# Harnessing the Genomic Revolution & Machine Learning to Pioneer Microbiome Therapeutics

**CORPORATE PRESENTATION | APRIL 2022**

# Forward-Looking Statements

Statements contained in this presentation regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Words such as "anticipates," "believes," "expects," "intends," "plans," "potential," "projects," "would" and "future" or similar expressions are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding: the timing and resolution of the FDA clinical hold on the Company's investigational new drug application for CP101 in connection with the Company's SARS-CoV-2 donor screening protocols and informed consent process and the impact of the clinical hold on the Company's clinical and preclinical programs; the structure, timing and anticipated milestones of the Company's clinical trials, including specifically its Phase 3 trial in recurrent *C. difficile* and the initiation and conduct of a Phase 1 trial in autism spectrum disorder; the Company's and its collaborators' ability to obtain regulatory approval of CP101, FIN-211, TAK-524, FIN-525 and any other current and future product candidates that it develops; the Company's ability to expand its pipeline and to develop additional product candidates; its expectations regarding the potential market size and the rate and degree of market acceptance for any product candidates that it develops; the therapeutic value and commercial potential of candidates developed using its *Human-First Discovery* platform; the strength of the Company's patent portfolio; and the Company's expected cash runway. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among others: the risk that the Company may not be able to address the FDA's concerns regarding SARS-Cov-2 testing protocols and informed consent quickly or at all; uncertainties relating to regulatory applications and related filing and approval timelines, including the risk that the FDA may not remove the clinical hold; the Company's limited operating history and historical losses; the Company's ability to raise additional funding to complete the development and any commercialization of its product candidates; the Company's dependence on the success of its lead product candidate, CP101; the possibility that the Company may be delayed in initiating, enrolling or completing any clinical trials; results of clinical trials may not be sufficient to satisfy regulatory authorities to approve the Company's product candidates in their targeted or other indications (or such authorities may request additional trials or additional information); results of clinical trials may not be indicative of final or future results from later stage or larger clinical trials (or in broader patient populations once the product is approved for use by regulatory agencies) or may not be favorable or may not support further development; the Company's product candidates, including CP101 and FIN-211, may not generate the benefits to patients that are anticipated; the Company's ability to comply with regulatory requirements; ongoing regulatory obligations and continued regulatory review may result in significant additional expense to the Company and the Company may be subject to penalties for failure to comply; competition from third parties that are developing products for similar uses; the Company's ability to maintain patent and other intellectual property protection and the possibility that the Company's intellectual property rights may be infringed, invalid or unenforceable or will be threatened by third parties; the Company's ability to qualify and scale its manufacturing capabilities in anticipation of commencement of multiple global clinical trials; the Company's lack of experience in selling, marketing and distributing its product candidates; the Company's dependence on third parties in connection with manufacturing, clinical trials and preclinical studies; and risks relating to the impact and duration of the COVID-19 pandemic on the Company's business. These and other risks are described more fully in the Company's filings with the Securities and Exchange Commission ("SEC"), including the section titled "Risk Factors" in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2022, as well as discussions of potential risks, uncertainties, and other important factors in the Company's other filings with the SEC. All forward-looking statements contained in this presentation speak only as of the date on which they were made. Except to the extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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# Management team composed of accomplished biopharma executives and leading microbiome and machine learning experts

**Mark Smith, PhD**
Chief Executive Officer

OPENBIOME · Massachusetts Institute of Technology

**Greg Perry**
Chief Financial Officer

novelion THERAPEUTICS · immunogen

**Debra Silberg, MD, PhD**
Interim Chief Medical Officer

Takeda · Shire

**Marc Blaustein**
Chief Operating Officer

Alkermes · akashi therapeutics

**Michelle Rose, PhD**
Chief Regulatory Officer

CHIMERIX · EMD SERONO

**Joe Vittiglio, JD**
Chief Business & Legal Officer

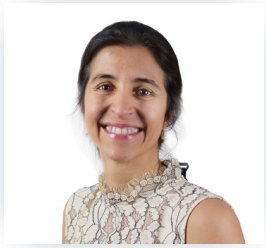
AVEO PHARMACEUTICALS, INC. · amag PHARMACEUTICALS

**Bryan Gillis, MBA**
Chief Technology Officer

RubiusTherapeutics · ALEXION

**Alka Batycky, PhD**
Chief Development Officer

akashi therapeutics · WarpDrive Bio



**Sonia Timberlake, PhD**
Senior VP Research

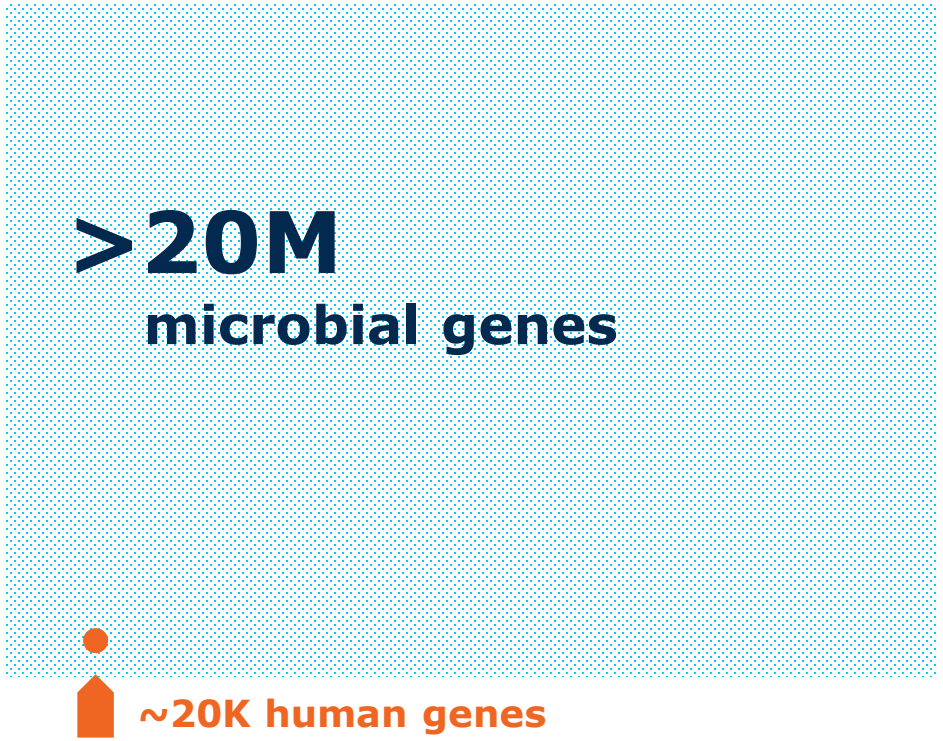
JUNO THERAPEUTICS · AbVitro

**Management team has collectively developed >40 approved therapeutics**

FINCH

# The microbiome is an untapped target for therapeutic intervention

## Humans carry 1000-fold more microbial genes than host genes




## The microbiome is an organ system fundamental to human health

- **Immune modulation**
- **Metabolic function**
- **Neurologic regulation**

**Enabled by genomics and data science, Finch is pioneering microbiome therapeutics**

Sources: Tierney Cell Host Microbe 2019

# Investment Highlights

**Positive pivotal data with lead asset provides foundation for future growth**

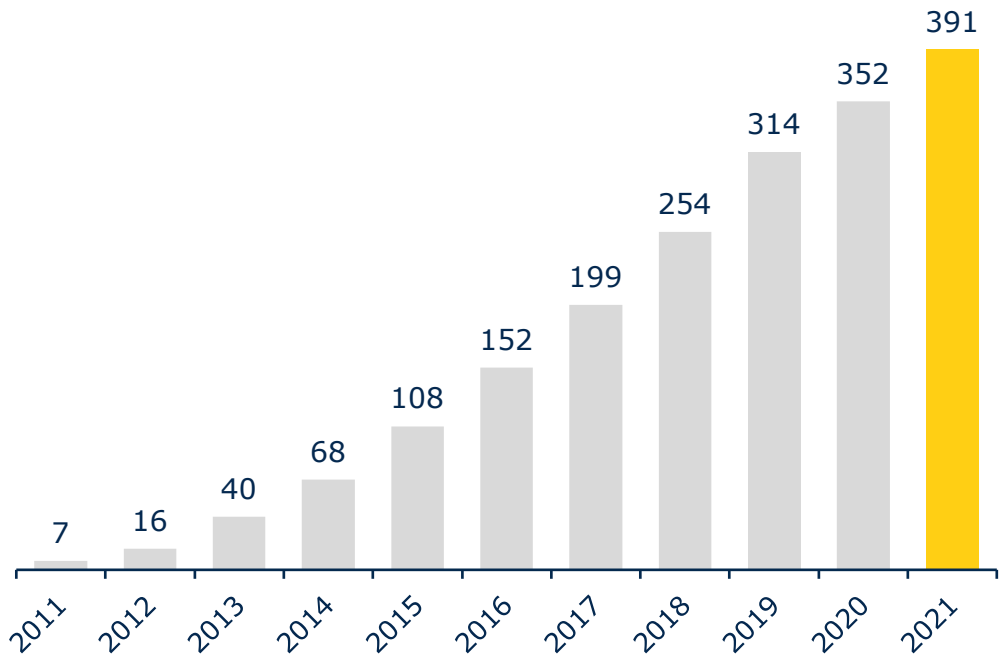
**Differentiated discovery process, with proof-of-concept clinical data leveraged to guide product design and de-risk development**

**Uniquely positioned to harness full diversity and potential of the microbiome across diverse therapeutic areas; platform supported by leading patent portfolio**

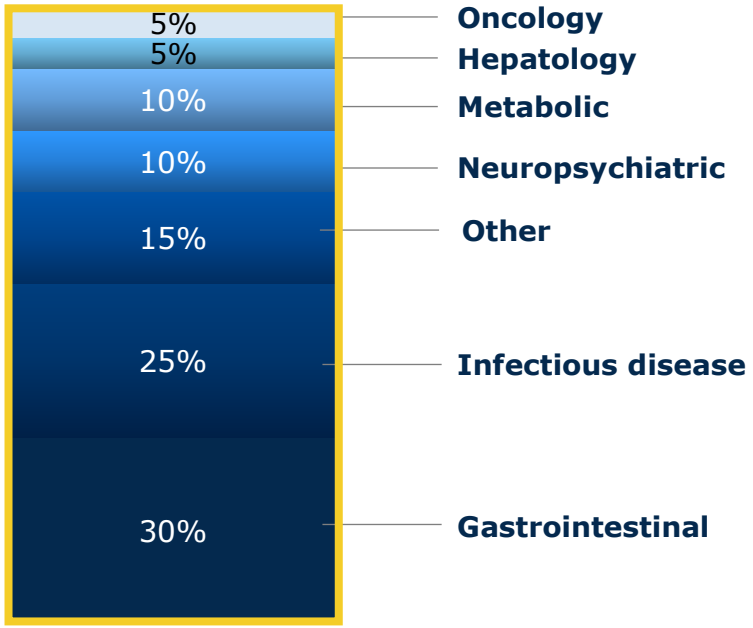
**Leading machine learning-based platform recognized by Takeda partnership**

# Growing body of clinical evidence across diverse therapeutic areas fuels our discovery engine and guides product design

## >300 registered clinical trials evaluating Fecal Microbiota Transplantation (FMT)




## Recent FMT research spans diverse therapeutic areas with significant unmet needs




**Finch has proprietary access to data through strategic partnerships with leading providers of FMT in the US, China and Australia**

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Source: Clinicaltrials.gov

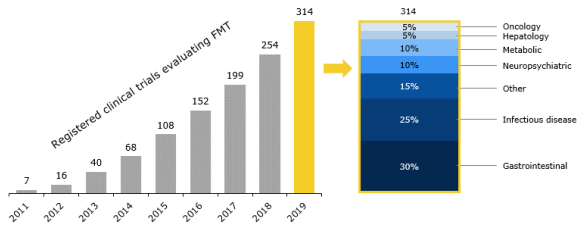
# Our *Human-First Discovery* platform is designed to enable capital efficient de-risking

**Program launch & capital commitment**

## 1. Clinical Proof-of-Concept *(3rd party data)*

*Enabled by:*

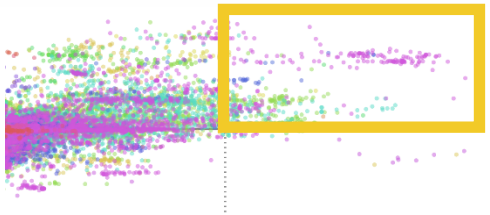
**Proprietary access to data**




## 2. Data-Mining for Mechanistic Insights

*Enabled by:*

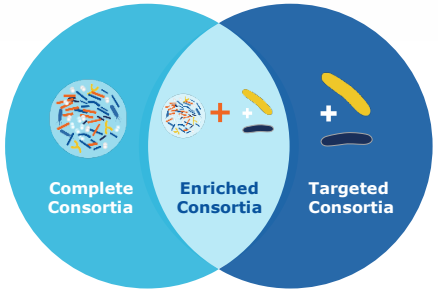
**Machine learning engine**



## 3. Product Development

*Enabled by:*

**Platform to target full microbiome**




**Starting discovery with proof-of-concept human data reduces risk early**

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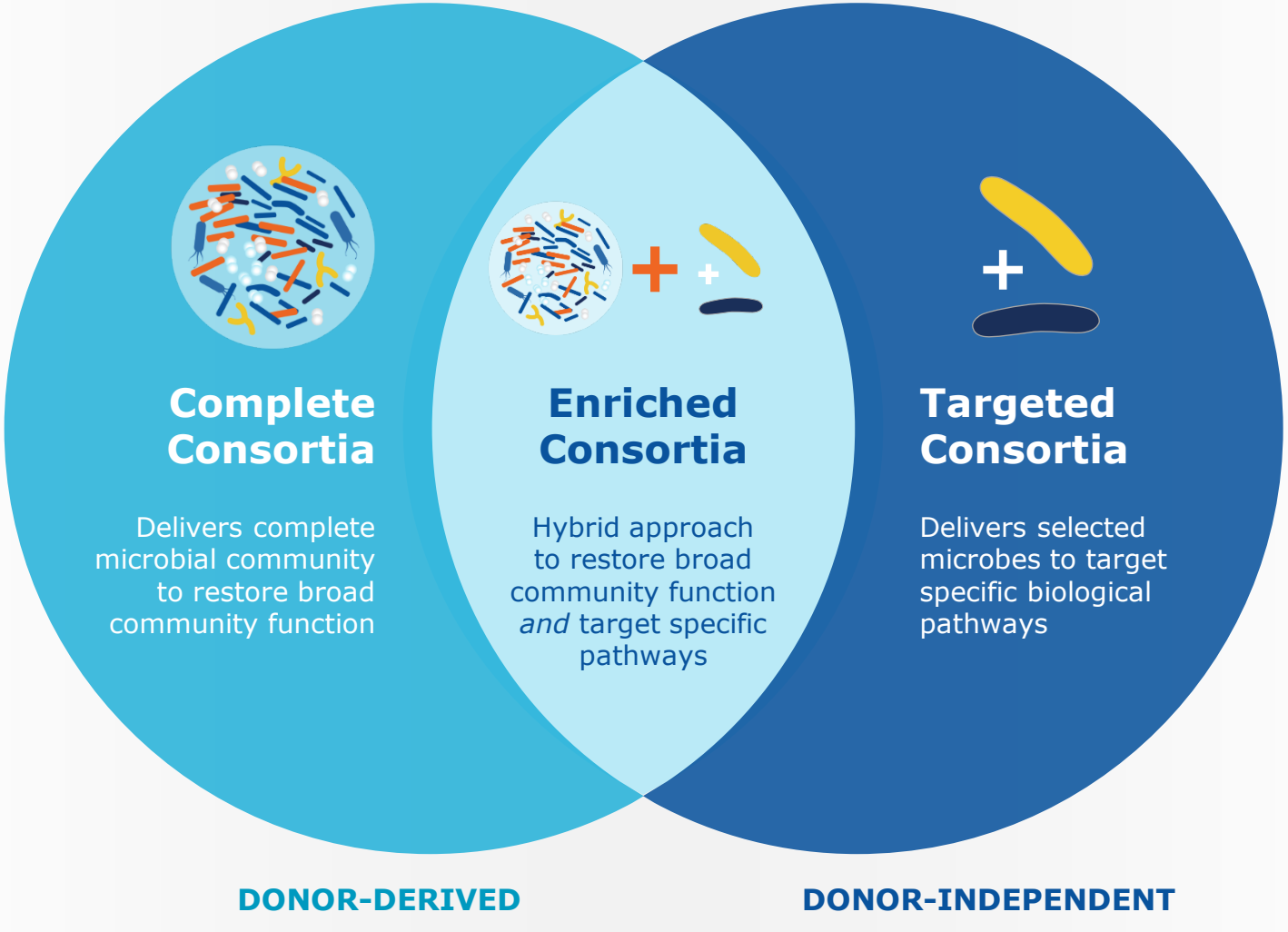
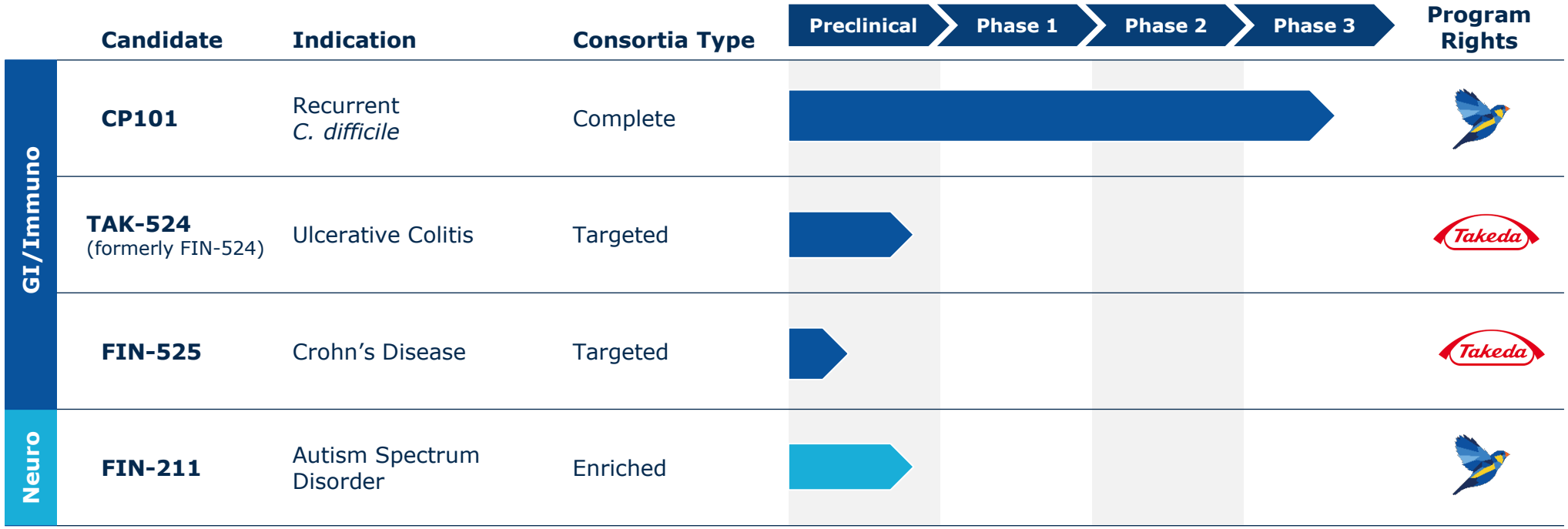
# Finch is the only company with both complete and targeted approaches for developing microbiome therapeutics



# Finch is advancing a diverse portfolio designed to establish entry points into new therapeutic areas

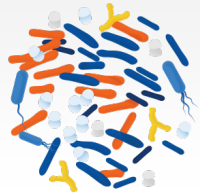



Enrollment in PRISM4 will remain paused until Finch is able to resolve the clinical hold on the IND for CP101 related to Finch's SARS-CoV-2 screening protocols, address recent FDA feedback and conduct additional manufacturing activities to satisfy requests related to SARS-CoV-2 screening. Because FIN-211 includes donor-derived components, the clinical hold and related manufacturing activities will also delay initiation of AUSPIRE. Finch is evaluating the extent of the expected delay to the timing for PRISM4 and AUSPIRE and, based on manufacturing timelines, expects at least a one quarter delay.

# CP101 for Recurrent *C. difficile* Infection (CDI)

# Recurrent CDI is an enormous human and economic burden

**CP101 Complete Consortia**
delivers full microbiome community



**44K**

Annual deaths attributable to CDI in the US

**2.4M**

Total inpatient days associated with CDI in the US

**$5B**

Annual direct costs of CDI in the US

**$27K**

Saved per patient by using microbiota transplantation

**CDC has declared *C. difficile* a top antibiotic resistance threat**



Sources: Zhang BMC Infect Dis 2016; Dehlholm-Lambertsen Ther Adv Gastroenter 2019 (1 EUR = 1.1482 USD); Desai BMC Infect Dis 2016; CDC Antibiotic Resistance Threat Report 2019

# CP101 is designed to deliver a complete microbiome in orally administered capsules

*Lyophilization technology optimized to preserve entire community, enabling use across multiple indications*

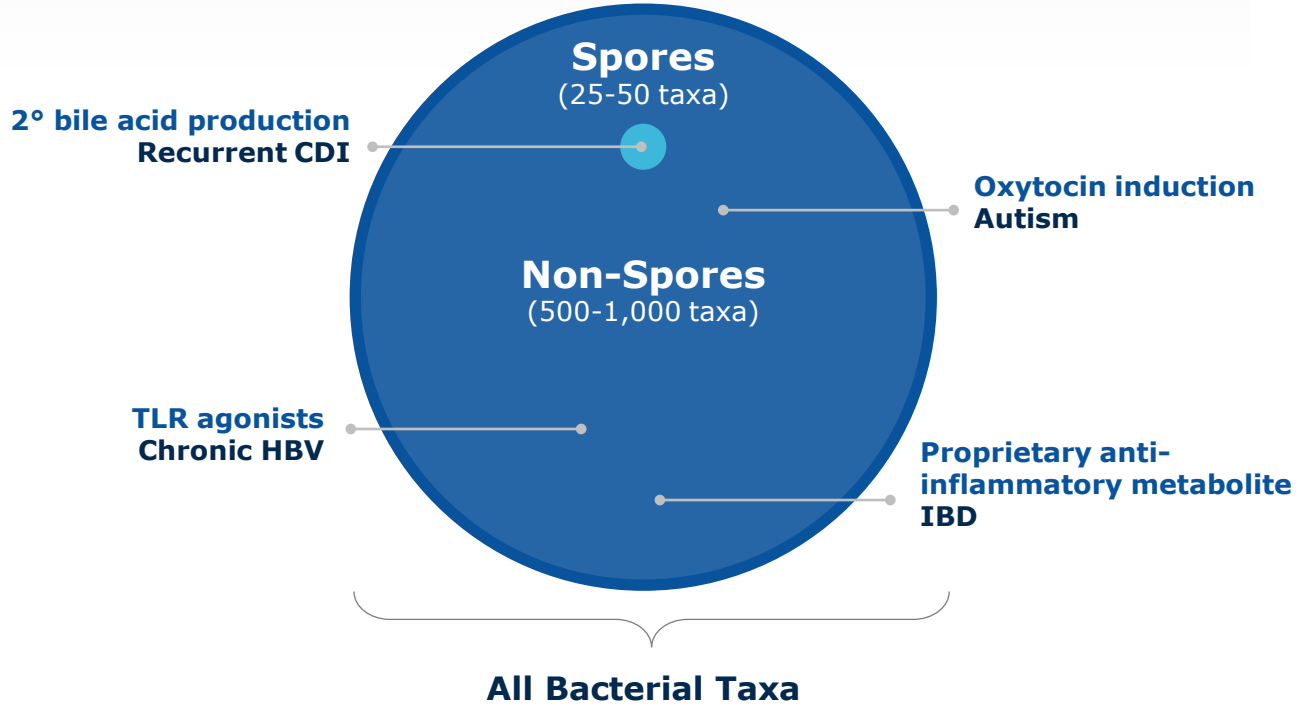
## Efficient, scalable manufacturing enabled by molecular screening of donors

**1. Healthy Donor Sourcing & Qualification**

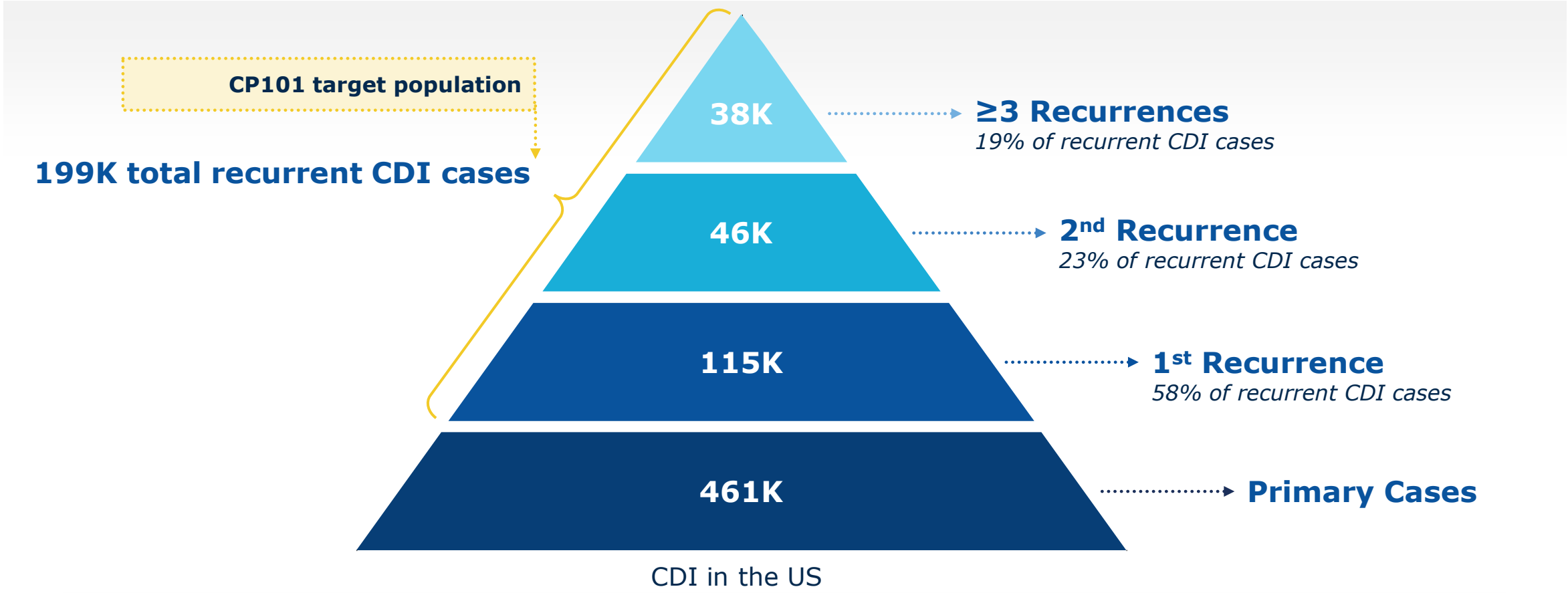
**2. Harvest, Purification, & Preservation**

**3. Lyophilization & Encapsulation**

## Complete consortia composition provides potential for broad pipeline expansion



# CP101 is positioned to serve a large population in recurrent CDI




**CP101 uniquely positioned to enable early intervention in the management of CDI**

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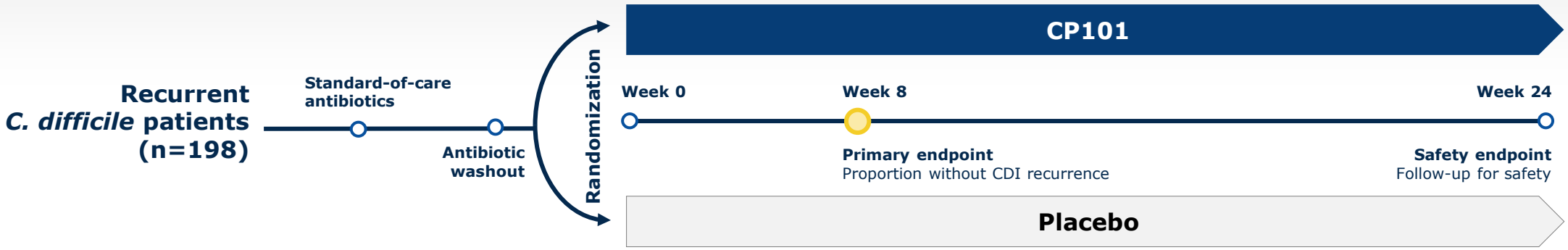
Sources: Desai BMC Infect Dis 2016

# PRISM3 Phase 2 trial designed to demonstrate superiority over SOC antibiotics plus placebo




## PRISM3 enrolled a broad population including:

**Participants experiencing their 1st CDI recurrence**
Relevance: 58% of all recurrent CDI cases are 1st recurrence

**Participants diagnosed with CDI via PCR testing**
Relevance: >80% of all CDI cases are diagnosed via PCR

**CP101 evaluated in a broad population to support labeling and market access**

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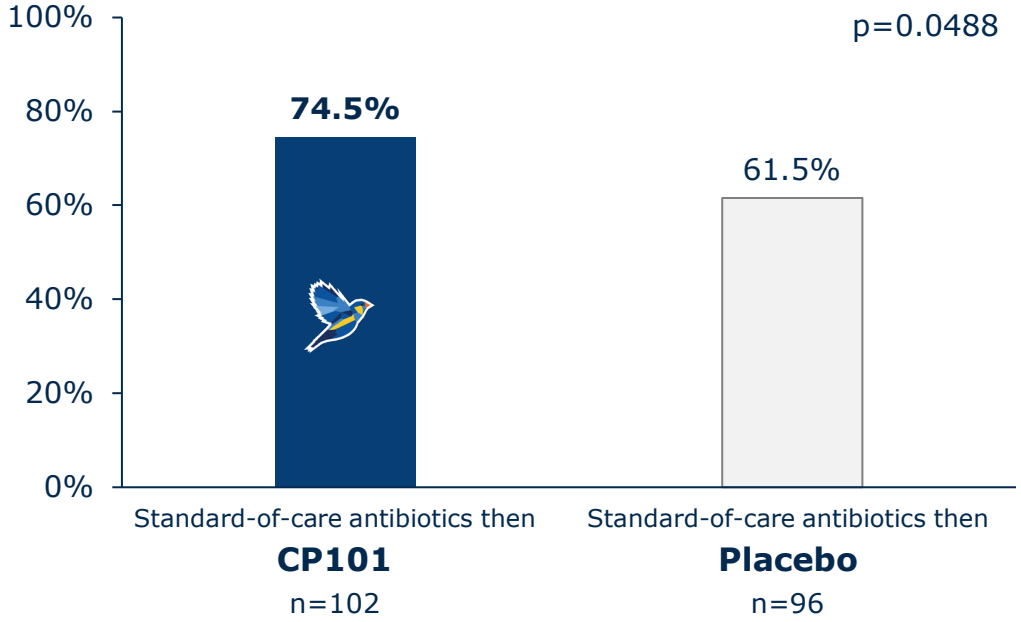
Notes: Participants entering study on 1st recurrence were required to be ≥65 years of age; Sources: Desai BMC Infect Dis 2016; Guh N Engl J Med 2020

# CP101 achieved its primary efficacy endpoint and had a safety profile similar to placebo in PRISM3

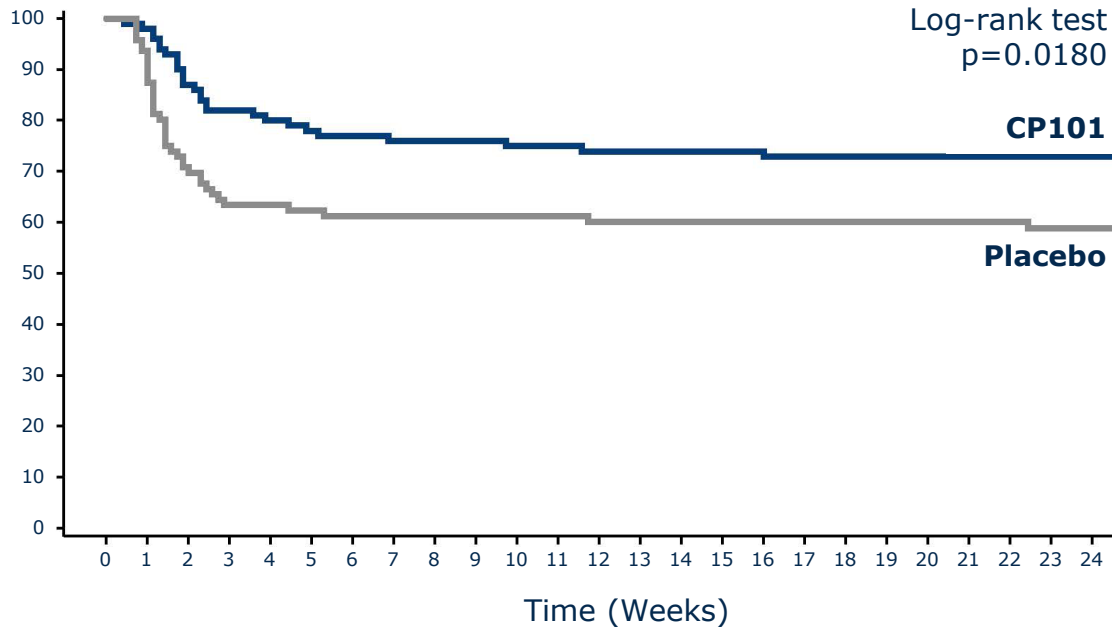
## CP101 achieved 33.8% relative risk reduction for CDI recurrence through Week 8

**Primary efficacy endpoint: Proportion without CDI recurrence through Week 8**




## Participants treated with CP101 had a lower risk of CDI recurrence through Week 24

**Recurrence-free (%) through Week 24**

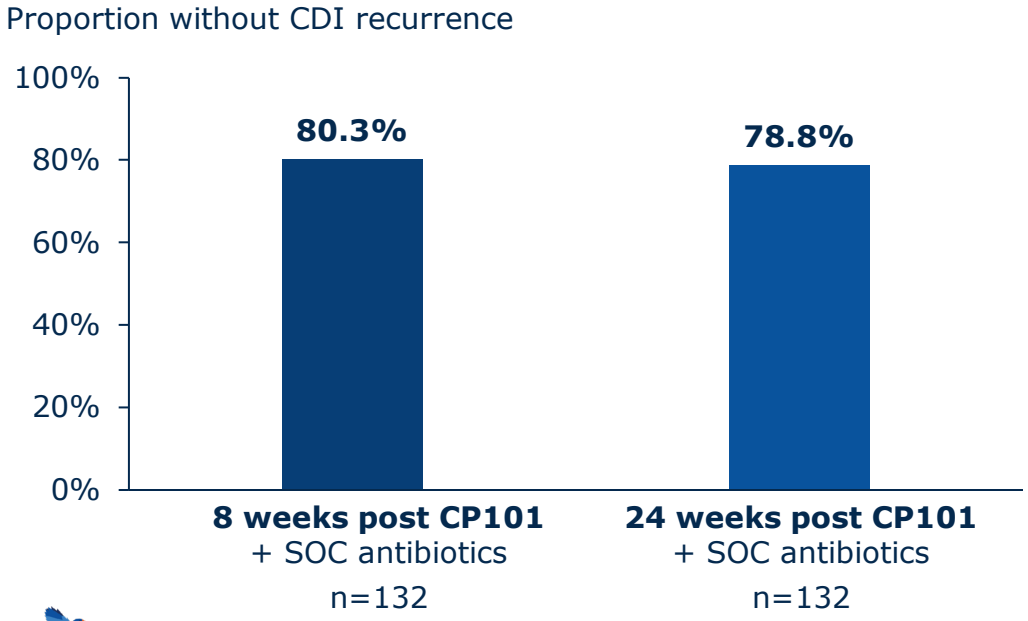



**CP101 met its primary efficacy endpoint, with no treatment-related SAEs in the CP101 arm**

SAEs: Serious adverse events

# Positive topline results from PRISM-EXT Phase 2 open-label trial of CP101 in recurrent CDI


## Robust prevention of CDI recurrence in PRISM-EXT with no treatment-related SAEs through 24 weeks



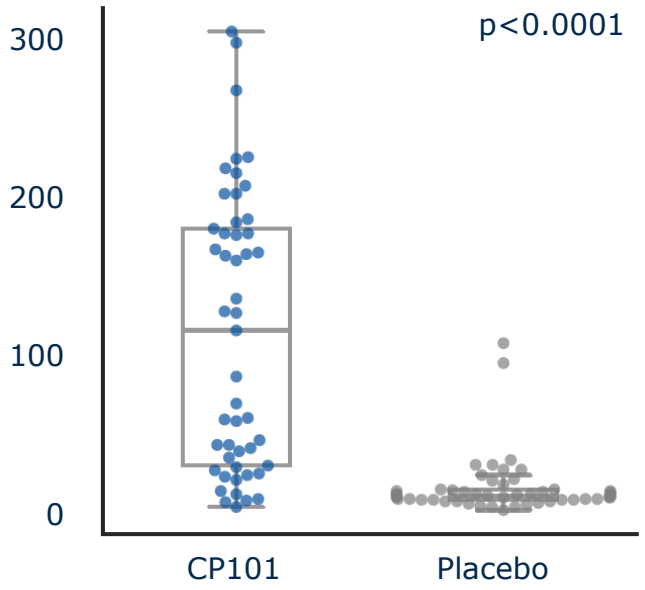

**Aggregated 88.2% of participants without CDI recurrence** through 8 weeks following last dose in a post-hoc analysis of participants that received up to two doses of CP101 in PRISM3 and PRISM-EXT*

SOC: Standard of care; SAEs: Serious adverse events; *Post-hoc analysis of 102 participants who received either a single dose of CP101 in PRISM3 (n=82) or two doses of CP101 by enrolling in PRISM-EXT (n=20)

# Strong relationship between CP101 engraftment and clinical outcomes in PRISM3

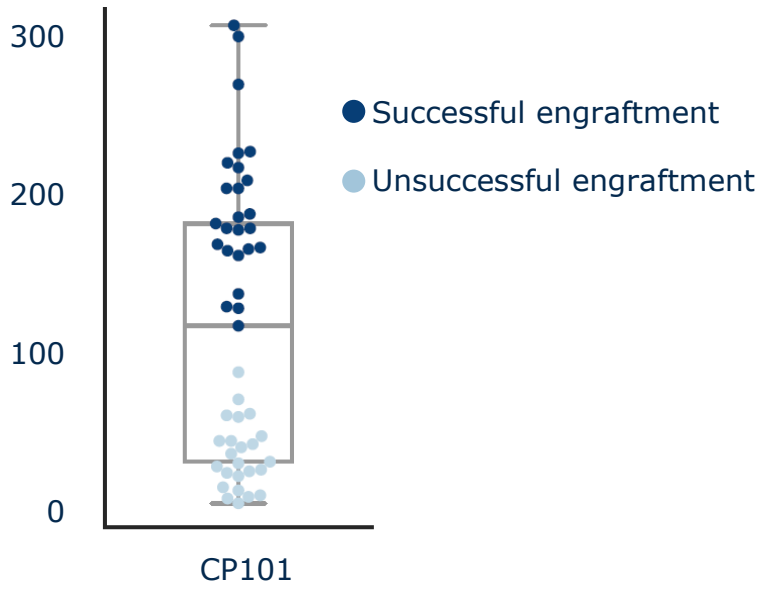
## CP101 showed significant engraftment overall

Number of engrafted CP101-associated taxa at Week 1



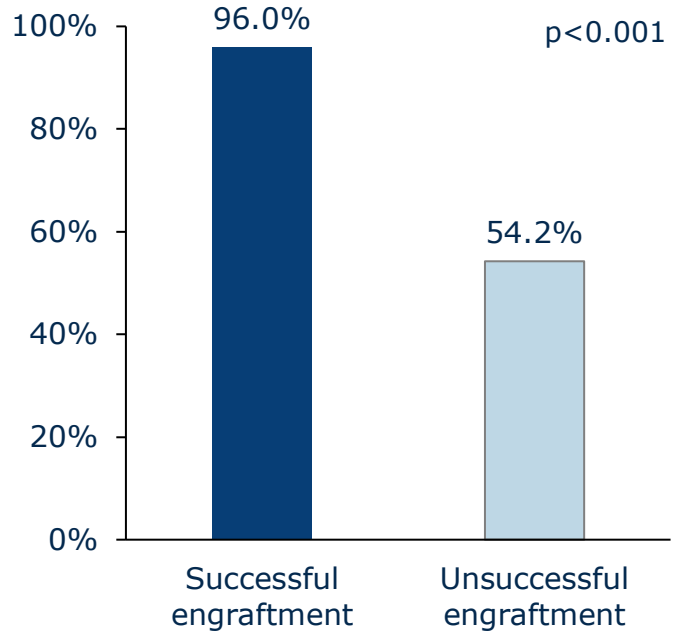

## Engraftment showed bimodal distribution

Number of engrafted CP101-associated taxa at Week 1




## Engraftment correlated with prevention of CDI recurrence

Proportion without CDI recurrence through Week 8 by engraftment group

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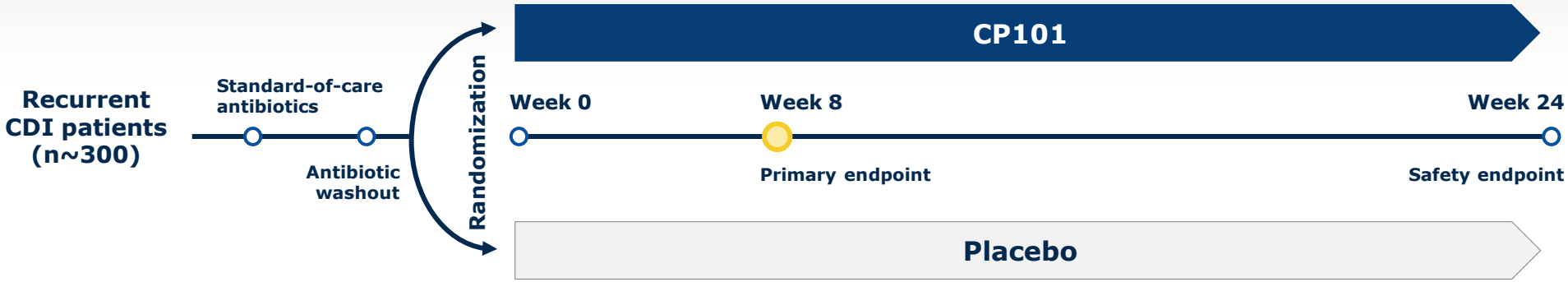
Source: CP101 Phase 2 study (PRISM3)

# PRISM4 Phase 3 trial of CP101 in recurrent CDI is designed to serve as a second pivotal trial to support a potential BLA for CP101




**Key Features**

1. Extension of antibiotic washout period to enhance engraftment
2. Sample size increased to enhance power
3. Global study to support marketing authorizations outside the US

Enrollment in PRISM4 will remain paused until Finch is able to resolve the clinical hold on the IND for CP101 related to Finch's SARS-CoV-2 screening protocols, address recent FDA feedback and conduct additional manufacturing activities to satisfy requests related to SARS-CoV-2 screening. Finch is evaluating the extent of the expected delay to the timing for resuming enrollment in PRISM4 and, based on manufacturing timelines, expects at least a one quarter delay.

# CP101 positioned to be market leader in recurrent CDI

**Convenient, one-time oral administration**

**Achieved primary endpoint in PRISM3, positioning CP101 to potentially serve a significant patient population:**

- All stages of recurrent CDI
- All test methods for CDI diagnosis

**Fast Track and Breakthrough Therapy designations for prevention of recurrent CDI**

**Efficient, scalable manufacturing enabled by molecular rather than chemical pathogen exclusion**

**Complete consortia composition provides potential for label expansion**

# TAK-524 & FIN-525 for Inflammatory Bowel Disease (IBD)

# Finch & Takeda working together to develop new therapeutics for IBD

**TAK-524 & FIN-525**

**Targeted Consortia**

**3.1M**

Affected by IBD in the US alone

**70,000**

Patients diagnosed with IBD per year in US

**20%**

With ulcerative colitis require colectomy

**$31B+**

In attributable costs per year in US

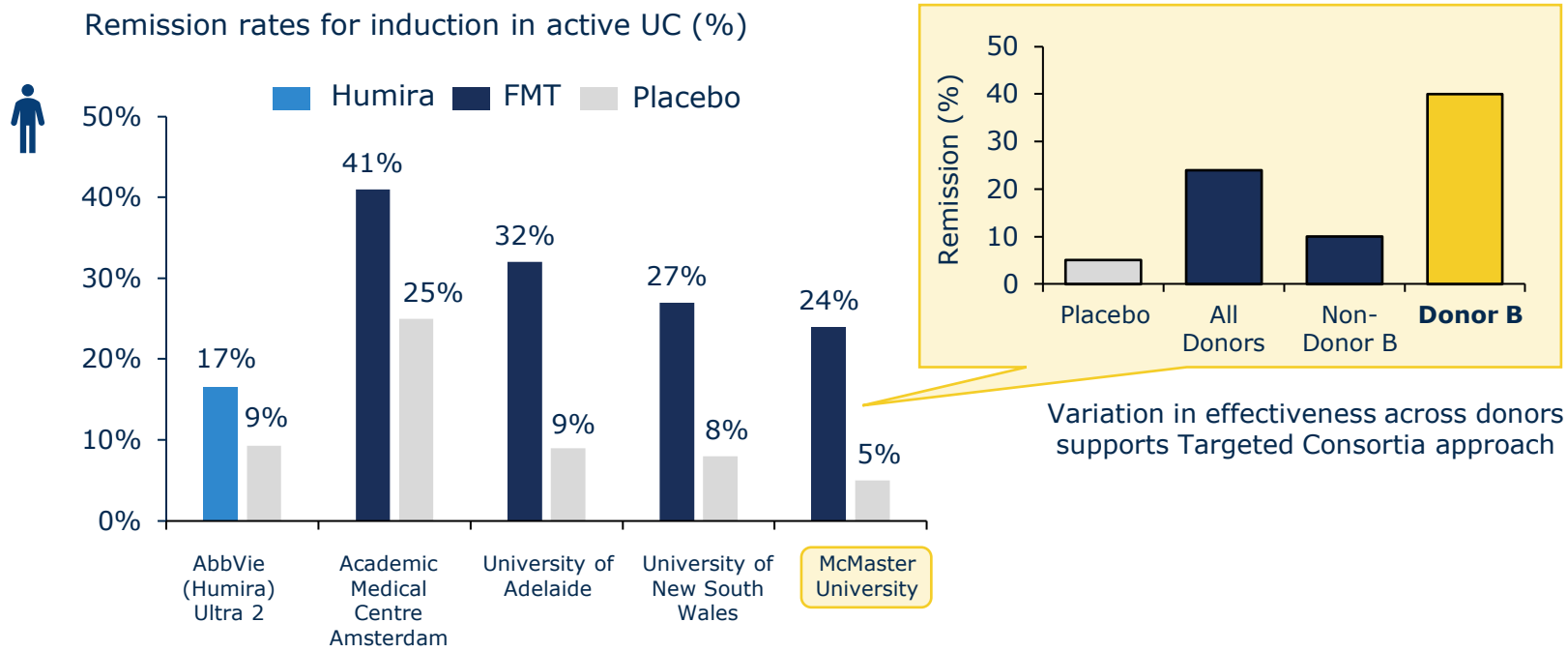
**Large unmet need for well-tolerated, effective therapeutics administered orally**

Sources: Dahlhamer MMWR 2016; Crohn's and Colitis Foundation: Facts About IBD 2014; Bernstein Inflamm Bowel Dis 2010

# Finch's machine learning platform enables identification and isolation of promising targets from clinical data

*TAK-524 illustrates the power of Finch's platform for the development of Targeted Consortia*

## Four placebo-controlled FMT trials show compelling results compared to current standard of care

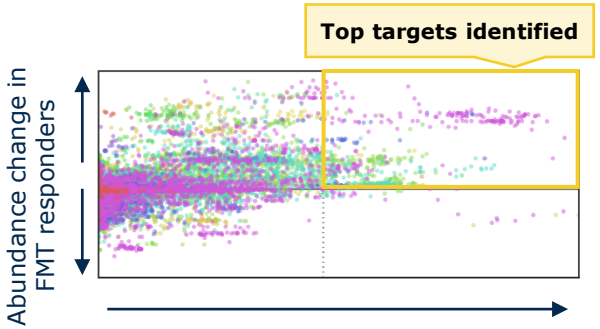



**TAK-524 ulcerative colitis development program advanced to Takeda for clinical development**

Sources: Rossen Gastroenterology 2015; Moayyedi Gastroenterology 2015; Paramsothy Lancet 2017; Costello JAMA 2017; Sandborn Gastroenterology 2012

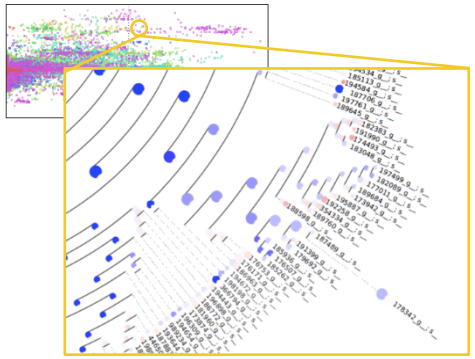
# Finch's combination of proprietary data and machine learning capabilities enable differentiated Targeted Consortia

**1. Reverse Translation Narrows Search Space**



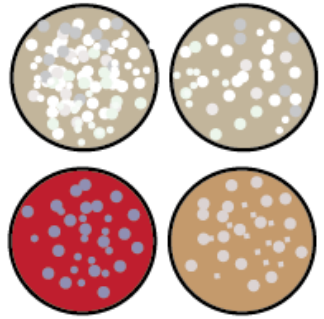

Depletion of microbes in patients with target condition, compared to healthy controls

**2. Proprietary Algorithms Uncover Strain-Level Hits**



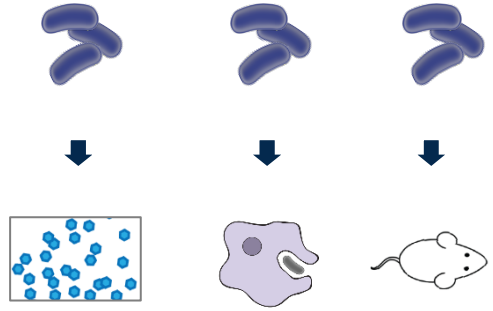
Phylogenetic analysis to identify strain-level signals

**3. Strain Isolation from Effective Donors**



Isolation of specific strains from donor samples that demonstrated promising results in the clinic

**4. Mechanism of Action Data Generation**



High throughput molecular screens | Human cells/tissue | *In vivo* models

**Finch's platform brings the power of AI to microbiome therapeutic development**

# TAK-524 is designed to engage multiple mechanisms that are important to ulcerative colitis

- TAK-524 contains 9 strains isolated directly from donors whose samples induced a response in clinical studies of FMT for UC
  - Consortia includes multiple phyla (spore and non-spore-forming organisms)
- TAK-524 is designed to include multiple strains targeting three key mechanisms and strategies:
  - 1: Production of immunoregulatory microbial metabolite class #1
  - 2: Empirical association with clinical efficacy in UC FMT studies
  - 3: Production of immunoregulatory microbial metabolite class #2

| TAK-524 strains | Target mechanisms | | | Supported by human FMT engraftment data |
|---|---|---|---|---|
| | 1 | 2 | 3 | |
| Strain 1 | ■ | ▫ | | ✓ |
| Strain 2 | ■ | ▫ | | ✓ |
| Strain 3 | ■ | | | ✓ |
| Strain 4 | ■ | | | ✓ |
| Strain 5 | | ■ | | ✓ |
| Strain 6 | | ■ | | ✓ |
| Strain 7 | | ■ | | ✓ |
| Strain 8 | ▫ | ▫ | ■ | ✓ |
| Strain 9 | | | ■ | ✓ |

■ Mechanism strongly engaged

▫ Mechanism engaged

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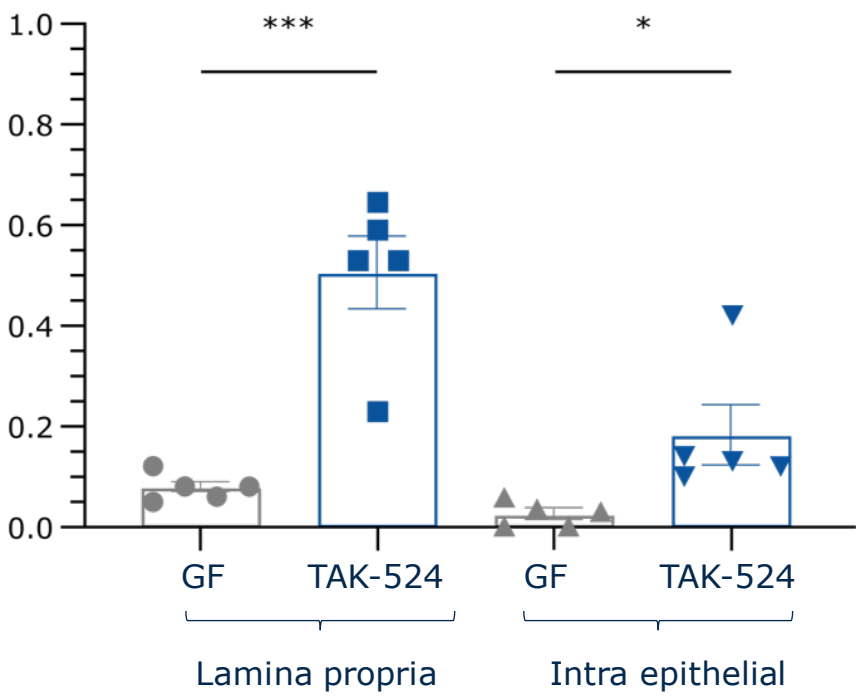
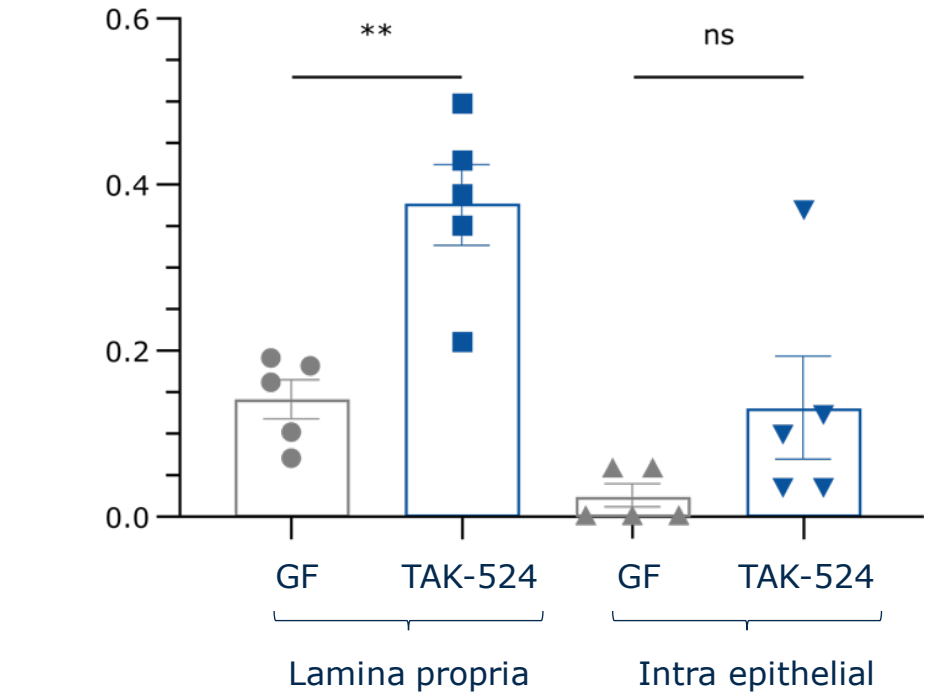
# Administration of TAK-524 *in vivo* expands GI regulatory T-cells that are important for immune suppression

## TAK-524 expands GI-*resident* Tregs




## TAK-524 expands GI-*induced* Tregs




**TAK-524 contains strains selected for their potential to provide targeted regulation of the immune system**

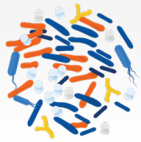
Tregs: Regulatory T cells; GF: Germ free

# FIN-211 for Autism Spectrum Disorder (ASD)

# ASD is a significant unmet need linked to the gut-brain axis

*Finch plans to initially focus on the subset of the ASD population suffering from significant GI symptoms*

**Complete Consortia** addresses community level dysbiosis



**FIN-211**

**Enriched Consortia**

**Targeted Consortia** ensure key mechanisms are consistently engaged

**4.6M**

Children and adults in the US with ASD

**>30%**

Report significant GI symptoms (diarrhea/constipation)

**0**

FDA-approved therapeutics for core symptoms of ASD

**$100B**

Annual cost to care for individuals with ASD in the US

**Autism is a large unmet need with no FDA-approved therapeutics for core symptoms**

FINCH

Sources: Chaidez J Autism Dev Disord 2014; Cao Shanghai Arch Psychiatry 2013; CDC Data and Statistics on ASD 2019; Leigh J Autism Dev Disord 2015

# Multiple lines of evidence point to a potential role of the microbiome in ASD

## 1. Epidemiology

- Early life events that impact the microbiome are associated with increased risk of ASD
  - Cesarean section: 33% higher ASD risk
  - Reduced breast feeding: 93% - 107% higher ASD risk
  - Antibiotics: 144% - 264% higher ASD risk

## 2. Mechanistic insights

**Oxytocin:**

- Findings of depleted levels of oxytocin in those with ASD
- Key, non-spore microbes induce oxytocin production

**Gut barrier:**

- Impaired gut barrier integrity and translocation of behavior-influencing metabolites (e.g. 4-EPS)
- Microbiome enhances gut barrier integrity

**Neuroinflammation:**

- Higher activation of microglia in those with ASD, which may impact neurological function and development

## 3. PoC FMT clinical studies

- Multiple FMT studies show improvements in both GI and behavioral endpoints

| Study | Number of participants | GI improvement | Behavioral improvement |
|---|---|---|---|
| Ward (2016) | **9** | N/A | ✓ |
| Kang (2017) | **18** | ✓ | ✓ |
| Zhao (2019) | **24** | ✓ | ✓ |
| Li (2019) | **85** | ✓ | ✓ |
| Huanlong (unpublished) | **31** | ✓ | ✓ |
| Li (2021) | **40** | ✓ | ✓ |
| **Total** | **207** | | |

**Recent Cell paper highlights the limitations of cross-sectional data and the value of interventional FMT evidence**

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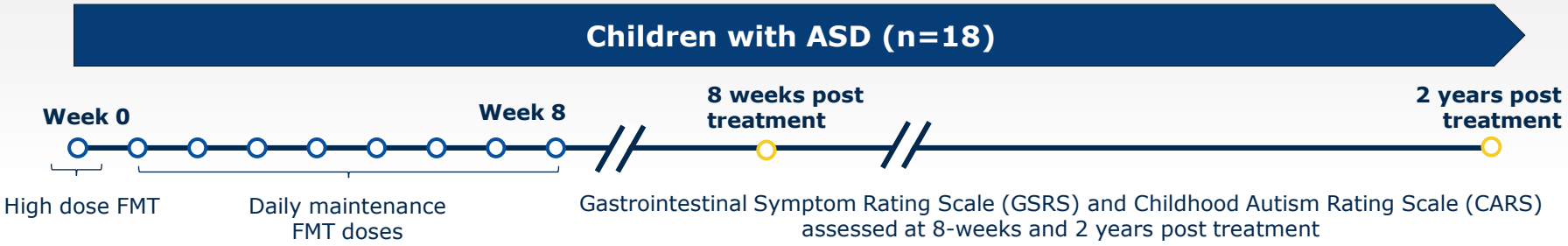
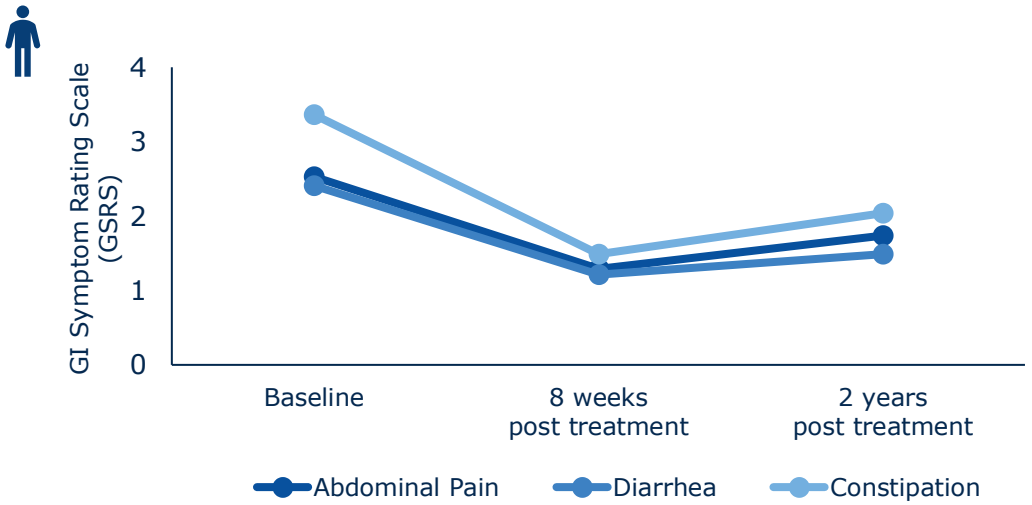
Sources: Ding J Autism Dev 2017; Zhang JAMA Netw Open 2019; Bittker Neuropsychiatr Dis Treat 2018; Modahl Biol Psychiatry 1998; Sgritta Neuron 2019; Needham Biol Psychiatry 2020; Hsiao Cell 2013; Antonini Front Immunol 2019; Suzuki JAMA Psychiatry. 2013; Kang Microbiome 2017; Kang Sci Rep 2019; Zhao Gastrointest Endosc 2019 (DDW Abstract); Ward Open Forum Infect Dis 2016 (ID Week Abstract); Li Zhonghua Wei Chang Wai Ke Za Zhi 2019; Li Front Cell Infect Microbiol 2021

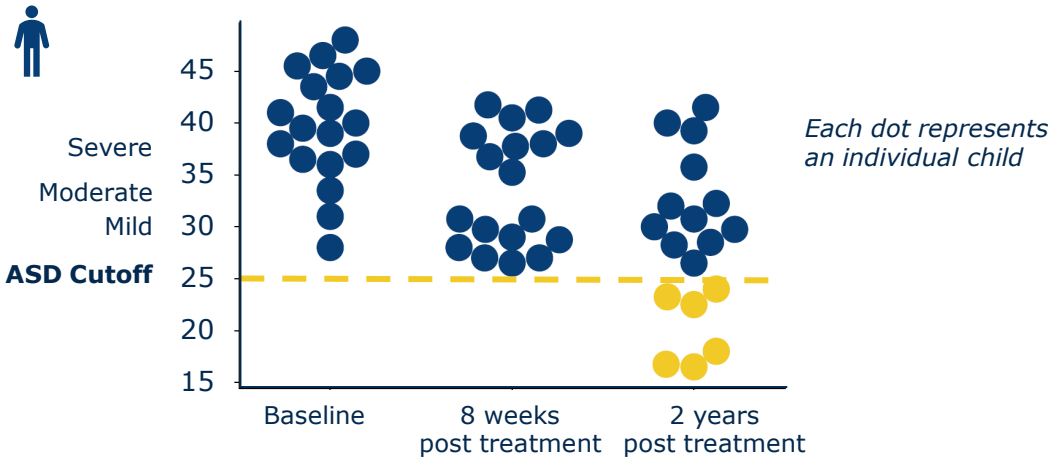
# Open label data shows improvements in both GI and behavioral symptoms following microbiota transplantation




## **58% reduction in GI symptoms** at 2 years post treatment compared to baseline




## **33% of children below the cutoff for ASD diagnosis** at 2 years post treatment

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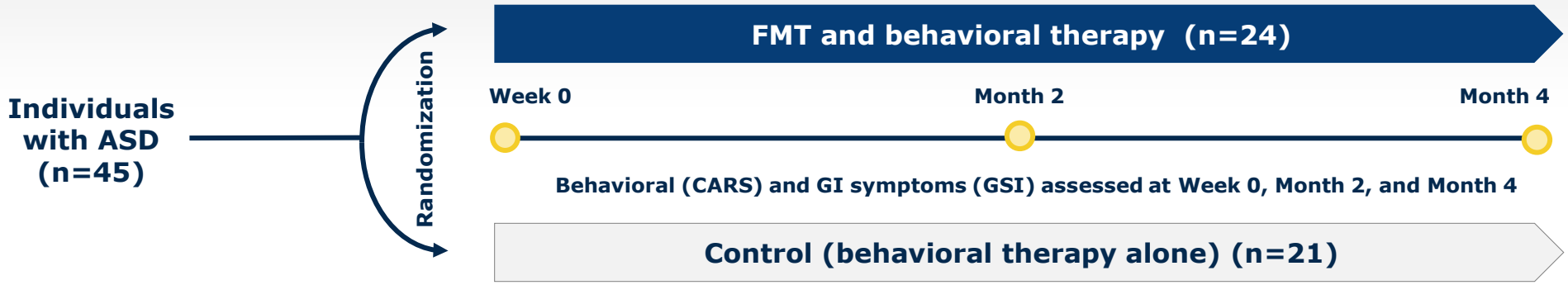
Sources: Kang Microbiome 2017; Kang Sci Rep 2019

# Randomized, independent clinical study showed improvement in both GI and behavioral symptoms following microbiota transplantation

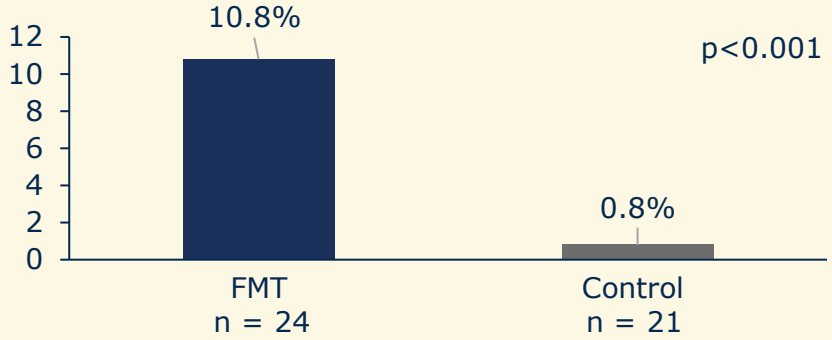



## Results at 2 months post FMT

- GI severity index (GSI) significantly improved
- Behavioral (CARS) scores significantly improved
- Microbiome shifted towards a healthy composition

### Behavioral scores significantly improved at 2 months post FMT

CARS score improvements at Month 2 (%)

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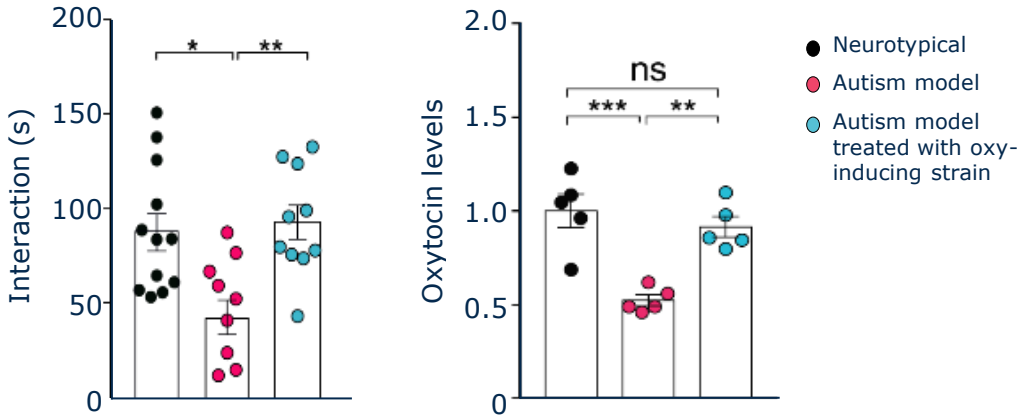
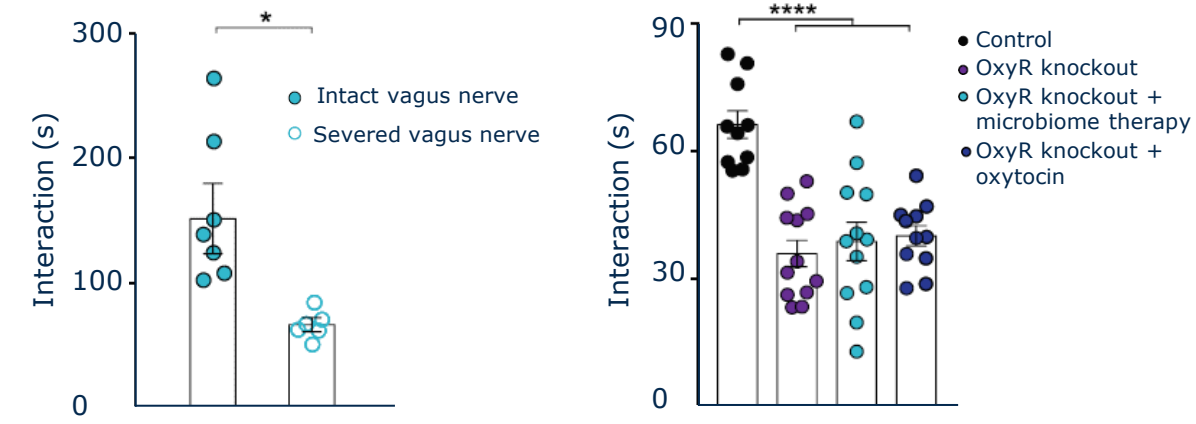
Source: Zhao Gastrointest Endosc 2019 (DDW Abstract)

# Preclinical data show oxytocin-dependent behavioral improvements with microbiome therapy

## Microbiome therapy restores neurotypical behavior and oxytocin production




## Therapeutic benefit is eliminated when vagus nerve is severed or oxytocin receptor knocked out

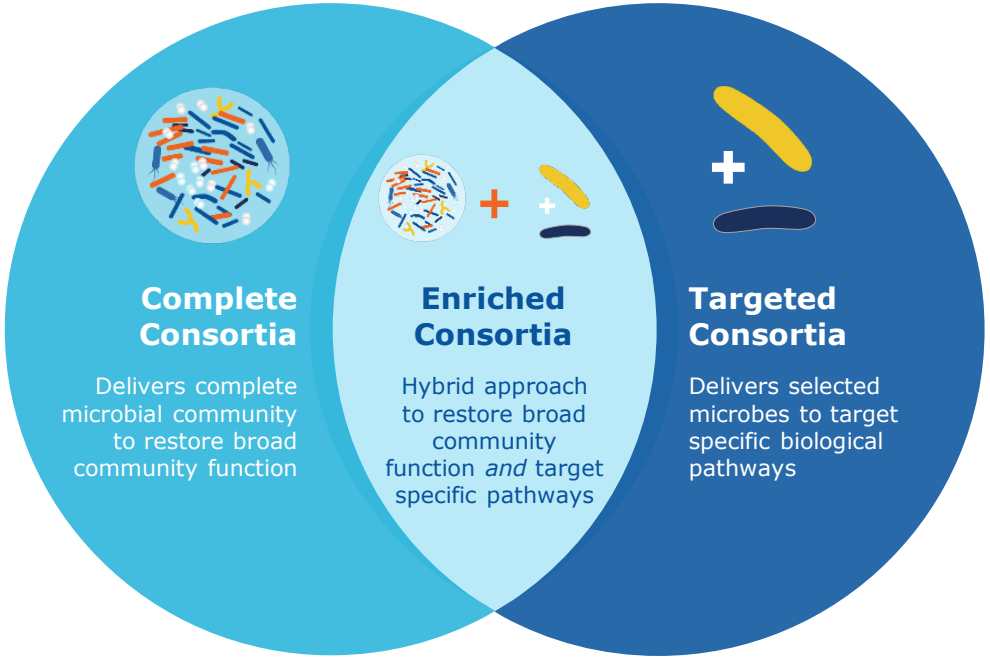



Sources: Sgritta Neuron 2019

# FIN-211 is designed to address both the gastrointestinal (GI) and behavioral symptoms of ASD

## Enriched Consortia product strategy

Designed to address both community-level and species-level dysbiosis in an oral formulation

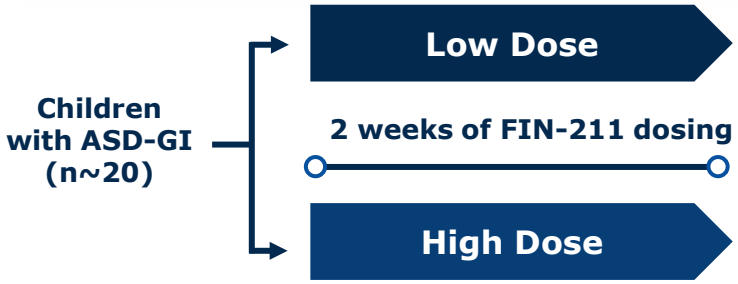



**Pre-IND FDA feedback yielded two key insights:**

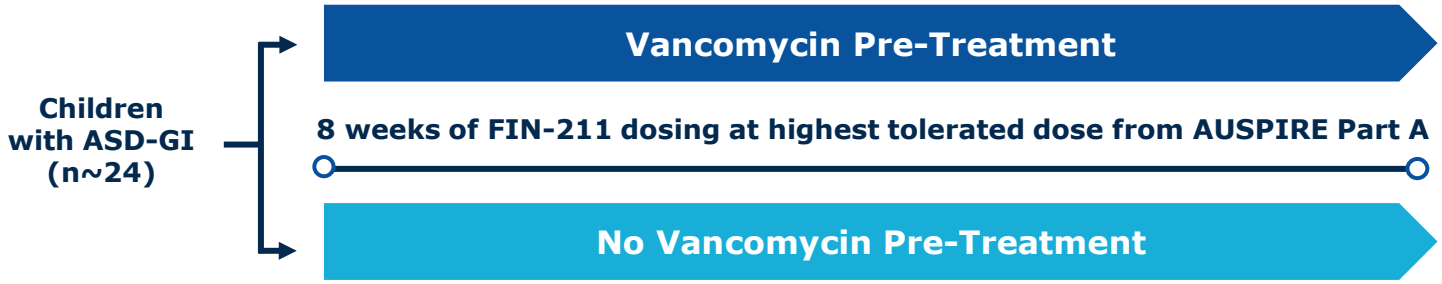
1. FIN-211 may proceed directly to children with ASD
2. Demonstrating benefit for *either* GI or behavioral symptoms could support a BLA

# Phase 1b AUSPIRE trial will evaluate multiple dosing regimens of FIN-211 in children with ASD and GI symptoms

## AUSPIRE Part A: Dose Escalation



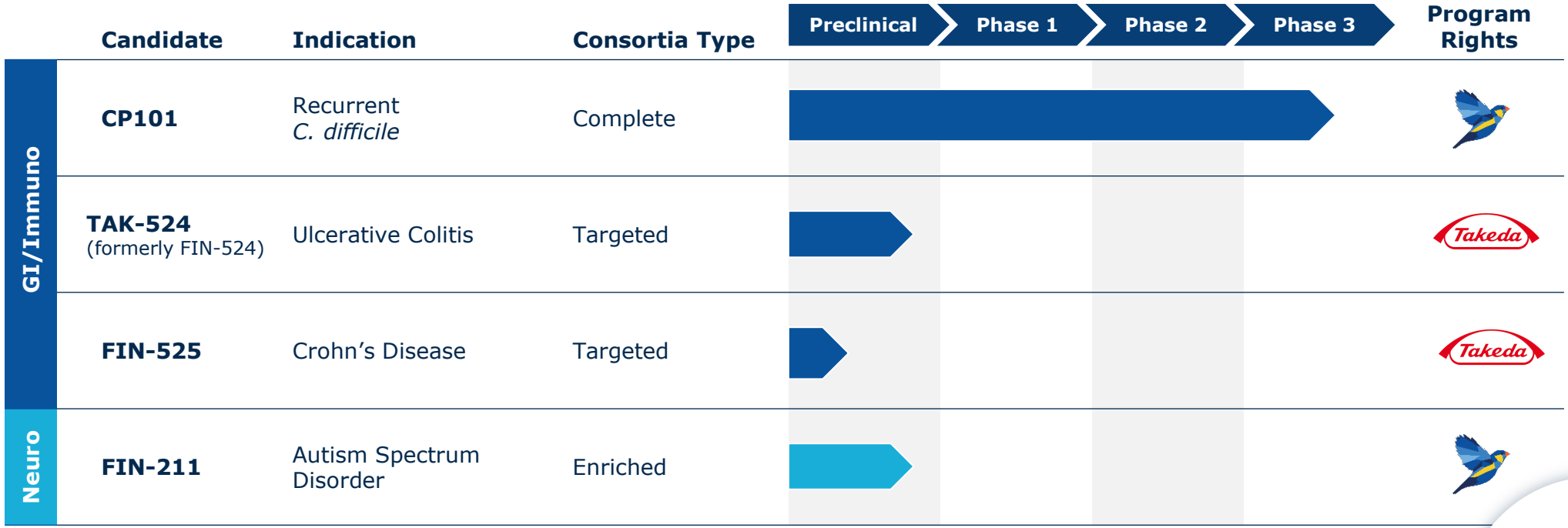

## AUSPIRE Part B: Expansion Cohort




| Ph1b Endpoints | |
|---|---|
| Primary endpoints | Safety & tolerability |
| Secondary endpoints | Pharmacokinetics (engraftment) |
| Exploratory endpoints | Behavioral endpoints, including CARS scores<br>GI endpoints, including spontaneous bowel movements |

The AUSPIRE trial of FIN-211, a product candidate that includes donor-derived components, will be delayed in connection with the clinical hold on the IND for CP101 related to Finch's SARS-CoV-2 screening protocols. Finch is evaluating the extent of the delay the clinical hold and related manufacturing activities will have on the expected timing of AUSPIRE and, based on manufacturing timelines, expects at least a one-quarter delay.

# Finch is advancing a diverse portfolio designed to establish entry points into new therapeutic areas




**Anticipated cash runway into mid-2023***

*As of 12/31/2021, cash and cash equivalents of $133.5 million

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# Harnessing the microbiome to transform patients' lives