# Seres Therapeutics Announces Initiation of Enrollment in SER-155 Phase 1b Study Cohort 2 in Individuals Undergoing Allogeneic Hematopoietic Stem Cell Transplantation

February 8, 2023

*– Company anticipates reporting initial SER-155 safety and pharmacological data from study Cohort 1 in the coming months –*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 8, 2023-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, today announced that enrollment in Cohort 2 in its SER-155 Phase 1b study is underway. SER-155, an investigational oral microbiome therapeutic, is designed to reduce the incidence of gastrointestinal (GI) infections, bloodstream infections, and graft versus host disease (GvHD) in individuals undergoing allogeneic hematopoietic stem cell transplantation (allo-HSCT).

"We are pleased to advance SER-155 as a potential new medicine for individuals undergoing allo-HSCT, a medically compromised group at substantial risk of life-threatening infections. The development of SER-155 is informed by robust clinical and pharmacologic results from the Phase 3 program evaluating SER-109, our lead microbiome program currently under FDA review for product approval. We believe these data clearly demonstrate the promise of microbiome therapeutics to provide transformative levels of Infection Protection through a novel modality," said Lisa von Moltke, M.D., Chief Medical Officer at Seres. "While we enroll SER-155 study Cohort 2, we are also continuing to add clinical sites to accelerate recruitment. We look forward to reporting initial SER-155 Cohort 1 safety and pharmacology data in the coming months while expeditiously working to complete the full study."

The development of SER-155 is informed by Phase 3 clinical and pharmacological data from Seres' lead investigational microbiome program, SER-109, showing reductions in the rate of recurrent *C. difficile* infection in a Phase 3 study, as well as diminished levels of bacterial pathogens in the gastrointestinal tract. SER-155 was designed to decrease the colonization and abundance of bacterial pathogens, including those that can harbor antibiotic-resistance, and to enhance epithelial barrier integrity in the GI tract to both reduce the likelihood of pathogen translocation and decrease the incidence of bloodstream infections. The SER-155 Phase 1b study will assess safety, pharmacology, and the potential impact on GI pathogens, clinical infections and/or GvHD in approximately 70 adults undergoing allo-HSCT. The study is enrolling subjects undergoing intensive treatments for hematologic malignancies such as leukemia, and based on historical analyses, over 50% of this medically compromised population will experience a serious infection or GvHD.

The SER-155 study includes two cohorts with Cohort 1 designed to assess safety and drug pharmacology including the engraftment of drug bacteria in the gastrointestinal tract. In Cohort 1, 13 subjects received SER-155 (i.e., safety population). Cohort 2 incorporates a randomized, double-blinded placebo-controlled design to further evaluate safety and engraftment, as well as clinical outcomes, and will enroll approximately 60 subjects administered either SER-155 or placebo at a 1:1 ratio. Seres recently announced that the study's Data and Safety Monitoring Board (DSMB) had reviewed available clinical data for Cohort 1 and cleared advancement to Cohort 2. The Company expects to report preliminary SER-155 Cohort 1 safety and pharmacology data in the coming months.

The Company believes that the medical benefit and commercial potential for SER-155 may be substantial. Approximately 9,000 individuals per year (U.S.) receive allo-HSCT and the estimated patient management costs, including complications such as infection, during the first year of the procedure are estimated at over $400,000[1] per patient. Seres fully owns worldwide rights for commercialization of SER-155. In addition to SER-155, the Company is evaluating other microbiome therapeutic preclinical programs for additional medically compromised patient populations and plans to provide further updates later in 2023.

**About SER-155**

SER-155 is a consortium of bacterial species selected using Seres' reverse translation discovery and development platform technologies. The design incorporates microbiome biomarker data from human clinical data and nonclinical human cell-based assays and in vivo disease models. The SER-155 composition aims to decrease the colonization and abundance of bacterial pathogens, including those that can harbor antibiotic-resistant, and to enhance epithelial barrier integrity in the GI tract to both reduce the likelihood of pathogen translocation and decrease the incidence of bloodstream infections. Further, SER-155 is designed to modulate host immune responses to decrease GvHD.

**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 to prevent further recurrences of *C. difficile* infection and has potential to become a first-in-class FDA-approved microbiome therapeutic. Seres is evaluating SER-155 in a Phase 1b study in patients receiving allogeneic hematopoietic stem cell transplantation to reduce incidences of gastrointestinal infections, bloodstream infections and graft-versus-host disease as well as additional preclinical stage programs targeting Infection Protection in medically compromised patients. The Company is also conducting research to inform further development of microbiome therapeutics for ulcerative colitis.

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 timing of clinical studies and results; the potential for microbiome therapeutics to protect against infection; 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 (SEC), on November 2, 2022, 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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[1] Broder, et al. "The Cost of Hematopoietic Stem-Cell Transplantation in the United States" Am Health and Drug Benefits 10 (2017) 366–374; Seres internal estimates.

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**IR and PR Contact**
Carlo Tanzi, Ph.D.
ctanzi@serestherapeutics.com

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