Seres Therapeutics Announces Achievement of Target Enrollment in SER-287 Phase 2b ECO-RESET Study for Ulcerative Colitis

March 2, 2021

- Topline clinical data expected in mid-2021 -

- Results will inform Seres' broader development efforts in UC and other programs targeting modulation of host inflammation and immunity -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 2, 2021--

Seres Therapeutics, Inc. (Nasdaq: MCRB) announced today that the Company has achieved target enrollment of the Phase 2b ECO-RESET clinical study of SER-287 in patients with mild-to-moderate ulcerative colitis (UC) in both the U.S. and Canada. SER-287, Seres' second microbiome therapeutic to reach late-stage clinical trials following a successful Phase 3 readout for SER-109, could represent a new therapeutic paradigm for UC by targeting underlying biological drivers of the disease. The results of this study will inform Seres' broader development efforts in ulcerative colitis and other programs that target modulation of host inflammation and immunity.

"People with ulcerative colitis and other inflammatory bowel diseases are in need of safe and effective treatment options, especially for mild-to-moderate forms of the disease. ECO-RESET achieved its target enrollment even amid the ongoing COVID-19 pandemic, a reflection of this high unmet need," said Lisa von Moltke, M.D., Chief Medical Officer of Seres. "We believe microbiome therapeutics offer the potential for an alternative treatment approach for inflammatory bowel diseases and have been committed to advancing microbiome therapeutics to address this need. We're pleased that SER-287, our most advanced UC program, has now reached this trial enrollment milestone."

The Phase 2b ECO-RESET study (Clinicaltrials.gov identifier: NCT03759041) is a multicenter, randomized, placebo-controlled study which has enrolled the targeted 201 patients with active mild-to-moderate UC. Two groups of patients are receiving different doses of SER-287, both following pre-conditioning with a short course of oral vancomycin. A third group is receiving 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.

Based upon feedback obtained from the U.S. Food and Drug Administration (FDA) on the SER-287 Phase 2b study design, Seres believes the study could serve as one of two required pivotal trials supporting a Biologics License Application (BLA). The Company expects to share topline clinical data from ECO-RESET in mid-2021.

Mild-to-moderate UC is the most common form of the disease, representing a majority of the patient population in the U.S. First-line therapies for UC are only modestly effective. Non-responders have limited treatment options because potent immunosuppressive therapies have serious side effects which may be hard to justify in patients with mild-to-moderate disease. An unmet need exists for an effective, safer alternative therapeutic approach for mild-to-moderate UC patients that is not immunosuppressive.

"Seres is grateful to the patients, principal investigators and clinical research teams who have made this study possible. Their commitment to the trial's successful execution despite the challenges of COVID-19 has been remarkable," said Eric Shaff, President and Chief Executive Officer of Seres. "The data generated from this important study will inform our ongoing clinical efforts for SER-287 and SER-301 in UC as well as other indications through our reverse translational approach, supporting Seres' efforts to continue driving forward microbiome therapeutics that can transform the standard of care for patients."

About SER-287

SER-287, an oral microbiome therapeutic candidate consisting of a consortium of highly purified Firmicute spores, is designed to normalize the gastrointestinal microbiome of individuals with UC. Preclinical colitis animal models and *in vitro* screens provide evidence that SER-287 administration has the potential to reduce pathology and modulate inflammatory and immunological functional pathways. SER-287 has been granted Fast Track Designation by the FDA for the induction and maintenance of clinical remission in adult subjects with active mild-to-moderate UC. SER-287 has been designated an Orphan Drug for pediatric UC by the FDA.

About Seres Therapeutics

Seres Therapeutics, Inc., (Nasdaq: MCRB) is a leading microbiome therapeutics platform 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 Orphan Drug designations from the FDA and is being evaluated in a Phase 2b study in patients with active mild-to-moderate UC. Seres is evaluating SER-401 in a Phase 1b study in patients with metastatic melanoma, SER-301 in a Phase 1b study in patients with ulcerative colitis, and 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 market for SER-287, the timing of clinical study results, the ability for the ECO-RESET study to serve as one of two pivotal trials, the results of our clinical studies, potential approval of SER-287, potential market acceptance, the promise of our microbiome therapeutics, and other statements that are not historical facts.

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; 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 9, 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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