



# Stifel 2017 Healthcare Conference

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President, Chief Executive Officer  
and Chairman

November 14, 2017



**SERES**  
THERAPEUTICS™

Leading the Microbiome Revolution

# Forward looking statements

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# Collaboration announced to advance microbiome therapeutic development for immuno-oncology



**MD Anderson  
Cancer Center**

**PARKER  
INSTITUTE**  
for CANCER IMMUNOTHERAPY

**Seres Therapeutics, MD Anderson Cancer Center, and the Parker Institute for Cancer Immunotherapy Announce a Collaboration to Support the Investigation of Microbiome Therapeutics for Immuno-Oncology**

**CAMBRIDGE, Mass., Nov. 14, 2017** — [Seres Therapeutics, Inc.](#) (NASDAQ:MCRB), The University of Texas MD Anderson Cancer Center (MD Anderson), and the Parker Institute for Cancer Immunotherapy (Parker Institute) today announced a collaboration to evaluate the potential of Seres' microbiome therapies to improve the outcomes of cancer patients treated with currently-available immunotherapy.

# Seres Investor highlights

## Opportunity

Phase 3 stage company developing microbiome-based therapeutics, a highly promising new area of medicine

## Platform

Leader in microbiome drug development with differentiated capabilities, field leading CMC and demonstrated GMP quality, and supportive clinical data

## Pipeline

Broad pipeline in infectious, metabolic diseases, inflammatory and immune, including immuno oncology

## Team

Experienced, accomplished leadership team

## Runway

Strong cash and strategic position

# The microbiome is essential to human health

## Infectious Disease

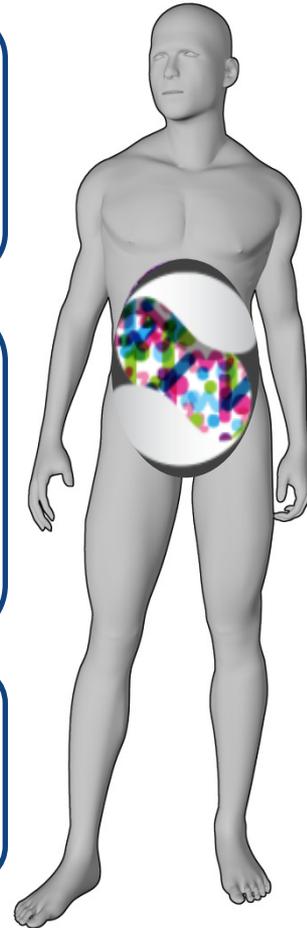
- A diverse microbiome resists colonization by exogenous pathogens
- Exposure to broad spectrum antibiotics, and resulting gut microbiome dysbiosis, increase risk for *C. difficile* infection and colonization / infection by multi-drug resistant organisms

## Inflammation and Immunology

- Microbiome known to alter regulatory T cells and Th17 T cell activation
- Role in inflammatory bowel disease (Ulcerative colitis and Crohn's disease) as well as allergy, rheumatoid arthritis and multiple sclerosis
- The composition of the microbiome has been demonstrated to impact the efficacy and safety of immuno-oncology checkpoint inhibitors

## Metabolic Disease

- Effects on glucose utilization, digestion and bile acid metabolism
- Role of microbiome implicated in several metabolic diseases (e.g. diabetes, obesity, liver diseases)



# Business strategy

## Focused clinical efforts

- Prioritize serious diseases where dysbiosis of the gut microbiome has a causal role

*C. difficile*  
infection

Inflammatory  
bowel disease

## World class, differentiated, microbiome expertise

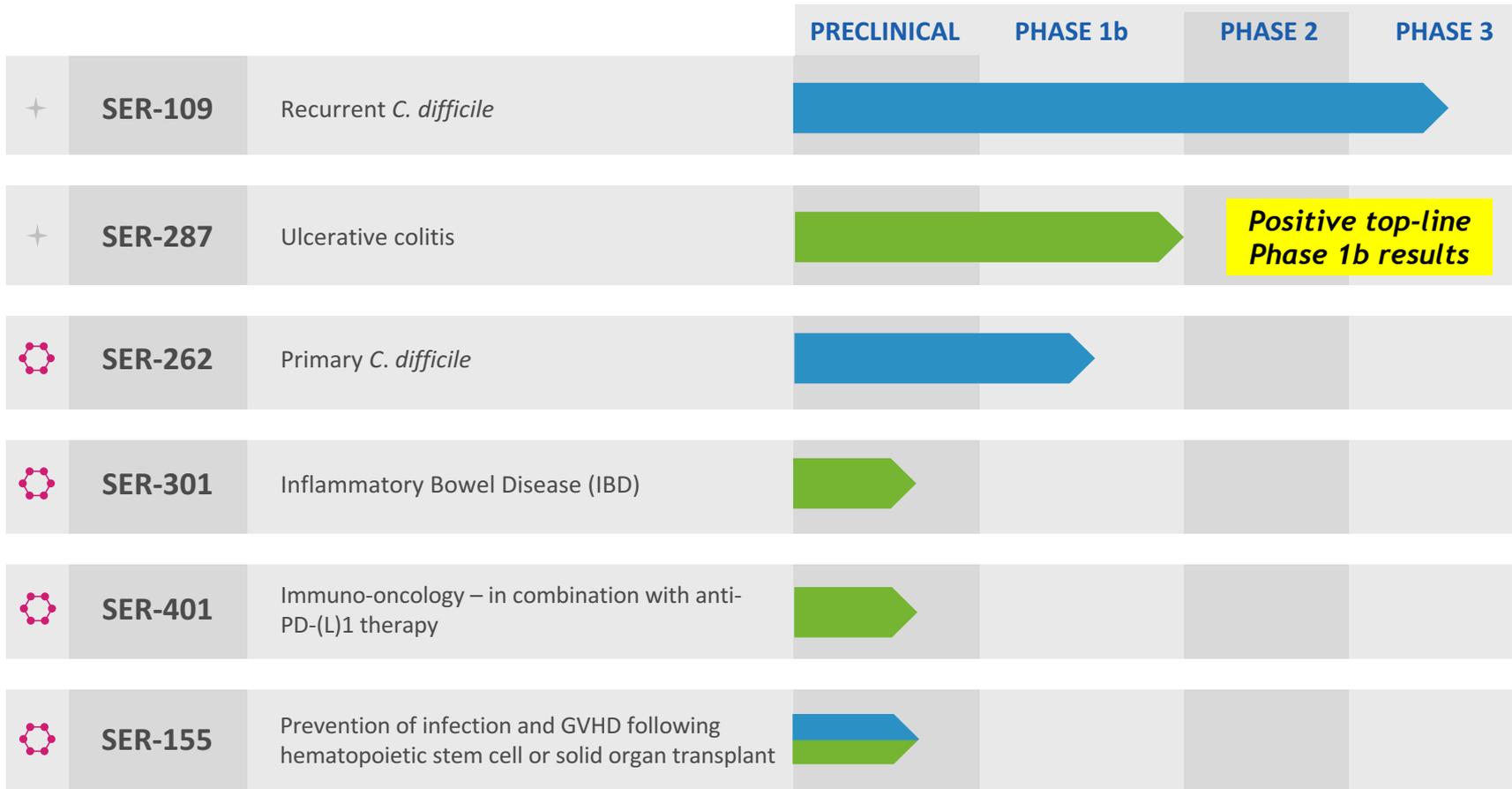
- Computational biology
- Basic microbiome research
- Microbiology
- Translational science
- Clinical development
- Advanced manufacturing

## Research in new therapeutic areas

- Collaborate with leading academic centers to advance research in promising therapeutic areas



# Robust microbiome therapeutics pipeline

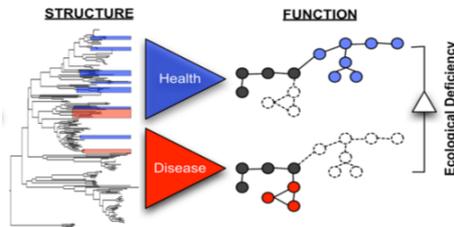


Synthetically fermented    
 Biologically sourced    
 Infectious    
 Inflammatory

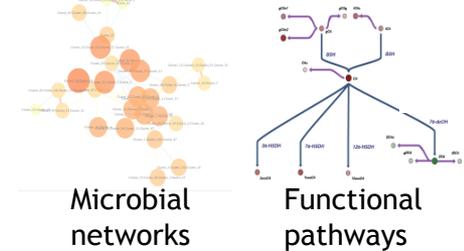
**Research Collaborations**

# Differentiated microbiome R&D platform

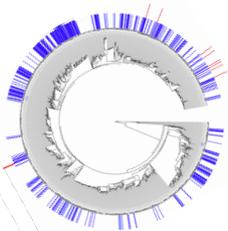
Computational discovery using human clinical datasets to allow rational design of microbiome drugs in multiple therapeutic areas



*In silico* derivation of 'backbone' functional microbial ecologies



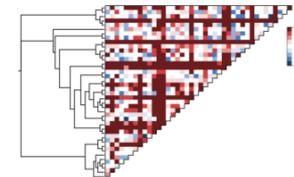
Vast microbial strain library and commensal bacteria culturing know-how



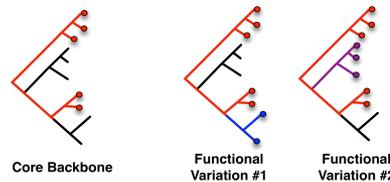
>14,000 strains spanning broad biological breadth

**Rationally Designed Ecologies**

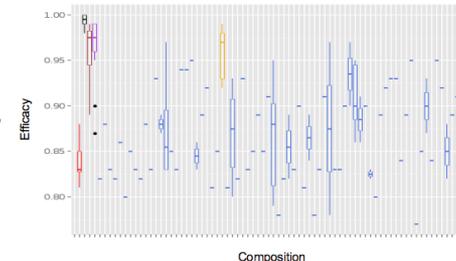
Genomic & phenotypic characterization of microbial strains & compositions using high resolution whole metagenomic shotgun sequencing, resolving down to strain level



Disease targeted metabolic, immunological, & efficacy screens for 'r-group' informed lead optimization



Phylogenetically-informed "R-group" Optimization

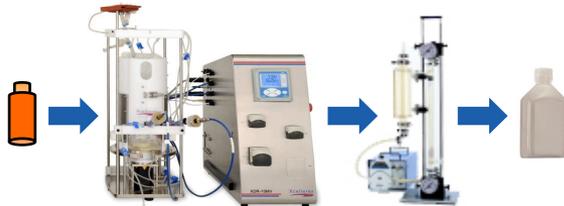


Only company with clinical stage development programs giving insights into how to therapeutically alter the microbiome to treat disease

# CMC platform enables manufacture of cGMP-compliant, oral, microbiome therapeutic candidates

Fermentation of anaerobic and spore-forming microbes

Synthetic candidates



cGMP Isolation of spores from complex biological materials

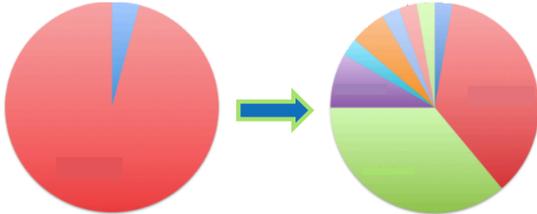


Biologically sourced

Novel germination, cultivation, and sporulation strategies enabling increased culture diversity and productivity

Unoptimized

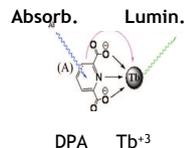
Optimized



Formulation, filling, delivery & packaging enabling active product delivery



Novel QC assays for safety, identity, strength, purity, and quality including microbiome characterization



# *Clostridium difficile* Infection

## Overview and R&D Programs



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# *C. difficile* infection overview

- Infectious disease caused by toxin producing anaerobic, spore-forming bacteria, resulting in diarrhea, abdominal pain, fever, and nausea
- Leading cause of hospital-acquired infection in the US
  - Approximately 29,000 deaths/year
  - Multiply recurrent *C. difficile* infection incidence increased 43% between 2001-2010
- ~25% of patients with primary *C. diff.* recur
- Risk of relapse increases with each recurrence



# Treatment landscape & disease burden

Modality	Characteristics
<b>Antibiotics</b> 	<ul style="list-style-type: none"> <li>• Perpetuates microbiome dysbiosis, creating <i>C. difficile</i> infection susceptibility</li> <li>• High recurrence rates, especially in recurrent cases</li> </ul>
<b>Fecal Transplant</b> 	<ul style="list-style-type: none"> <li>• Typically invasive procedure (colonoscopy or NG-tube)</li> <li>• Potential for transmission of human pathogens</li> <li>• No FDA approved products</li> </ul>
<b>Antibodies</b> 	<ul style="list-style-type: none"> <li>• Modest efficacy in Phase 3 studies</li> <li>• Does not address underlying microbiome dysbiosis</li> <li>• Complex administration, not patient-friendly</li> </ul>

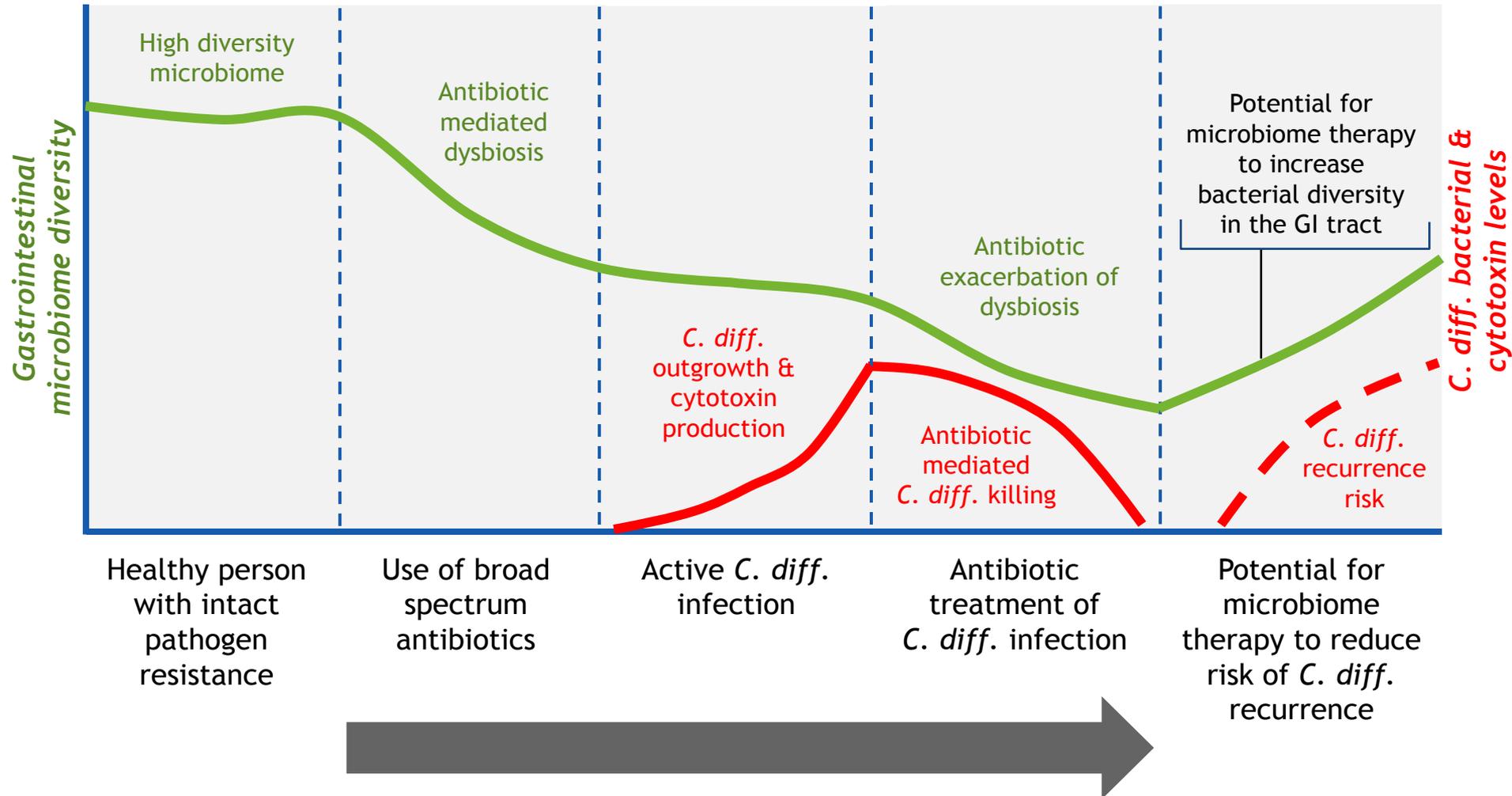
High Unmet Medical Need

- Economic burden of \$4.8B in U.S. acute-care facilities<sup>1</sup>
- Recurrent CDI episode ~\$18K<sup>2</sup>; >\$50K for cycle of recurrences

High Treatment Costs

# Dysbiosis and potential for therapeutic intervention

## Hypothetical patient course



# SER-109 Phase 1b and Phase 2 (8-week) study results

	Phase 1b Open Label, Single-Arm (n=30; 4 sites)	Phase 2 - Interim results Randomized, Placebo-Controlled (n=89; randomized 2:1; 28 sites)
<b>Primary Endpoint</b>	CDI recurrence up to 8 weeks defined by: >3 unformed stools over 1 day	CDI recurrence up to 8 weeks defined by: $\geq 3$ unformed stools/day for $\geq 2$ days
<b>Efficacy</b>	<ul style="list-style-type: none"> <li>• 87% non recurrence, per protocol</li> <li>• 3 of 4 patients with recurrent transient diarrhea, did not require antibiotic treatment and tested negative for <i>C. diff.</i> at 8 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• SER-109: 59% (33 of 59) non recurrence</li> <li>• Placebo: 47% (14 of 30) non recurrence</li> <li>• Relative risk recurrence between arms not significant</li> </ul>
<b>Safety</b>	<ul style="list-style-type: none"> <li>• Most AEs were mild to moderate and transient</li> <li>• Most frequent AEs were gastrointestinal symptoms similar in nature to that seen in FMT trials or following CDI</li> </ul>	<ul style="list-style-type: none"> <li>• SER-109 is well-tolerated with an acceptable safety profile, it was associated with a small increase in gastrointestinal adverse effects, particularly diarrhea, compared to placebo (25% vs 14%)</li> </ul>

# SER-109 Phase 2 study post read-out analyses and findings

SER-109 analyses	Key issues addressed
Clinical	<ul style="list-style-type: none"><li>• Detailed analyses of clinical data</li><li>• Investigation of <i>C. difficile</i> diagnostics</li></ul>
Pharmacodynamics / microbiome analyses	<ul style="list-style-type: none"><li>• Investigation of drug activity</li></ul>
Chemistry, Manufacturing and Controls (CMC)	<ul style="list-style-type: none"><li>• Drug product distribution and handling</li><li>• Phase 1b to Phase 2 manufacturing and formulation changes, and potential impact on drug activity</li></ul>



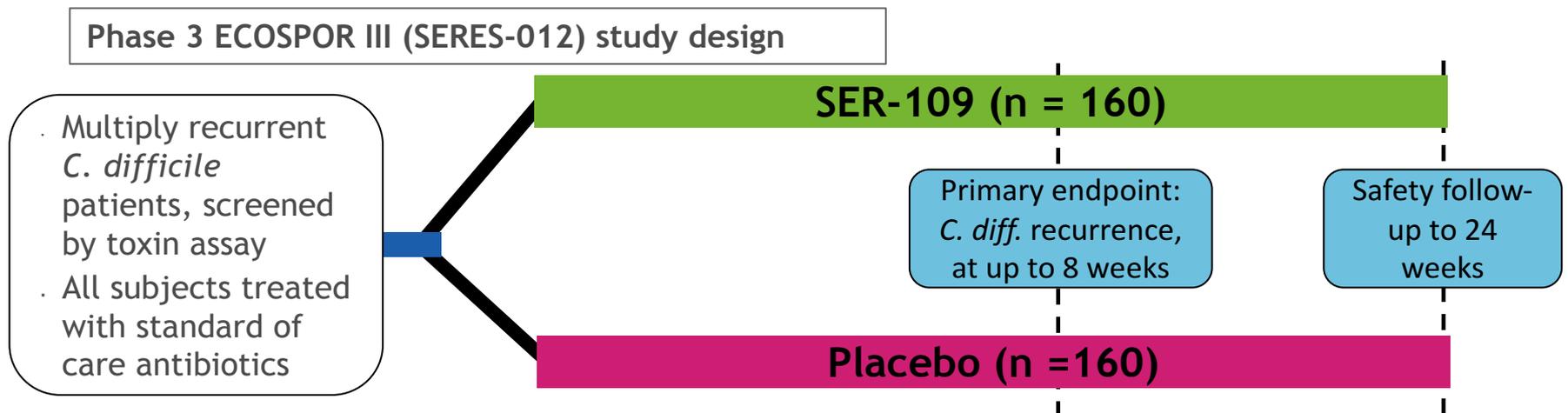
## Key Findings: Factors contributing to SER-109 Phase 2 study result

**Diagnosis** - Misdiagnoses may have occurred both in some patients entering the trial, as well as for recurrences diagnosed during the study

**Dose** - The dose used in the Phase 2 study may have been suboptimal in certain patients

# Phase 3 SER-109 ECOSPOR III study underway

- Based on FDA feedback, ECOSPOR III designated as a Phase 3 study
- The ECOSPOR III Phase 3 study is the first pivotal trial in the emerging field of oral microbiome therapeutics
- ECOSPOR III to utilize a SER-109 dose approximately 10-fold higher than the dose used in the prior Phase 2 study, administered over three days



# SER-262: Synthetic Ecobiotic® therapeutic candidate for primary *C. difficile* infection

- Oral, microbiome therapeutic candidate comprising twelve strains of fermented, rationally selected bacterial spores
- Bacteria species selected based on analysis of SER-109 Phase 1b microbiome data, biological and phylogenetic heterogeneity, and preclinical efficacy in *C. difficile* infection mouse model
- Data support a mechanism of action in which SER-262 strains compete for *C. difficile* preferred carbon sources

## SER-262 strains utilize multiple carbon sources

Strain Designation	Sugars, sugar alcohols, glucosides														Carboxylic acids				
	f r u	g l u	m a n	r a b	r i b	x y l	c e l	s t r	t r e	m e l	p e l	m t r	s a r	N A G	g l a	s a r	f o r	s p y	
<i>C. difficile</i>																			
1																			
2																			
3																			
4																			
5																			
6																			
7																			
8																			
9																			
10																			
11																			
12																			

## *In vitro* fermentation



# SER-262 Phase 1b dosing study in patients with primary *C. difficile* infection

60+ patients with primary *C. difficile* infection

Cohort A: Tx with  $10^4$  spores (n=10); placebo (n=2); single dose

Cohort B: Tx with  $10^5$  spores (n=10); placebo (n=2); single dose

Cohort C: Tx with  $10^6$  spores (n=10); placebo (n=2); single dose

Cohort D: Tx with  $10^7$  spores (n=10); placebo (n=2); single dose

Cohort E: Tx with  $10^8$  spores (n=10); placebo (n=2); single dose

Multi Dose Cohorts: Tx spores (n=10); placebo (n=2); Dosing provided over three days

## Primary Objective

- Safety and tolerability at 24 weeks
- Relative risk of *C. difficile* recurrence compared to placebo at up to 8 weeks

## Secondary Objectives

- Microbiome engraftment
- Time to *C. difficile* recurrence
- Relative risk of recurrence at up to 4, 12, and 24 weeks after treatment

# Inflammatory Bowel Disease

## Overview and R&D Programs



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# Multiple FMT studies provide proof of concept for microbiome therapy in ulcerative colitis

## THE LANCET

### Multidonor intensive faecal microbiota transplantation for active ulcerative colitis: a randomised placebo-controlled trial

*Sudarshan Paramsothy, Michael A Kamm, Nadeem O Kaakoush, Alissa J Walsh, Johan van den Bogaerde, Douglas Samuel, Rupert W L Leong, Susan Connor, Watson Ng, Ramesh Paramsothy, Wei Xuan, Enmoore Lin, Hazel M Mitchell, Thomas J Borody*

	Faecal microbiota transplantation (n=41)	Placebo (n=40)	Risk ratio (95% CI)	p value
<b>Primary outcome</b>				
Steroid-free clinical remission and endoscopic remission or response*	11 (27%)	3 (8%)	3.6 (1.1-11.9)	0.021

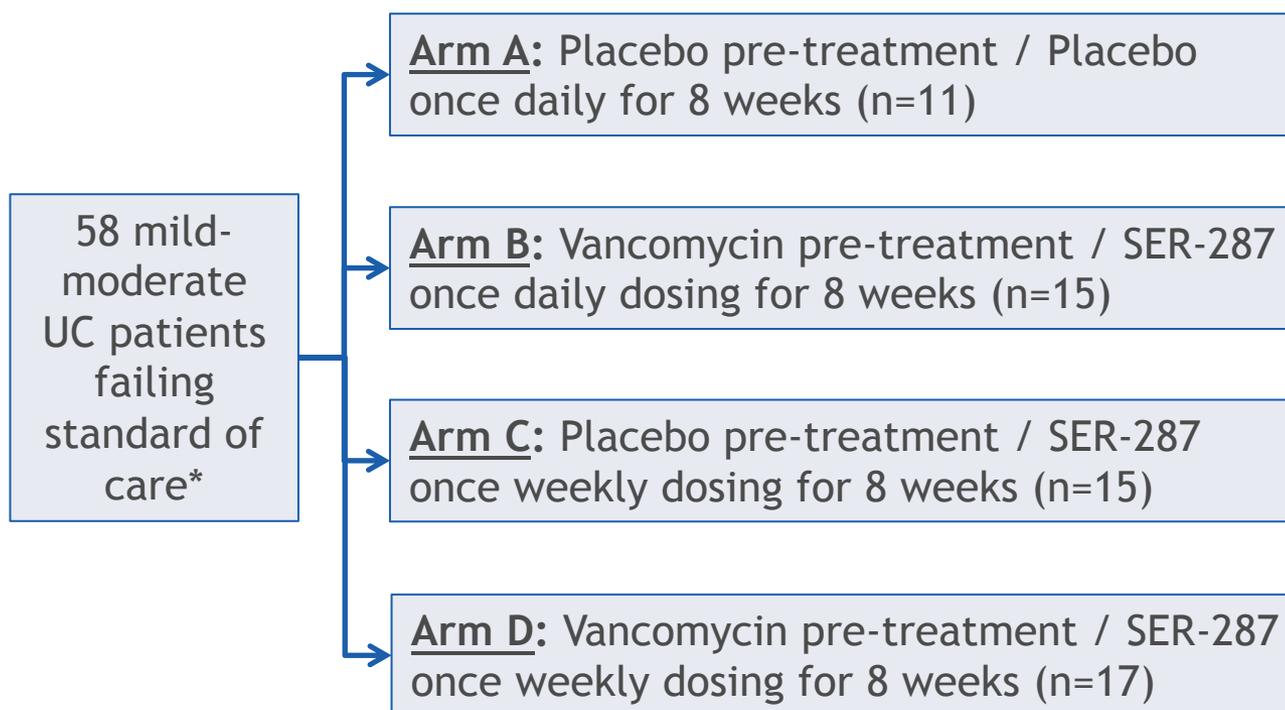
Subject A, Baseline



Subject A, 8-wk post FMT



# SER-287 Phase 1b Ulcerative Colitis study



\* Study designed to enroll 55 patients, with 15 in SER-287 treatment arms and 10 in the placebo / placebo arm

# SER-287 Phase 1b study endpoints

## Primary Objectives

- Safety and tolerability
- Change in composition of intestinal microbiome at 8 weeks \*

## Secondary Objectives

- Clinical remission, endoscopic improvement, and response through measure of the total modified Mayo Score
- Change in serum and fecal biomarkers \*
- Complement of microbiome metabolic pathways from stool, urine and blood \*
- Immunological and pathologic changes in mucosal biopsies \*

\* Microbiome data and other biomarker data are expected in early 2018

# SER-287 Phase 1b efficacy analyses

Two prespecified Intent-to-Treat (ITT) statistical methods were used to analyze SER-287 Phase 1b efficacy outcomes:

Intent-to-Treat statistical analyses	Patients analyzed
<p>Limited to observed data</p> <ul style="list-style-type: none"><li>All patients with post-treatment endoscopy results were <u>included in the efficacy analysis</u> if they remained in the trial until Day 48</li><li>Typically used in earlier stage clinical studies</li></ul>	53 / 58 subjects
<p>All subjects, missing data counted as failure</p> <ul style="list-style-type: none"><li>Patients who discontinued without post-treatment endoscopy or with protocol violations were <u>considered treatment failures in the efficacy analysis</u></li><li>Typically used in registrational clinical studies</li></ul>	58 / 58 subjects

*Initial top-line reported results*

Note: A patient in the placebo study arm experienced a disease flare and was treated with corticosteroids (a protocol violation) prior to the end of treatment endoscopy. Endoscopy showed improvement and the patient was assessed as having achieved clinical remission per the observed data statistical approach however in the all subjects, missing data approach they were considered a failure due to the protocol violation.

## Efficacy analysis: Limited to observed data

Endpoint	Intent-to-Treat Population: Limited to Observed Data			
	Placebo / Placebo (N = 10) (%)	Vancomycin / SER-287 daily (N = 15) (%)	Placebo / SER-287 weekly (N = 14) (%)	Vancomycin / SER-287 weekly (N = 14) (%)
<b>Clinical Remission:</b>				
	1/10 (10%)	6/15 (40%)	2/14 (14.3%)	3/14 (21.4%)
Difference from placebo (SER-287 minus placebo)		30.0%	4.3%	11.4%
p-value		0.1794	0.9999	0.6146
<b>Endoscopic Improvement:</b>				
	1/10 (10%)	6/15 (40%)	5/14 (35.7%)	4/14 (28.6%)
Difference from placebo (SER-287 minus placebo)		30.0%	25.7%	18.6%
p-value		0.1794	0.3408	0.3577
<b>Clinical Response:</b>				
	6/10 (60%)	9/15 (60%)	6/14 (42.9%)	4/14 (28.6%)
Difference from placebo (SER-287 minus placebo)		0.0%	-17.1%	-31.4%
p-value		0.9999	0.6802	0.2112

# Efficacy analysis: All subjects, missing data counted as failure

Endpoint	Intent-to-Treat Population: All Subjects, Missing Data Counted as Failure			
	Placebo / Placebo (N = 11) (%)	Vancomycin / SER-287 daily (N = 15) (%)	Placebo / SER-287 weekly (N = 15) (%)	Vancomycin / SER-287 weekly (N = 17) (%)
<b>Clinical Remission:</b>				
	0/11 (0%)	6/15 (40%)	2/15 (13.3%)	3/17 (17.7%)
Difference from placebo (SER-287 minus placebo)		40.0%	13.3%	17.7%
p-value		0.0237	0.4923	0.2579
<b>Endoscopic Improvement:</b>				
	1/11 (9.1%)	6/15 (40%)	5/15 (33.3%)	4/17 (23.5%)
Difference from placebo (SER-287 minus placebo)		30.9%	24.2%	14.4%
p-value		0.1783	0.1973	0.6195
<b>Clinical Response:</b>				
	5/11 (45.5%)	9/15 (60%)	6/15 (40%)	4/17 (23.5%)
Difference from placebo (SER-287 minus placebo)		14.5%	-5.5%	-22.0%
p-value		0.6922	0.9999	0.4087

# Definitions of clinical efficacy endpoints

Endpoint	Protocol Definition	New FDA Definition (2016)*
Clinical Remission	Total Modified Mayo Score $\leq 2$ and an endoscopic subscore of 0 or 1	Stool Frequency subscore =0, Rectal Bleeding subscore=0 and Endoscopic subscore = 0 or 1 (modified) on Mayo Score
Endoscopic Improvement	Decrease in endoscopic subscore of $\geq 1$	Endoscopic subscore = 0 or 1*, but no histological assessment of the mucosa
Clinical Response	Decrease of $\geq 3$ points in Total Modified Mayo Score from baseline, along with either a decrease of $\geq 1$ point in rectal bleeding subscore or absolute rectal bleeding subscore of 0 or 1	Not recommended in FDA Guidance

\*FDA Ulcerative colitis: Clinical Trial Endpoints - Guidance for Industry; August 2016

# Efficacy analysis: Limited to observed data (Per FDA definition from 2016 guidance)

Endpoint	Intent-to-Treat Population: Limited to Observed Data			
	Placebo / Placebo (N = 10) (%)	Vancomycin / SER-287 daily (N = 15) (%)	Placebo / SER-287 weekly (N = 14) (%)	Vancomycin / SER-287 weekly (N = 14) (%)
<b>Clinical Remission:</b>				
	1/10 (10%)	6/15 (40%)	1/14 (7.1%)	3/14 (21.4%)
Difference from placebo (SER-287 minus placebo)		30.0%	-2.9%	11.4%
p-value		0.1794	0.9999	0.6146
<b>Endoscopic Improvement:</b>				
	1/10 (10%)	8/15 (53.3%)	4/14 (28.6%)	5/14 (35.7%)
Difference from placebo (SER-287 minus placebo)		43.3%	18.6%	25.7%
p-value		0.0405	0.3577	0.3408
<b>Clinical Response:</b>				
Difference from placebo (SER-287 minus placebo)	Not defined or recommended in FDA Guidance			
p-value				

# Efficacy analysis: All subjects, missing data counted as failure (Per FDA definition from 2016 guidance)

Endpoint	Intent-to-Treat Population: All Subjects, Missing Data Counted as Failure			
	Placebo / Placebo (N = 11) (%)	Vancomycin / SER-287 daily (N = 15) (%)	Placebo / SER-287 weekly (N = 15) (%)	Vancomycin / SER-287 weekly (N = 17) (%)
<b>Clinical Remission:</b>				
	0/11 (0%)	6/15 (40%)	1/15 (6.7%)	3/17 (17.6%)
Difference from placebo (SER-287 minus placebo)		40.0%	6.7%	17.6%
p-value		0.0237	0.9999	0.2579
<b>Endoscopic Improvement:</b>				
	0/11 (0%)	8/15 (53.3%)	4/15 (26.7%)	5/17 (29.4%)
Difference from placebo (SER-287 minus placebo)		53.3%	26.7%	29.4%
p-value		0.0074	0.1134	0.1247
<b>Clinical Response:</b>				
Difference from placebo (SER-287 minus placebo)	Not defined or recommended in FDA Guidance			
p-value				

# SER-287 safety and tolerability profile very favorable

- No drug related serious adverse events associated with SER-287
- Lower rate of GI related adverse events in SER-287 daily arm provides supportive evidence of SER-287 benefit on symptoms seen in Ulcerative Colitis

System Organ Class	Safety Population				
	(Placebo / placebo) (N = 11) n (%)	(Vancomycin / SER-287 daily) (N = 15) n (%)	(Placebo / SER-287 weekly) (N = 15) n (%)	(Vancomycin / SER-287 weekly) (N = 17) n (%)	SER-287 (N = 47) n (%)
Gastrointestinal disorders	5 (45.5)	2 (13.3)	7 (46.7)	8 (47.1)	17 (36.2)
General disorders and administration site conditions	1 (9.1)	1 (6.7)	0	3 (17.6)	4 (8.5)
Immune system disorders	0	0	0	1 (5.9)	1 (2.1)
Infections and infestations	3 (27.3)	4 (26.7)	1 (6.7)	6 (35.3)	11 (23.4)
Injury, poisoning and procedural complications	2 (18.2)	0	0	0	0
Investigations	0	0	0	1 (5.9)	1 (2.1)
Metabolism and nutrition disorders	0	1 (6.7)	0	1 (5.9)	2 (4.3)
Musculoskeletal and connective tissue disorders	0	2 (13.3)	3 (20.0)	1 (5.9)	6 (12.8)
Nervous system disorders	0	3 (20.0)	0	1 (5.9)	4 (8.5)
Psychiatric disorders	1 (9.1)	1 (6.7)	0	0	1 (2.1)
Reproductive system and breast disorders	0	0	0	1 (5.9)	1 (2.1)
Respiratory, thoracic and mediastinal disorders	0	1 (6.7)	1 (6.7)	2 (11.8)	4 (8.5)
Skin and subcutaneous tissue disorders	0	3 (20.0)	0	1 (5.9)	4 (8.5)

# SER-301: Synthetic Ecobiotic® therapeutic candidate for inflammatory bowel disease

- Follow-on therapeutic candidate to SER-287 in preclinical development for inflammatory bowel disease
- Oral, microbiome therapeutic candidate comprising fermented, rationally selected bacteria
- Selection of SER-301 bacterial composition to be based on:
  - SER-287 study data (clinical and microbiome analysis)
  - Existing collaborations evaluating analysis of FMT ulcerative colitis clinical study data
  - Preclinical screening for microbial function, immunological assay, and animal models

# Additional Pipeline Programs



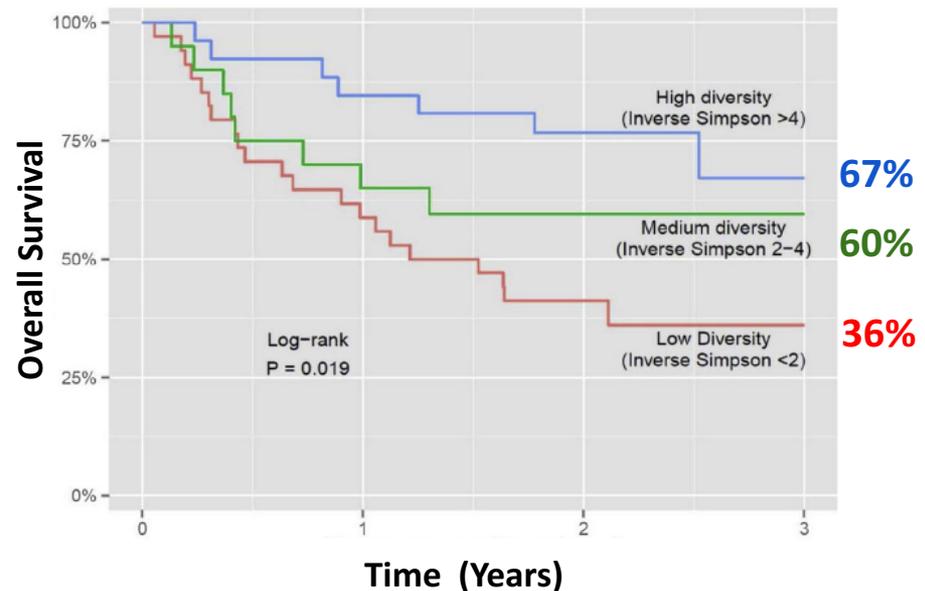
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# SER-155: Synthetic Ecobiotic<sup>®</sup> therapeutic candidate to improve transplantation outcomes

- Synthetically-derived Ecobiotic<sup>®</sup> therapeutic candidate to improve outcomes in patients receiving allogeneic hematopoietic stem cell transplantation (HSCT) or solid organ transplants
- Designed to reduce both infection risk, and Graft vs. Host Disease (GvHD)

HSCT Patient Microbiome Health Correlates with Overall Mortality Risk<sup>3</sup>



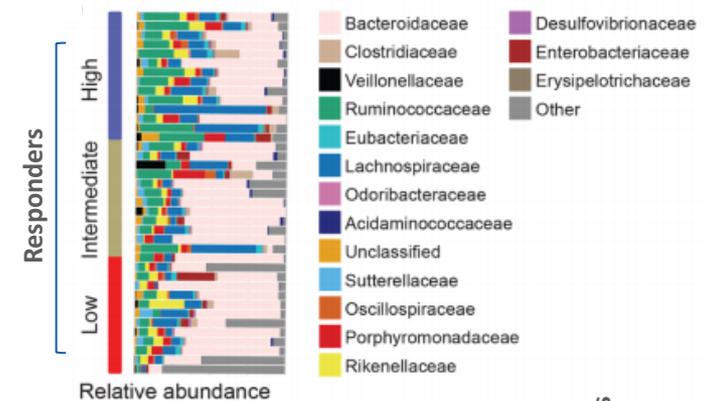
**CARB-X**  
Xccelerating global antibacterial innovation

Nov. 2017: CARB-X grant of up to \$5.6M obtained to support preclinical research and early development work for SER-155

# Collaboration to advance immuno-oncology microbiome therapeutic into clinical development



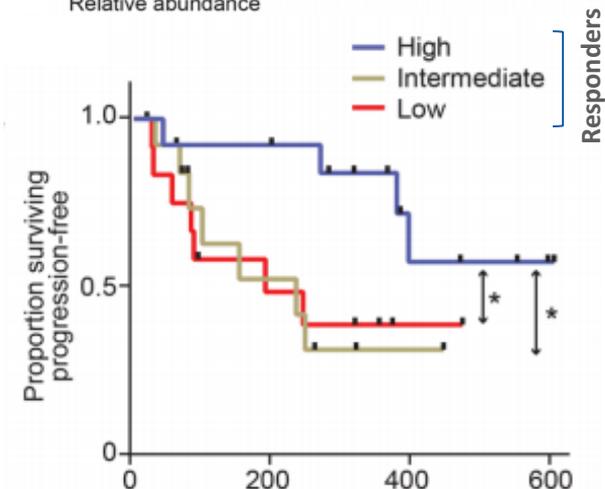
- Research by MD Anderson collaborators indicates specific microbiome signatures may impact response to anti-PD-1 (e.g., KEYTRUDA®) immunotherapy
- Seres has received an option to license foundational IP from MD Anderson related to the use of bacteria in combination with checkpoint inhibitors



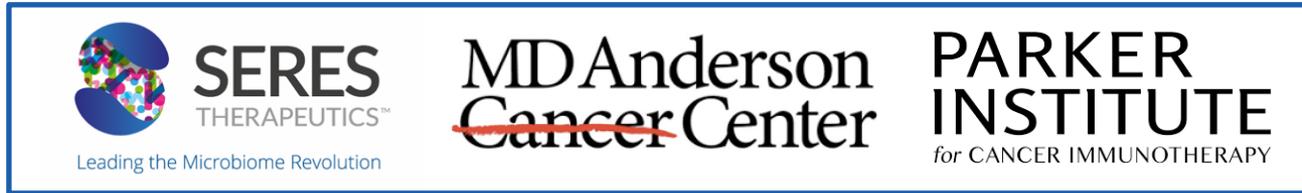
## Science

### Gut microbiome modulates response to anti-PD-1 immunotherapy in melanoma patients

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# Immuno-oncology microbiome development next steps



- Collaboration to initiate a randomized, placebo-controlled clinical study at MD Anderson, sponsored by the Parker Institute, in patients with advanced metastatic melanoma
- Clinical trial to evaluate impact of anti-PD-1 checkpoint inhibitor with adjunctive microbiome therapy on patient outcomes

# Broad IP portfolio and regulatory exclusivity

## 7 ISSUED US PATENTS + LICENSED IP\*

- Demonstrates rationally designed ecologies of spores and microbes are patentable
- Composition of matter and method claims, including option to license foundational IP from MD Anderson related to the use of bacteria in combination with checkpoint inhibitors
- Claims related to SER-109/ *C. difficile* & colitis lead candidates through **2033**

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## SERES PATENT PORTFOLIO

**16** Families of Applications

**9** Nationalized

**2** Pending PCT

**5** Pending Provisionals

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## REGULATORY EXCLUSIVITY



**12** years for new biological composition



**10** years for new drug

\* Includes additional IP rights including 1) a worldwide exclusive license to Memorial Sloan Kettering Cancer Center patent applications related to the use of bacterial compositions for treating HSCT patients and related areas, 2) exclusive option, with pre-defined financial terms, to license intellectual property rights from MD Anderson related to the use of bacteria in combination with checkpoint inhibitors.

# Well positioned for success

SER-109: Multiply recurrent *C. difficile* infection - Phase 3 ongoing

SER-287: Ulcerative colitis - Microbiome Data (early 2018); FDA feedback (2018)

SER-262: Primary *C. difficile* infection - Phase 1b read-out (early 2018)

Advancing new pipeline programs in infectious diseases, inflammatory and immune diseases (including immuno-oncology), metabolic and liver diseases

## Resources to operate through 2018

Balance Sheet	As of Sept. 30, 2017
Cash, cash equivalents and investments	\$171.3 M