Seres Therapeutics Announces Further Constructive Feedback from FDA on SER-155 Phase 2 Study Protocol and Implements Cost Reduction Actions to Extend Cash Runway

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Following recent constructive FDA feedback, Seres anticipates finalizing SER-155 Phase 2 study protocol for the prevention of bloodstream infections in adults undergoing allogeneic hematopoietic stem cell transplant for the treatment of hematological malignancies

Company continues to engage in discussions aimed at obtaining capital and other resources to advance the SER-155 Phase 2 study and is preparing to rapidly operationalize the study, pending securing capital, with interim clinical results anticipated within 12 months of study initiation

Seres is reducing operating costs and decreasing workforce by approximately 25%; based on these actions and current operating plans, the Company expects to extend cash runway well into Q2 2026

CAMBRIDGE, Mass., Sept. 23, 2025 (GLOBE NEWSWIRE) -- Seres Therapeutics, Inc. (Nasdaq: MCRB), (Seres or the Company), a leading live biotherapeutics company, today announced receipt of additional constructive feedback from the U.S. Food and Drug Administration (FDA) on the Phase 2 study protocol for the Company's lead program, SER-155, for the prevention of bloodstream infections (BSIs) in adults undergoing allogeneic hematopoietic stem cell transplant (allo-HSCT). The feedback is expected to support Seres' finalization of the protocol.

The Company continues to engage with multiple parties intending to secure capital and other resources to support advancement of the Phase 2 study of SER-155, which has received Breakthrough Therapy designation, as well as further development of additional live biotherapeutic candidates. The Company also announced the implementation of actions to reduce operating costs, including a reduction in the workforce. As a result of the anticipated cost savings arising from these initiatives and current operating plans, the Company expects to extend its cash runway well into the second quarter of 2026.

"We are progressing start-up activities for our Breakthrough Therapy designated SER-155 live biotherapeutic program and are pleased with the further constructive feedback from the FDA, including on key parameters such as study size, primary endpoint, and interim analysis plan, that we expect will allow us to finalize the Phase 2 study protocol," said Thomas DesRosier and Marella Thorell, co-CEOs of Seres. "While we advance SER-155 Phase 2 study start-up activities, we continue to engage in active discussions with multiple parties seeking capital to initiate the study, and to support our broader portfolio of product candidates with applications for inflammatory diseases. The cost reduction actions, and the resultant operating runway extension, are intended to provide the Company with additional opportunity to advance these strategic priorities. We recognize the outstanding contributions our departing team members have made and thank them for their efforts in bringing meaningful live biotherapeutic products to patients."

Incorporating FDA feedback, the SER-155 Phase 2 is designed to be a well-powered, placebo-controlled study that will evaluate prevention of BSIs through 30 days post allo-HSCT as its primary endpoint and includes a planned interim analysis to evaluate efficacy and futility, enabling an expedited initial data readout. The study is planned to enroll approximately 248 participants, and the interim data analysis is expected when approximately half of the enrolled participants have reached the primary endpoint. This interim analysis, which is projected to be within 12 months following study initiation, will facilitate timely engagement with the FDA on the design of a Phase 3 study and inform development in adjacent medically vulnerable patient populations. The Company anticipates that positive results from the Phase 2 study, if achieved, could enable advancement into a single Phase 3 trial to support registration.

Additionally, in conjunction with streamlining operations, Seres is reducing its workforce by approximately 25%, including reductions that were effective in August 2025. Seres plans to retain the capabilities and personnel most critical to continue the preparatory activities for its planned SER-155 Phase 2 study. The workforce reduction is expected to result in cash payments of approximately $1.0 -$1.4 million, primarily related to severance costs, to be paid in the fourth quarter of 2025.

About SER-155
SER-155 is an investigational, oral, live biotherapeutic designed to decolonize gastrointestinal pathogens, improve epithelial barrier integrity, and induce immune homeostasis, to prevent bacterial bloodstream infections, including those that can harbor antimicrobial resistance, as well as other pathogen associated negative clinical outcomes, in patients undergoing 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 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 BSIs 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; current or future product candidates and their potential benefits; clinical development plans and commercial opportunities; communications with, feedback from, or submissions to the FDA; operating plans; cost reduction actions, their anticipated benefits, and related cash payments; our cash runway; our ability to secure a strategic, R&D, or other partnership and/or generate or obtain additional capital, financing or other resources; our planned strategic focus; the 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 cost reduction actions may not achieve their intended benefits, including an extended cash runway; (5) our limited operating history; (6) the expected payments from the VOSWT sale are subject to risks and uncertainties; (7) 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; (8) 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; (9) our novel approach to therapeutic intervention; (10) our reliance on third parties to conduct our clinical trials and manufacture our product candidates; (11) our ability to achieve market acceptance necessary for commercial success; (12) the competition we will face; (13) our ability to protect our intellectual property; and (14) our ability to manage our recent CEO transition, 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 August 6, 2025, as well as 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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