Seres Therapeutics Issues Statement Regarding U.S. Food and Drug Administration Safety Alert Related to Use of Fecal Microbiota Transplantation

June 19, 2019

FDA alert does not impact Seres' microbiome investigational therapeutic candidates

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 19, 2019-- Seres Therapeutics, Inc. (Nasdaq: MCRB) ("Seres") 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 June 13th, 2019, the agency stated 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. The donor stool used was not tested for the pathogen linked to the infection.

Seres' investigational therapeutic candidates, highly purified consortia of spore based commensal bacteria, are fundamentally distinct from FMT and are not impacted by the FDA alert. In contrast to unapproved FMT, Seres' therapeutic candidates are being evaluated in controlled clinical studies conducted under an Investigational New Drug application (IND) with rigorous safety monitoring and reporting procedures. The Company's therapeutic candidates are manufactured under GMP conditions and quality-controlled using stringent standards to ensure product quality and consistency.

Unapproved FMT is widely used under an FDA Enforcement Discretion policy for the treatment of recurrent *C. difficile* infection (CDI) not responsive to standard therapies. This policy does not require the safety monitoring and oversight that are standard requirements for investigational therapies under an IND. The new FDA safety alert indicated that additional protections are needed for any investigational use of FMT, including appropriate donor screening questions, testing of donor stool for MDROs and informing patients of the potential risk of infection and serious adverse reactions. The agency encourages healthcare providers to report suspected adverse events to the FDA.

Until a safe and effective FDA-approved microbiome drug is available for the treatment of *C. difficile*, Seres remains supportive of continued patient access to FMT, particularly for those patients who may lack access to clinical trials. However, Seres believes that all FMT use should be performed under an IND using pre-specified and mandatory safety reporting requirements appropriate for unapproved investigational therapies. In addition, Seres also supports increased FDA scrutiny regarding unproven promotional claims related to FMT efficacy and safety.

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. 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 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.

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