



## Seres Therapeutics Corporate Overview

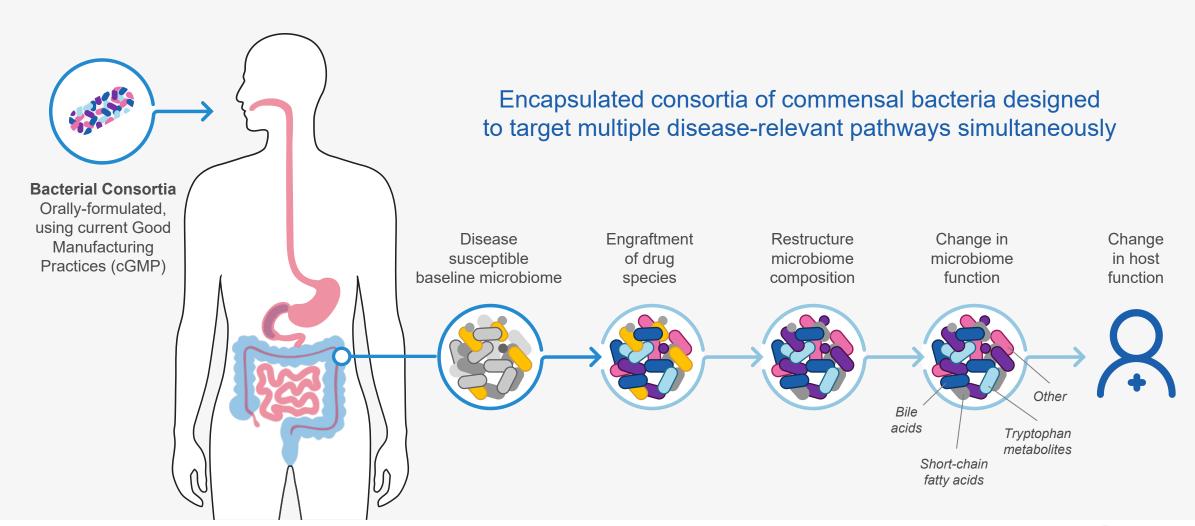
March 2023

## **Forward Looking Statements**

Some of the statements in this presentation constitute "forward looking statements" under the Private Securities Litigation Reform Act of 1995, including, but not limited to the potential approval and launch of SER-109; the anticipated indication for SER-109; the anticipated supply of SER-109; the potential for microbiome therapeutics to protect against infection; the timing of clinical development; our development opportunities and plans; the ultimate safety and efficacy data for our products; the sufficiency of cash to fund operations; and other statements which are not historical fact. Such statements are subject to important factors, risks and uncertainties, such as those discussed under the caption "Risk Factors" in the Company's Annual Report on Form 10-K filed on March 7, 2023, and its other filings with the SEC, that may cause actual results to differ materially from those expressed or implied by such forward looking statements. Any forward-looking statements included herein represent our views as of today only. We may update these statements, but we disclaim any obligation to do so.



# Seres Mission: Transforming the Lives of Patients Worldwide with Revolutionary Microbiome Therapeutics





## Strategic Priorities | Expanding Microbiome Therapeutic Leadership

Bring SER-109, potential firstin-class oral microbiome therapeutic, to adult recurrent CDI patients

- SER-109 BLA submission complete
- PDUFA date April 26, 2023
- Anticipated launch soon after potential FDA approval
- Co-commercialization agreement with Nestlé Health Science

Maximize opportunities in Infection Protection

- in
- Phase 1b to explore SER-155 in preventing bacterial infections, including those caused by organisms that harbor antimicrobial resistance, in allo-HSCT patients, and GvHD
- DSMB clearance to SER-155 Phase 1b cohort 2, based on preplanned assessment of initial safety data
- Broad preclinical portfolio for medically compromised patients, including cancer neutropenia, cirrhosis and solid organ transplant

Continue research to inform further development in ulcerative colitis and immune modulation

Potential for biomarker-based patient selection



## Corporate Priority is to Advance SER-109 to FDA Approval and Execute Successful Product Launch

FECTION PF	ROTECTION	Preclinical	Phase 1b	Phase 2b	Phase 3	Collaborators
SER-109	Recurrent <i>C. difficile</i> – ECOSP	OR III and ECOSPOR IV stud	ies completed; BLA acc	epted and priority review ເ	underway	Nestle 1,2 HealthScience
SER-155	Bloodstream and antimicrobial GvHD in allogenic hematopoie					Memorial Sloan Kettering Cancer Center
	geting antimicrobial-resistant infectio groups (e.g., cancer neutropenia, ci					
MUNE MOD	ULATION					
SER-287	Ulcerative colitis <sup>4</sup>			Research ongoing to determine future		Nestle 1 HealthScience ®
SER-301	Ulcerative colitis <sup>4</sup>			ulcerative colitis develop	ment plans	Nestle 1 HealthScience 8
		mation to improve				

- 1. Collaboration with Nestlé Health Science, announced Jan. 11, 2016, regarding C. difficile and IBD programs for markets outside of North America.
- 2. SER-109 co-commercialization agreement for North America with Nestlé Health Science announced July 1, 2021
- 3. SER-155 preclinical work was supported in part by CARB-X
- 4. Translational research activities are ongoing, informed by learnings from SER-287 Phase 2b and SER-301 Phase 1b study data, to evaluate the potential to utilize biomarker-based patient selection and stratification in future clinical development efforts



SER-109 and Recurrent *C. difficile* Infection





### **CDI – Urgent Public Health Threat**



**Spore-forming**, toxin-producing, gram-positive, anaerobic bacteria



Symptoms include colitis and severe, watery diarrhea with up to 15 bowel movements a day



Acute onset of severe symptoms leads to hospitalization for many patients



High probability of recurrence >20%, usually within 1-2 weeks after completion of antibiotic therapy

~156K

Recurrent CDI cases estimated for 2023 (U.S.)

20,000+

CDI deaths per year (U.S.)









40-50%

Risk of recurrence escalates
once a patient has an initial
recurrence, which can trap patients
in a vicious cycle

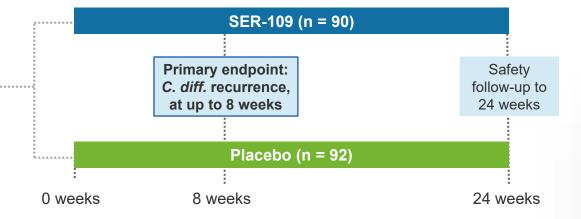
1. Centers for Disease Control and Prevention. Antibiotic Resistance Threats in the United States, 2019. US Department of Health and Human Services, CDC; 2019. doi:10.15620/cdc:82532 2. Feuerstadt P et al. J Med Econ. 2020;23(6):603-609. 3. Chilton CH et al. Clin Microbiol Infect. 2017;24(5):476-482. 4. Ofosu A. Ann Gastroenterol. 2016;29(2):147-154. 5. Cole SA, Stahl TJ. Clin Colon Rectal Surg. 2015;28(2):65-69. doi:10.1055/s-0035-1547333. 6. Wilcox MH et al. Open Forum Infect Dis. 2020;7(5):ofaa114. doi:10.1093/ofid/ofaa114 7. Centers for Disease Control and Prevention. Your risk of C. diff. Accessed January 28, 2022. https://www.cdc.gov/cdiff/risk.html 8. Jiang ZD et al. Aliment Pharmacol Ther. 2017;45(7):899-908.9. McFarland LV et al. Am J Gastroenterol. 2002;97(7):1769-1775, https://www.fda.gov/news-events/press-announcements/fda-approves-first-fecal-microbiota-product.



## **SER-109 ECOSPOR III Study Results**

#### TRIAL DESIGN

- Multiply recurrent
   C. difficile patients (n=182)
- All subjects treated with standard of care antibiotics



#### PRIMARY EFFICACY ENDPOINT RESULTS

Time point	SER-109 (N =89) n (%) of recurrences	Placebo (N =93)  n (%) of recurrences	Relative risk (95%CI)	p-value (p1/p2)
Week 8	<b>11</b> (12.4)	<b>37</b> (39.8)	<b>0.32</b> (0.18-0.58)	<0.001 / <0.001

Approximately

88%

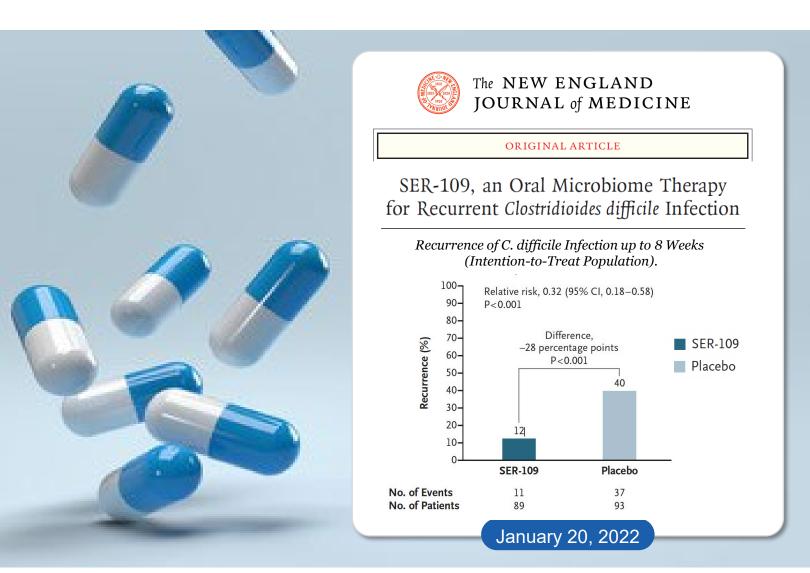
Recurrence-free rate\*

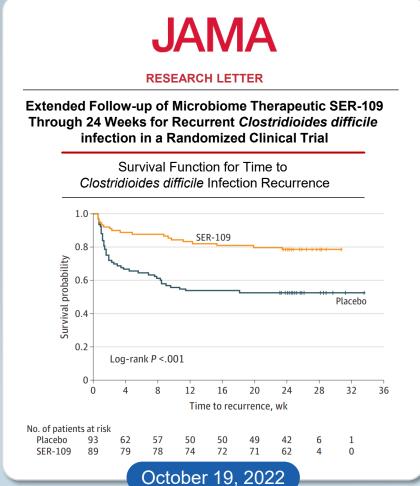
Note: Sustained clinical response % is calculated as 100% minus % with recurrence



<sup>·</sup> Compared to 60% in the placebo arm

#### **SER-109 Phase 3 Results Published in Premier Journals**







## **ECOSPOR III – Well Tolerated Safety Profile Observed**

Adverse Events (AEs) Through 8 Weeks (Safety Population) <sup>2</sup>	SER-109 (n=90) n (%)	Placebo (n=92) n (%)
Any adverse event	84 (93)	84 (91)
Adverse event related or possibly related to SER-109 or placebo	46 (51)	48 (52)
Serious adverse event <sup>3</sup>	7 (8)	15 (16)
Adverse event of special interest that occurred or worsened after initiation of SER-109 or placebo	1 (1)	1 (1)
Serious adverse event or an adverse event of special interest that occurred or worsened after initiation of SER-109 or placebo and was related or possibly related to SER-109 or placebo	0	0
Serious adverse event leading to withdrawal from the trial	0	1 (1)
Adverse event leading to death <sup>4</sup>	2 (2)	0



<sup>1.</sup> Feuerstadt P et al. *N Engl J Med*. 2022;386(3):220-229. 2. Adverse events were coded with the use of the Medical Dictionary for Regulatory Activities, version 20.0. Adverse events of special interest included invasive infections such as bacteremia, meningitis, and abscess. 3. Many of the serious adverse events were related to the primary endpoint of recurrent *C. difficile* infection, which was more common in the placebo group than in the SER-109 group. 4. Three deaths occurred in the SER-109 group, all of which were reported by the investigator as being unrelated to SER-109; 2 of the participants had onset of fatal adverse events within the 8-week period after dosing, but only 1 of these 2 participants died during that period.

## ECOSPOR IV Open-label Study (n=263) Published in JAMA

#### **Results Extend ECOSPOR III Data**

Overall safety profile through 24week follow up:

SER-109 was well tolerated, and extend the safety population

**Recurrence-free rate:** 

91%

similar to 88% rate observed in ECOSPOR III

Recurrence-free rate in patients with first recurrence:

94%

Seres believes that based on disease pathophysiology and overall Phase 3 results, SER-109 may provide clinical benefit across entire recurrent CDI patient population



## Delivering SER-109 to Patients; PDUFA Date April 26, 2023

#### **BLA** submission

- BLA submission completed Q3 2022; acceptance confirmed by FDA Oct. 2022
- Expanded access program ongoing across multiple US sites

We are here

Priority FDA review

- Accelerated review based on Breakthrough Therapy Designation
- Orphan Drug Designation

Potential SER-109 approval and launch

• PDUFA date April 26, 2023



### SER-109 May Fill an Important Unmet Need – Prevention of Recurrence

- Early and urgent intervention in the cycle of recurrence may prevent further recurrences
- SER-109 could have a unique place in the treatment algorithm, potentially transforming standard of care

If approved, SER-109 may serve as appropriate foundational therapy for a broad set of patients caught in the vicious cycle of recurrence



#### **Well Positioned for Commercial Success**

1

Highly Favorable Product Profile, Pending Approval

2

Substantial Market Opportunity

3

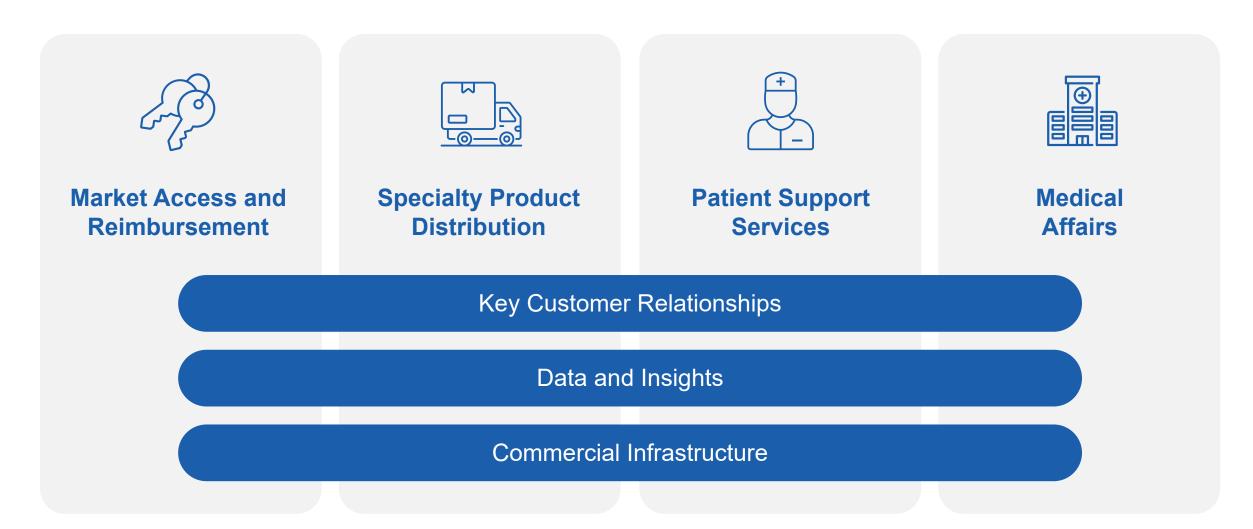
Commercial Capabilities, Including Manufacturing

Preparing for successful SER-109 commercial launch alongside collaborator, Nestlé Health Science





# Seres and Nestlé Health Science Have Full Suite of Resources and Complementary Capabilities to Support SER-109 Launch, if Approved





# Focusing on the Most Important Areas at Launch to Set Up SER-109 for Long Term Success, if Approved

#### LAND First 12 months

## **EXPAND** >12 months

Patient Access



Product Choice

- Implement payer policies as quickly as possible to ease access to treatment
- Access programs to support positive early experience
- Ensure high quality HUB and partner support for patients
- Focus awareness and education efforts on highest volume HCPs
- Establish supportive ecosystems in high volume hospitals
- Patient activation strategies focused on highly engaged patients

- Optimize patient support offerings
- Continue to address remaining access barriers

- Expand demand generation efforts
- Broaden patient activation efforts



## Well Positioned to Supply Commercial Demand at Launch and Beyond

10+ years of Investment in Technology and Facilities for anaerobic bacterial therapeutics:

Recipharm

- In-house GMP Manufacturing and Quality Control
- Supported by high-quality CMOs: Recipharm, PCI





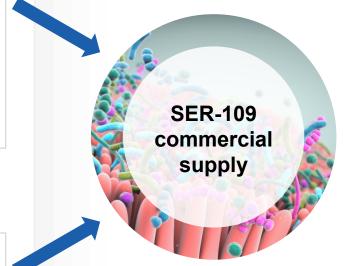








Joint venture between Chr. Hansen and Lonza with offices in Switzerland and Denmark



Anticipate Bacthera commercial drug production in 2024 for release in 2025, as the expected number of patients treated with SER-109 expands



SER-155 and Infection Protection Franchise





## **Antimicrobial Resistant Infections - Urgent Public Health Threat**

#### **Major burden to society**



Declared "one of the world's most urgent threats"



**\$20 billion** excess direct healthcare costs

**35,000 deaths** per year in US

#### Many high-risk patient populations

- Allogeneic HSCT recipients at risk for bloodstream infections
- Additional patients with suppressed immune systems (e.g., transplant recipients, cancer patients)
- Patients with chronic diseases (e.g., cirrhosis)

Limited innovation despite substantial and growing impact

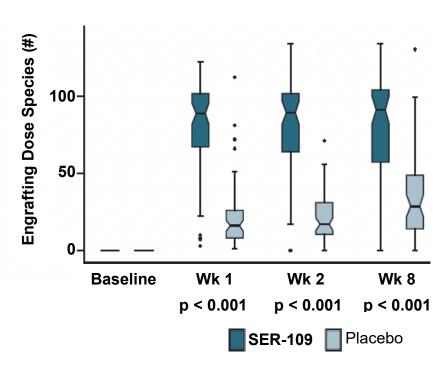


## **SER-109 Clinical Data Provide Proof of Concept for SER-155**



Engraftment of SER-109 dose species

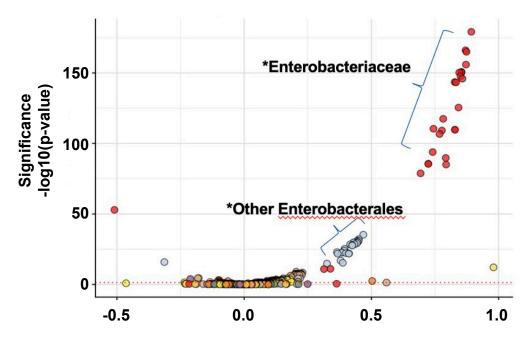
#### **SER-109 Dose Species Engraftment**



N = 182 patients enrolled; figure shows data for 143 patients at baseline Feuerstadt P NEJM 2022; 386:220-9



Engraftment reduces proteobacteria\* associated with antimicrobial resistance genes



Correlation between abundance of bacterial family and antibiotic resistance genes by drug class

Seres Thereapeutics unpublished data



# Potential Novel Approach to Address Infection - SER-155 Phase 1b Study Ongoing

	SER-155
Microbiome drug type	Rationally designed, cultivated product; spore + vegetative species
Stage	Phase 1b - study ongoing
Indication	Infection, bacteremia & GvHD in HSCT for cancer
Lead Collaborator	Memorial Sloan Kettering Cancer Center

#### Phase 1b study design and objectives

~70

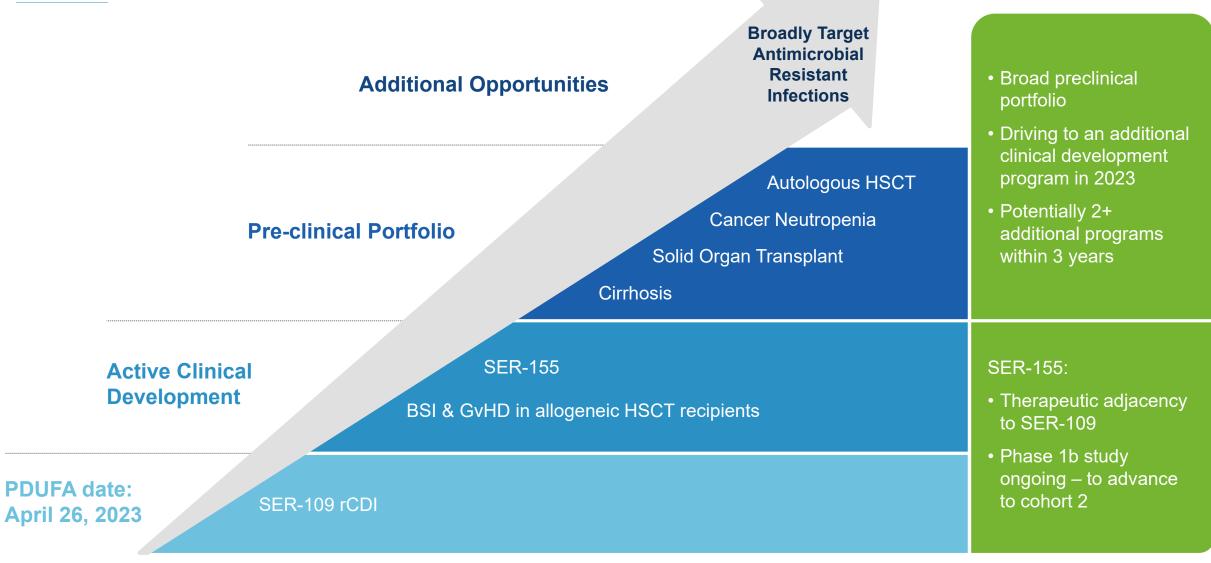
patients in an open-label and a randomized, double-blind, placebo-controlled cohort

 To evaluate safety and tolerability before and after allogeneic hematopoietic stem cell transplantation, as well as SER-155 engraftment bacteria and efficacy of SER-155 in preventing infections and GvHD

- Enrollment of Study Cohort 2 ongoing, following DSMB clearance of Cohort 1
- Initial safety and pharmacological data from Cohort 1 expected in May 2023



## Maximizing the Opportunity in Infection Protection and AMR





## Well Positioned to Extend Microbiome Therapeutic Leadership in 2023

#### Potential SER-109 BLA approval and successful launch for rCDI

- BLA submission complete; FDA PDUFA target action date of April 26, 2023
- Working closely with Nestlé to prepare for commercial launch
- Producing supply to support commercial demand
- \$125M milestone payment anticipated from Nestlé upon FDA approval

#### **Opportunities in Infection Protection**

- SER-155 Phase 1b ongoing; initial safety and pharmacological data in May 2023
- Preclinical programs ongoing with potential to address large immunocompromised patient populations

#### Continued research in UC and microbiome therapeutic platform

- Ongoing research to inform plans for continued development in UC
- Extend industry-leading microbiome therapeutic platform capabilities

Dec. 31, 2022 cash balance:

\$181.3 million



# Continued Microbiome Therapeutic Leadership, Anticipated Compelling Growth and Value Creation

**2023** 

**2025** 

Potential SER-109 approval and successful launch for rCDI

Advancing opportunities in Infection Protection and other therapeutic areas



- SER-109 transforming standard of care for a broad population of rCDI patients
- SER-155 in late-stage clinical development
- 2+ additional Infection Protection candidates in clinical development
- Extend industry-leading microbiome therapeutic platform

