Seres Therapeutics Receives Feedback From FDA on SER-155 Allogeneic Hematopoietic Stem Cell Transplant (allo-HSCT) Development Approach

March 3, 2025

FDA has provided input on key elements of the SER-155 allo-HSCT clinical development plans including support for the proposed primary efficacy endpoint of reduction in bloodstream infections (BSIs) as of 30 days post HSCT in the next study

Seres has submitted clarification questions to FDA and expects a response in the coming weeks, which will inform the proposed protocol for the next SER-155 study in allo-HSCT, which the Company anticipates submitting to FDA in Q2

CAMBRIDGE, Mass., March 03, 2025 (GLOBE NEWSWIRE) -- Seres Therapeutics, Inc. (Nasdaq: MCRB) (Seres or the Company), a leading live biotherapeutics company, today announced that it has received constructive feedback from a Type B Breakthrough Therapy designation engagement with the U.S. Food and Drug Administration (FDA or the agency) regarding the Company's development strategy for its lead live biotherapeutic, SER-155 in patients undergoing allo-HSCT. The FDA provided feedback on important elements of the next study that included a recommendation that it be a Phase 2 and support for a reduction in bloodstream infections as of 30 days post HSCT as the primary endpoint; and confirmed their expectations for the manufacture and control of SER-155. Further interaction with FDA is expected in the coming weeks as the Company has submitted questions to clarify certain feedback received. Seres is evaluating the next study design, which could be either a Phase 2, or a Phase 2/3 that offers operational efficiencies, and anticipates submitting a proposed protocol, incorporating FDA's feedback, for the next study of SER-155 in allo-HSCT to the agency in the second quarter of this year.

"We are pleased to have obtained productive FDA feedback supporting our goal of bringing SER-155 to allo-HSCT patients," said Eric Shaff, President and Chief Executive Officer of Seres Therapeutics. "Obtaining FDA's input is vital to aligning on our development approach, consistent with the benefits provided by Breakthrough Therapy designation, and to derisking the regulatory path forward. Based on the guidance and pending further FDA feedback, we expect to submit a protocol for our next study to the agency in the second quarter and look forward to further FDA engagement on the SER-155 development plan. Notably, the next study design is expected to retain many of the elements of our SER-155 placebo controlled Phase 1b Cohort 2 trial in allo-HSCT, which showed an impressive 77% relative risk reduction in bloodstream infections, a significant reduction in systemic antibiotic exposure, as well as lower incidence of febrile neutropenia. We continue to advance discussions seeking a partner to support the further development of SER-155 in allo-HSCT."

About SER-155
SER-155 is an investigational, oral, live biotherapeutic designed to decolonize GI pathogens, improve epithelial barrier integrity, and induce immune tolerance to prevent bacterial bloodstream and antimicrobial resistant (AMR) infections, as well as other pathogen associated negative clinical outcomes, in patients undergoing allo-HSCT for the treatment of hematological malignancies.

SER-155 has been evaluated in a Phase 1b placebo-controlled study in patients undergoing allo-HSCT, which demonstrated a significant reduction in both BSIs (77% relative risk reduction) and systemic antibiotic exposure, as well as lower incidence of febrile neutropenia. SER-155 has received Breakthrough Therapy designation for the reduction of BSIs and Fast Track designation for reducing the risk of infection and GvHD, in both cases in patients undergoing HSCT.

About Seres Therapeutics
Seres Therapeutics, Inc. (Nasdaq: MCRB) is a clinical-stage company focused on improving patient outcomes in medically vulnerable populations through novel live biotherapeutics. Seres led the successful development and approval of VOWST™, the first FDA-approved orally administered microbiome therapeutic, which was sold to Nestlé Health Science in September 2024. The Company is developing SER-155, which has received Breakthrough Therapy designation for the reduction of bloodstream infections in adults undergoing allo-HSCT and Fast Track designation for reducing the risk of infection and graft-versus-host disease in adults undergoing allo-HSCT, and which has demonstrated a significant reduction in bloodstream infections and related complications (as compared to placebo) in a Phase 1b clinical study in patients undergoing allo-HSCT. SER-155 and the Company's other pipeline programs are designed to target multiple disease-relevant pathways and are manufactured from standard clonal cell banks via cultivation, rather than from the donor-sourced production process used for VOWST. In addition to allo-HSCT, the Company intends to evaluate SER-155 and other cultivated live biotherapeutic candidates in other medically vulnerable patient populations including autologous-HSCT patients, cancer patients with neutropenia, CAR-T recipients, individuals with chronic liver disease, solid organ transplant recipients, as well as patients in the intensive care unit and long-term acute care facilities. 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 about: the timing and results of our clinical studies and data readouts; our clinical development plans; communications with, feedback from, or submissions to the FDA; the impact, value or potential benefits of Breakthrough Therapy designation, Fast Track designation or any other regulatory designations; our ability to secure a partnership and/or generate additional capital; the timing of any of the foregoing; and other statements that 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: (1) if we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or any collaborators will not be able to commercialize our product candidates or will not be able to do so as soon as anticipated; (2) we have incurred significant losses, are not currently profitable and may never become profitable; (3) our need for additional funding; (4) our history of operating losses; (5) our novel approach to therapeutic intervention; (6) our reliance on third parties to conduct our clinical trials and manufacture our product candidates; (7) the competition we will face; (8) our ability to protect our intellectual property; (9) our ability to retain key personnel and to manage our growth; (10) the effect of the VOWST sale on our ability to retain and hire key personnel and maintain relationships with our customers, suppliers, advertisers, partners and others with whom we do business, or on our operating results and businesses generally; (11) the risks associated with the disruption of management's attention from ongoing business operations due to the obligation to provide transition services; (12) our failure to receive the installment payment or the milestone payments in the future; (13) the uncertainty of impact of the 50/50 profit and loss sharing arrangement on our reported results and liquidity; and (14) we may not be able to realize the anticipated benefits of the VOWST sale. 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 (SEC), on November 13, 2024, 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.

Investor and Media Contacts:
IR@serestherapeutics.com

Carlo Tanzi, Ph.D.
Kendall Investor Relations
ctanzi@kendallir.com

Source: Seres Therapeutics, Inc.