Seres Announces Preliminary SER-287 Phase 2b ECO-RESET Study Microbiome Data Analysis

December 16, 2021

– Microbiome data demonstrate the successful engraftment of SER-287 –

– Microbiome assessments suggest potential for biomarker-based patient selection –

– Company continues to evaluate SER-287 study data, and available preliminary SER-301 Phase 1b study clinical and microbiome data, to inform plans for continued development in ulcerative colitis –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 16, 2021-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, today announced preliminary microbiome data analyses from the Phase 2b ECO-RESET study evaluating SER-287 in patients with mild-to-moderate ulcerative colitis (UC). Following the topline clinical data readout in July, which noted that the SER-287 Phase 2b study did not achieve its primary endpoints, analysis of the microbiome data demonstrated the successful engraftment of SER-287 bacterial species. The Company continues to conduct analyses on its SER-287 and SER-301 UC clinical stage programs to inform next steps for further development.

Based on the SER-287 Phase 2b microbiome data analyses, engraftment of SER-287 bacteria was statistically significant in patients receiving SER-287 versus placebo ($p \leq 0.001$ at all timepoints). The magnitude and kinetics of engraftment were comparable to Seres' Phase 1b study. However, unlike the Phase 1b study, anticipated changes in disease-relevant metabolites post-administration with SER-287 in the Phase 2b study were not observed.

Analysis of the genomic and metabolomic data characterizing the microbiome of SER-287 study participants at baseline and post dosing suggest potential biomarkers for inclusion in future development efforts. UC is a biologically and clinically heterogeneous disease and the Company believes that a biomarker-based patient selection approach may enable future development to focus on individuals most amenable to a microbiome-based therapeutic intervention.

"Our SER-287 Phase 2b data suggests that there may be an opportunity to utilize biomarker-based patient selection in our future UC development efforts. We continue to evaluate SER-287 study data, while also examining preliminary SER-301 Phase 1b study clinical and microbiome data, including analysis of changes in disease-relevant metabolites. We expect to provide a further update on these programs and our plans for future development in UC in the coming months," said Eric Shaff, Chief Executive Officer at Seres.

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 without limitation: the potential impact of microbiome therapeutics; the safety, efficacy and regulatory and clinical progress of our product candidates; the ability to utilize biomarker-based patient selection in UC development; plans, timing and potential impact of the release of additional preclinical and clinical data; our development opportunities, including the future of development in UC; 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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