Seres Therapeutics Announces First Patient Enrolled in Phase 1b Study of SER-155, an Investigational Microbiome Therapeutic to Reduce the Risk of Antibiotic-Resistant Bacterial Infections and Graft-Versus-Host Disease (GvHD)

November 30, 2021

– SER-155 is designed to reduce the incidence of infection, mortality and GvHD in adults undergoing hematopoietic stem cell transplantation (HSCT) –

– Seres is collaborating with Memorial Sloan Kettering Cancer Center and The University of Chicago for the study –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 30, 2021-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, announced today that the first patient has been enrolled in the SER-155 Phase 1b study. SER-155 is an investigational, oral, cultivated microbiome therapeutic. The consortia is a rationally-designed selection of bacteria optimized to enhance desired pharmacological properties to reduce the incidence of gastrointestinal bacterial infections, bacteremia and graft-versus-host disease (GvHD) in immunocompromised patients, including patients receiving allogeneic hematopoietic stem cell transplantation (HSCT). Prior published studies by Memorial Sloan Kettering Cancer Center collaborators indicate that HSCT patients with a disrupted, low diversity microbiome are at substantially increased risk for bacterial infections, including antibiotic resistant infection, and poor clinical outcomes.

The trial (NCT04995653) is designed to evaluate the efficacy, safety and microbiome alterations associated with SER-155 in adult subjects who are undergoing HSCT. The primary endpoints of the study are to assess safety as well as engraftment, which is characterized by the growth of drug bacteria in the gastrointestinal tract. SER-155 strains are measured before and after treatment courses through Day 100. The trial will enroll approximately 70 patients in both an open-label and a randomized, double-blind, placebo-controlled, multicenter study that will evaluate safety and tolerability before and after HSCT.

“Antibiotic-resistant bacterial infections are a top priority to address globally, especially given the significant implications for HSCT and other cancer and immunocompromised patients,” said Lisa von Moltke, M.D., Chief Medical Officer at Seres. “SER-155 is designed to reduce the risk of infection and GvHD, so we’re eager to enroll patients and advance our investigation of this promising therapeutic candidate.”

Eric Shaff, Chief Executive Office at Seres, added, “Building on the compelling results we have obtained from our lead SER-109 program, we will continue to advance additional preclinical programs for novel microbiome therapeutics that have the potential to reduce the detrimental patient outcomes often caused by anti-infective or immunosuppressive agents. The potential to combat the continued rise in antibiotic-resistant bacterial infections is promising given the major threat these infections pose to patients.”

Antibiotic-resistant infections and GvHD are frequent and serious complications of stem cell transplantation, and more broadly organ transplants and other conditions where patients are immunocompromised, which can lead to death. The World Health Organization has declared antibiotic resistant infections a “top ten” global public health threat and according to the Center for Disease Control’s *Antibiotic Resistance Threats in the United States, 2019* report, more than 2.8 million antibiotic-resistant infections occur in the U.S. each year, and more than 35,000 people die as a result.

Current standard of care is leaving many patients vulnerable to these devastating complications. Antibiotics are ineffective against resistant organisms and current prevention efforts have limited ability to broadly impact rates of resistant infections. These infections can lead to medical complications in immunocompromised patients including additional damage to the microbiome which may aggravate and/or predispose patients to GvHD. Current therapies for the prevention of GvHD rely on broad immunosuppression, which increases the risk of infection, and has limited efficacy for a significant portion of patients.

“Our team is eager to continue our long-standing research collaboration with Seres to develop microbiome therapeutics for serious unmet medical needs and to initiate clinical development of SER-155 for immunocompromised patients who are at risk of antibiotic-resistant bacterial infections, bacteremia and GvHD,” said Marcel van den Brink, M.D., Ph.D., Head of the Division of Hematologic Oncology at Memorial Sloan Kettering Cancer Center.

Seres fully owns worldwide rights for commercialization of SER-155.

Dr. van den Brink has intellectual property interests and other financial interests related to Seres. Memorial Sloan Kettering has intellectual property rights and associated interests by virtue of licensing agreements between Memorial Sloan Kettering and Seres.

About SER-155
SER-155, an oral consortium of cultivated bacteria, is a microbiome therapeutic candidate in clinical development. SER-155 is designed using microbiome biomarker data from human clinical data, human cell-based assays, and *in vivo* disease models, with the aim to decrease infection and translocation of antibiotic-resistant bacteria in the gastrointestinal tract and modulate host immune responses to decrease GvHD. The rationale for this program is based in part on published clinical evidence from Seres’ collaborators at Memorial Sloan Kettering Cancer Center showing that allogeneic HSCT patients with decreased diversity of commensal microbes are significantly more likely to die due to infection and/or lethal GvHD. SER-155 was developed using Seres’ reverse translational discovery platform to reduce morbidity and mortality due to gastrointestinal infections, bacteremia and GvHD in immunocompromised patients, including in patients receiving allogeneic HSCT or solid organ transplants.

About Seres Therapeutics
Seres Therapeutics, Inc. (Nasdaq: MCRB) is a leading microbiome therapeutics company developing a novel class of multifunctional bacterial consortia that are designed to functionally interact with host cells and tissues to treat disease. Seres' SER-109 program achieved the first-ever positive pivotal clinical results for a targeted microbiome drug candidate and has obtained Breakthrough Therapy and Orphan Drug designations from the FDA. The SER-109 program is being advanced for the treatment of recurrent *C. difficile* infection and has potential to become a first-in-class FDA-approved microbiome therapeutic. Seres is evaluating SER-301 in a Phase 1b study in patients with ulcerative colitis and SER-155 in a Phase 1b study to address gastrointestinal infections, bacteremia and graft-versus-host disease. For more information, please visit www.serestherapeutics.com.

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 the potential of microbiome therapeutics to decrease infection, complications, and/or mortality, the timing and results of our clinical studies, the benefits of our collaborations, the ultimate market for SER-155, the ultimate efficacy data for our products, and other statements which are not historical fact.

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; our limited operating history; the impact of the COVID-19 pandemic; our unproven approach to therapeutic intervention; the lengthy, expensive and uncertain process of clinical drug development; our reliance on third parties and collaborators to conduct our clinical trials, manufacture our product candidates and develop and commercialize our product candidates, if approved; and our ability to retain key personnel and to manage our growth. 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 10, 2021, 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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