Seres Therapeutics Announces Interim Results from SER-109 Phase 2 ECOSPOR Study in Multiply Recurrent Clostridium difficile Infection

July 29, 2016

- Primary efficacy endpoint was not achieved -

- Conference call at 8:30 AM ET today -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 29, 2016-- Seres Therapeutics, Inc. (NASDAQ:MCRB), a leading microbiome therapeutics company, today announced interim 8-week results from the ongoing SER-109 Phase 2 ECOSPOR™ clinical study for the prevention of multiply recurrent *Clostridium difficile* infection (CDI). The study's primary endpoint of reducing the relative risk of CDI recurrence at up to 8-weeks was not achieved. Seres continues to gather and analyze study data, and in consultation with the FDA, plans to make appropriate adjustments to its SER-109 development plans.

Study Design and Results

- Study Design: The Phase 2 study enrolled 89 subjects with multiply recurrent CDI, defined as 3 or more recent recurrences, in a randomized, double-blind, placebo-controlled 24-week study conducted to evaluate the safety and efficacy of SER-109. Subjects were randomized at a 2:1 ratio with 59 subjects receiving SER-109 and 30 subjects receiving placebo. SER-109 was administered orally as a single dose, of 1 X 10^8 bacterial spores, following the completion of antibiotic treatment for CDI. The study was conducted at 36 centers across the United States. Reported interim results reflect the available eight-week study data, including the primary efficacy endpoint, for the intent-to-treat study population.
- Summary of Efficacy: The predefined study primary efficacy endpoint is the relative risk of CDI recurrence up to 8 weeks after treatment comparing subjects in the placebo arm with the SER-109 arm. CDI recurrence is defined as diarrhea for 2 or more consecutive days, a positive CDI test, and the requirement for antibiotic treatment. Based on 8-week data, CDI recurrence occurred in 44% of subjects (26 of 59) who received SER-109, compared to 53% of subjects (16 of 30) who received placebo. The relative risk of CDI recurrence for the placebo population compared to the SER-109 population was not statistically significant. As part of the prespecified design, subjects were stratified into two groups: <65 years old and ≥65 years old. In subjects <65 years old, CDI recurrence occurred in 43% of subjects who received SER-109 (12 of 28) and in 27% of subjects who received placebo (4 of 15). In subjects ≥65 years old, CDI recurrence occurred in 45% of subjects who received SER-109 (14 of 31), and in 80% of those who received placebo (12 of 15).
- Summary of Safety: Based on the eight-week data, we did not observe any difference in the adverse event frequency or type in the subjects receiving SER-109 compared to those receiving placebo. The most commonly reported adverse events in both the SER-109 and placebo arms were in the gastrointestinal category. The most common adverse events reported in the SER-109 arm were diarrhea, abdominal pain and flatulence. No drug-related serious adverse events were observed.

Roger Pomerantz, MD, President, Chief Executive Officer and Chairman of Seres commented: "These are unexpected clinical results in view of the positive data in our prior investigator-sponsored Phase 1b trial, as well as in a wide range of supporting clinical and preclinical data. Specifically, the recurrence rates observed in the overall SER-109 treatment group, in the age stratified subgroups, and in the placebo groups are inconsistent with our expectations. Our priority is to complete a full review of the clinical results and microbiome data of the Phase 2 study and to compare it to data from the prior investigator sponsored Phase 1b. Based on this information and pending discussions with the FDA, we plan to make any necessary changes to our development plans for SER-109."

Dr. Pomerantz continued: "*C. difficile* infection treatment options, including unregulated fecal microbial transplants, remain poor. The confounding placebo data obtained in this study further highlight the significant need for new, effective, FDA regulated therapeutic options for these patients. We will take our learnings from this study and continue in our pioneering efforts to develop meaningful new microbiome therapeutics for *C. difficile* infection and other serious diseases."

Conference Call Information

Seres management will host a conference call today, July 29, 2016, at 8:30 AM ET. A webcast of the conference call may be accessed in the Investors & Media section of Seres' website at www.serestherapeutics.com. To participate in the conference call, please dial 844-277-9450 (domestic) or 336-525-7139 (international) and provide conference ID number 58835398.

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' program SER-109 continues to be evaluated in a Phase 2 study in multiply recurrent CDI. Seres' second clinical candidate, SER-287, is being evaluated in a Phase 1b study in patients with mild-to-moderate ulcerative colitis (UC). Seres is also developing SER-262, the first ever synthetic microbiome therapeutic candidate, in a Phase 1b study in patients with primary CDI. For more information, please visit www.serestherapeutics.com. Follow us on Twitter @SeresTx.

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 SER-109, including our continuing review and assessment related to the interim results from our Phase 2 clinical trial of SER-109, our evaluation, in consultation with the FDA, of future development plans for SER-109, our development of microbiome therapeutics, and the ability of microbiome therapy to treat 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: 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; any fast track or Breakthrough Therapy designation may not lead to faster development, regulatory approval or marketing approval; 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on May 16, 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.

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