Seres Therapeutics Announces Publication of Positive SER-109 Phase 1b/2 Study Results in The Journal of Infectious Diseases

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87 percent of patients with recurrent C. difficile infection met primary endpoint; 97 percent achieved clinical cure

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 9, 2016-- Seres Therapeutics, Inc. (NASDAQ:MCRB), a leading microbiome therapeutics company, announced that positive results from the Phase 1b/2 study of SER-109 in recurrent *Clostridium difficile* infection (CDI) were published today in *The Journal of Infectious Diseases.*

The study evaluated the efficacy and safety of SER-109 for recurrent CDI, and measured corresponding alterations in the gut microbiota. Results 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. Most importantly, 97 percent of patients (29 of 30) achieved clinical cure during the eight-week period after SER-109 dosing, as defined by the absence of CDI requiring antibiotic treatment. By contrast, the expected cure rates in people treated with the standard of care, i.e. antibiotics, for recurrent CDI range from 23-31 percent, according to a recent well-controlled study.[1]

“The impressive level of efficacy observed with SER-109 treatment is striking when compared with the high rate of recurrence expected in this population,” said Dr. Stuart H. Cohen, MD, Chief, Division of Infectious Diseases, University of California, Davis. “These results demonstrate the potential of SER-109 to effectively treat recurrent CDI. With current treatment approaches having significant limitations, SER-109 has the potential to fundamentally change the management of this urgent health issue.”

SER-109 induced clinical cures occurred in parallel with a rapid and sustained remodeling of the gut microbiome, supporting the treatment premise, i.e. mechanism of action, that addressing the underlying dysbiosis (unhealthy microbiome) that gives rise to CDI will produce a profound clinical benefit.

“This study showed that we can address the root cause of *C. difficile* infection by inducing a healthy and diverse microbiome,” said Roger Pomerantz, MD, President, Chief Executive Officer and Chairman of Seres. “We are now building on these important results by advancing our ongoing SER-109 Phase 2 study in recurrent CDI and by developing SER-262, a synthetically derived product candidate, for patients with primary CDI. The microbiome represents a critically important new modality to address CDI and multiple other clinical indications, and we are proud to be leading the way. Our goal is for all patients with CDI, whether primary or recurrent, to be treated with a Seres microbiome drug to stop recurrence in this expanding epidemic in the United States and around the world.”

Study Details

The Phase 1b/2 open-label, single arm, descending-dose study enrolled 30 patients with recurrent CDI at four leading medical centers in the United States: Massachusetts General Hospital in Boston, Mass.; Mayo Clinic in Rochester, Minn.; Miriam Hospital in Providence, R.I., and Emory University Hospital in Atlanta, Ga. All enrolled patients received standard-of-care antibiotic treatment, followed by oral administration of SER-109.

Of the 30 study patients, 26 (87%) achieved the primary endpoint of absence of diarrhea with a positive *C. difficile* test up to eight weeks following dosing. Three of the four patients who did not meet the primary endpoint were determined by their primary investigator to be recovering from CDI, and all symptoms resolved without further therapeutic intervention or antibiotics. In total, 29 of 30 patients (97%) achieved full clinical cure of recurrent CDI following SER-109 administration.

SER-109 was well tolerated in the study, with the most common adverse events being mild to moderate gastrointestinal symptoms. No drug related serious adverse events were observed.

In a corresponding finding, microbial diversity increased significantly at eight weeks, driven by engraftment of SER-109 related microbiota, as well as the augmentation of key bacterial species following administration. The reduction or elimination of pathobionts, species that colonize the gut and can cause infection in susceptible individuals, was observed in a majority of patients. These changes were detected as early as day four and were durable through 24 weeks of observation, with subjects’ microbiomes returning to a state reflective of healthy individuals.

About SER-109

SER-109, an oral capsule, is Seres’ lead 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 a healthier state.

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.

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 characterized by an increased presence of pathogenic bacterial species, where the natural state of bacterial diversity 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.

1. van Nood et al., New England Journal of Medicine, 2013.

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-109 to treat CDI and fundamentally change the management of CDI, and dysbiosis of the microbiome as an underlying cause of CDI.

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 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 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 possible inability to receive orphan drug designation should we choose to seek it; 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; the potential failure of our product candidates to be accepted on the market by the medical community; our lack of experience selling, marketing and distributing products and our lack of internal capability to do so; failure to compete successfully against other drug companies; 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; recently enacted or future legislation; compliance with environmental, health, and safety laws and regulations; 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; compliance with patent regulations; 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; managing our growth could result in difficulties; risks associated with international operations; potential system failures; the price of our common stock may fluctuate substantially; our executive officers, directors, and principal stockholders have the ability to control all matters submitted to the stockholders; a significant portion of our total outstanding shares are eligible to be sold into the market in the near future; unfavorable or lacking analyst research or reports; 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 November 12, 2015 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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