Delivering on the Promise of the Microbiome to Transform Human Health

Microbiome Drug Development Summit
June 30, 2016

“The microbiome is the only “organ” that can be replaced without surgery”
-Ed Yong, NYT, Nov ’14

“The microbiome is a massive, untapped source of new health solutions

“What’s really exciting is not only understanding what role the microbiome plays in disease but how to use it to prevent disease and to invent new ways to treat various diseases
-Alison Morris. University of Pittsburgh, May ’16

“It’s still very early for developing therapeutics from the microbiome, but it’s moving very quickly.”
-Michael Fischbach. UCSF, Feb ’15

Image Source: New York Times
Targeting the microbiome for health solutions has the potential to be...

MORE NATURAL  CLOSER TO ROOT CAUSE  CLOSER TO A "POLYPILL"

In-Human Discovery Opens the Door for a New Development Paradigm

TODAY: 97% efficacy observed in FMT for C. diff

- Impact of donor/recipient characteristics on success
  - Optimized engraftment for greater efficiency
  - Best way to translate into safe product
- Impact of pre-treatment

TOMORROW: Insights into mechanism drive new opportunities
The microbiome will play a critical role at every point along the wellness spectrum

Microbiome Solutions Along A Patients Health Journey

Health

Disease

The future of the microbiome:

- The microbiome is central to health management
- Dozens of FDA approved microbiome products spanning Rx, OTC, and Dx on market
- Consumers & physicians routinely deploy microbiome solutions to maintain and restore health
- Methods for building protectable IP established
- Advanced understanding of how microbes affect disease unlocks the next wave of microbiome therapeutics
- Big data is an accelerant spurring new healthcare solutions
Many Challenges Must be Addressed to Deliver Novel Therapies

Venturing into unchartered territory requires assessment of challenges faced and capabilities required

The Janssen Human Microbiome Institute
We are advancing a collaborative model to deliver on the microbiome’s potential

**OUR MISSION**

Partner with external innovators to translate microbiome science into therapies and products that will transform human health

**OUR COMMITMENT TO PARTNERS**

- Counsel to shape promising products
- Novel tools and platforms to drive innovation
- Access to a world-class network of internal and external experts
- Thought leadership to advance the field

Cross-sectional / longitudinal studies are instructive... prospective and interventional cohorts are critical compliments to developing actionable insights
Diverse Partnering Opportunities Across Specialties

- Specimen Collection, Preservation & Transport
- In-human Insights Generation
- Specimen Processing
- Microbiome Analytics
- Data Generation
- Sample- and Strain Characterization
- Strain Isolation
- In vivo / In vitro Models
- GMP Manufacturing Facilities

Commodity 2016
Commodity 2020
Continuous Value

Pursuing transformative therapies today: VE202 for IBD

VE202 is just the beginning; next steps will only further define the pathway to product
JHMI brings focus to 5+ years of microbiome efforts across Janssen/J&J

Teams exploring the microbiome today:
- IBD – Vedanta, APC, Enterome
- Disease Interception Accelerator – T1D, Gestational Diabetes
- Consumer – Dermatology & Gut Health
- T2D, Obesity, Metabolic Disorder – Intrexon
- Plus various efforts by Oncology, Infectious Diseases, Janssen Prevention Center and JLINX

Access Expertise in All Aspects of Discovery, Development, and Commercialization

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- Incubation (JLABS)
- EIR & Innovator Programs
- NewCo Creation
- Sponsored research
- R&D collaborations
- Licensing and M&A
- Venture funding
Linking Partners to an Expert Global Network

Big opportunities can come from the smallest places
Thank You

Dirk Gevers, PhD
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