Seres Therapeutics Publishes Positive SER-287 Phase 1b Ulcerative Colitis Study Results in Journal Gastroenterology

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- Phase 1b study results demonstrate an impact on clinical remission and endoscopic improvement with a favorable safety profile in patients with mild-to-moderate ulcerative colitis-

- Detailed microbiome and metabolomic study results provide scientific insights into the SER-287 mechanism of action and support for additional ongoing Seres pipeline programs -

- SER-287 Phase 2b study enrollment is ongoing; Topline data are expected in the second half of 2021 -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 6, 2021-- Seres Therapeutics, Inc. (Nasdaq: MCRB) today announced the publication of data analyses from the Company's Phase 1b trial of SER-287 in patients with active mild-to-moderate ulcerative colitis (UC), most of whom were failing current therapies. The study results demonstrated that SER-287 administration was associated with positive impacts on clinical remission, endoscopic improvement, modulation of the gastrointestinal microbiome, and a favorable tolerability profile.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20210106005265/en/

(Photo: Business Wire)

The paper, titled "A Phase 1b Safety Study of SER-287, a Spore-Based Microbiome Therapeutic, For Active Mild-To-Moderate Ulcerative Colitis," was published as the highlighted cover article in the January 2021 print edition of the leading journal *Gastroenterology*.

"Individuals with ulcerative colitis are in need of effective therapies with a favorable safety profile, and this Phase 1b study provided promising evidence suggesting that SER-287 has the potential to transform how this disease is managed," said Lisa von Moltke, M.D., Chief Medical Officer of Seres. "We look forward to furthering our understanding of SER-287 in our ongoing Phase 2b ECO-RESET study. The Phase 2b study continues to recruit patients, and though COVID-19 continues to impact operations, we're encouraged to see that many clinical sites remain active. The study is nearly 90% enrolled, and we expect to obtain topline results in the second half of 2021."

"The SER-287 Phase 1b clinical and pharmacological data are highly encouraging and suggest that SER-287 could represent a new therapeutic paradigm for ulcerative colitis by targeting underlying biological drivers of the disease. The SER-287 program, and our highly positive SER-109 Phase 3 study results for recurrent *C. difficile* infection, support the broad opportunity for microbiome therapeutics. We believe that our programs provide clear clinical evidence demonstrating the therapeutic potential of bacterial consortia that target multiple disease-relevant pathways simultaneously and further validate Seres' reverse translational microbiome platforms for drug discovery and development," said Matthew Henn, Ph.D., Executive Vice President and Chief Scientific Officer of Seres and the manuscript's senior author. "The mechanistic data that we obtain from our clinical studies are invaluable, as these enable us to refine our understanding of how the microbiome can modulate the metabolic landscape in the gastrointestinal tract and, in combination with our preclinical platforms, propel both the discovery of novel microbiome disease targets and the expansion of our microbiome therapeutics pipeline."

Phase 1b Study Details

The randomized, double-blind, placebo-controlled, multiple-dose, Phase 1b induction trial randomized 58 patients to one of four arms: daily SER-287 (preceded by short vancomycin conditioning regimen), weekly SER-287 (preceded by short vancomycin conditioning regimen), weekly SER-287 (preceded by placebo), and daily placebo (preceded by placebo).

The highest efficacy was observed in the daily SER-287 arm of the study, with a remission rate of 40% compared to 0% in the placebo group. SER-287 engraftment was dose-dependent, durable for four weeks post-dosing, and associated with clinical remission across arms. An SER-287-associated benefit in endoscopic improvement was also observed. SER-287 engraftment, reflecting the germination and growth of drug bacteria, was associated with compositional and functional changes in the microbiome, including increased diversity of spore-forming Firmicutes implicated in colonic homeostasis, declines in non-spore forming species such as pro-inflammatory Enterobacteriaceae, and changes in the abundance of microbe-associated metabolites that impact epithelial barrier function and immune signaling. The SER-287 safety and tolerability profile were favorable, and study results demonstrated no imbalance in adverse events in patients treated with SER-287 compared to patients treated with placebo. There were no drug-related serious adverse events (SAEs) associated with SER-287.

About SER-287

SER-287 is an oral, biologically-derived microbiome therapeutic candidate designed to have pharmacological effects on multiple pathways relevant to ulcerative colitis that can be modulated by the gastrointestinal microbiome. Seres has obtained FDA Fast Track designation for SER-287 in active mild-to-moderate UC. The SER-287 ECO-RESET induction study in patients with active mild-to-moderate UC remains ongoing. Seres has implemented a number of COVID-19-related mitigation strategies, and the study continues to enroll patients.

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 potential impact of SER-287 on patients and the treatment of UC overall, the promise of our microbiome therapeutics, the potential impact of the COVID-19 pandemic, 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; the impact of the COVID-19 pandemic; our unproven approach to therapeutic intervention; the lengthy, expensive and uncertain process of clinical drug development; 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; the success of our leadership transition; our ability to retain key personnel and to manage our growth; and 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 November 9, 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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