MICROBIOME MOVEMENT DRUG DEVELOPMENT *Europe*

CELEBRATING OUR 4TH YEAR

February 4-6, 2020 | London, UK

Pursuing Disease Causation to Foster the Creation of Microbiome-Based Therapeutics, Biomarkers & Diagnostics

Rikke Nielsen
CEO & Founder
Beo Therapeutics

Luc Sterkman
CEO
Caelus Health

Sebastien Guery
Human Microbiome Venture Leader
Dupont Microbiome Venture

Rafael Suarez
Senior Director Gastroenterology & Mirobiome
Ferring Pharmaceuticals

Mike Romanos
CEO
Microbiotica

Tomas de Wouters
CEO & Co-Founder
PharmaBlome

Ken Blount
CSO
Rebiotix

Imke Mulder
Director of Research
4D Pharma

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WELCOME TO THE MICROBIOME MOVEMENT

A LETTER FROM OUR PROGRAM DIRECTOR & CO-FOUNDER

Overcome Translational Challenges, Understand the Market and Establish Valuable Connections to Push Your Microbiome Program to Commercialisation

As the first microbiome-based therapeutic steps closer to market approval, the scientific community continue to demonstrate the functional role of the human microbiome as a novel source of therapeutic, biomarker and diagnostic development. Despite this progress, the vast potential to develop effective treatments that target the human microbiome is still limited by the complex challenges in developing them.

Part of the foremost conference series for microbiome researchers in industry, the **4th *Microbiome Movement* – Drug Development Europe** 2020 returns to unite leading scientists from the biopharmaceutical and academic community to pursue the causal role of the microbiome in disease, and help create a new generation of microbiome-targeted therapeutics with predictable modes of action and consistent clinical outcomes.

Across three days of case-studies, discussion and debates, learn how industry and academic leaders are understanding microbiome functionality across key therapeutic modalities, leveraging big data platforms to deduce causality, and overcoming regulatory, clinical and manufacturing hurdles to further accelerate their pipeline across new disease targets.

At this critical time, and as the microbiome community waits for the first clinical breakthrough, join your peers and unlock the potential of the human microbiome to create the next generation of microbiome-based therapeutics and diagnostic candidates of the future.

Alexander Puttick

Program Director & Co-Founder
Microbiome Movement

10 KEY QUESTIONS TO BE TO BE EXPLORED & ASNWERED

01 What are the Targets, Platforms, and Challenges for Novel Live Biotherapeutics?

02 How can you Demonstrate a Causative Clinical Benefit for Microbiome-based Therapeutics?

03 How are Organisations Scaling and Manufacturing Microbiome-based Therapeutics?

04 What are the Limitations when Translating Animal Studies to Humans?

05 What is the Role of the Microbiome in Cancer Therapy Response?

06 How can Strategic Collaborations Drive the Future of Microbiome-based Applications in Healthcare?

07 How can Start-Ups Raise Capital to Accelerate Microbiome-Focused Drug Platforms?

08 How is the Human Microbiome Blurring the Lines Between Food and Pharma?

09 How can Researchers Utilise Synthetic Biology to Engineer Bacteria as Living Therapeutics?

10 Will Phage Therapeutics Hold the Key to Modulating the Microbiome?

2 DEDICATED TRACKS OF CONTENT

35+
Expert Speakers

Functionality, Mechanisms & Pre-Clinical Development of Microbiome-based Therapeutics

Learn how the leaders in the field are defining host microbiome interactions, identifying new targets and addressing the current challenges in the pre-clinical development of microbiome-based therapeutics across a broad range of modalities and disease phenotypes

Clinical Translation, Manufacturing & Commercialization of Microbiome-based Therapeutics

Navigate through the evolving translational, clinical, and manufacturing challenges of microbiome-based therapeutics to help improve clinical outcomes and bring these products to a commercial scale

12+
Hours of Networking & Collaboration

WHAT THE MICROBIOME COMMUNITY SAYS:

"**The right people, size of event and content all make this a must attend conference for anyone in the commercial microbiome discovery and therapuetic field.**"

Sean Macleod, CEO & Founder, **Fenologica**

"**This conference series gets better and better every year, demonstrating and tracking the progress of the microbiome therapeutics field. Certainly the best conference on this theme that I have attended in my 10+ years in the field.**"

Gerard Honig, Associate Director Research Innovation, **Crohn's & Colitis Foundation**

"**What I like the most about the Microbiome Movement - Drug Development Summit are the type of people here. This conference is really focused on drug development, biotech and creating real products.**"

Travis Whitfill, CSO, **Azitra**

"**It's one of the best conferences targeting the microbiome area. Over the last two years, the program has grown really nicely to address many of the different hurdles and opportunities that we're facing in the microbiome area.**"

Sara Malcus, CEO, **Metabogen**

AGENDA AT A GLANCE

PRE-CONFERENCE WORKSHOP DAY
TUESDAY 4TH FEBRUARY

WORKSHOP A
Treating Women's Health through the Human Microbiome

WORKSHOP B
Using Metagenomics and the Human Microbiome to Address Antimicrobial Resistance

WORKSHOP C
Learning from FMT to Inform Clinical Trial Development of Microbiome-based Therapeutics

CONFERENCE DAY 1
WEDNESDAY 5TH FEBRUARY

Morning Plenary - Microbiome Leaders Panel Discussion

Speed Networking

STREAM A: Microbiome Functionality & Pre-Clinical Development	STREAM B: Clinical Translation, Manufacturing & Commercialisation
LBP Discovery & Development	Demonstrating a Causative Clinical Benefit

Lunch & Networking

Microbiome-derived Molecules Discovery & Development	Manufacturing & Scaling LBPs
Translating Animal Studies to Humans	

Afternoon Refreshments & Networking

Afternoon Plenary - Interactive Mastermind Session

CONFERENCE DAY 2
THURSDAY 6TH FEBRUARY

Morning Plenary – The Human Microbiome in Cancer Therapy Response

Morning Refreshments & Networking

STREAM A: Microbiome Functionality & Pre-Clinical Development	STREAM B: Clinical Translation, Manufacturing & Commercialisation
Synthetic Biology to Engineer Living Therapeutics	Strategic Collaborations for Microbiome-based Applications in Healthcare
Phage Therapies to Modulate the Microbiome	Raising Capital for Microbiome-based Therapeutic Programs

Lunch & Networking

Afternoon Plenary - The Borderline Between Pharma and Food

Close of 4th Microbiome Movement – Drug Development Europe

WORLD-CLASS SPEAKER FACULTY

Lothar Steidler
Chief Technology Officer
ActoBiotherapeutics

Andrea Doolan
CEO
Atlantia Food Clinical Trials

Rikke Nielsen
CEO & Founder
Beo Therapeutics

Adrien Nivoliez
CEO
biose industrie

Elran Haber
CEO
Biomica Ltd.

Assaf Oron
Chief Business Officer
BiomX

Dora Nagy-Szakal
CMO
Biotia, Inc.

Jeffrey Heiser
Director Microbiology
Boston Analytical

Luc Sterkman
CEO
Caelus Health

Arne Materna
Vice President Product
CosmosID

Michael Osso
President & CEO
Crohn's & Colitis Foundation

Jean de Gunzburg
CSO
DaVolterra

Sebastien Guery
Human Microbiome Venture Leader
Dupont Microbiome Venture

Igor Stzepourginski
Head of Preclinical Operations
Eligo Biosciences

Christophe Lacroix
Professor, Food Biotechnology
ETH Zurich

James McIlroy
Founder & President
Enterobiotix

Romain D'Ailiere
Head of Preclinical Research & Co-Founder
EverImmune

Rafael Suarez
Senior Director Emerging Brands, Global Marketing, Gastroenterology & Microbiome
Ferring Pharmaceuticals

Kristin Wannerberger
Director R&D Alliance Management
Ferring Pharmaceuticals

Suhyun Kim
Postdoctoral fellow
Harvard University

Shahram Lavasani
CEO & Founder
Immune Biotech

WORLD-CLASS SPEAKER FACULTY

Lars Engstrand
Professor
Karolinska Institutet

Ina Schuppe-Koistinen
Alliance Director, CTMR
Karolinska Institutet

Georges Rawadi
CEO
LNC Therapeutics

Jason Ryan
Upstream Manager
Luina Bio

Damien Keogh
CEO
Maiden Therapeutics

Sophie Durand
Co-Founder
Microbiome Foundation

Mike Romanos
CEO
Microbiotica

Trevor Lawley
CSO
Microbiotica

Herwig Bachmann
Expertise Group Leader
Fermentation
NIZO

Maria Akerman
Director Process R&D
Oxthera

Tomas de Wouters
CEO & Co-Founder
PharmaBlome

Aurelien Baudot
International Business
Developer
ProDigest

Ryan Wilson
Head of Live-Bio
Programmes
Quay Pharma

Ken Blount
CSO
Rebiotix

Anna Williamson
Senior Director
Head of UK Business
Development
Roche/Genentech

Isabelle de Cremoux
CEO
Seventure Partners

Alain Roulet
Laboratory Director
Vaiomer

Kareem Barghoti
Co-Founder
VastBiome

Bruce Roberts
CSO
Vedanta Biosciences

Imke Mulder
Director of Research
4D Pharma

PRE-CONFERENCE WORKSHOP DAY | TUESDAY, 4 FEBRUARY

WORKSHOP A
9:00 - 11:30

Treating Women's Health through the Human Microbiome

With most of the research attention on the gut microbiome, there is a growing interest in the microbiome to better understand female reproductive, vaginal, and offspring health. More specifically, recent evidence has demonstrated that the vaginal microbiome plays an important role in successful fertilisation and health pregnancies. This workshop will review the current understanding of microbes in female health, as well as the opportunity to develop new microbiome-targeted products for diseases including HPV infections, bacterial vaginosis as well as pregnancy health.

Join this session to:

- Better identify how techniques are applied to determine a "healthy" vaginal microbiome
- Understand how the composition of the microbiome change for pregnant and postpartum women?
- Identify which health conditions can be better understood through analysis of the vaginal, oral and gut microbiome of women?
- Develop new microbiome-targeting products that help tackle widespread needs in women's health

Ina Schuppe-Koistinen
Alliance Director, CTMR
Karolinska Institutet

WORKSHOP B
12:00 - 14:30

Using Metagenomics and the Human Microbiome to Address Antimicrobial Resistance

As the spread of infectious diseases and growing AMR continues within the hospital environment, information gathered from the microbiome, metagenomics, and bioinformatic analysis has been identified as a tool to help diagnose infections and stop the spread of infectious disease. This workshop will outline the tools required to create efficient microbiome systems that can help identify AMR pathogens, manage hospital systems, and protect humans against infectious disease.

Join this session to:

- Harness microbial information to understand how microbes evolve and spread in various environments, including hospitals
- Understand how new bioinformatics tools can be used to provide new insights on AMR pathogens
- Learn how artificial intelligence can better predict patterns to guide patient treatments
- Leverage insights gathered from the microbiome to fight infectious disease through the development of precision diagnostics

Dora Nagy-Szakal
CMO
Biotia, Inc.

WORKSHOP C
15:00 - 17:30

Learning from FMT to Inform Clinical Trial Development of Microbiome-based Therapeutics

Often seen as the origin of microbiome-targeting therapies, FMT can provide important insights to drug developers and healthcare practitioners on the clinical efficacy of bacteria-based therapeutics to help treat disease. This workshop will gather insights from clinical experts to discuss the important milestones of FMT as a therapeutic modality and understand how these insights can be leveraged to design more targeted microbiome-based therapeutics.

Join this session to:

- Gain an update on the current use of FMT as a modality to treat disease
- Understand the successes and challenges of using FMT in practice
- Learn how results from FMT interventions can help the drug development community learn the key clinical trial considerations for future microbiome-targeting therapies
- Develop standards in clinical microbiome intervention studies to better assess comparability of results

James McIlroy
Founder & President
Enterobiotix

Microbiome Leaders Panel Discussion – Is Microbiome Causation a Reality for Patients?

Introduction and Purpose:

The gut microbiome continues to be at the fore front of medical research and both the industrial and academic communities expect that insights gained from microorganisms will soon become a critical component of health management across a gamut of critical indications. However, the biggest hurdle in translating promising gut microbiome research into effective therapeutic candidates is demonstrating the causative role of human microbiome in disease pathology. Although there are a growing number of microbiome-based candidates showing promising results in both pre-clinical and clinical settings, the approaches that are likely to have well-validated mechanisms of action are limited. This opening discussion will look to unite leaders from industry to review the current thinking in approaching the human microbiome mechanistically and understanding what is needed to overcome to translate novel findings into therapeutics of the future.

Tomas de Wouters
CEO & Co-Founder
PharmaBlome

Mike Romanos
CEO
Microbiotica

Ken Blount
CSO
Rebiotix

Isabelle de Cremoux
CEO
Seventure Partners

8.30 **Microbiome Leaders Panel Discussion**

- What are the current strategies to take microbiome-based therapeutics to market?
- What role will partnerships play in future therapeutic strategies?
- What can public institutions and regulators do to support the microbiome sector?
- What tools can be utilised to reveal causation and molecular mechanism of microbiome-based therapeutics?
- Given the status of the microbiome, where do you see the industry developing in five years?

9.30 **Shotgun Sequencing & Strain-Level Analysis: Study Design for Pre-Clinical & Clinical Development**

- Study design considerations for safety and efficacy studies
- Standards, controls and compliance for clinical studies
- QC of Live Microbial Products (LBPs, FMT and Probiotics)

Arne Materna
Vice President Product
CosmosID

10.00 **Gut Microbiome Endgame: Ramping up cGMP Program Design to Ensure Regulatory Preparedness for Microbiome Products**

- Implementing program design approaches in order to ensure regulatory approval for IND filings
- Evaluation of successful clean room commissioning, release testing characterisation and stability testing approaches
- Providing an in-depth evaluation of the expertise required in order to successfully bring a microbiome-based product into the next phase of a program's lifescycle

Jeffrey Heiser
Director Microbiology
Boston Analytical

10.30 **Morning Refreshments and Speed Networking**

STREAM A: FUNCTIONALITY, MECHANISMS & PRE-CLINICAL DEVELOPMENT OF MICROBIOME-BASED THERAPEUTICS

What are the Targets, Platforms, and Challenges for Novel Live Biotherapeutics?

Introduction and Purpose:

LBPs have the promise of providing the same efficacy as FMTs but with more characterised, and therefore predictable safety profiles. Currently, there has been a growing body of the use of LBPs across a variety of disease phenotypes, including IBD, Diabetes, Cancer, Autism and many more. The purpose of this theme will be to review cutting-edge case studies on the use of LBPs to reverse disease phenotypes driven by an unwanted dysbiosis in the human microbiome.

11.30 **Bottom-Up Design of Therapeutic Consortia Using Co-Cultivation**

- Development of indication specific consortia addressing key modes of action
- Biologically validated rules of assembly for engineering of consortia
- Strong biotechnology allowing co-cultivation of strains for validation and production of consortia
- Focus on maintenance of functionality, viability and composition in the product

Tomas de Wouters, CEO & Co-Founder, **PharmaBlome**

12.00 **Novel Therapeutic Approaches Targeting the Microbiome in Metabolic Diseases**

- From medical food to microbiome-based drugs: LBP or Live Biotherapeutic Product
- Discovering the therapeutic potential of christensenella
- Discussing the challenges of LBP development

Georges Rawadi, CEO, **LNC Therapeutics**

STREAM B: CLINICAL TRANSLATION, MANUFACTURING & COMMERCIALISATION OF MICROBIOME-BASED THERAPEUTICS

How Can You Demonstrate a Causative Clinical Benefit for Microbiome-based Therapeutics?

Introduction and Purpose:

As a number of microbiome-based therapeutics enter a pivotal stage in clinical development, there are still major questions surrounding best practice in designing, scaling and progressing through the clinic. Successful in-human clinical efficacy data will help cement the success of microbiome-based therapeutics and continue to fuel the industry. The purpose of this theme will be to outline developments from industry and academia when executing clinical trials for therapies that aim to target the human microbiome.

11.30 **Unlocking the Potential of the Microbiome: Oxalobacter formigenes for the Treatment of Primary Hyperoxaluria**

- Pursuing the development of Oxabact®, a live biotherapeutic drug made of lyophilized Oxalobacter formigenes.
- OxThera has completed three double-blinded phase II/III clinical studies with different formulations (OC3 and OC5)
- Confirmation of long-term efficacy and safety through the ongoing phase III, double-blind, placebo-controlled study

Maria Akerman, Director Process R&D, **Oxthera**

12.00 **Prevention of Recurrent Clostridium Diifficule Following Treatment with Microbiota-based Therapy: Clinical Results and Considerations**

- Demonstrating how RBX2660 was efficacious for the prevention of rCDI with long-term durability at 6 months post-treatment
- Evaluating consistency with other ongoing clinical studies
- Exploring clinical trial design and considerations when working with LBP products

Ken Blount, CSO, **Rebiotix**

12.30 **Developing Microbiome-Empowered Therapeutics for the Treatment of Immune-Mediated and Infectious Disease**

- Powering discovery and development using an advanced computational platform for high-resolution taxonomy and functional profiling of the microbiome
- Integrating AI to characterise host-microbiome interactions
- Sharing two compounds in GI and Immuno-Oncology (in combination with ICI)

Elran Haber, CEO, **Biomica Ltd.**

12.30 **Culturing and Scale up of Live Biotherapeutic Products**

- One key challenge in the microbiome field is the culturing and scale up of new Live Biotherapeutic Products (LBPs)
- The translation of the culturing, processing and formulation of these bacteria from lab to production scale including downstream processing is very species and strain specific
- The combination of our expertise and pipeline ranging from lab to production scale, enable the optimization of the economics of LBPs

Herwig Bachmann, Expertise Group Leader Fermentation, **NIZO**

13.00 **Delivery, Survival, Engraftment & Activity of LBPs in the GI Tract**

- Sharing how validated *in-vitro* technology platforms are a key tool for the pre-clinical work in LBPs development
- Exploring how the SHIME system enables integrated simulation of the full GI track, including lumen, mucosa and host
- Investigating the MoAs of LBPs in areas of the gut, which are not easily accessible, generating data complementary to *in vivo* studies

Aurelien Baudot, International Business Developer, **ProDigest**

13.00 **Clinical Trial Considerations for Microbiome-targeted Therapeutics**

Andrea Doolan, CEO, **Atlantia Food Clinical Trials**

13.10 **Lunch and Networking**

How are Microbial-Derived Metabolites Changing the Face of Microbiome Therapeutics?

Introduction and Purpose:

Many researchers are identifying and characterising microbial by-products that modulate host function and can therefore be used as a viable therapeutic. Due to the unknown regulatory/ manufacturing requirements for LBPs, many organisations are exploring the small molecule route as it is closely aligned to traditional pharmacology strategies. The purpose of this theme will be to review how organisations are targeting and validating new therapeutics based on by products of clinically relevant microbial species.

14.00 **Mining the Microbiome for Novel Therapeutics**

Kareem Barghoti, Co-Founder, **VastBiome**

14.30 **Discovering Molecular Therapeutics from Natures 'Transfer Microbiome' – Human Milk**

- Contributions of microbiomes across pregnancy, birth, and breastfeeding to human development
- The Importance of Asian Microbiomes
- Developing microbiome-derived molecular therapeutics

Damien Keogh, CEO, **Maiden Therapeutics**

From Lab to Commercialisation – How are Organisations Scaling and Manufacturing Microbiome-based Therapeutics?

Introduction and Purpose:

As drug developers prepare to scale from early proof of concept to commercial scale therapeutics, downstream processing and formulation within the microbiome have been largely unexplored. The purpose of this theme will be to review the current industry thinking on manufacturing and scale-up of microbiome-based therapeutics.

14.00 **Clinical and Manufacturing Considerations for Rationally Designed Live Bacterial Cocktails**

Bruce Roberts, CSO, **Vedanta Biosciences**

What are the Limitations when Translating Animal Studies to Humans?

Introduction and Purpose:

Prior to initial Phase 1 studies, a preliminary characterisation of a microbiome therapeutic has to be made using a combination of, in-vitro/in-silico assays, animal models . The purpose of this theme will be to outline the most predictive preclinical strategies that address key regulatory and safety considerations whilst guaranteeing future clinical success.

15.00 **Intestinal Microbiota Dysbiosis in Antibiotic-induced C. difficile Infection: an Example of Inferences from Animal Studies and Translation to Humans**

- DAV131A dose-range studies with several antibiotics allowed to modulate antibiotic concentrations in the gut of hamsters, changes in diversity and intestinal microbiota composition were analysed by16S rRNA gene targeted metagenomics
- Various statistical and machine learning approaches were used to identify the bacterial taxa affected by antibiotic treatments, and predict those that were key to protect hamsters from lethal CDI.
- Possible translation of the results to humans will be discussed

Jean de Gunzburg, CSO, **DaVolterra**

15.30 **The Blood Microbiome: New Source of Biomarkers for Infectious and Non-Infectious Diseases**

- Demonstrating the existence of a highly diverse blood microbiome in health human donors
- Understanding the role of bacterial translocation in diseases to discover new diagnostic and companion biomarkers
- Designing assays to analyze bacterial DNA in blood and tissues of healthy donors

Alain Roulet, Laboratory Director, **Vaiomer**

15.40 **Early Break for Afternoon Refreshments**

14.30 **Novel Technologies for the Production of Strict Anaerobic Gut Microbes**

- Exploring the complex growth requirements for intestinal microbes, including growth in continuous fermentations with high degrees of cross feeding
- Discussing new strategies to improve the manufacturing of LBPs including single strains and consortia
- Highlighting the importance of continuous fermentations, bacterial immobilization, and microbial biomass stabilization to efficiently manufacture LBPs while reducing costs for global health applications

Christophe Lacroix, Professor, Food Biotechnology, **ETH Zurich**

15.00 **Development of Oral LBPs – a CDMOs Perspective**

- Key CMC considerations for the development of an LBP
- Understanding critical factors affecting timelines when outsourcing GMP manufacturing activities of LBPs
- Incorporating quality systems and regulations into early phase dosage from design of LBPs

Ryan Wilson, Head of Live-Bio Programmes, **Quay Pharma**

15.30 **Scale Up & GMP Manufacture of LBPs**

- Consideration for technology transfer and development of LBPs prior to GMP
- Assessing the scale-up considerations and challenges associated with LBPs in early clinical trial material
- Outlining viability and yield considerations throughout the manufacturing process to bulk drug product

Jason Ryan, Upstream Manager, **Luina Bio**

15.40 **Making the Difference in LBP Drug Development and Manufacturing**

- Assembling the right team
- Building a strong platform to achieve consistent scaleup of LBPs
- What we do we know so far?

Adrien Nivoliez, CEO, **biose industrie**

15.50 **Afternoon Refreshments and Networking**

Mastermind Session

Introduction and Purpose:

This session will facilitate in-depth discussion amongst participants in an informal setting. After splitting into groups, participants will have the opportunity to discuss three key areas that are related to the future application and success of microbiome-based therapeutics. Notes from this session will be shared with attendees after the meeting.

1. 16.30 **Standalone Therapy or Co-Therapy: Where is the Microbiome Most Relevant?**

Thmas de Wouters
CEO & Co-Founder
PharmaBIome

2. 16.30 **How Can Industry Partners Streamline Regulatory Guidelines for Microbiome-based Therapeutics?**

Luc Sterkman
CEO
Caelus Health

3. **16.30 Harnessing the Microbiome to Develop Breakthrough Diagnostic Tools**

Dora Nagy-Szakal
CMO
Biotia, Inc.

17.10 **Chairperson Closing Remarks**

17.20 **Evening Drinks Reception & Scientific Poster Session Hosted by *The Microbiome Movement***

Close of Conference Day One

What is the Role of the Human Microbiome in Cancer Therapy Response?

Introduction and Purpose:

As our understanding of the human microbiome matures, there has been an injection of scientific interest and investment into the microbiome-oncology intersection. The cancer community is realising the next wave of innovation through microbiome-based approaches that improve patient stratification and response to already existing cancer therapies. This theme will highlight the new opportunity set into motion by the collision of microbiome and cancer research.

8.30 **Applying Microbiotica's Platform to Modulate Cancer Immunotherapy Response & Identify Bacterial Biomarkers & Medicines**

Trevor Lawley
CSO
Microbiotica

9.00 **Developing Live Biotherapeutics to Target Immuno-Oncology**

- Discussing how LBPs offer a novel approach to immuno-oncology in monotherapy and combination settings
- Addressing how MRx0518 inhibits tumour growth in multiple preclinical models, affects tumour immune populations and has a strong immunostimulatory profile
- Pinpointing mode of action: TLR5-mediated immune activation via bacterial flagellin

Imke Mulder
Director of Research
4D Pharma

9.30 **Improving Cancer Treatment Through Oncobax-Based Therapeutics**

- Intestinal commensals dictate our systemic and anticancer immunity
- Harnessing the microbiome for the discovery of diagnosis and therapeutic tools in cancer is key for modulating the clinical outcome of anticancer regimens
- EverImmune is developing oncobax-based therapeutics to improve the efficacy of anticancer treatments

Romain D'Ailiere
Head of Preclinical Research & Co-Founder
EverImmune

10.00 **Panel Discussion: Where do we Stand with Current Innovation & Future Integration of Microbiome-Based Approaches into Routine Oncology Practice?**

- What is the biggest bottleneck in achieving success with microbiome-based approaches in the oncology space?
- Which microbiome-targeted application (1 - LBP as an adjuvant for improved safety, 2 - for improved will be most impactful in the short and long term?
- If the industry wasn't cost-limited, how could we accelerate microbiome-based LBPs to the cancer drug market?
- What are healthcare practioners concerned about when considering microbiome-based approaches in cancer care, and how can these concerns be addressed?
- What would we like to know about large pharma's assessment of the potential of the microbiome in cancer?

Romain D'Ailiere
Head of Preclinical Research & Co-Founder
EverImmune

Trevor Lawley
CSO
Microbiotica

Bruce Roberts
CSO
Vedanta Biosciences

Elran Haber
CEO
Biomica Ltd.

Imke Mulder
Director of Research
4D Pharma

10.30 **Morning Refreshments & Networking**

STREAM A: FUNCTIONALITY, MECHANISMS & PRE-CLINICAL DEVELOPMENT OF MICROBIOME-BASED THERAPEUTICS

Will Phage Therapeutics Hold the Key to Modulating the Microbiome?

Introduction and Purpose:

Broad based subtractive approached through the use of antibiotics can lead to unintended reduction of commensal bacteria, causing the patient to become vunerable to chronic disease, including C.Difficile infection. Bacteriophage-based therapies focus target highly specific strains of bacteria through the use of viral parasites. The purpose of this theme will be to review current practice in discovery and development of bacteriophage-based therapies and address any unique challenges when selecting a subtractive approach to modulate the immune microbiome.

11.30 **Delivery of Therapeutic Genetic Circuits by Engineered Phage Capsids**

- Engineering eligobiotics, (new modalities) to manipulate the microbiome in-situ
- Eligobiotics are phage capsids filled with engineered genetic circuits to enable the expression of therapeutic proteins in target populations of the microbiome
- Demonstrating efficient engineering of capsids themselves to manipulate the host range of the vectors
- Demonstrating efficient killing of target bacterial populations by delivering an exogenous CRISPR-Cas system

Igor Stzepourginski, Head of Preclinical Operations, **Eligo Biosciences**

12.00 **Native and Synthetically Engineered Phage Cocktail for Treating Chronic Diseases**

- Revealing novel phage therapies for eradicating pro-inflammatory bacteria in IBD
- Identifying when to apply phage synthetic engineering – Host range expansion, conversion of lysogenic to lytic
- Focusing on applicability of phage therapy for cancer and liver diseases

Assaf Oron, Chief Business Officer, **BiomX**

STREAM B: CLINICAL TRANSLATION, MANUFACTURING & COMMERCIALISATION OF MICROBIOME-BASED THERAPEUTICS

How can Strategic Collaborations Drive the Future of Microbiome-based Applications in Healthcare?

Introduction and Purpose:

To help commercialize breakthrough microbiome-based therapeutics, strategic collaborations between start-ups, large pharmaceutical companies and academic institutions continue to be established. The purpose of this theme will be to review the important role of these partnerships to ensure the future success of the human microbiome.

11.30 **Fireside Chat: Microbiotica and Genentech**

In June 2018, Microbiotica entered a multiyear collaboration with Genentech to develop and commercialise biomarkers, targets and medicines for IBD. As one of the most high profile partnerships to date, this intimate session will provide an insight into this recent collaboration, and provide guidance on how emerging microbiome-focused start-ups can distinguish themselves against competitors, and establish complimentary partnerships with pharmaceutical companies.

Anna Williamson, Senior Director Oncology Business & Head of UK Business Development, **Genentech**

Mike Romanos, CEO, **Microbiotica**

12.00 **Fireside Chat: Rebiotix and Ferring Pharmaceuticals**

In April 2018, Ferring Pharmaceuticals had announced the acquisition of Rebiotix, a leading biotech developing microbiome-based therapeutics. As both parties continue to develop this exciting partnership, this session will provide a deep dive into the story behind the deal, and what both companies are excited for as they look into the future application of LBPs across a range of disease targets.

Rafael Suarez, Senior Director Emerging Brands, Global Marketing, Gastroenterology & Microbiome, **Ferring Pharmaceuticals**

Ken Blount, CSO, **Rebiotix**

12.30 **Bacteriophages Alliances in Ferring**

- Outlining Ferring Pharmaceutical's involvement in the phage therapy space and how Ferring has helped to evolve projects through its drug development expertise
- Addressing considerations regarding the creation of bacterial libraries and supply of bacteria and bacteriophages in different geographical regions
- Discussing how to work with academic groups to define projects with translational results and commercially viable potential

Kristin Wannerberger, Director R&D Alliance Management, **Ferring Pharmaceuticals**

12.30 **The Microbiome Foundation: At The Forefront of a Health Revolution**

- Why the Microbiome Foundation will help fund new medical research on the gut microbiota and raise public awareness on the importance of diet as a key factor in gut microbiota modulation
- Organising a team of entrepreneurs and leading research to help unlock the potential of the human microbiome in the healthcare industry
- Addressing how you can help with this initiative

Sophie Durand, Co-Founder, **Microbiome Foundation**

13.00 **Lunch & Networking**

How can Researchers use Synthetic Biology to Engineer Bacteria as Living Therapeutics?

Introduction and Purpose:
One approach to developing microbiome-based therapeutics with known mechanisms of action is through the synthetic engineering of commensal bacteria that confer specific properties to treat disease. Although most of the studies have been performed on lactic acid bacteria, there have been extensive studies in the use of engineered microbes for the treatment of immunological and metabolic diseases. The purpose of this theme will be to review the latest academic and industrial efforts in 'programming' the human microbiome to create a new class of therapeutics.

14.00 **ACTOBIOTICS®, LACTOCOCCUS-BASED BIOPHARMACEUTICALS for Expression and Local Delivery of Therapeutics at Target Sites**

- A unique delivery platform, based on Lactococcus lactis, genetically engineered to produce specific therapeutic proteins
- Precisely tailored for disease modification in areas with high unmet medical need
- Targeted delivery via oral capsule, oral rinse or topical solution with robust and scalable manufacturing process and demonstrated safety and tolerability.

Lothar Steidler, Chief Technology Officer, **ActoBiotherapeutics**

14.30 **Learning from Nature in Designing Therapeutic Bacteria to Specifically Target Pathogens**

- Bacteria in nature use narrow-host-spectrum antimicrobial peptides to obtain niche advantage
- Designing novel therapy to infectious diseases: engineered probiotics that secrete antimicrobial peptides that kill foodborne pathogens, without disturbing the rest of the gut microbial flora
- Building a probiotic that optimally produces multiple antimicrobial peptides to increase efficiency and decrease resistance development

Suhyun Kim, Postdoctoral fellow, **Harvard University**

How can Start-Ups Raise Capital to Accelerate Microbiome-Focused Drug Platforms?

Introduction and Purpose:
The majority of innovators in the microbiome field are small or early-stage biotechnology companies, eager to obtain financing to fuel developments. However, like other scientific breakthrough that have seen significant venture and pharmaceutical interest, sufficient clinical trial data is not available, making it difficult to evaluate the potential of the science underlying these investments. The purpose of this discussion will be to explore the developing landscape for microbiome-focused start-ups and understand the thought process in raising funding to build and a sustain successful drug development company.

14.00 **Panel Discussion: How can Start-Ups Raise Capital to Accelerate Microbiome-Focused Drug Platforms?**

- How do start-up organisations raise funds in a field that isn't validated?
- How do you optimise R&D efforts to attract investment?
- How do start-ups prepare for an IPO?
- How do early stage microbiome start-ups raise capital in an ever crowded space?
- What role do strategic investors play in the success of microbiome-based therapeutics?

Georges Rawadi, CEO, **LNC Therapeutics**

Sebastien Guery, Human Microbiome Venture Leader, **Dupont Microbiome Venture**

Michael Osso, President & CEO, **Crohn's & Colitis Foundation**

15.00 **Afternoon Refreshments & Networking**

The Borderline between Pharma and Food – How Is the Human Microbiome Blurring the Lines?

Introduction and Purpose:

As researchers continue to seek for microbiome-targeting therapeutics that prevent or treat disease, the role of food and dietary supplements that demonstrate therapeutic efficacy has shown great promise. With diet playing a fundamental role in shaping microbiome composition and function, this theme will explore the recent approaches by organisations to address microbiome-related conditions.

15.30 **Targeting the Brain-Gut-Microbiome Axis by Immunebioticstm, a New Therapeutic Avenue for Management of Multiple Sclerosis**

- Brain-gut-microbiome axis; potential therapeutic targets and probiotic treatments
- Designing multi-targeted therapeutic microbial consortium; translational success for GutMagnificTM in management of IBS
- ImmuneBioticsTM, new generation of probiotic products designed to boost the immunotherapy treatments

Shahram Lavasani
CEO & Founder
Immune Biotech

16.00 **Optimising the Gut Microbiome to Rebalance Urate Metabolism and Pre-empt Hyperuricemia**

- Screening for functionality in microbiome-based therapeutics
- Relevance of animal models in microbiome R&D
- Pre-clinical development, biomarkers and translation into the clinic

Rikke Nielsen
CEO & Founder
Beo Therapeutics

16.30 **Panel Discussion: The Borderline Between Pharma and Food – How is the Microbiome Blurring the Lines?**

Rikke Nielsen
CEO & Founder
Beo Therapeutics

Shahram Lavasani
CEO & Founder
Immune Biotech

Sebastien Guery
Human Microbiome Venture Leader
Dupont Microbiome Venture

Sophie Durand
Co-Founder
Microbiome Foundation

17.30 **Chairperson Closing Remarks**

17.40 **Close of Conference Day Two and 4th *Microbiome Movement* – Drug Development Summit Europe 2020**

WHO WILL YOU MEET?

"This is a tremendous event, everyone who's important in this field, we're seeing them here and it's helping stimulate innovation in our own programs."

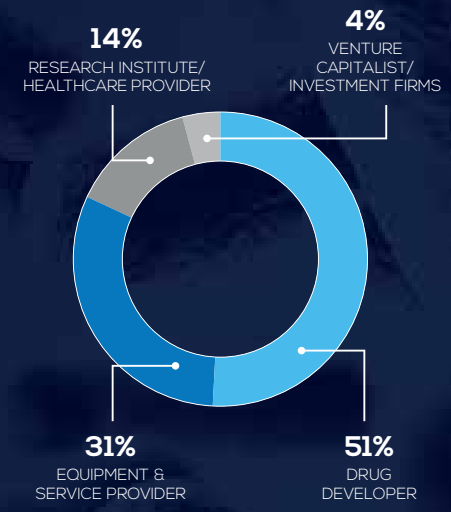
Ken Blount, Chief Scientific Officer, **Rebiotix**

30+ SPEAKERS

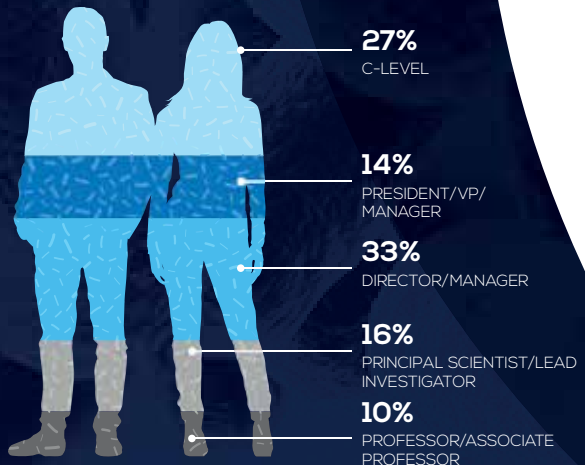
200+ ATTENDEES

150+ COMPANIES

COMPANY TYPE*



SENIORITY*



* Based on the last two years of the *Microbiome Movement* - Drug Development Series in Boston and Paris.

SNAPSHOT OF PREVIOUS ATTENDEES*

PHARMACEUTICALS

Allergan, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Daiichi-Sankyo, Lilly, Ferring Pharmaceuticals, GlaxoSmithKline, Janssen, Merck, Novartis, Pfizer, Sanofi, Shionogi Inc., Takeda

BIOTECH

AOBiome, Assembly Biosciences, Axial, Enterome, Evelo, Gusto Global, Microbiotica, OpenBiome, 4D pharma plc, Rebiotix, Ritter Pharmaceuticals, Second Genome, Seres Therapeutics, Synthetic Biologics, Vedanta Biosciences, Whole Biome

ACADEMICS, GOVERNMENT & INVESTORS

Baylor University, Bill & Melinda Gates Foundation, Caltech, Cleveland Clinic, FDA, INRA, Karolinska Institutet, MIT, NIST, Seventure, Flagship Pioneering

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PROUD TO PARTNER WITH

"The Microbiome Movement has proven to deliver a superior conference where scientific content is consistently emphasized concurrently with business relationship building opportunity. CosmosID has found each event to be an excellent platform for advancement of the microbiome industry, no matter which facet of the field was being promoted."

Manoj Dadlani, CEO, **CosmosID**

COSMOSID®

EXPERTISE PARTNER:

CosmosID®, based in Rockville, MD, provides award-winning Next-Generation Sequencing & Bioinformatics solutions for unlocking the microbiome through rapid identification and characterization of microorganisms for pharmaceutical R&D, molecular diagnostics, public health, food safety, agriculture, and environmental applications.

www.cosmosid.com

Boston ANALYTICAL

EXPERTISE PARTNER:

Boston Analytical, the Life Sciences Division of Alpha Analytical, is a cGMP compliant, FDA/DEA registered, ISO/IEC-17025:2005 certified analytical laboratory located in Salem, NH. We can provide all of the identity, purity and potency analyses necessary to characterize your microbiome product. Boston Analytical has a proven track record with sponsors on a variety of Microbiome programs including both Spore Fraction and Defined Drug Product manufacturing processes. We employ Labware Inc's™ LIMS & ELN software with on-line data access for your convenience.

www.bostonanalytical.com

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CosmosID®, based in Rockville, MD, provides award-winning Next-Generation Sequencing & Bioinformatics solutions for unlocking the microbiome through rapid identification and characterization of microorganisms for pharmaceutical R&D, molecular diagnostics, public health, food safety, agriculture, and environmental applications.

www.nizo.com

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PROGRAM PARTNER:

Quay Pharmaceuticals is a privately owned CDMO working from FDA and MHRA inspected facilities. We are licensed to formulate and manufacture the finished dosage forms for live biotherapeutics as well as small and large molecules. In the live biotherapeutic space we work with consortia and single strains for drug delivery in oral and topical formats. Working as part of your team we rapidly and effectively bring products through development to First In Human studies to deliver success.

www.quaypharma.com

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GET INVOLVED

Adam Haras-Gummer
Partnerships Director
Tel: +44 (0) 203 1418 727
Email: partner@microbiome-movement.com

INNOVATION PARTNER:

Biose Industrie is a Contract Development and Manufacturing Organization (CDMO), specialised in Live Biotherapeutic Products. Founded in 1951 by pharmacists and microbiologists, Biose Industrie has been manufacturing drug substance and drug products based on microorganisms for 60 years. Company, with 10 000m² of GMP facilty, offers product development at laboratory and pilot scale specialised in microbiology for aerobie and anaerobie strains and is Drug GMP certified for the manufacturing of API, clinical batches and commercial products.

www.biose.com/en/cdmo

INNOVATION PARTNER:

ProDigest is a product leader in the development of unique laboratory models of the human and animal gastrointestinal tract (SHIME®). These models allow to obtain unique insight in gut processes associated to the intestinal fate of actives and to study the complete gut microbiome under controlled conditions. ProDigest is globally active as a service provider for food and pharmaceutical companies and installs its technology in selected R&D facilities around the world. Furthermore, ProDigest has set up a number of product development projects in relation to the gut microbiota management and novel biotherapeutics.

www.prodigest.eu

INNOVATION PARTNER:

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carries out microbial aerobic and anaerobic fermentation, yeast fermentation, cell banking, vaccine production, process development,
analytical services, stability studies, storage and distribution of investigative material for clinical studies.

www.luinabio.com.au

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www.atlantiafoodclinicaltrials.com

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Team Discounts*

- 10% 2 Colleagues
- 15% 3 Colleagues
- 20% 4+ Colleagues

Group discounts only apply when booking a full 2-day conference package, and cannot be used in conjunction with any other discount (including academic or start-up rates). Group discounts can still be applied to earlybird savings. For more information on group rates and eligibility criteria, please email info@microbiome-movement. com or visit the website. Full T&Cs apply.

*A start-up rate is available to allow newer, less established organisations to attend this meeting. Eligibility criteria states that the company needs to be less than 3 years old or have fewer than 10 full time employees. Solution providers are excluded. All bookings at this rate are subject to organizer approval. T&Cs apply.

VAT will be charged at 20%

Top 3 Reasons to Attend

1. **Save** time and resources by learning how leading companies are overcoming critical translational hurdles to drive microbiome R&D into a therapeutic reality
2. **Gain** an important market update on the progress of microbiome-based therapeutics to benchmark your progress
3. **Establish** lasting connections by joining the foremost series of industry conference for microbiome researchers

Drug Developers: Pharma & Biotech	Register & Pay By Friday 8th November	Standard Pricing
Conference + 3 Workshops	£2,396 **(save £600)**	£2,696 **(save £300)**
Conference + 2 Workshops	£2,097 **(save £500)**	£2,397 **(save £200)**
Conference + 1 Workshop	£1,798 **(save £400)**	£2,098 **(save £100)**
Conference Only	£1,499 **(save £300)**	£1,799
Workshop Only	£399 + VAT	

Solution & Service Providers	Register & Pay By Friday 8th November	Standard Pricing
Conference + 3 Workshops	£3,396 **(save £600)**	£3,696 **(save £300)**
Conference + 2 Workshops	£3,097 **(save £500)**	£3,397 **(save £200)**
Conference + 1 Workshop	£2,798 **(save £400)**	£3,098 **(save £100)**
Conference Only	£2,499 **(save £300)**	£2,799.00
Workshop Only	£399 + VAT	

Start-Up, Academic & Not For Profit	Register & Pay By Friday 8th November	Standard Pricing
Conference + 3 Workshops	£1,996 **(save £600)**	£2,296 **(save £300)**
Conference + 2 Workshops	£1,697 **(save £500)**	£1,997 **(save £200)**
Conference + 1 Workshop	£1,398 **(save £400)**	£1,698 **(save £100)**
Conference Only	£1,099 **(save £300)**	£1,399.00
Workshop Only	£399 + VAT	

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TERMS & CONDITIONS

Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.
Changes to Conference & Agenda: Hanson Wade reserves the right to postpone or cancel an event, to change the location or alter the advertised speakers. Hanson Wade is not responsible for any loss or damage or costs incurred as a result of substitution, alteration, postponement or cancellation of an event for any reason and including causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade or industrial disputes, terrorism or hostilities.
Data Protection: The personal information shown and/or provided by you will be held in a database. It may be used to keep you up to date with developments in your industry. Sometimes your details may be obtained or made available to third parties for marketing purposes. If you do not wish your details to be used for this purpose, please write to: Database Manager, Hanson Wade, Suite A, 6 Honduras Street, London EC1Y 0TH

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