



SERES
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Seres Therapeutics Announces Discontinuation of Enrollment in SER-401 Study in Metastatic Melanoma

March 8, 2021

- Enrollment meaningfully impacted by COVID-19 -

- The Company reiterates opportunity in oncology and continues advancement of its preclinical efforts -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 8, 2021-- [Seres Therapeutics, Inc.](#) (Nasdaq: MCRB) announced today that the Company, in collaboration with study partners, The Parker Institute for Cancer Immunotherapy (PICI) and The University of Texas MD Anderson Cancer Center, has voluntarily discontinued further enrollment in the Melanoma Checkpoint and Gut Microbiome Alteration With Microbiome Intervention (MCGRAW) study evaluating the safety and drug activity of SER-401 or fecal microbiota transplant (FMT) in combination with nivolumab in patients with metastatic melanoma.

"While we are disappointed to discontinue enrollment, we are encouraged by the opportunity to apply the learnings from this study towards future development programs at Seres that can directly benefit the oncology community in search of new treatment options," said Matthew Henn, Ph.D., Chief Scientific Officer at Seres. "We want to thank the patients, their care partners, our collaborators and the medical professionals who participated in this study, despite the COVID-19 pandemic, and helped further advance our understanding of the role microbiome therapeutics play in the treatment of cancer."

A preliminary analysis of results from 10 subjects who received either SER-401 or placebo in combination with nivolumab indicated that SER-401 was safe and well-tolerated. There were no patients enrolled in the FMT portion of the study. Subjects currently enrolled in the study will complete the study protocol. Given challenges in enrollment due to the COVID-19 pandemic, subsequent anticipated time to study completion, and progress in its preclinical oncology pipeline, Seres has decided to deprioritize further development of SER-401. The Company will continue to advance its research and development efforts in cancer, applying learnings from the SER-401 trial.

Evidence continues to emerge that suggests gut microbiome modulation may augment responses to cancer immunotherapy, including improving responses in PD-1 refractory patients¹.

Seres and its collaborators continue to be excited about the opportunity to develop next-generation therapeutics targeting gut microbes for the treatment of individuals living with cancer. Seres will continue to engage with MD Anderson and PICI to advance the development of medicines in this field, and maintains a robust preclinical program in oncology as well as a collaboration with Memorial Sloan Kettering Cancer Center centered on advancing microbiome therapeutics in various settings of oncology. Seres' immuno-oncology patent portfolio includes the option to exclusively license foundational intellectual property from MD Anderson, based upon the work of Jennifer Wargo, M.D., professor of Surgical Oncology and Genomic Medicine.

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-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 receipt of additional data from clinical studies, the potential role and advancement of microbiome therapeutics in the treatment of cancer, the promise of our microbiome therapeutics, 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; 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on

March 2, 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.

¹ Davar et al. 2021. Fecal microbiota transplant overcomes resistance to anti-PD-1 therapy in melanoma patients. Science, DOI: 10.1126/science.abf3363; Baruch et al. 2021. Fecal microbiota transplant promotes response in immunotherapy-refractory melanoma patients. Science, DOI: 10.1126/science.abb5920

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