Seres Therapeutics Announces Initiation of a Phase 1b Clinical Trial of SER-262 for Primary Clostridium difficile Infection

July 7, 2016

- First ever clinical study of a synthetic microbiome therapeutic -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 7, 2016-- Seres Therapeutics Inc. (NASDAQ:MCRB), a leading microbiome therapeutics company, announced today that it has initiated a Phase 1b clinical trial evaluating SER-262 in patients with primary *Clostridium difficile* infection (CDI). SER-262 is an Ecobiotic® rationally-designed, fermented microbiome therapeutic derived by a manufacturing process that does not require human donor material. SER-262 is the first synthetically-derived and designed microbiome therapeutic ever to reach clinical-stage development.

SER-262, an oral capsule, contains a consortium of twelve bacterial strains in spore form. The strains included in SER-262 were selected based on multiple criteria including analysis of human microbiome data, efficacy in animal models of CDI, and bacterial strain level characterization.[1] The composition of SER-262 was selected among Seres' field-leading human microbiome library containing over 14,000 well-characterized strains of bacteria.

The SER-262 Phase 1b study, a 24-week randomized, placebo-controlled, dose escalation study is expected to enroll approximately 60 patients who have experienced a first episode of CDI. The primary endpoint of the study will compare the CDI recurrence rate between the SER-262 and placebo groups at up to 8 weeks after dosing. Approximately 640,000 and 820,000 individuals in U.S. each year experience a primary occurrence of CDI, and about 25 percent will suffer from a subsequent recurrence.

"Advancing SER-262 to the clinic is a landmark event for Seres and the microbiome field in general. The SER-262 program has demonstrated our ability to rapidly develop a new class of synthetic microbiome therapeutics comprised of rationally designed bacterial compositions," said Roger Pomerantz, M.D., President, Chief Executive Officer and Chairman of Seres. "We intend to continue to utilize our platform technology and unique knowledge of bioinformatics, microbiology, manufacturing and regulatory requirements to develop additional rationally designed microbiome therapeutics for serious diseases in each of our three therapeutic franchises: infectious disease, immunology and metabolic disease.

With the initiation of the SER-262 Phase 1b study in primary CDI, and the ongoing SER-109 Phase 2 study in multiply recurrent CDI, Seres now has ongoing microbiome clinical programs across the entire CDI population. Initial study results from the SER-109 Phase 2 study are expected in mid-2016.

About Seres Therapeutics
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, where the natural state of bacterial diversity and function is imbalanced. Seres' most advanced program, SER-109, has successfully completed a Phase 1b/2 study demonstrating a clinical benefit in patients with recurring *Clostridium difficile* infection (CDI) and is currently being evaluated in a Phase 2 study in recurring CDI. The FDA has granted SER-109 Orphan Drug, as well as Breakthrough Therapy, designations. Seres' second clinical candidate, SER-287, is being evaluated in a Phase 1b study in patients with mild-to-moderate ulcerative colitis (UC). For more information, please visit www.serestherapeutics.com. Follow us on Twitter @SeresTx.

About *Clostridium Difficile* infection
Clostridium 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. CDI is a rapidly growing problem associated with antibiotic use. 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., and approximately 85,000 to 110,000 CDI patients in the U.S. have more than one recurrence each year.

Reference:
[1]Wortman JR et al., Design and Evaluation of SER-262: A Fermentation-Derived Microbiome Therapeutic for the Prevention of Recurrence in Patients with Primary *Clostridium difficile* Infection; poster at ASM Microbe 2016.

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 potential of SER-262 to treat CDI and fundamentally change the management of CDI, and ability to develop additional rationally designed microbiome therapeutics for certain diseases.

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 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; 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; 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; 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; 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; potential system failures; the price of our common stock may fluctuate substantially; a significant portion of our total outstanding shares are eligible to be sold into the market; and we may be subject to securities class action litigation. These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 14, 2016 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.

View source version on businesswire.com: http://www.businesswire.com/news/home/20160707005525/en/

Source: Seres Therapeutics Inc.

PR & IR Contact:
Seres Therapeutics
Carlo Tanzi, Ph.D., 617-203-3467
Head of Investor Relations and Corporate Communications
Ctanzi@serestherapeutics.com