



Seres Therapeutics to Present Key Data on Investigational Microbiome Therapeutics for Recurrent *C. difficile* Infection and Ulcerative Colitis at the Digestive Disease Week (DDW) Annual Meeting

May 11, 2021

- Data demonstrates Seres' leadership in microbiome sciences and therapeutics across multiple diseases -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 11, 2021-- [Seres Therapeutics, Inc.](https://www.seres-therapeutics.com) (Nasdaq: MCRB), a leading microbiome therapeutics company, today announced that it will present recent research findings from its microbiome drug development portfolio at Digestive Disease Week® (DDW), which is taking place virtually from May 21-23, 2021. With two oral presentations and two posters of distinction, Seres will demonstrate the potential of microbiome-based therapies for patients with serious diseases like recurrent *Clostridioides difficile* infection (CDI) and ulcerative colitis (UC).

CDI is one of the top three most urgent bacterial threats in the U.S., according to the Centers for Disease Control, and is a leading cause of hospital-acquired infection. It is associated with significant morbidity and mortality, with one study showing that the annual cost to the U.S. healthcare system is approximately \$6.3 billion. UC is a serious chronic condition marked by persistent inflammation in the gastrointestinal tract and can greatly reduce an individual's quality of life.

"As the world's largest gathering of physicians and researchers in the digestive disease field, the DDW Annual Meeting is a great opportunity to highlight the potential of microbiome therapeutics as an alternative treatment approach for hard-to-treat diseases like recurrent CDI and UC," said Lisa von Moltke, MD, Chief Medical Officer at Seres. "These patients face a significant unmet need for safer, more effective treatments that alleviate the medical and economic burden of disease, and we're committed to delivering a new class of therapeutic options that will make a meaningful difference in their lives."

Seres' data at DDW feature three orally administered, live microbiome therapeutic candidates: SER-109, SER-287, and SER-301, all of which are part of a novel class of multifunctional bacterial consortia designed to functionally interact with other microbes, host cells and tissues to treat disease. Data highlights include:

- **Poster of Distinction Presentation:** 24-Week Efficacy and Safety Data from ECOSPOR-III: A Phase 3 Double-Blind, Placebo-Controlled, Randomized Trial of **SER-109**, an Investigational Microbiome Therapeutic for Recurrent *Clostridioides Difficile* Infection, May 21, 12:15 PM – 1:00 PM; Lead Author: Louis Korman, MD
- **Poster of Distinction Presentation:** In Vivo Characterization of **SER-301**, A Rationally-Designed Investigational Microbiome Therapeutic for Patients with Active Mild-To-Moderate Ulcerative Colitis, May 21, 12:15 – 1:00 PM; Lead Author: Tim Nelson, MS
- **Oral Presentation:** **SER-301**, An Investigational, Rationally-Designed Bacterial Consortium for Mild-To-Moderate Ulcerative Colitis, Recapitulates the Effects of **SER-287** on Remission Associated Microbial Metabolites and Host Gene Expression, May 23, 10:00 – 11:30 AM; Lead Author: Asunción Martínez, PhD
- **Oral Presentation:** Rapid Conversion of Primary to Secondary Bile Acids in Subjects with Recurrent *Clostridioides Difficile* Infection (CDI) Following **SER-109**, An Investigational Microbiome Therapeutic, May 23, 3:30 – 5:30 PM; Lead Author: Jessica Bryant, PhD

Posters and presentations will be available for 90 days on the DDW conference website.

About SER-109

SER-109 is an oral microbiome therapeutic candidate consisting of a consortium of highly purified Firmicute spores, which normally live in the healthy microbiome. SER-109 is designed to prevent further recurrences of CDI in patients with a history of multiple infections by modulating the disrupted microbiome to a state that resists *C. difficile* colonization and growth. The SER-109 manufacturing purification process is designed to remove unwanted microbes thereby reducing the risk of pathogen transmission beyond donor screening alone. The FDA has granted SER-109 Breakthrough Therapy designation and Orphan Drug designation for the treatment of recurrent CDI.

About SER-287

SER-287, an investigational oral microbiome therapeutic candidate consisting of a consortium of highly purified Firmicute spores, is designed to normalize the gastrointestinal microbiome of individuals with UC. Preclinical colitis animal models and *in vitro/ex vivo* and *in vivo* disease models. SER-287 administration has the potential to reduce pathology and modulate inflammatory and immunological functional pathways. SER-287 has been granted Fast Track Designation by the FDA for the induction and maintenance of clinical remission in adult subjects with active mild-to-moderate UC. SER-287 has been designated an Orphan Drug for pediatric UC by the FDA.

About SER-301

SER-301 is a consortium of cultivated bacteria designed using our reverse translational discovery platform that incorporates analysis of microbiome biomarkers from human clinical data and preclinical assessments using human cell-based assays and *in vitro/ex vivo* and *in vivo* disease models. SER-301 is designed to reduce induction of pro-inflammatory activity, improve epithelial barrier integrity and TNF- α driven inflammation in intestinal epithelial cells, or IECs, and modulate UC-relevant anti-inflammatory, innate and adaptive immune pathways. SER-301 is being produced using our

advanced fermentation, formulation and delivery platforms. It includes strains delivered in spore form, as well as strains cultivated in non-spore (vegetative) form and delivered using enterically-protected technology designed to release in the colon.

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 UC. Seres is evaluating SER-301 in a Phase 1b study in patients with ulcerative colitis, and plans to initiate a clinical program with 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 potential of microbiome therapeutics to treat and prevent disease, the potential approval of any of our products, the ultimate safety and efficacy data for our products; and other statements which are not historical fact.

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; 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 May 4, 2021, 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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