Seres Therapeutics Announces FDA Clearance of IND for SER-155, an Investigational Microbiome Therapeutic for the Prevention of Antibiotic-Resistant Bacterial Infections and Graft-versus-Host Disease (GvHD)

June 1, 2021

– SER-155 aims to prevent mortality in immunocompromised patients due to gastrointestinal infections, bacteremia and GvHD –

– In collaboration with Memorial Sloan Kettering Cancer Center, Seres will now advance SER-155 into a Phase 1b clinical study –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 1, 2021-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, announces the U.S. Food and Drug Administration (FDA) has indicated studies for SER-155 may proceed under an Investigational New Drug (IND) application. SER-155 is an investigational oral, rationally-designed, cultivated microbiome therapeutic designed to reduce the incidence of gastrointestinal antibiotic-resistant 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 dysbiotic microbiome are at substantially increased risk for bacterial infections and poor outcomes.

“Antibiotic-resistant bacterial infections represent one of the most pressing public health threats with significant implications for HSCT patients and, more broadly, other cancer and immunocompromised patients,” said Matthew Henn, Ph.D., Chief Scientific Officer at Seres. “SER-155 represents a novel microbiome technology with the potential to address antibiotic-resistant bacterial bloodstream infections and further to modulate host immunomodulatory responses to decrease graft-versus-host disease.”

The SER-155 Phase 1b study is designed to include approximately 70 patients in both an open-label and a randomized, double-blind, placebo-controlled cohort that will evaluate safety and tolerability before and after HSCT. Additionally, the engraftment of SER-155 bacteria (a measure of pharmacokinetics) and the efficacy of SER-155 in preventing infections and GvHD will be evaluated. Seres developed SER-155 with support from a CARB-X grant, including financial and operational support into Phase 1b. Seres fully owns worldwide rights for commercialization of SER-155.

“This milestone represents another exciting opportunity to support patients through Seres microbiome therapeutic candidates and illustrates the potential for microbiome therapeutics to change how disease is treated for immunocompromised patients,” said Eric Shaff, Chief Executive Officer at Seres. “Our commitment is to provide more options for people living with serious diseases, and we look forward to an eventful year with additional clinical milestones from our investigational pipeline.”

Antibiotic-resistant infections and GvHD are frequent and serious complications of organ and stem cell transplantation, which can lead to mortality. Additionally, such infections can lead to medical complications in immunocompromised patients more broadly. Antibiotics used to treat infections in HSCT individuals are not always effective and can have significant side effects. Current therapies for the prevention of GvHD rely on broad immunosuppression, which increases the risk of infection, and has limited efficacy for a significant proportion of patients.

About SER-155
SER-155, an oral consortium of cultivated bacteria, is a microbiome therapeutic candidate intended to advance into 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’ SER-287 program has obtained Fast Track and pediatric Orphan Drug designations from the FDA and is being evaluated in a Phase 2b study in patients with active mild-to-moderate ulcerative colitis. Seres is evaluating SER-301 in a Phase 1b study in patients with ulcerative colitis, and plans to initiate a clinical program with SER-155 to prevent mortality due to 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, the timing of our clinical studies, the benefits of our collaborations, the impact of microbiome therapeutics, 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 May 4, 2020, 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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