SER-109 Investor Day

Creating a new wave of medicines powered by the human microbiome

May 27, 2020

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, our development plans, the promise and potential impact of any of our microbiome therapeutics or clinical trial data, the ability of our clinical trials to support approval, the timing of clinical studies, the sufficiency of cash to fund operations, and the potential benefits of Seres’ collaborations. 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-Q filed on May 7, 2020, 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.

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Seres Therapeutics Overview

Platform	Leader in microbiome drug development with differentiated drug discovery, manufacturing and clinical capabilities
Focus	Prioritized pipeline in *C. difficile* infection, ulcerative colitis, oncology
Pipeline	• SER-109 for *C. difficile* infection; Phase 3 top-line data in mid 2020 • SER-287 for ulcerative colitis in Phase 2b • SER-401 for metastatic melanoma in Phase 1b • SER-301 for ulcerative colitis; clinical development initiated • SER-155 for infection, bacteremia & GvHD in HSCT for cancer; clinical development initiated
Team	Experienced, highly accomplished leadership team

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Agenda and Speakers

Introductory remarks

Eric Shaff
President and Chief Executive Officer, Seres Therapeutics

SER-109 Clinical development

Lisa von Moltke, M.D.
Chief Medical Officer, Seres Therapeutics

SER-109 Manufacturing

John Auniņš, Ph.D.
Chief Technology Officer, Seres Therapeutics

Clinical burden of *Clostridioides difficile* infection

Mark Wilcox, M.D.
Professor of Medical Microbiology, University of Leeds, and Deputy Chair of the U.K. Department of Health's Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)

SER-109 Drug pharmacology

Matt Henn, Ph.D.
Chief Scientific Officer, Seres Therapeutics

Q&A

Panel

Key Messages for Today

- Seres is the leader in microbiome therapeutic development
- *C. difficile* infection is disease area that is in desperate need of a new approach, where the safety AND efficacy of existing choices are suboptimal and poorly understood
- We have a differentiated approach, including rigorous study protocol (toxin) and safety (CMC) that set us up for success
- Microbiome therapeutics are here, now. We believe SER-109 will be the tipping point

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Clinical burden of *Clostridioides difficile* infection

Mark Wilcox, M.D.

Professor of Medical Microbiology
University of Leeds & Leeds Teaching Hospitals;
National Health Service Antimicrobial Resistance Programme Board; and
Lead on *C. difficile* for Public Health England, UK.

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C. difficile infection is a toxin-mediated disease leading to inflammatory colitis

Hallmark of this bacterial disease is diarrhea

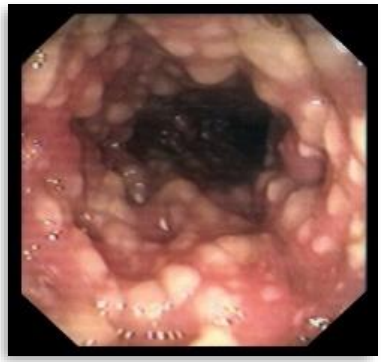
- Can be severe with 10-15 bowel movements in a day

Other symptoms:

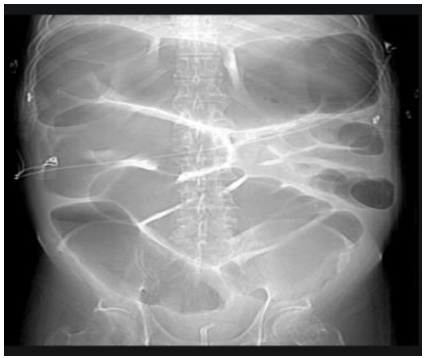
- Nausea, abdominal cramping
- Low grade fever
- Fatigue, weight loss

***C. difficile* bacteria**

Severe disease



Pseudomembranous colitis



Toxic megacolon

Risk of perforation and death

Feuerstadt P Clin Transl Gastro 2015; Smits WK Nature Rev 2016

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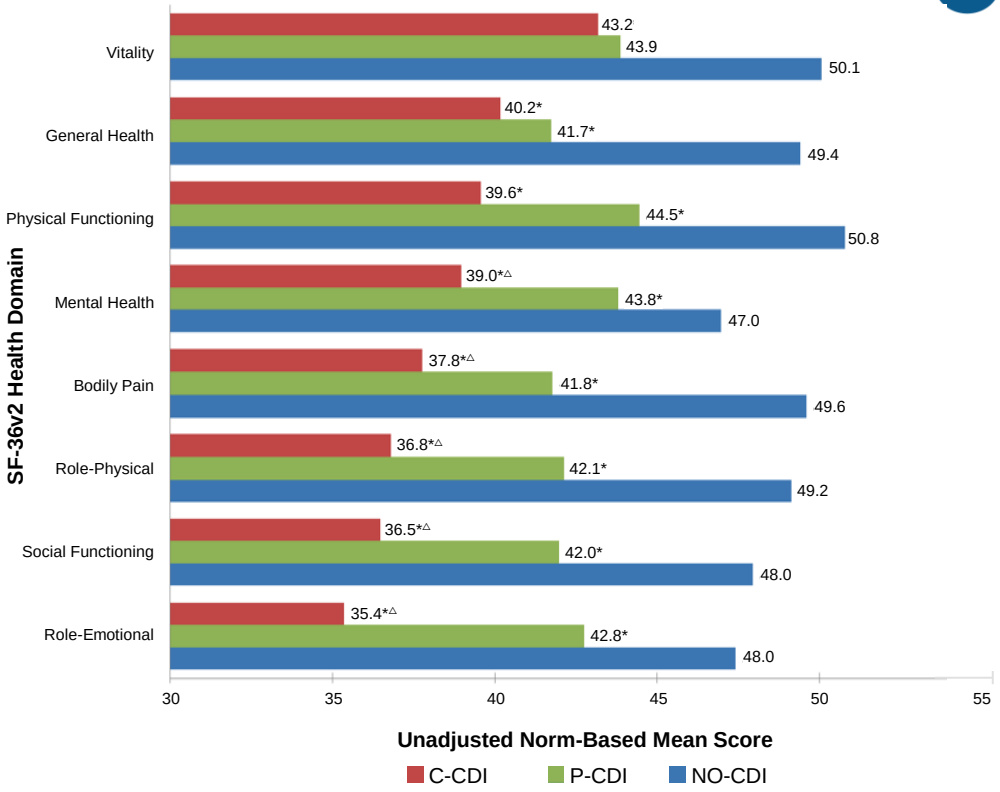
C. difficile infection is associated with significantly lower quality of life

Severe burden on patients

- Poor quality of life and loss of productivity due to disabling diarrhea

Survey of 350,370 participants with lower QOL in all health domains:

- General health and vitality
- Mental and emotional health
- Physical and social functioning



Heinrich *Dig Dis Sci 2018*

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Burden of *C. difficile* infection on healthcare systems

ESTIMATED BURDEN OF *C. DIFF* INFECTION CASES: 462,100 (95% CI 428,600 to 495,600)

224,000
hospitalizations

20,500
in-hospital deaths

Greater incidence in patients ≥65 years
than all other age groups combined

ADVERSE IMPACT ON SHORT AND LONG-TERM OUTCOMES AT 30 DAYS

2.5x
risk of skilled nursing facility transfer

1.7x
risk long-term care facility transfer

1.77x
Increased risk of overall death and 10.9% attributable mortality

TREATMENT COSTS ESTIMATED >$5B ANNUALLY

Driven by length of hospital stay and readmissions with additional burden of CMS penalties

2-DAY
increase in hospital length-of-stay

25%
of *C. difficile* infection patients will experience ≥1 readmissions

34,000
total annual cost of a recurrent *C. difficile* infection patient

1. Desai, *BMC Infectious Diseases* 2016; Zhang,*Clinical Infectious Diseases* 2018 Rodrigues *Infect Control Hosp Epidemiol* 2016; Lessa *N Engl J Med* 2015; Guh *N Engl J Med* 2020; Nitzan *World J Gastroenterol* 2013; Olsen *Infect Control Hosp Epidemiol* 2019.

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Current treatment options are suboptimal

Primary *C. difficile* infection:

Vancomycin or fidaxomicin associated with rapid recurrence in 25% within 1 to 3 weeks of antibiotic completion due to original strain

Risk factors: age >65 years, female gender, hospitalization

Bezlotoxumab for those at high-risk for recurrence

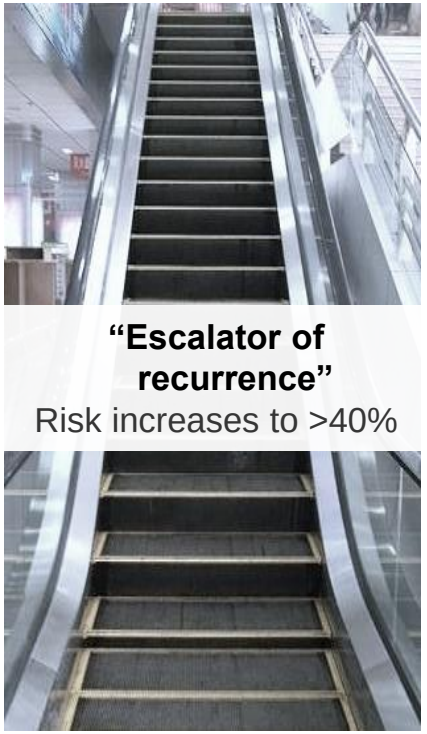
- **Lower efficacy in those with recurrent disease vs *primary C. difficile* infection**

Treatment options are more limited for multiply recurrent disease:

Long-term treatment with vancomycin over 6-10 weeks

- High rates of recurrence of 42-74%

None of these approaches address disease pathogenesis



"Escalator of recurrence"
Risk increases to >40%

McDonald *Clin Infect Dis* 2018; Wilcox NEJM 2017; Louie *NEJM* 2011; Hengel *Open Forum Infect Dis* 2020; Hota *Clin Infect Dis* 2017.

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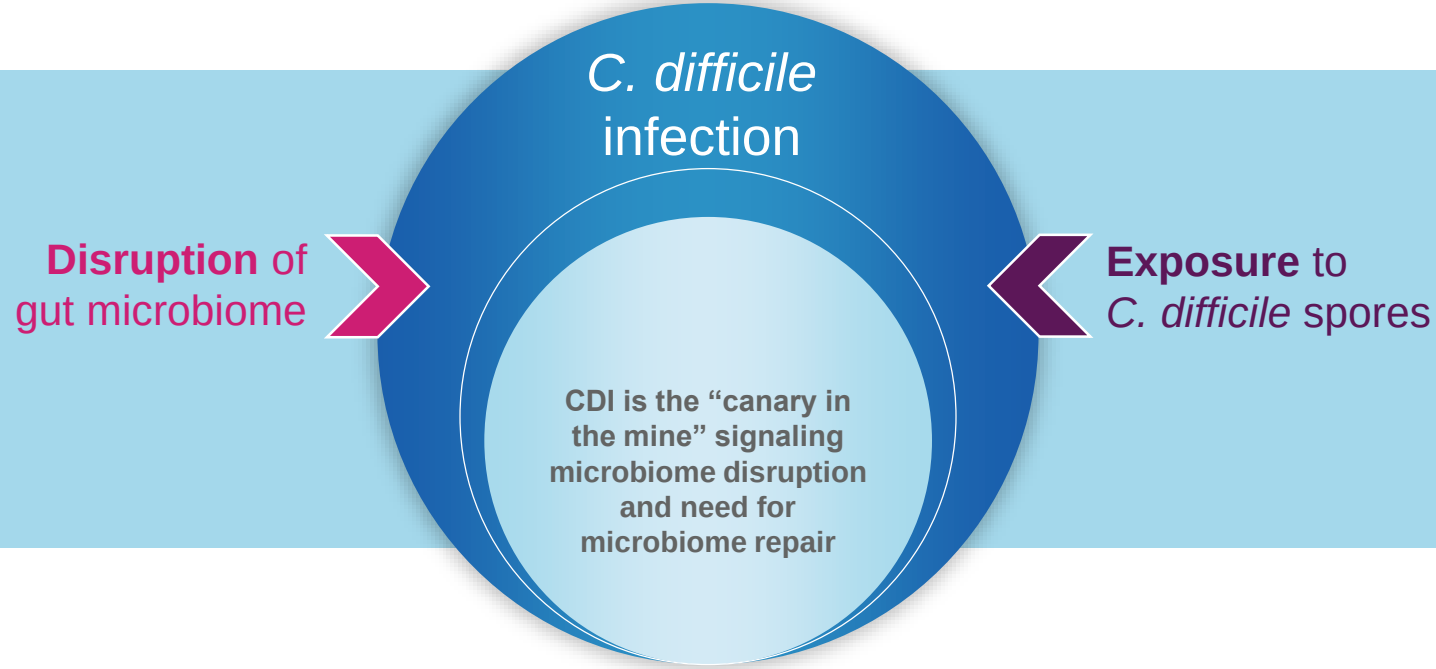
The pathogenesis of *C. difficile* infection is a two-hit process:
Disruption and Exposure

Leading risk factor for *C. difficile* infection is exposure to antibiotics, which disrupt the microbiome



McGovern *Clin Infect Dis* 2020; Theriot *Ann Review Micro* 2015

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Fecal transplant is a proof-of-concept supporting importance of microbiome recovery

Transfer of minimally processed stool from a screened donor to a recipient

- Wide range of efficacy reported with lower cure rates in randomized trials (67%) than open-label studies (82%)
- Sustained recovery associated with gain of Firmicute bacteria
- FMT delivery via colonoscopy appears more efficacious than enema

IDSA recommended FMT for recurrent *C. difficile* infection after 3 trials of antibiotics based on only "moderate quality evidence"

"FMT Efficacy Likely Influenced By"

Time from last *C. difficile* infection episode
Subjects with distant history of *C. difficile* infection

Treatment prior to FMT
Subjects on long-term vancomycin

Patient selection
Use of inappropriate *C. difficile* infection diagnostics for suspected recurrence

Wilcox *Open Forum Infect Dis* 2020; McDonald *Clin Infect Dis* 2018

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Selection of study subjects: The impact of the diagnostic approach

Two Categories of Diagnostic Assays

- **Testing for toxin production**
  (Hallmark of disease)
- **Testing for *C. difficile* by PCR**
  (whether or not it makes toxin)

Why is this important?

- +Toxin test strongly correlates with active disease and is recommended by IDSA for suspected recurrence
- PCR cannot differentiate colonization from infection leading to overdiagnosis

No published controlled trial of FMT or FMT-like microbiome drugs has required toxin testing in clinical trials, including those with read-out in 2020, with one exception of ECOSPOR-III

Wilcox *Open Forum Infect Dis* 2020; McDonald *Clin Infect Dis* 2018; Polage JAMA *Intern Med* 2015; Fang *J Clin Micro* 2017

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FMT safety concerns amplified by recent high-profile FDA alerts

The NEW ENGLAND JOURNAL of MEDICINE

Drug-Resistant *E. coli* Bacteremia Transmitted by Fecal Microbiota Transplant → **Transmission of drug-resistant bacteria discovered during clinical**

U.S. FOOD & DRUG ADMINISTRATION

Safety Alert Regarding Use of Fecal Microbiota for Transplantation and Risk of Serious Adverse Events Likely Due to Transmission of Pathogenic Organisms → **Contaminated FMT due to inadequate donor**

U.S. FOOD & DRUG ADMINISTRATION

Safety Alert Regarding Use of Fecal Microbiota for Transplantation and Additional Safety Protections Pertaining to SARS-CoV-2 and COVID-19 → **New concerns about potential COVID-19 transmission via FMT**

Using the universe of microbes in stool brings unintended consequences

Need a better, more focused approach to microbiome repair

DeFillip *NEJM* 2019; Blaser *NEJM* 2019; Wilcox *Open Forum Infect Dis* 2020; https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/safety-alert-regarding-use-fecal-microbiota-transplantation-and-risk-serious-adverse-events-likely; https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/safety-alert-regarding-use-fecal-microbiota-transplantation-and-additional-safety-protections

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Summary

- *C. difficile* infection causes debilitating toxin-mediated diarrhea with a significant impact on morbidity and mortality and quality of life
- The pathogenesis of *C. difficile* infection requires “two hits”: Disruption of the microbiome and exposure to *C. difficile* spores
- Patients suffer recurrences because current treatments do not address the disrupted microbiome, the proximal cause of disease
- Although FMT provides proof-of concept supporting the need for microbiome recovery, estimates of efficacy are unclear and FDA safety alerts highlight the inherent risks of using minimally processed stool

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In Search of a Sustained Clinical Response: The Role of Advanced Microbiome Therapeutics

Lisa von Moltke, M.D.

Chief Medical Officer

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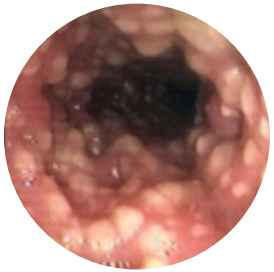
C. difficile targeted antibiotics are necessary but insufficient for treatment

When the microbiome is disrupted, *C. difficile* spores germinate into toxin-producing bacteria

Diarrhea and colitis



Pseudomembranous colitis

Antibiotics without any effect on *C. difficile* spores

***C. difficile* spores**

***C. difficile* bacteria**

Antibiotics kill *C. difficile* and reduce toxin that cause disease

***C. difficile* spores are the reservoir that feed the vicious cycle of recurrence**
Pathogenesis is a two-hit process and requires a two-pronged treatment approach

McGovern *Clin Infect Dis* 2020

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SER-109 is an investigational, donor derived, spore-based therapeutic designed to break the cycle of recurrent *C. difficile* infection

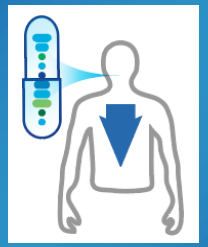
Strong Scientific Rationale

- Spore-forming Firmicute bacteria prevent *C. difficile* germination and growth

Oral Formulation

- Spores are resistant to gastric acid, facilitating oral delivery to gastrointestinal tract

SER-109



Oral formulation of Firmicute bacteria spores

Granted FDA Status

- Obtained FDA Breakthrough & Orphan Drug designations

Safety

- Prior clinical studies demonstrate favorable tolerability & safety
- Spore purification mitigates risk of transmission of known and unknown infectious agents

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Phase 3 ECOSPOR-III trial design informed by prior clinical studies

Diagnosis of qualifying episode in Phase 2 likely led to inclusion of subjects without recurrent *C. difficile* infection

- PCR utilized in most patients, which confounded results

Dosing matters

- Reanalysis of Phase 1 dose-ranging cohort gave critical insights into importance of dose

LESSONS LEARNED FORM FOUNDATION FOR ECOSPOR-III

- Toxin testing required at study entry and time of suspected recurrence to ensure accuracy
- Total dose increased to $3x10^7$ SCFUs a day for 3 days, to ensure rapid onset of action of SER-109 before recurrence

Editorial Commentary by Vince Young, MD, PhD, University of Michigan:

> *"The results of their analysis, including the potential confounding effects of PCR versus toxin-based methods used to diagnose CDI should inform others conducting clinical studies and trials of this important nosocomial infection."*

McGovern *Clin Infect Dis* 2020

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Favorable safety profile of SER-109 in Phase 2

- Mainly mild or moderate AEs
- Most common AEs were gastrointestinal disorders including diarrhea, abdominal pain, flatulence and nausea
- None of the serious adverse events were considered drug-related by the investigators

Favorable safety profile may result from the fact that SER-109 is composed of Firmicutes spores, which normally reside within the healthy microbiome

McGovern *Clin Infect Dis* 2020

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Phase 3 ECOSPOR-III Trial: Study population

Adults ≥ 18 years of age

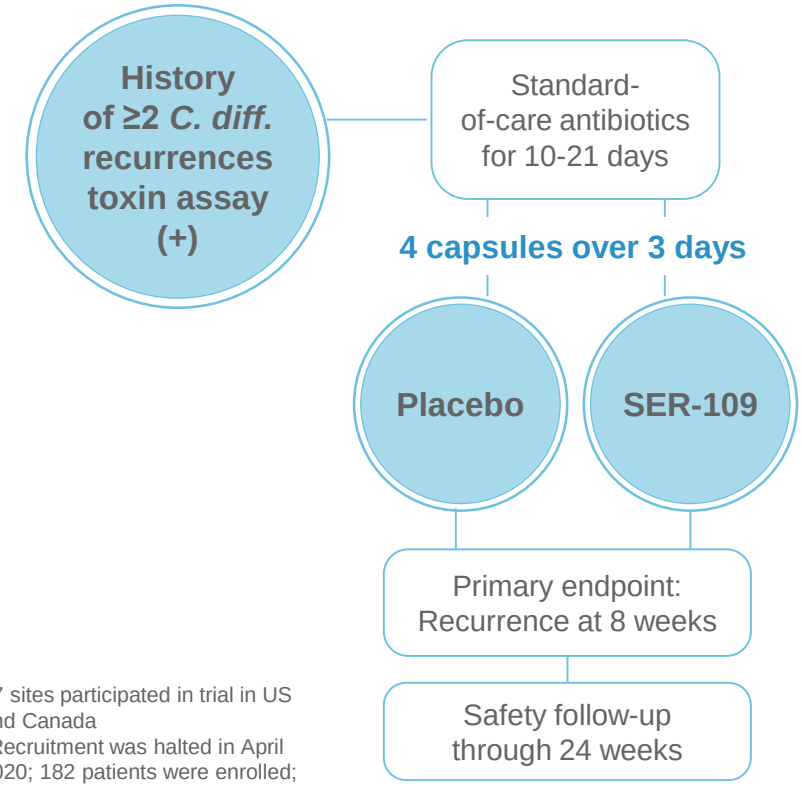
Inclusion criteria

A qualifying episode of *C. difficile* infection as defined by:
- ≥ 3 unformed stools per day for 2 consecutive days plus
- Positive *C. difficile* stool toxin assay
- A clinical response to antibiotics (<3 unformed stools in 24 hours for 2 or more consecutive days before randomization

Other criteria:
- ≥ 3 episodes of *C. difficile* infection within the previous 12 months, inclusive of the current episode, with documented history of ≥ 2 episodes, inclusive of the current (qualifying) episode

ECOSPOR-III is the model for all *C. difficile* infection trials

Top-line results in mid-2020



67 sites participated in trial in US and Canada
*Recruitment was halted in April 2020; 182 patients were enrolled; mainly outpatients

Key features that differentiate ECOSPOR-III from other trials

1

All subjects with recent onset of *C. difficile* infection

2

Subjects on suppressive antibiotics excluded

3

Placebo arm is well-blinded and will provide valuable insights on safety and efficacy

4

Strict diagnostic criteria

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ECOSPOR-III is the model for all *C. difficile* infection trials

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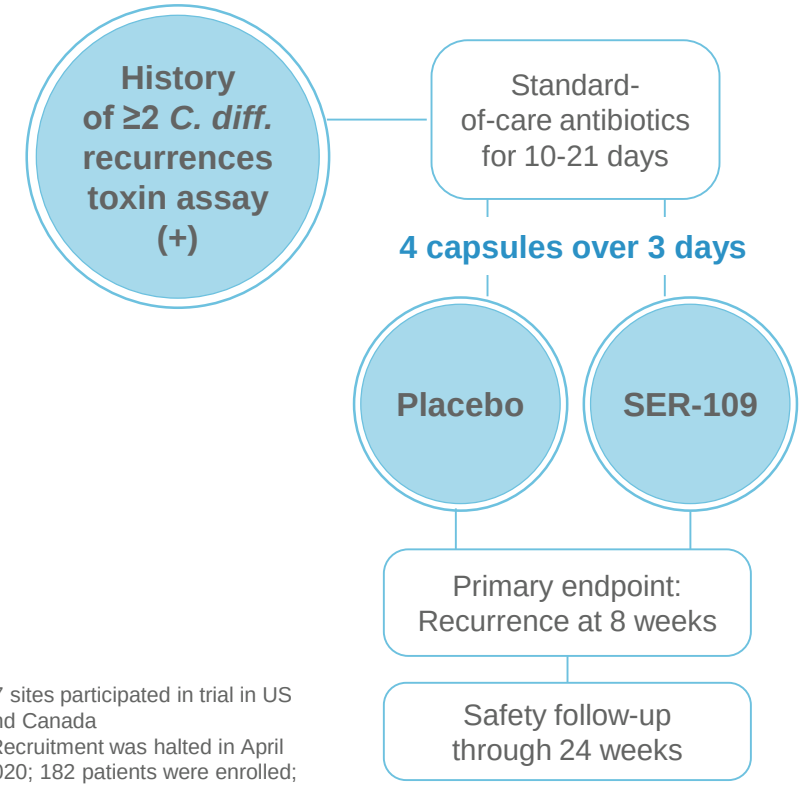

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Strict diagnostic criteria

Critical importance of toxin testing already confirmed in ECOSPOR-III trial
The most common reason for screen failure was a negative toxin assay

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ECOSPOR-III: What does success look like?
Clinical viewpoint

SER-109 efficacy and safety will be demonstrated in patients with true *C. difficile* infection

- Clinically compelling data with statistically significant delta between placebo and SER-109 arms
- Safety and tolerability will be consistent with Ph1 and Ph2 trials

Seres will deliver on all key aspects of this Phase 3 clinical trial

- First rigorously controlled trial of a microbiome therapeutic to require *C. difficile* toxin assays, enhancing confidence in efficacy estimates
- Safety profile may reflect that Firmicute spores are dominant in the healthy microbiome
- SER-109 will stand in a class of its own based on inactivation and purification processes that mitigate risk, beyond donor screening alone

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ECOSPOR-III: What does success look like?
Regulatory viewpoint

- With favorable ECOSPOR III data, plan to engage with FDA regarding path to approval
- ECOSPOR III has potential to be a single pivotal study to support SER-109 product registration, though additional safety data may be required
- SER-109 has obtained Breakthrough and Orphan Drug Designations
- Seres position on FMT: Enforcement discretion for FMT should be eliminated with the approval of a microbiome therapeutic for recurrent *C. difficile* infection

Summary

- *C. difficile* infection is a two-hit process that requires a two-pronged treatment approach to prevent the vicious cycle of recurrence
- SER-109 is an investigational, orally-delivered ecology of Firmicute spores essential for gut health
- Our purification and inactivation processes are designed to deliver only the essential components needed for microbiome repair while mitigating patient risk
- ECOSPOR-III will set the bar for all *C. difficile* infection trials in the field based on prior learnings and Seres' scientific leadership in microbiome sciences
- We are hopeful that with increased SER-109 dosing, ECOSPOR-III will demonstrate compelling efficacy and a favorable safety profile
- ECOSPOR-III has potential to be single pivotal study, though additional safety data may be required

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SER-109 Drug Pharmacology

Matthew Henn, Ph.D.

Chief Scientific Officer

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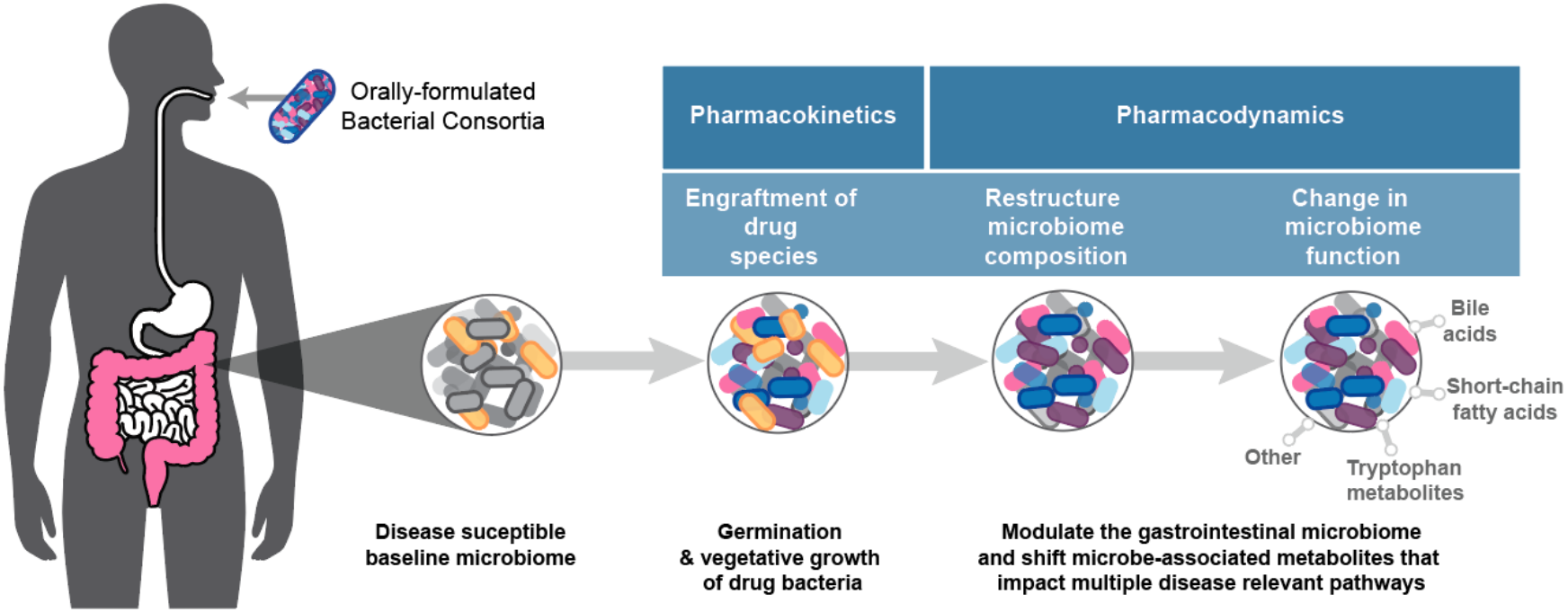
Seres microbiome therapeutics are designed to rapidly restructure the microbiome and modulate disease relevant pathways



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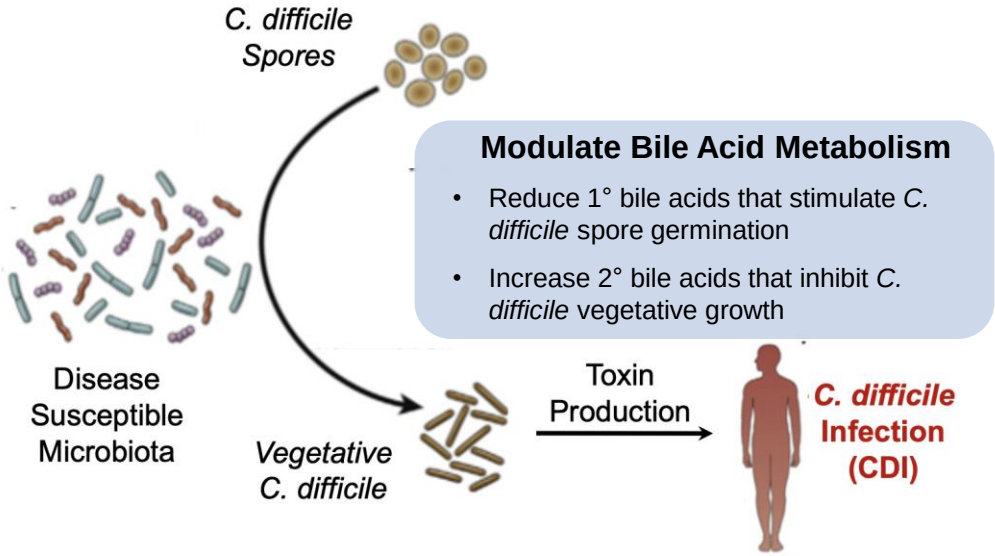
SER-109 mechanism targets disrupted microbiota and prevention of *C. difficile* germination and growth

Engraft commensal Firmicute spore-forming bacteria that compete with *C. difficile*

- *In human* studies show loss of Firmicutes diversity in *C. difficile* subjects
- *In vivo* studies support Firmicutes as active bacteria



Modulate Bile Acid Metabolism

- Reduce 1° bile acids that stimulate *C. difficile* spore germination
- Increase 2° bile acids that inhibit *C. difficile* vegetative growth

SER-109 targets the proximal cause of disease, the gastrointestinal microbiome

Figure adapted from Britton *Gastroenterology* 2014.

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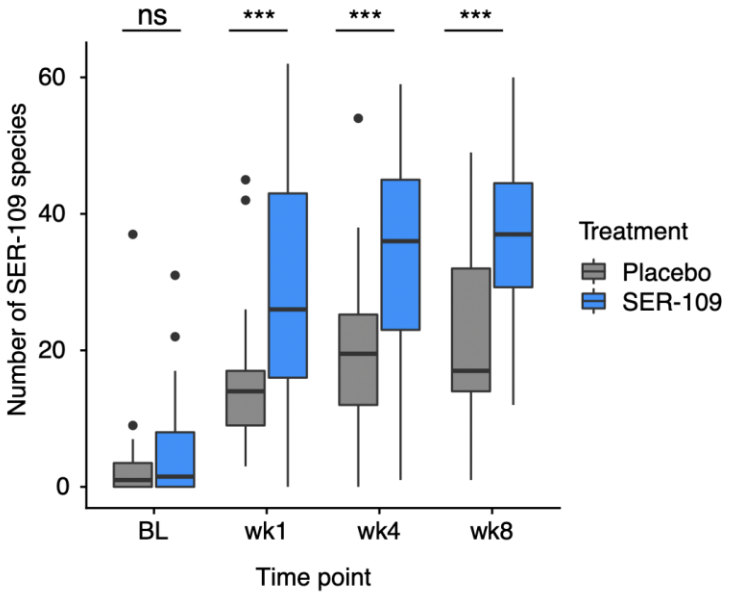
Engraftment of SER-109 bacteria occurs rapidly with significantly greater number of drug species observed in treated versus placebo subjects

Engraftment of drug species was observed by one-week post treatment & was durable through 8 weeks

- Pre-treatment diversity of drug species in subjects was not different between placebo and SER-109 subjects
- SER-109 arm significantly greater than placebo by one week
- Engraftment did not vary by drug lot



Species detected using genomic markers based on whole metagenomic shotgun sequence

McGovern *Clin Infect Dis* 2020

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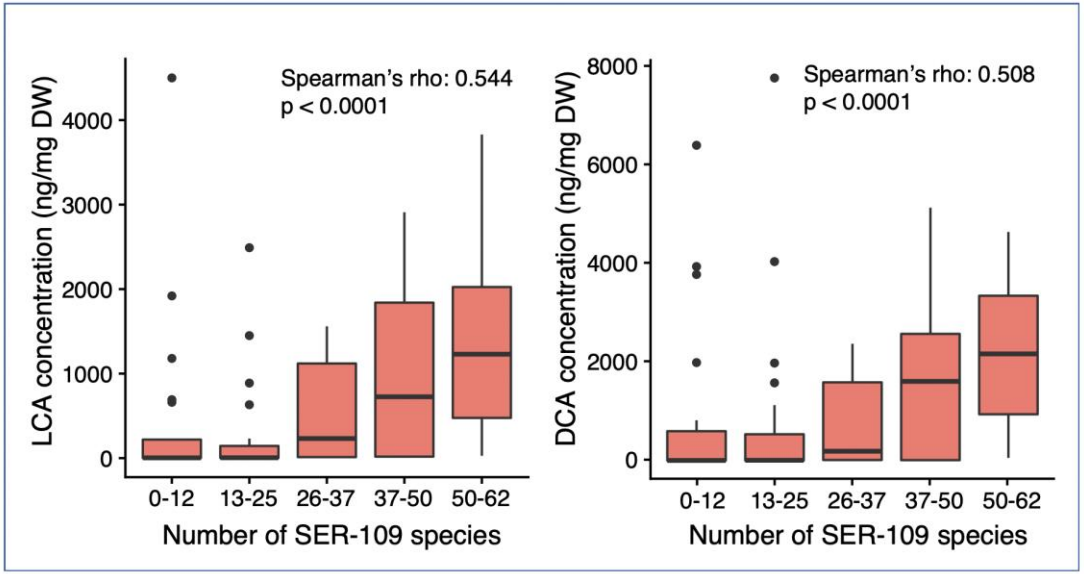
Presence of SER-109 bacteria is associated with a metabolite shift that inhibit *C. difficile* spore germination and bacterial growth

By week 1, positive correlation seen between SER-109 species and concentration of 2° bile acids LCA & DCA



LCA = Lithocholic acid
DCA = Deoxycholic acid

McGovern *Clin Infect Dis* 2020

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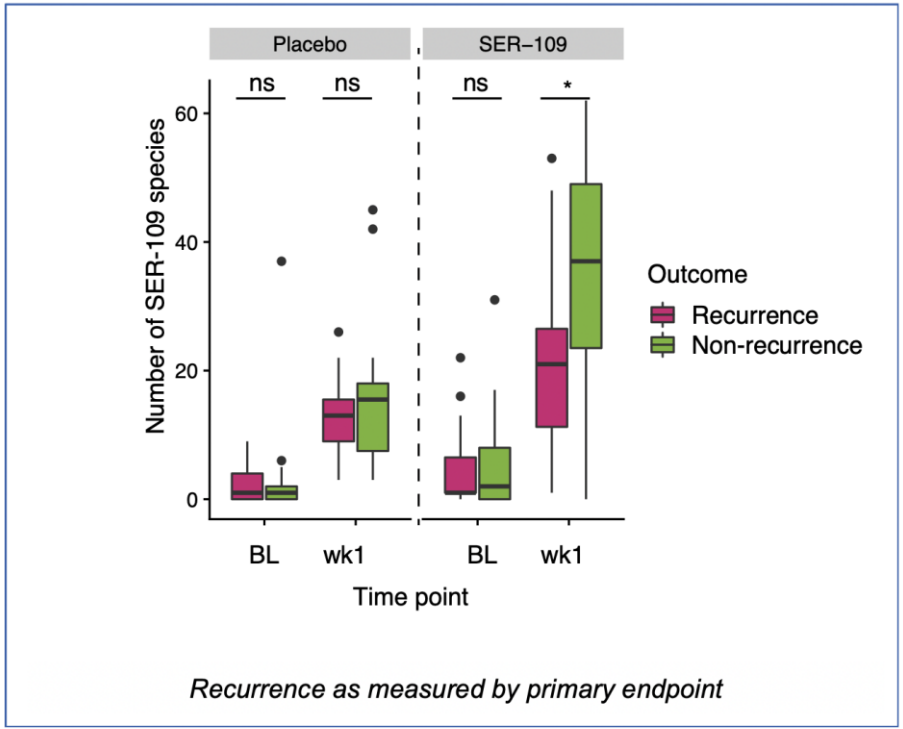
Greater engraftment of SER-109 is associated with reduction of *C. difficile* infection recurrence

Significantly greater engraftment of SER-109 species at week-1 ($p<0.05$) was correlated with reduced rates of *C. difficile* infection recurrences

- Differences between non-recurrent & recurrent not observed in placebo subjects
- Early engraftment is likely important since >50% of recurrences occurred by this early timepoint

Therapeutic window is early after antibiotic treatment



Recurrence as measured by primary endpoint

McGovern *Clin Infect Dis* 2020

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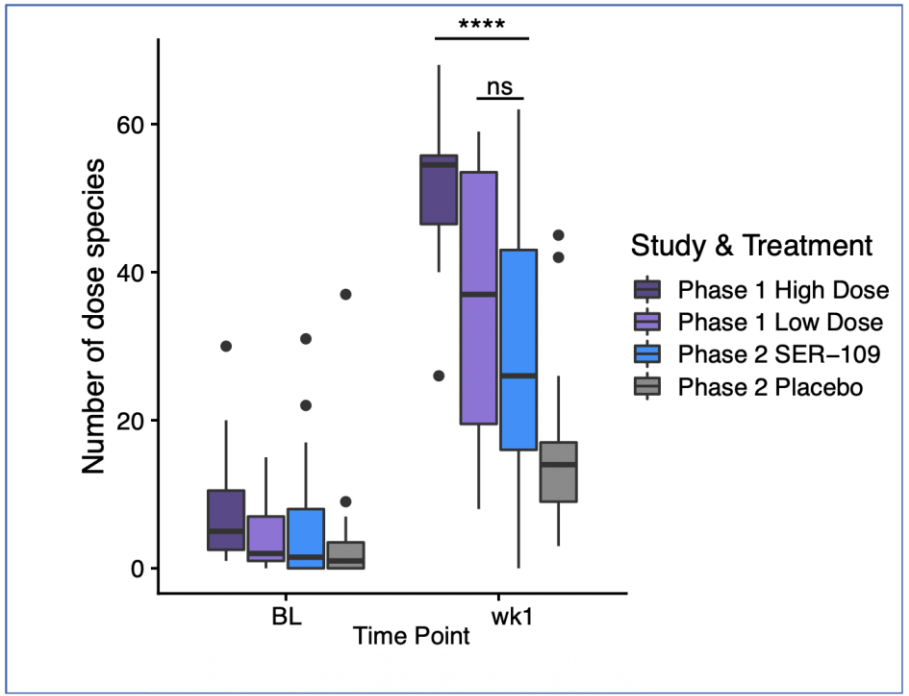
Higher dose of SER-109 can achieve greater engraftment of drug bacteria in treated patients

Re-evaluation of engraftment in the dose ranging cohort of Phase 1b in light of therapeutic window support a higher dose

- Prior to treatment, the number of SER-109 species was comparable across dose groups and clinical studies
- Phase 1b high-dose group had significantly greater and less variable engraftment at week-1 than Phase 2

Impact of dose on early engraftment informed Phase 3 dose



McGovern *Clin Infect Dis* 2020

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SER-109 treatment targets the proximal cause of *C. difficile* infection, the GI microbiome

- SER-109 mechanisms include the durable engraftment of drug bacteria (PK) and modulation of disease-relevant microbial-associated metabolites (PD)
- Rapid engraftment is associated with prevention of *C. difficile* infection recurrence and is dose-dependent
- Learnings from SER-109 pharmacology informed Phase 3 trial design and microbiome endpoints
- Seres in-house reverse translation platforms are powerful tools for drug discovery and pharmacology

SER-109 Production

John Auniņš, Ph.D.

Chief Technology Officer

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SER-109: A novel biologically-derived product adapted from proven approaches

Well-established Inactivation Paradigm, Validated by Pathogen Challenge Studies

Multi-Component, High Potency Active analogous to other natural biologics: IVIG, Premarin®, Otosporin®

Highly Stable Spore Drug Product

Donor Collection | **Pathogen Inactivation** | **Spore Purification** | **Drug Substance** QC | **Formulation & Encapsulation** | **Drug Product** QC | **Packaging & Distribution**

Follow Blood, Urine, and Tissue Product Paradigms

Conventional, Simple, Well-Understood Purification Steps

Off the Shelf Formulation and Capsule Packaging

Room Temp storage

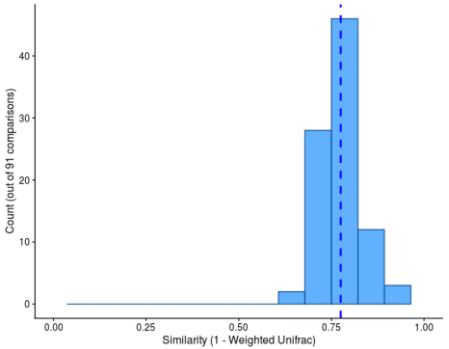
Straightforward Production Elements

- Individual operations and their features are well-established
- Modest production scales
- Hard shell capsule delivery enables standard processing, storage, distribution

Live vaccine-like product

- Provide small, potent spore dose, using the human gut as a bioreactor to amplify
- Modest donor program scale
- Results in a consistent product

Weighted UniFrac comparison of SER-109 lot composition



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Comprehensive safety approach to product

- Comprehensive donor program developed for SER-109 product
- Pathogen inactivation and clearance steps for vegetative bacteria and many potential pathogens incorporated into the process and validated
- Controlled cGMP bioprocessing environment
- Rigorous product testing to detect non-product microbiological contamination

ORGANISMS STUDIED FOR PATHOGEN CLEARANCE VALIDATION	
Virus	**Vegetative Bacteria**
Adenovirus 41	*Salmonella enterica*
Tulane Virus	*Helicobacter pylori*
Herpes Simplex Virus 1	*Listeria innocua*
Poliovirus 1	*Enterococcus faecalis*
Hepatitis A Virus	*Staphylococcus aureus*
Rotavirus A	
Fungi	**Parasites**
Candida albicans	*Cryptosporidium parvum* oocysts
Aspergillus brasiliensis spores	

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GMP manufacturing and quality systems

- Specialized, dedicated facilities addressing FDA and EMA guidance on manufacturing with spore-forming organisms
- Integrated manufacturing capabilities including Quality Control and Quality Assurance for Seres' products
- Overall > 98% success rate in batch release from initiation
- Product controls consistent with FDA statements for Live Biological Products
- FDA consultations collaborative and constructive with respect to CMC expectations

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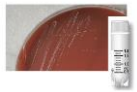
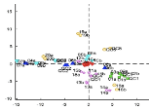
Fermented products platform (SER-301, SER-155)

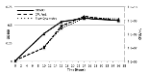
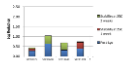
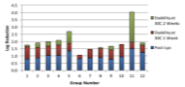
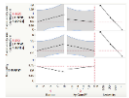
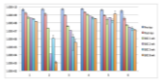




R&D Culture Starting Point → Primary cGMP Media Screen → Secondary cGMP Media Screen → Medium Balancing & Optimization → Process Optimization & Scale-up

Platform Fermentation Process Development

Platform Formulation and Delivery Technology

Fermentation Optimization → Strain Stability in Base Formulations → Candidate Formulation Screening → Formulation & Process Optimization → Long-term Stability Confirmation


Cell Banking & Inoculum


Drug Substance

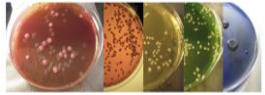

Drug Product

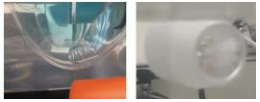

Quality Control

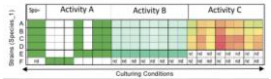
In-house GMP Manufacturing and Quality Control Capabilities

Novel QC assays

Dose Potency


Microbial Purity


Pharmaceutical Quality



Product Characterization

SERES THERAPEUTICS™

Summary

- SER-109 is unusual to manufacture, yet Seres has mastered the elements of manufacturing the product
- SER-109 is a well-characterized and consistent product candidate
- We have taken multiple safety precautions to ensure a safe product, which should not be impacted by emerging pathogens such as SARS-CoV-2
- Learnings from our most advanced product are being leveraged to feed newer fermented products including SER-301 and SER-155

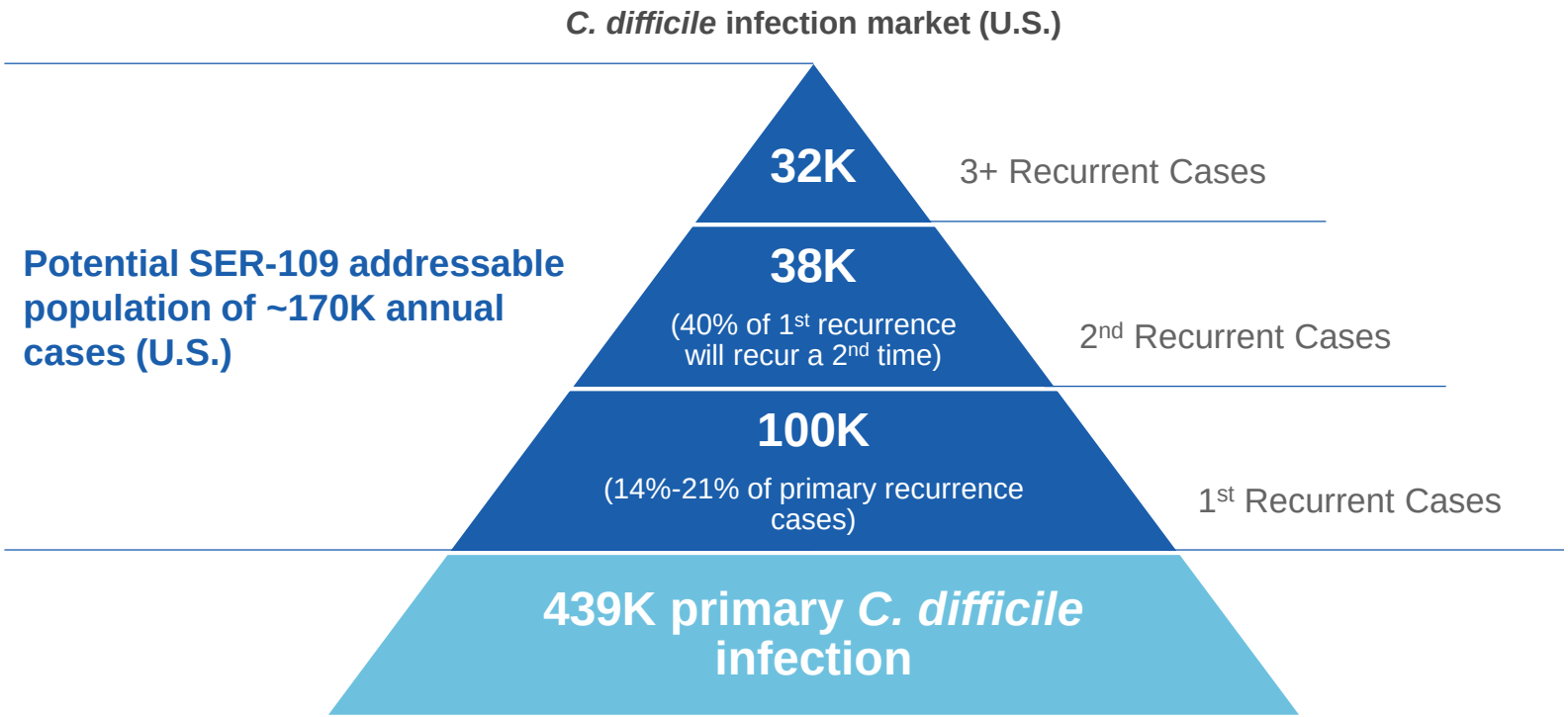
Closing Remarks

Eric Shaff

Chief Executive Officer

SERES THERAPEUTICS™

Broad SER-109 commercial potential in the U.S. and globally



1. Desai *BMC Infectious Diseases* 2016). Zhang *Clinical Infectious Diseases* 2018. Rodrigues, In*fect Control Hosp Epidemiol* 2016. Lessa *N Engl J Med* 2015.

SERES THERAPEUTICS™

Commercial readiness activities initiated

- *C. difficile* market opportunity assessment
- Key stakeholder primary research (physician, patient, and payer)
- Recurrent *C. difficile* infection patient segmentation and site-of-care analysis
- Publication and congress plan
- Deepening advocacy relationships
- Brand name development

SERES THERAPEUTICS™

SER-109 Investor Day

Creating a new wave of medicines powered by the human microbiome

May 27, 2020