacterial Spores, Purified Suspension, Encapsulated), its lead product candidate under investigation for the prevention of recurrent *Clostridium difficile* infection (CDI) in adults, has been granted breakthrough therapy designation by the U.S. Food and Drug Administration (FDA). Breakthrough therapy designation is intended to expedite the development and review of therapeutics for serious or life-threatening conditions where preliminary clinical evidence indicates that the product may demonstrate a substantial improvement over existing therapies on one or more clinically significant endpoints. This designation allows for more intensive FDA guidance on an efficient drug development program, an organizational commitment involving senior managers, and eligibility for rolling review and priority review (if supported by clinical data at the time of submission).

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"Recurrent CDI is a life-threatening condition affecting between 85,000 and 110,000 people each year in the United States," said Roger Pomerantz, M.D., Chairman, President and CEO of Seres. "We are encouraged by the FDA's grant of breakthrough therapy designation for SER-109 and the potential for an expedited review by the FDA of our lead product candidate."

Seres is conducting a multicenter, randomized, placebo-controlled Phase 2 clinical study to assess the efficacy and safety of SER-109 in prevention of recurrent CDI. The primary outcome measure is the absence of CDI through eight weeks, following administration of SER-109 compared to placebo. SER-109 will be administered orally as a single dose, following administration of the standard of care antibiotics for CDI. The trial is actively enrolling and is expected to be conducted at approximately 35 centers across the U.S. The estimated study completion date is mid-2016. For additional information about this trial, please visit https://clinicaltrials.gov/ct2/show/NCT02437487.

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 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.

About Breakthrough Therapy Designation

The FDA defines a breakthrough therapy as a drug intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The FDA seeks to expedite the development and review of drugs that receive breakthrough therapy designation. For more information please visit: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm329491.htm.

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