Seres Therapeutics Presents Expanded SER-155 Exploratory Biomarker Data at 2025 ASCO Annual Meeting

May 27, 2025

Results highlight potential role of SER-155 in promoting peripheral T-cell recovery and immune reconstitution to support favorable outcomes post allogeneic hematopoietic stem cell transplant (allo-HSCT)

CAMBRIDGE, Mass., May 27, 2025 (GLOBE NEWSWIRE) -- Seres Therapeutics, Inc. (Nasdaq: MCRB) (Seres or the Company), a leading live biotherapeutics company, today announced the Company will be presenting new exploratory biomarker data from its SER-155 Phase 1b study in a poster session at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place May 30 –June 3 in Chicago.

The Company previously reported exploratory biomarker data from the SER-155 Phase 1b study showing evidence of improved intestinal epithelial barrier integrity and modulation of systemic inflammatory responses. The results are consistent with SER-155's intended therapeutic mechanisms to reduce the risk of intestinal bacterial translocation-associated bloodstream infections (BSIs) and are supportive of the observed significant reduction in BSIs with SER-155 treatment (77% relative risk reduction). They also demonstrate the broader potential of live biotherapeutics to treat inflammatory and immune-mediated diseases. New biomarker data presented at ASCO build on these findings, focusing on the potential of SER-155 to promote immune reconstitution following allo-HSCT through the modulation of homeostatic cytokines and peripheral T-cell expansion. In post hoc analyses from the SER-155 Phase 1b study, significantly higher levels of the homeostatic cytokine IL-7 were observed both after the second course of SER-155 (administered after neutrophil recovery) and at HSCT Day 100, as compared to placebo. Additionally, a higher frequency of CD4+ T cells was observed in peripheral blood at these same timepoints in the SER-155 arm. These findings support that SER-155 may play an important role in promoting T-cell populations, essential for immune reconstitution after allo-HSCT, reducing infection risk and improving clinical outcomes.

"Patients undergoing allo-HSCT are highly susceptible to life-threatening bloodstream infections, making effective immune reconstitution and restoration of a diverse, functional T-cell population after allo HSCT important for positive long-term outcomes," said Marcel van den Brink, M.D., Ph.D., President of City of Hope Cancer Center and National Medical Center, Chief Physician Executive and the Deana and Steve Campbell Chief Physician Executive Distinguished Chair. "The observed increases in IL-7 levels and CD4+ T-cells associated with SER-155 administration are particularly encouraging and consistent with a beneficial immunoregulatory effect of SER-155. These results suggest that SER-155 may help drive more robust and functional immune recovery, and, along with the significant reduction in blood stream infections observed in the study, support continued clinical development."

The Company plans to submit a Phase 2 trial protocol for SER-155 in allo-HSCT to the FDA in the coming weeks and is actively seeking partners to support continued clinical development.

Presentation Details
Abstract Number: 6554
Title: Exploratory analyses of immune reconstitution biomarkers from a Ph1b study of an investigational, oral, live biotherapeutic product, SER-155, in adult allo-HCT
Poster Board #: 170
Date and Time: Sunday June 1, 2025; 9:00 AM-12:00 PM CT
Presenter: Emily Walsh, Ph.D. – Director, Research Technologies at Seres Therapeutics

About SER-155
SER-155 is an investigational, oral, live biotherapeutic designed to decolonize gastrointestinal (GI) pathogens, improve epithelial barrier integrity, and induce immune homeostasis, to prevent bacterial bloodstream infections, including those that can harbor antimicrobial resistance (AMR), as well as other pathogen associated negative clinical outcomes, in patients undergoing allogeneic hematopoietic stem cell transplantation (allo-HSCT).

SER-155 has been evaluated in a Phase 1b placebo-controlled study in patients undergoing allo-HSCT, which demonstrated a significant reduction in both bacterial bloodstream infections (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 bloodstream infections in adults undergoing allo-HCST and Fast Track designation for reducing the risk of infection and graft-versus-host disease in patients undergoing allo-HCST. The early development of the program was supported by Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), a global non-profit partnership accelerating antibacterial products to address drug-resistant bacteria.

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, 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; upcoming presentations and conferences; any potential benefits of our product candidates; future product candidates, clinical development plans and commercial opportunities; communications with, feedback from, or submissions to the FDA; our plans to seek or our ability to find partners to support continued clinical development and any intended benefits therefrom; anticipated 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) our need for additional funding; (2) our ability to continue as a going concern; (3) we have incurred significant losses, are not currently profitable and may never become profitable; (4) our history of operating losses; (5) the expected payments from the VOSWT sale are subject to risks and uncertainties; (6) we may not be able to realize the anticipated benefits of the VOWST sale, and may face new challenges as a smaller, less diversified company; (7) we have in the past and may in the future receive notice of the failure to satisfy a continued listing rule from The Nasdaq Stock Market LLC; (8) our novel approach to therapeutic intervention; (9) our reliance on third parties to conduct our clinical trials and manufacture our product candidates; (10) our ability to achieve market acceptance necessary for commercial success; (11) the competition we will face; (12) our ability to protect our intellectual property; and (13) our ability to retain key personnel and to manage our growth. 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 May 7, 2025, 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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