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Seres Therapeutics Announces Academic Collaborations to Support Development of Microbiome Therapeutics for Inflammatory Bowel Disease

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 4, 2016-- Seres Therapeutics, Inc. (NASDAQ: MCRB), a leading microbiome therapeutics platform company, today announced it has entered into two separate research collaborations with leading academic groups to support Seres' ongoing development of the first potential microbiome therapeutics for inflammatory bowel disease (IBD).

Under the agreements, Seres will collaborate with leading researchers at the Research Institute of St. Joseph's Hamilton and the Medical University of Graz to enhance the company's efforts to develop microbiome-based therapeutics for IBD. Seres' pipeline includes SER-287, a biologically sourced candidate currently being evaluated in an ongoing Phase 1b study in patients with mild-to-moderate ulcerative colitis (UC) and SER-301, a rationally-designed, preclinical stage therapeutic candidate comprised of bacterial species cultured *in vitro*. SER-287 is the first microbiome therapeutic candidate to reach clinical-stage development in a chronic disease, and the first in an indication outside of infectious disease.

Investigators at the Research Institute of St. Joseph's Hamilton and the Medical University of Graz, as well as other academic groups, have described clinical results demonstrating that repetitive fecal microbiota transplantation (FMT) resulted in clinical remissions in certain UC patients.¹⁻³ These data suggest a causal role for the microbiome in contributing to UC and we believe provide validation for IBD as a target for microbiome therapeutics. Under the terms of these collaborations, Seres has agreed to obtain donor and patient samples from completed and ongoing FMT clinical studies and to perform metagenomic and other analyses on these clinical samples to better characterize the microbiome signatures associated with clinical response.

"While we believe repetitive fecal transplantation is not a viable long-term clinical solution for patients suffering from IBD, FMT studies have provided compelling evidence that modification of the microbiome can lead to meaningfully improved clinical outcomes. Seres is pleased to be collaborating with some of the leading academic research groups in this important work. We are well positioned to learn from these studies, which we expect will provide important insights into the design of SER-301," said David Cook, Ph.D., Executive Vice President of R&D and Chief Scientific Officer of Seres.

About Seres Therapeutics

Seres Therapeutics, Inc. 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. Seres' most advanced program, SER-109, has successfully completed a Phase 1b/2 study demonstrating a clinical benefit in patients with recurring *Clostridium difficile* infection (CDI) and is currently being evaluated in a Phase 2 study in recurring CDI. The FDA has granted SER-109 Orphan Drug, as well as Breakthrough Therapy, designations. Seres' second clinical candidate, SER-287, is being evaluated in a Phase 1b study in patients with mild-to-moderate ulcerative colitis (UC). For more information, please visit www.serestherapeutics.com. Follow us on Twitter @SeresTX.

About Inflammatory Bowel Disease and Ulcerative Colitis

Inflammatory bowel disease is a group of inflammatory conditions with chronic or recurring immune response and inflammation of the gastrointestinal tract. The two most common inflammatory bowel diseases are ulcerative colitis and Crohn's disease. Inflammation affects the entire digestive tract in Crohn's disease and only the large intestine in ulcerative colitis. Both illnesses are characterized by an abnormal response of the body's immune system.

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 result in debilitating symptoms including abdominal pain, bowel urgency and diarrhea.

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 statements regarding our ongoing development of the potentially first microbiome therapeutic for IBD, the causal role of the microbiome in contributing to UC, FMT studies validating IBD as a target for microbiome-based therapeutics, FMT studies providing compelling evidence that modification of the microbiome can lead to improved clinical outcomes and data under the collaboration agreements providing important insights for the design and development of microbiome-based therapeutics for IBD.

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: 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 our ability to commercialize our product candidates and affect our ability to generate revenue; our reliance on our collaboration with Nestlé to develop and commercialize our CDI and IBD product candidates; 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; protection of our proprietary technology; protection of the confidentiality of our trade secrets; changes in United States patent law; our patents being found invalid or unenforceable; 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; and ability to attract and retain key executives. These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 14, 2016 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.

References

1. Moayyedi P. et al., Fecal microbiota transplantation induces remission in patients with active ulcerative colitis in a randomized controlled trial, *Gastroenterology*, 2015.
2. Kump P. et al., Impact of antibiotic treatment before faecal microbiota transplantation (FMT) in chronic active ulcerative colitis, abstract presented at United European Gastroenterology Week, 2015.
3. Paramsothy S. et al., Multi-donor intense faecal microbiota transplantation is an effective treatment for resistant ulcerative colitis: a randomised placebo-controlled trial, oral presentation from European Crohn's and Colitis Foundation meeting, 2016.



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