Seres Therapeutics Announces FDA Orphan Drug Designation for SER-287 in Treatment of Pediatric Ulcerative Colitis

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 4, 2017-- Seres Therapeutics, Inc., (NASDAQ:MCRB) today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to microbiome therapeutic candidate SER-287 for the treatment of Ulcerative Colitis (UC) in pediatric patients.

Orphan Drug Designation provides incentives designed to advance drug development for rare diseases or conditions that affect fewer than 200,000 people in the United States. The FDA's designation of SER-287 follows a review of data which established a medically plausible basis for the use of SER-287 – specifically, the Phase 1b clinical data that highlights the potential of SER-287 as a novel treatment modality for patients suffering from UC.

Seres successfully completed a placebo-controlled Phase 1b study of SER-287 in patients with mild-to-moderate UC who were failing current therapies. SER-287 administration resulted in a dose-dependent improvement of both clinical remission rates and endoscopic scores, and demonstrated a very favorable safety profile. The Phase 1b results demonstrate the potential for SER-287 to provide an effective and safer alternative treatment modality for patients suffering from UC. SER-287 Phase 1b microbiome data are expected in early 2018.

"We are pleased to receive FDA Orphan Drug Designation for SER-287 and we look forward to advancing the program into further development for Ulcerative Colitis. Based on the highly encouraging Phase 1b clinical results and favorable safety profile, we intend to evaluate SER-287 in a pediatric UC population as part of our overall development plan. Safety is of particular importance to the pediatric population, and given the positive safety profile observed in our clinical trial to date, we believe our microbiome approach may be well suited to address this group," said Roger J. Pomerantz, M.D., President, CEO and Chairman of Seres.

About SER-287

SER-287 is a biologically sourced, oral formulation containing a consortium of live bacterial spores that is being developed for Ulcerative Colitis and other forms of inflammatory bowel disease. SER-287 is hypothesized to act through a novel mechanism of action by modulating the dysbiotic microbiome thereby reducing inflammation without immunosuppression effects. A healthy microbiome has been shown to maintain the integrity of the colonic barrier, reduce the signaling by pro-inflammatory molecules produced by certain bacteria, and induce regulatory T cells in the colon to modulate immune responses.[1]

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, 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' lead program, SER-109, has obtained Breakthrough Therapy and Orphan Drug designations from the U.S. Food and Drug Administration and is in Phase 3 development for multiply recurrent *C. difficile* infection. Seres' clinical candidate SER-287 has successfully completed 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.

References

1. Blander J.M. et al., Regulation of inflammation by microbiota interactions with the host, *Nature Immunology*, 2017; Lynch S. and Pedersen O., The Human Intestinal Microbiome in Health and Disease, *The New England Journal of Medicine*, 2016.

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 timing of microbiome data, the potential for SER-287 to treat UC patients, including pediatric UC patients, the timing of the potential approval of SER-287, and the overall development of SER-287.

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, including potential delays in regulatory approval; 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 lack of experience in manufacturing, selling, marketing, and distributing our product candidates; orphan drug designation may not lesd to faster development, failure to compete successfully against other drug companies; protection of our proprietary technology and the confidentiality of our trade secrets; potential lawsuits for, or claims of, infringement of third-party intellectual property or challenges to the ownership of our intellectual property; our patents being found invalid or unenforceable; risks associated with international operations; our ability to retain key personnel and to manage our growth; the potential volatility of our common stock; our management and principal stockholders have the ability to control or significantly influence our business; 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 November 8, 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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