Seres Therapeutics Announces Early Clinical Data Showing Potential for SER-155 in Immune Checkpoint Inhibitor-Related Enterocolitis (irEC), a Frequent Adverse Reaction That Forces Many Patients to Halt Cancer Treatment

July 8, 2026

80% of SER-155 recipients achieved immunosuppressive-free clinical response of diarrhea (a primary symptom of irEC) at Day 15 in the Investigator-Sponsored Trial (IST) conducted by Memorial Sloan Kettering Cancer Center (MSK)

SER-155 has potential to treat irEC, a frequent side effect of immune checkpoint inhibitors (ICIs) that often causes halting of cancer treatment, without requiring treatment with systemic immunosuppressive drugs

SER-155 was well tolerated, with no drug-related serious adverse events observed

Drug pharmacology data provide confirmatory evidence of Seres' live biotherapeutics operating as designed to repair the mucosal epithelial barrier and reduce gastrointestinal inflammation, which supports possible expansion into multiple other inflammatory and immune diseases

Company to host webcast today, July 8, at 8:30 am ET

CAMBRIDGE, Mass., July 08, 2026 (GLOBE NEWSWIRE) -- Seres Therapeutics, Inc. (Nasdaq: MCRB), (Seres or the Company), a leading live biotherapeutics company, today announced encouraging top-line results from an IST evaluating SER-155 in patients with irEC. The study (NCT06801067), conducted at MSK, by Principal Investigator David Faleck, M.D., Director of Inflammatory and Immune-Related Bowel Diseases, evaluated SER-155 in 15 patients with moderate-to-severe (Grade 2- 3) irEC, which affects approximately 25% of all immune checkpoint inhibitor (ICI) therapy recipients in the US. Clinical guidelines for these patients stipulate halting of ICI cancer treatment and initiation of systemic immunosuppressive corticosteroids, which are associated with clinically meaningful toxicities and other negative consequences, including: systemic immunosuppression, increased infection risk, metabolic complications, and potential interference with cancer treatment. There remains a significant unmet need for systemic immunosuppressive-free therapeutic approaches that reduce gastrointestinal inflammation and diarrhea and may allow patients who develop irEC to avoid disruption of their life-saving ICI cancer treatment. Participants in the study were on a wide range of ICI types, including PD-1 inhibitors (Keytruda®, Opdivo®, Zynz®), PD-L1 inhibitors (Imfinzi®, Bavencio®), CTLA-4 inhibitors (Yervoy®, Imjudo®), LAG-3 inhibitor (Opdualag®), and combinations thereof. The promising study results support continued development of SER-155 to treat irEC.

Topline Clinical Results

Day 15 Data

- Following SER-155 dosing, 12 of 15 participants (80%) achieved an immunosuppressive-free clinical response at Day 15, the primary endpoint, defined as at least a 1-grade improvement in diarrhea symptoms without immunosuppressive therapy (i.e., a corticosteroid and/or biologic immunomodulator drug). Notably, 8 of these 12 responders (67%) achieved greater than or equal to a 2-grade improvement in diarrhea symptoms without immunosuppressive therapy at Day 15.
- At Day 15, 5 of 15 participants (33%) achieved immunosuppressive-free complete clinical remission, defined as total resolution of diarrhea symptoms to Grade 0, without immunosuppressive therapy.

Day 43 Data

- At Day 43, 5 of 15 participants (33%) maintained immunosuppressive-free clinical response, and, notably, 2 of 15 participants (13%) maintained immunosuppressive-free complete clinical remission.
- All 12 participants with immunosuppressive-free clinical response at Day 15 had the same, or better, diarrhea grade at Day 43. As noted, 5 maintained immunosuppressive-free clinical response at Day 43. The other 7 were treated with non-systemically acting, gastrointestinal-targeted immunosuppressives after Day 15.

Safety

- SER-155 was generally well tolerated through Day 43, with no safety concerns identified, consistent with the outcome in Seres' Phase 1b study of SER-155 in participants undergoing allogeneic hematopoietic cell transplantation (allo-HCT). There were no serious adverse events assessed as related to SER-155 and no bloodstream infections reported in the study through Day 43. Two participants experienced 2 non-serious adverse events each, assessed as possibly related to vancomycin and SER-155. All 4 adverse events were moderate in severity and were resolved.

Pharmacology

- SER-155 bacterial strain engraftment (a measure of drug pharmacokinetics and strain growth in the gastrointestinal tract) was robust, with the majority of SER-155 strains observed across the study participants, and with kinetics, magnitude, and durability comparable to that observed in prior Seres clinical studies.
- Translational biomarkers of gastrointestinal inflammation (fecal calprotectin) and of mucosal epithelial barrier integrity (fecal albumin), which were elevated in participants at baseline, prior to SER-155 dosing, both showed decreases post SER-155 treatment, with statistically significant reductions achieved by Day 43, reflecting improvement in two mechanistically linked dimensions of irEC disease. Data suggest that administration of SER-155 led to improvement in mucosal epithelial barrier integrity, providing support for potential further development in multiple other inflammatory and immune diseases.

"We are extremely pleased with the study data from our long-time collaborator, MSK, which highlight SER-155's potential as a non-immunosuppressive treatment for irEC, which could enable patients to continue their ICI cancer treatment," said Richard Kender, Executive Chairman and Interim CEO of Seres. "We are engaging with potential partners, including companies with ICI franchises, as we evaluate next steps for the development of SER-155 in irEC. We also continue to engage with potential collaborators and financing partners as we seek funding to advance the Phase 2 study of SER-155 in allo-HCT, and development in our broader pipeline."

Matthew Henn, Ph.D., President and Chief Scientific Officer of Seres added, "These clinical and pharmacological results underscore the potential of SER-155 to address mucosal epithelial barrier dysfunction and gastrointestinal inflammation through disease pathways not targeted by existing therapies. Beyond irEC, we believe these encouraging data support continued development of Seres' live biotherapeutic platform to target microbe-specific functions linked to multiple inflammatory and immune diseases in addition to irEC, such as ulcerative colitis and Crohn's disease."

"Patients receiving ICI treatment who develop irEC face significant challenges, as current management often necessitates interruption or discontinuation of checkpoint inhibitor therapy and treatment with systemic immunosuppressives, which are associated with clinically significant side effects," commented Dr. Faleck. "These results suggest SER-155 may offer a promising, novel approach to managing irEC, with the potential to reduce reliance on systemic immunosuppressive therapies, while also helping patients continue ICI treatment. We look forward to continued development to further understand the role microbiome therapeutics could play in this setting and the broader opportunity to support the growing number of patients receiving checkpoint inhibitors across multiple cancer types. We intend to present the IST results at a future medical conference."

Jonathan Peled, M.D., Ph.D., Bone Marrow Transplant Specialist and Cellular Therapist, MSK, noted, "MSK has partnered with Seres for over a decade, advancing research aimed at improving outcomes for cancer patients. As an investigator in Seres' Phase 1b study of SER-155 in allo-HCT, I observed the meaningful reduction in bloodstream infections in patients receiving SER-155. I am now further encouraged by the results of SER-155 in patients with irEC."

Webcast Information
Seres' management will host a webcast today, July 8, 2026, at 8:30 a.m. ET. To listen to the audio portion of the webcast, please dial 800-715-9871 (domestic) or 646-307-1963 (international) and reference the conference ID number 3327556. To join the live webcast, please visit the "Events and Presentations" tab within the "Investors and News" section of the Seres website at www.serestherapeutics.com. A replay will be available on the Seres website after the event and will be archived for at least 21 days.

About the Investigator-Sponsored Trial (IST) (NCT06801067)
This investigator-sponsored, open-label trial evaluated SER-155 in 15 participants with Grade 2-3 (moderate to severe) irEC who were naïve to immunosuppressive therapy. Participants received microbiome conditioning with oral vancomycin on Days 1 and 2, followed by oral administration of SER-155 (2 capsules per day) for 12 consecutive days. The primary efficacy endpoint was the proportion of participants achieving an immunosuppressive-free clinical response on Day 15, defined as at least a 1-grade improvement in diarrhea symptoms, without the use of immunosuppressive therapy. The study is also evaluating the safety, tolerability, and drug pharmacology of SER-155. The IST is designed to inform if SER-155 may provide an alternate treatment for irEC with the potential to prevent interruption of the patient's ICI cancer treatment. Participants in the study were on a wide range of ICI types, including PD-1 inhibitors (Keytruda®, Opdivo®, Zynyz®), PD-L1 inhibitors (Imfinzi®, Bavencio®), CTLA-4 inhibitors (Yervoy®, Imjudo®), LAG-3 inhibitor (Opdualag®), and combinations thereof. All ICIs administered include irEC as adverse reactions in their labels.

About Immune Checkpoint Inhibitors (ICIs)
ICIs have revolutionized cancer treatment across multiple tumor types. ICIs represent one of the largest and fastest-growing segments of the oncology market, with the worldwide market valued at well over $50 billion in 2025. Well known ICI brands include: Keytruda®, Opdivo® and Yervoy®. ICIs work by blocking "checkpoint" proteins—such as PD-1, PD-L1, and CTLA-4—that tumor cells exploit to hide from and inactivate T-cells, effectively turning the immune system's attack mode back on. The amplified immune response can also attack healthy tissue, causing serious immune-related adverse events, such as immune checkpoint inhibitor-related enterocolitis (irEC).

About Immune checkpoint inhibitor-related enterocolitis (irEC)
IrEC, also called immune-mediated colitis, is among the most frequent and severe immune-related adverse reactions in ICI recipients. irEC can result in diarrhea, gastrointestinal inflammation, abdominal pain, blood in stool, among other symptoms, and may significantly affect quality of life and can progress to serious and life-threatening consequences. irEC has been linked to hospitalizations with longer lengths of stay, higher ICU use, high rehospitalization rates and mortality. Current standard of care for those who suffer from moderate to severe irEC (in the US this approximates 25% of all ICI recipients) requires halting their ICI cancer therapy and initiating a systemic immunosuppressive corticosteroid and/or biologic, further compromising the patient's immune system. There are numerous toxicities associated with systemic immunosuppressives, and the immunosuppression may negate the anti-cancer effect of the ICI therapy, putting patient cancer outcomes at risk. A significant unmet need remains for systemic immunosuppressive-free therapeutic approaches that reduce gastrointestinal inflammation and diarrhea and may allow patients who develop irEC to avoid disruption of their ICI therapy.

About Seres Therapeutics
Seres Therapeutics, Inc. (Nasdaq: MCRB) is a clinical-stage biotechnology company developing novel live biotherapeutics, with a focus on therapies designed to allow patients to maintain their cancer therapy when faced with significant side effects, and that treat inflammatory and immune diseases. The Company led the development and FDA approval of VOWST™, the first orally administered microbiome therapeutic, which was subsequently

divested to Nestlé Health Science. SER-155, a cultivated multi-strain biotherapeutic, which has received Breakthrough Therapy and Fast Track designations, is being advanced for the prevention of bloodstream infections in patients undergoing allogeneic hematopoietic stem cell transplant (allo-HCT), and is Phase 2 ready, pending receipt of funding. An investigator-sponsored trial of SER-155 in immune checkpoint inhibitor–related enterocolitis (irEC) to further evaluate the potential breadth of the Company's live biotherapeutic platform is ongoing. The Company is advancing IND-enabling studies for SER-603, which is in development for inflammatory bowel disease. Mechanistically, Seres' biotherapeutics target the mucosal epithelial barrier-immune interface and are optimized to modulate host function to increase epithelium integrity, induce immune homeostasis, and prevent the colonization and overgrowth of harmful bacteria in the gastrointestinal tract. 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: SER-155 and its intended uses and benefits in irEC; our clinical development plans for SER-155 and SER-603; potential accessibility for patients; the timing and results of clinical studies and data readouts; current or future product candidates and their potential impacts and outcomes; engagement with potential partners and financing sources; our ability to access capital to advance our programs; 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) 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; (13) impact of our recent management transitions and appointments and our ability to retain key personnel; and (14) disruptions at the FDA or other government agencies. These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended May 5, 2026, 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, except as required by law, 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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