Seres Therapeutics Announces Completion of Patient Enrollment for SER-155 Phase 1B Cohort 2 Clinical Trial in Allogenic HSCT

April 9, 2024

Clinical data readout expected end of Q3 2024

SER-155 and other Seres microbiome therapeutic candidates have potential to expand microbiome therapeutic franchise into additional medically vulnerable patient populations

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 9, 2024-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, announced today that enrollment is complete in the placebo-controlled Cohort 2 of its Phase 1b trial of SER-155 in patients who received Allogeneic Hematopoietic Stem Cell Transplantation (Allo HSCT). SER-155 is an orally administered, consortium of bacteria, cultivated from cell banks and designed to reduce the incidence and severity of enteric-derived infections and resulting bloodstream infections, including those that may harbor antibiotic resistance. Infections are a leading cause of mortality and morbidity in this immunocompromised patient population. SER-155 is also designed to induce immune tolerance responses to reduce the incidence of GvHD.

"We are pleased to complete enrollment in Cohort 2 of our SER-155 Phase 1b study and are looking forward to a robust dataset late in the third quarter of this year," said Eric Shaff, President and Chief Executive Officer of Seres. "The initial study data will include safety, drug pharmacology, and efficacy-related measures through day 100 following HSCT, a period in which many patients experience infections. There are an estimated 40,000 Allo HSCT procedures annually worldwide and infection is one of the most common causes of mortality in these patients. Our pending clinical results could validate the promise of microbiome therapeutics to prevent poor outcomes associated with pathogens in the GI tract. We intend to evaluate SER-155 and other microbiome therapeutic candidates in several other high prevalence, medically vulnerable patient populations, including chronic liver disease, cancer neutropenia, and solid organ transplants. We envision a future where Seres is pioneering a new standard of care, potentially protecting millions of immunocompromised patients from life-threatening infections."

The SER-155 Phase 1b study (NCT04995653) is being conducted across 13 clinical centers in the US, including Memorial Sloan Kettering. Study Cohort 1, which included 13 participants, was designed to assess safety and drug pharmacology, including the engraftment of drug bacteria in the gastrointestinal tract. Cohort 1 clinical data, announced in May 2023, showed favorable tolerability, successful drug bacteria engraftment, and a substantial reduction in pathogen domination in the gastrointestinal microbiome. Study Cohort 2, which includes 45 participants, incorporates a randomized, double-blinded placebo-controlled 1:1 design to further evaluate safety and engraftment, as well as clinical outcomes.

About SER-155

SER-155 is a consortium of bacterial species selected using Seres' reverse translation discovery and development MbTx 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 is designed to prevent and decrease the colonization and abundance of bacterial pathogens 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 and GvHD. SER-155 has received FDA Fast Track Designation.

About Seres Therapeutics

Seres Therapeutics, Inc. (Nasdaq: MCRB) is a commercial-stage company developing novel microbiome therapeutics for serious diseases. Seres' lead program, VOWST™, obtained U.S. FDA approval in April 2023 as the first orally administered microbiome therapeutic to prevent recurrence of *C. difficile* infection (CDI) in adults following antibacterial treatment for recurrent CDI and is being commercialized in collaboration with Nestlé Health Science. Seres is evaluating SER-155 in a Phase 1b study in patients receiving allogeneic hematopoietic stem cell transplantation. 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 statements about the timing and results of our clinical studies, the promise and potential therapeutic impact of microbiome therapeutics, future product candidates and development plans, 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 novel approach to therapeutic intervention; our reliance on third parties to conduct our clinical trials and manufacture our product candidates; the competition we will face; our ability to protect our intellectual property; 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC), on March 5, 2024, 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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