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Seres Therapeutics Announces Completion of Enrollment for SER-287 Phase 1b Study in Patients with Ulcerative Colitis

June 5, 2017

- Study results expected in the second half of 2017 -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 5, 2017-- [Seres Therapeutics, Inc.](#) (NASDAQ:MCRB) today announced that it has completed enrollment for its ongoing SER-287 Phase 1b clinical study of 58 patients suffering from mild-to-moderate ulcerative colitis who are failing current therapies. SER-287 is the first microbiome therapeutic candidate to reach clinical-stage development in a chronic inflammatory disease, and the first in an indication outside of infectious disease.

"The completion of enrollment in our SER-287 Phase 1b study marks an important step towards our goal of developing a novel microbiome-based approach to treat ulcerative colitis, a serious disease where many patients are not well managed by currently available therapies," said Roger J. Pomerantz, M.D., President, Chief Executive Officer and Chairman of Seres. "We believe that SER-287 has the potential to offer ulcerative colitis patients a novel, non-immunosuppressive treatment option."

Several encouraging proof-of-concept studies using repetitive fecal microbiota transplantation support the rationale for development of microbiome therapeutics in ulcerative colitis.¹ The SER-287 Phase 1b study is a randomized, placebo-controlled, multiple-dose study in subjects with mild-to-moderate ulcerative colitis who are failing current therapies. The primary objectives of the study are to evaluate safety, tolerability and change in the microbiome at up to 8 weeks after dosing. Initial study results, including microbiome, clinical, and endoscopy data, are expected in the second half of 2017.

About SER-287

SER-287 is a biologically sourced oral capsule developed using Seres' proprietary microbiome therapeutics platform. The SER-287 Phase 1b study [clinicaltrials.gov](#) identifier is NCT02618187. In addition to SER-287, Seres' pipeline in ulcerative colitis includes SER-301, a rationally designed, synthetic product comprised of *in vitro* cultured bacterial species for development in ulcerative colitis and other chronic gastrointestinal disorders with high unmet medical need.

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 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 natural state of bacterial diversity and function is imbalanced. The company is planning to initiate the ECOSPOR III clinical study with its lead program, SER-109, in patients with multiply recurrent *C. difficile* infection. Seres' second clinical candidate, SER-287, is being evaluated in a Phase 1b study in patients with mild-to-moderate ulcerative colitis. Seres is also developing SER-262, the first ever synthetic microbiome therapeutic candidate, in a Phase 1b study in patients with primary *C. difficile* infection. For more information, please visit www.serestherapeutics.com. Follow us on Twitter [@SeresTx](#).

References

1. Moayyedi, P, et al., *Gastroenterology*. 2015; Paramsothy S. et al., *The Lancet*. 2017

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 development potential for SER-287, the timing and results of our clinical trials, and dysbiosis as an underlying cause of disease.

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, which may not be available; our limited operating history; the unpredictable nature of our early stage development efforts for marketable drugs; the unproven approach to therapeutic intervention of our microbiome therapeutics; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; potential delays in enrollment of patients which could affect the receipt of necessary regulatory approvals; potential delays in regulatory approval, which would impact the ability to commercialize our product candidates and affect our ability to generate revenue; any fast track or Breakthrough Therapy designation may not lead to faster development, regulatory approval or marketing approval; our possible inability to receive orphan drug designation should we choose to seek it; our reliance on third parties to conduct our clinical trials and the

potential for those third parties to not perform satisfactorily; our reliance on third parties to manufacture our product candidates, which may delay, prevent or impair our development and commercialization efforts; our lack of experience in manufacturing our product candidates; the potential failure of our product candidates to be accepted on the market by the medical community; our lack of experience selling, marketing and distributing products and our lack of internal capability to do so; failure to compete successfully against other drug companies; potential competition from biosimilars; failure to obtain marketing approval internationally; post-marketing restrictions or withdrawal from the market; anti-kickback, fraud, abuse, and other healthcare laws and regulations exposing us to potential criminal sanctions; recently enacted or future legislation; compliance with environmental, health, and safety laws and regulations; protection of our proprietary technology; protection of the confidentiality of our trade secrets; changes in United States patent law; potential lawsuits for infringement of third-party intellectual property; our patents being found invalid or unenforceable; compliance with patent regulations; claims challenging the inventorship or ownership of our patents and other intellectual property; claims asserting that we or our employees misappropriated a third-party's intellectual property or otherwise claiming ownership of what we regard as our intellectual property; adequate protection of our trademarks; ability to attract and retain key executives; managing our growth could result in difficulties; risks associated with international operations; potential system failures; the price of our common stock may fluctuate substantially; our executive officers, directors, and principal stockholders have the ability to control all matters submitted to the stockholders; a significant portion of our total outstanding shares are eligible to be sold into the market; unfavorable or lacking analyst research or reports; and we are currently subject to securities class action litigation. 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 May 7, 2017 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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