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Seres Therapeutics Announces Collaboration with Massachusetts General Hospital to Identify Microbiome Therapeutics for Obesity and Metabolic Syndrome

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 22, 2016-- Seres Therapeutics, Inc. (NASDAQ:MCRB), a leading microbiome therapeutics platform company, today announced a collaboration with Massachusetts General Hospital (MGH) of the Harvard Medical School to support translational research focused on identifying microbiome therapeutics for obesity and metabolic syndrome.

Under the terms of the agreement, Seres will help fund a placebo-controlled, proof-of-concept clinical study initiated by professors Elaine Yu, M.D., and Elizabeth Hohmann, M.D., of MGH. The study will evaluate the impact of fecal microbiota transplantation (FMT) derived from lean individuals on the body weight and glycemic control of adults suffering from clinically-significant obesity and metabolic disorders, including insulin resistance and metabolic syndrome. As part of the collaboration, Seres will analyze patient samples to determine metagenomic signatures, metabolic markers and other key clinical biomarkers that are expected to inform the design of microbiome therapeutics for treatment of obesity and associated metabolic disease.

Previous clinical and preclinical evidence supporting this research indicated that the gut microbiota has a critical role in regulating human metabolism and weight control, via effects on caloric availability, chronic inflammation and the production of hormone-like small molecules¹⁻³.

"Drs. Yu and Hohmann are conducting groundbreaking research to elucidate the impact of gut bacteria on body weight and other metabolic parameters," said David Cook, Ph.D., Executive Vice President of Research and Development and Chief Scientific Officer of Seres. "While FMT is not a practical long-term clinical solution, FMT studies do provide important insights about the role of the microbiome in human health. We believe that this research will provide critical insights to support the development of new microbiome therapeutics for obesity."

"Better treatment options are desperately needed to address obesity, and microbiome-based drugs are promising new approaches," said Dr. Hohmann. "In entering into this agreement with Seres, a leader in the development of microbiome therapeutics, we aim to advance our understanding of the role of the microbiome in obesity and related metabolic disorders and accelerate the development of meaningful new treatments for patients."

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.

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 the identification and development of microbiome therapeutic candidates, including those for obesity, metabolic syndrome or other indications.

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 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, Breakthrough Therapy or PRIME 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 may be subject to securities class action litigation. 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. Ridaura VK et al., Gut microbiota from twins discordant for obesity modulate metabolism in mice. *Science*. 2013.
2. Vrieze A et al., Transfer of intestinal microbiota from lean donors increases insulin sensitivity in individuals with metabolic syndrome. *Gastroenterology*. 2012.
3. Perry RJ et al., Acetate mediates a microbiome–brain– β -cell axis to promote metabolic syndrome. *Nature*. 2016.



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