Seres Therapeutics Issues Statement Regarding U.S. Food and Drug Administration's March 12, 2020 Safety Alert Related to Use of Fecal Microbiota Transplantation

March 13, 2020

FDA alert is related to unapproved fecal microbiota transplantation (FMT) and does not impact Seres' investigational microbiome therapeutic candidates

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Seres Therapeutics, Inc. (Nasdaq: MCRB) today provided a statement on a safety alert from the U.S. Food and Drug Administration (FDA) regarding bloodstream infections with multi-drug resistant organisms (MDROs) transmitted through fecal microbiota transplantation (FMT). On March 12, 2020, the FDA stated that it became aware of six infections caused by enteropathogenic *Escherichia coli* (EPEC) and Shiga toxin-producing *Escherichia coli* (STEC) that have occurred following investigational use of FMT. The FDA suspects that these infections were due to transmission of pathogenic organisms from FMT product supplied by a stool bank company based in the United States. Four of the six patients who received the contaminated FMT required hospitalization. An additional two patients who received FMT from the STEC-positive donor died.

The FDA previously issued a safety alert on June 13, 2019, stating that two immunocompromised adults who received FMT developed invasive infections caused by extended-spectrum beta-lactamase (ESBL)-producing *E. coli*, and that one individual died.

Seres' therapeutic candidates, including its SER-109 product candidate currently under investigation in a Phase 3 study for recurrent *C. difficile* infection, are comprised of highly purified consortia of spore-based commensal bacteria. SER-109 is manufactured under Good Manufacturing Practices (GMP) conditions and is quality-controlled using stringent standards to ensure product quality and consistency. In addition to conducting rigorous donor screening, Seres utilizes a unique manufacturing process that has been demonstrated to inactivate numerous potential pathogens, including species of vegetative bacteria such as *Escherichia coli* and viruses. The Company's manufacturing process effectively inactivates emerging potential pathogens where diagnostic assays may not yet be available, such as SARS-CoV-2, the virus linked to COVID-19.

Seres believes that donor and product screening are necessary but insufficient to minimize infection risk for donor-derived microbiome and FMT products. Seres' additional step of inactivation of potential pathogens represents a critical intervention to increase quality assurance and minimize the risk to patients.

About Seres Therapeutics

Seres Therapeutics, Inc. (Nasdaq: MCRB), 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 state of bacterial diversity and function is imbalanced. Seres' SER-287 program has obtained Fast Track and Orphan Drug designation from the U.S. Food and Drug Administration and is being evaluated in a Phase 2b study in patients with active mild-to-moderate ulcerative colitis. Seres' SER-109 program has obtained Breakthrough Therapy and Orphan Drug designations from the FDA and is in Phase 3 development for recurrent *C. difficile* infection. Seres is also developing SER-401 in a Phase 1b study in patients with metastatic melanoma and SER-301 for ulcerative colitis. For more information, please see 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 statements relating to FDA approval of Seres' therapeutic candidates. Any forward-looking statements represent management's opinions 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.

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 unproven approach to therapeutic intervention; 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; that we have no experience manufacturing products at commercial scale; our products may become subject to unfavorable pricing restrictions; we may face product liability lawsuits; we may face competition from biosimilars; our ability to protect our trade secrets and know-how; potential changes in U.S. patent law; and the risk of third party lawsuits alleging we are infringing on their intellectual property. 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, 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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