# Seres Therapeutics Announces VOWST™ Commercial Launch Update and US FDA Fast Track Designation for SER-155

January 9, 2024

***VOWST preliminary net sales of approximately $10.4 million (unaudited) for the fourth quarter of 2023***

***Significant adoption of VOWST since commercial launch in June 2023 through year-end 2023 with 2,833 patient enrollment forms received and 2,015 new patient starts***

***SER-155 Phase 1b placebo-controlled Cohort 2 data readout anticipated in third quarter of 2024***

***Seres to Present at 42nd Annual J.P. Morgan Healthcare Conference on January 10, 2024***

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 9, 2024-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, today announced preliminary key VOWST (fecal microbiota spores, live-brpk) launch metrics and receipt of US FDA Fast Track Designation for SER-155 ahead of its presentation at the 42nd Annual J.P. Morgan Healthcare Conference on Wednesday, January 10th. VOWST, the first FDA approved orally administered microbiome therapeutic, received FDA approval in April of 2023 and is indicated to prevent the recurrence of *Clostridioides difficile* infection (CDI) in adults following antibacterial treatment for recurrent CDI (rCDI). VOWST is being commercialized by Nestlé Health Science in collaboration with Seres. SER-155 builds upon the clinical success of VOWST and is an investigational oral, cultivated microbiome therapeutic designed to prevent GI-associated bacterial infections, including blood stream infections, and to reduce the incidence of severe acute graft-versus-host disease (GvHD) in immunocompromised patients undergoing allogeneic hematopoietic stem cell transplantation (allo-HSCT).

“In 2023, VOWST received FDA approval with a broad indication, which includes use in first recurrence patients. We are thrilled, along with our collaborators at Nestlé Health Science, to help patients exit the vicious cycle of recurrence that happens far too often with CDI,” said Eric Shaff, President and Chief Executive Officer at Seres. “The strong adoption of VOWST since launch is indicative of the high unmet need in this category, the highly compelling clinical profile of VOWST, and the early success we have demonstrated in educating healthcare providers, payers and patients about this new treatment option.”

“Seres is looking forward to 2024 as we continue to build on our initial VOWST commercial success. The SER-155 Cohort-2 readout is expected in the third quarter, and we are excited to announce receipt of Fast Track Designation for SER-155 to reduce the risk of infection and GvHD in allo-HSCT patients. Fast Track Designation is awarded to expedite both drug development and FDA review of drugs to treat serious conditions and fulfill an unmet medical need.”

“I’m pleased with the significant progress made on our launch priorities since the commercial availability of VOWST in June,” said Terri Young, Ph.D., Chief Commercial and Strategy Officer at Seres. “Healthcare provider education efforts have scaled creating a positive customer experience with faster and higher conversion of enrollments to new patient starts. We look forward to continuing our efforts in 2024 with Nestlé Health Science and expect to make significant progress increasing the adoption of VOWST and achieving additional payer coverage.”

Seres will present at the 42nd annual J.P. Morgan Healthcare Conference on Wednesday, January 10, 2024, at 12:45 pm ET / 9:45 am PT. The live presentation and archived webcast will be accessible from the company’s website at www.serestherapeutics.com.

**VOWST Commercial Performance**

Broad demand for VOWST has been observed across rCDI patients and healthcare providers since product launch in June 2023:

- Fourth quarter net sales were approximately $10.4 million (unaudited) and reflected a gross-to-net reduction of 11%. Total 2023 net sales since launch in June were approximately $19.6 million (unaudited) and reflected a gross-to-net reduction of 13%.
- Fourth quarter completed prescription enrollment forms received for VOWST were 1,322; of those 1,082 resulted in new patient starts by year-end 2023.
- Total 2023 completed prescription enrollment forms received for VOWST since launch were 2,833; of those 2,015 resulted in new patient starts by year-end 2023.
- In 2023, prescription enrollment forms were submitted by approximately 1,330 unique healthcare providers (HCPs) since launch; approximately 340 HCPs have prescribed VOWST to more than one patient.

**Seres 2023 Highlights**

- VOWST received FDA approval in April as the first and only FDA approved orally administered microbiome therapeutic to prevent recurrence of CDI in patients with rCDI, after treatment with standard of care antibacterials.
- Strong adoption of VOWST since commercial launch in June 2023 with broad utilization, continued quarter over quarter growth, and significant progress achieving patient access.
- Production of VOWST commercial supply enabled a strong commercial launch within weeks of approval; progress in expansion of VOWST manufacturing capacity.
- SER-155 Phase 1b Cohort 1 clinical data showed favorable tolerability, successful drug bacteria engraftment, and a substantial reduction in pathogen domination in the gastrointestinal microbiome supporting progression to the placebo-controlled Cohort 2.
- SER-155 received US FDA Fast Track Designation.
- Completed strategic restructuring of Company to focus resources and investment on continued VOWST growth, completion of SER-155 Phase 1b study and supporting longer-term business sustainability.
- Named to “TIME 100 Most Influential Companies” list of 100 companies making an extraordinary impact around the world.

**Anticipated 2024 Milestones**

- Expect continued progress in 2024 towards commercial priorities including:
    - Expansion of the number of HCPs prescribing VOWST as a result of new efforts scaled in Q4 2023 such as strengthened promotional campaigns and expanded reach of HCP and patient digital promotion.
    - Growth of VOWST utilization earlier in the treatment paradigm including in patients experiencing their first recurrence.
    - Maintenance of strong patient access and expansion of payer coverage for VOWST across Commercial and Medicare Part D plans.
    - Increasing penetration of the hospital outflow patient segment.
- SER-155 Phase 1b placebo-controlled Cohort 2 data readout anticipated in third quarter of 2024.

Seres ended 2023 with preliminary cash, cash equivalents and investments of approximately $128 million (unaudited). Seres anticipates that this year-end cash balance, in conjunction with the anticipated savings from the restructuring announced in November 2023 and the expected receipt of the $45 million Tranche B under its existing senior secured debt facility (the Term Loan Facility) with Oaktree Capital Management, L.P. (Oaktree), will support its operations into the fourth quarter of 2024.

**INDICATION AND IMPORTANT SAFETY INFORMATION FOR VOWST**

**INDICATION**

VOWST is indicated to prevent the recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI.

Limitation of Use: VOWST is not indicated for treatment of CDI.

**IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS**

**Transmissible infectious agents:** Because VOWST is manufactured from human fecal matter, it may carry a risk of transmitting infectious agents. Report any infection that is suspected to have been transmitted by VOWST to Aimmune Therapeutics, Inc. at 1-833-246-2566.

**Potential presence of food allergens:** VOWST may contain food allergens. The potential to cause adverse reactions due to food allergens is unknown.

**ADVERSE REACTIONS**

The most common adverse reactions (reported in ≥5% of participants) were abdominal distension (31.1%), fatigue (22.2%), constipation (14.4%), chills (11.1%), and diarrhea (10.0%).

To report SUSPECTED ADVERSE REACTIONS, contact Aimmune Therapeutics at 1-833-AIM-2KNO (1-833-246-2566), or the FDA at 1-800-FDA-1088, or visit www.fda.gov/MedWatch.

**DRUG INTERACTIONS**

Do not administer antibacterials concurrently with VOWST.

**Please see Full Prescribing Information and Patient Information**

**About Seres Therapeutics**

Seres Therapeutics, Inc. (Nasdaq: MCRB) is a commercial-stage company developing novel microbiome therapeutics for serious diseases. Seres' lead program, VOWST™, obtained U.S. FDA approval in April 2023 as the first orally administered microbiome therapeutic to prevent recurrence of *C. difficile* infection (CDI) in adults following antibacterial treatment for recurrent CDI and is being commercialized in collaboration with Nestlé Health Science. Seres is evaluating SER-155 in a Phase 1b study in patients receiving allogeneic hematopoietic stem cell transplantation. 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 the commercial success and continued growth of VOWST, the timing and results of our clinical studies, access to additional debt tranches, the sufficiency of cash to fund operations, and other statements which 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: we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding; our limited operating history; our novel approach to therapeutic intervention; our reliance on third parties and collaborators to conduct our clinical trials, manufacture our product or product candidates and develop and commercialize our product or product candidates, if approved; the unknown degree and competing factors of market acceptance for VOWST; the competition we will face; our ability to protect our intellectual property; and 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 November 2, 2023, 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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