Seres Therapeutics Announces Achievement of Target Enrollment of SER-109 Phase 2 Study for the Prevention of Recurrent Clostridium difficile Infection

May 2, 2016

Phase 2 data expected in mid-2016

New SER-109 Expanded Access Program initiated at Phase 2 clinical sites

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 2, 2016-- Seres Therapeutics, Inc. (NASDAQ:MCRB), a leading microbiome therapeutics platform company, announced today that the target enrollment of 87 patients has been achieved for its ongoing SER-109 Phase 2 clinical study. SER-109 is an oral, potential first-in-field microbiome therapeutic that has been granted Orphan Drug and Breakthrough Therapy designations by the U.S. Food and Drug Administration (FDA), and is being investigated for use in preventing recurrent *Clostridium difficile* infection (CDI).

"We are pleased to reach this important milestone in our ongoing development of SER-109, which has the potential to be the first therapy for *C. difficile* infection to treat the underlying cause of this disease, and the first microbiome drug for a human disease. This is the first placebo controlled trial for patients with multiply-recurrent CDI," said Roger Pomerantz, M.D., Chairman, President, and CEO of Seres. "*C. difficile* infection is an extremely serious condition responsible for approximately 29,000 deaths each year in the United States alone. We are moving with urgency to develop SER-109 as quickly and safely as possible. We expect initial results of the Phase 2 study in the middle of this year, and we plan to initiate a Phase 3 study later in 2016."

The SER-109 Phase 2 study (ClinicalTrials.gov identifier: NCT02437487) is a multicenter, randomized, placebo-controlled study being conducted at approximately 40 centers across the U.S. The current study builds on a completed, successful Phase 1b/2 trial, which demonstrated that 87 percent of patients (26 of 30) met the predefined endpoint of preventing recurrent CDI within eight weeks following administration of SER-109. In that study 97 percent of patients (29 of 30) achieved a clinical cure during the eight-week period after SER-109 dosing, as defined by the absence of CDI requiring antibiotic treatment. Results from the Phase 1b/2 have been published in *The Journal of Infectious Disease.*[1]

The Company has initiated a SER-109 Expanded Access Program at selected sites participating in the ongoing Phase 2 study. The Expanded Access Program will enable eligible patients with multiply-recurrent CDI to have continued access to SER-109. Furthermore, maintaining Phase 2 study sites open ahead of the anticipated start of the Phase 3 study expected to support and augment Phase 3 study execution and enrollment.

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. Khanna S. et al., A novel microbiome therapeutic increases gut microbial diversity and prevents recurrent *Clostridium difficile* infection, *Journal of Infectious Disease*, 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 timing of results from the Phase 2 clinical trial of SER-109, plans to initiate a SER-109 Phase 3 study later this year, the value for the Phase 3 study of the Expanded Access Program and the potential of SER-109 to be the first therapy for *Clostridium difficile* infection to treat the underlying cause of the disease.

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: 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 our ability to commercialize our product candidates and affect our ability to generate revenue; our reliance on our collaboration with Nestlé to develop and commercialize our CDI and IBD product candidates; 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; protection of our proprietary technology; protection of the confidentiality of our trade secrets; changes in United States patent law; 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; and ability to attract and retain key executives. 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/20160502005097/en/

Source: Seres Therapeutics, Inc.

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