Seres Therapeutics Announces Initiation of Phase 1b Trial of SER-301 for the Treatment of Ulcerative Colitis

November 6, 2020

– *SER-301 is designed to target the physiological triggers of inflammation believed to be central to the underlying pathology of ulcerative colitis* –

– *Program represents Seres' second active clinical program targeting ulcerative colitis, in addition to its ongoing SER-287 Phase 2b study* –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 6, 2020-- Seres Therapeutics, Inc. (Nasdaq: MCRB) today announced that it has dosed the first patient in its Phase 1b trial evaluating SER-301 for the treatment of active mild-to-moderate ulcerative colitis (UC). SER-301 is an oral, rationally-designed microbiome therapeutic designed to dampen the aberrant gastrointestinal inflammation central to ulcerative colitis and induce clinical remission in patients suffering from active UC.

SER-301 is designed to modify the gastrointestinal microbiome and microbe-associated metabolites to modulate multiple pathways associated with ulcerative colitis. SER-301 is a consortium of bacteria designed using Seres' reverse translational discovery platform that incorporates analysis of microbiome biomarkers from human clinical data and preclinical assessments using human cell-based assays and *in vitro* and *in vivo* disease models. SER-301 is designed to reduce induction of pro-inflammatory activity, improve epithelial barrier integrity and TNF-α driven inflammation in intestinal epithelial cells, and modulate UC-relevant anti-inflammatory, innate and adaptive immune pathways. The design of SER-301 incorporated learnings obtained through the Company's prior SER-287 Phase 1b clinical study conducted in patients with ulcerative colitis. SER-287 Phase 1b study results demonstrated favorable pharmacodynamic changes, signals of clinical activity, and a favorable safety profile.

SER-301 was developed with innovative and novel manufacturing methods that do not require human donor material. It includes strains delivered in spore form and strains fermented in non-spore (vegetative) form. The product candidate is delivered using enterically-protected technology designed to release in the colon. GMP manufacturing technologies developed through the SER-301 program broaden the breadth of biology that can be incorporated into Seres' microbiome therapeutics.

"Ulcerative colitis is a serious disease impacting approximately 700,000 individuals in the U.S. alone, and effective patient management can be challenging. Currently approved treatments are unable to induce disease remission in the large majority of patients, and many existing drugs are associated with a suboptimal safety profile," said Matthew Henn, Ph.D., Executive Vice President and Chief Scientific Officer of Seres. "We believe that microbiome therapeutic approaches have the opportunity to address this condition in an entirely novel way which targets the underlying drivers of disease by modulating multiple disease-relevant pathways simultaneously, and with a favorable safety profile. We are pleased to have applied the deep scientific and clinical learnings obtained from our SER-287 and other clinical programs combined with our advanced microbiology and functional modeling capabilities to bring SER-301 into this Phase 1b study."

The SER-301 Phase 1b study is being conducted in Australia and New Zealand in subjects with mild-to-moderate UC and is designed to include approximately 65 patients distributed across two cohorts. A first open-label cohort of 15 subjects will evaluate safety and pharmacokinetics (PK), as measured by bacterial engraftment. In the second cohort, 50 subjects will be randomized to receive either SER-301 or placebo, with a 3:2 randomization, respectively. The study utilizes an independent blinded central reader for the endoscopic component. The objectives for this cohort are to evaluate safety and PK, clinical remission, and other measures of drug pharmacology and efficacy as secondary endpoints.

Seres is entitled to receive a $10 million milestone payment associated with the clinical trial initiation from Nestlé Health Science, the Company's ex-North American collaborative partner for this program.

About SER-301

SER-301 is an investigational, oral, rationally-designed, fermented microbiome therapeutic for the treatment of mild-to-moderate ulcerative colitis (UC). SER-301 is a consortium of multiple bacterial strains manufactured by fermenting each strain individually and then combining to form drug product. The composition includes strains formulated in spore form and strains fermented in non-spore, vegetative form. The product candidate is delivered using enterically-protected technology designed to release in the colon. SER-301 is designed to modify the microbiome and microbe-associated metabolites in the gastrointestinal tract to modulate pathways linked to gastrointestinal inflammation and to improve epithelial barrier integrity in patients with ulcerative colitis.

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 ulcerative colitis. 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 timing and results of our clinical studies, the ability of SER-301 to modulate the microbiome of UC patients, the safety profile of our product candidates, the receipt of milestone payments, the promise and success of 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; our unproven approach to therapeutic intervention; the lengthy, expensive, and uncertain process of clinical drug development; our reliance on third parties to manufacture, develop, and commercialize our product candidates, if approved; the ability to develop and commercialize our product candidates, if approved; the potential impact of the COVID-19 pandemic; our ability to retain key personnel and to manage our growth; and that 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 [July 28, 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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