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Seres Therapeutics Announces Initiation of SER-287 Phase 2B ECO-RESET Clinical Study for Ulcerative Colitis

January 3, 2019

– Recent FDA correspondence indicates this SER-287 Phase 2B study may support Biologics License Application (BLA) –

– Company has received \$40 million in milestone payments with Phase 2B study start –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 3, 2019-- [Seres Therapeutics, Inc.](#) (Nasdaq:MCRB) today announced that it has enrolled the first patient in its Phase 2B trial, ECO-RESET, evaluating microbiome development candidate SER-287 in patients with active mild-to-moderate ulcerative colitis. Seres has received \$40 million in milestone payments associated with this study start from Nestlé Health Science.

“Advancing SER-287 into a late stage Phase 2B trial is a significant achievement,” said Kevin Horgan, M.D., Executive Vice President and Chief Medical Officer. “We are hopeful that SER-287 may provide individuals with ulcerative colitis with a novel microbiome-based, non-immunosuppressive therapy that addresses the underlying pathology of this serious disease. If this study is successful, we believe the trial results could provide important support for registration of SER-287.”

The SER-287 Phase 2B ECO-RESET study has been designed as a pivotal trial. The Company recently obtained feedback from the FDA indicating that results from this study, in conjunction with data from a second pivotal study, could enable a SER-287 Biologics License Application.

The Phase 2B study is a three-arm placebo-controlled trial of approximately 200 patients with active mild-to-moderate ulcerative colitis. Two groups of patients will receive different doses of SER-287, both following pretreatment with a short course of oral vancomycin. A third study arm will receive placebo. The study’s primary endpoint will evaluate clinical remission measured after 10 weeks of SER-287 administration. Endoscopic improvement will be measured as a secondary efficacy measure.

About SER-287

SER-287 is a biologically sourced oral capsule developed using Seres’ proprietary microbiome therapeutics platform. The SER-287 Phase 2b study clinicaltrials.gov identifier is [NCT03759041](#). A SER-287 Phase 1b placebo-controlled induction study in patients with mild-to-moderate active ulcerative colitis demonstrated a dose-dependent improvement of clinical remission rates and endoscopic scores and a favorable tolerability profile.

About Ulcerative Colitis

Ulcerative colitis is a serious chronic condition affecting approximately 700,000 individuals in the United States. The disease results in inflammation of the colon and rectum and can cause debilitating symptoms, including abdominal pain, bowel urgency and diarrhea. Severe cases of ulcerative colitis may result in surgical removal of the colon.

About Seres Therapeutics

Seres Therapeutics, Inc. (Nasdaq:MCRB) is a leading microbiome therapeutics platform company developing a novel class of biological drugs that are designed to treat disease by restoring the function of a dysbiotic microbiome, where the state of bacterial diversity and function is imbalanced. Seres’ lead program, SER-109, has obtained Breakthrough Therapy and Orphan Drug designations from the U.S. Food and Drug Administration and is in Phase 3 development for multiply recurrent *C. difficile* infection. SER-287 is currently being evaluated in a Phase 2B study in patients with active mild-to-moderate ulcerative colitis. Seres is advancing SER-401 to augment the efficacy of immuno-oncology treatment. In addition, the Company has several other microbiome therapeutic candidates in preclinical development for various serious diseases. For more information, please visit [www.serestherapeutics.com](#). Follow us on Twitter [@SeresTx](#).

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 ability of ECO-RESET to support SER-287 approval.

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; 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; our ability to retain key personnel and to manage our growth; and our management and principal stockholders have the ability to control or significantly influence our business. 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 8, 2018 and our other reports filed with the SE 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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