Part of the Microbiome Movement Series

Paris, France

29 January- 1 February 2018

MICROBIOME DRUG DEVELOPMENT *Europe*

Accelerate the Translation of the Human Microbiome into Safe, Effective and Commercially Scalable Therapeutic Products

Expert Speakers Include:

Outi Vaarala
VP Head of Translational Biology
AstraZeneca

Olga Danilchanka
Microbiome Lead, Exploratory Science Center (ESC)
Merck

Laurence Zitvogel
Professor
Institut Gustave Roussy

Lee Jones
CEO
Rebiotix

Kristin Wannerberger
Director, R&D Alliance Management
Ferring Pharmaceuticals

John Aunins
EVP of Manufacturing and Chief Technology Officer
Seres Therapeutics

Jim Brown
Director, Computational Biology and Senior Fellow
GSK

Daniel van der Lelie
Chief Scientific Officer
Gusto Global

Christian Freguia
Director of Research
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WELCOME

Part of the Microbiome Movement Series, the Microbiome Drug Development Summit Europe kick starts 2018 to help large pharma, biotech and academic institutions accelerate the discovery and clinical development of safe, effective and commercially scalable microbiome-based therapeutics across a broad spectrum of disease indications.

Set to tackle the greatest scientific, regulatory, clinical, manufacturing and commercialization challenges across the entire microbiome-drug development value chain, MDDS Europe will help reveal the applicability of microbiome understanding to develop new therapeutics.

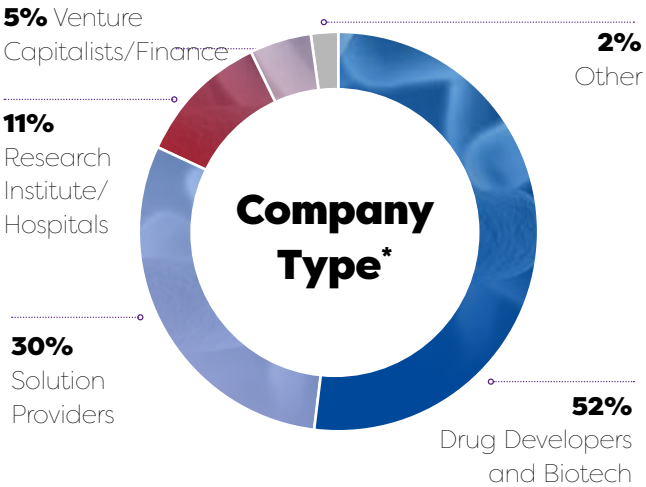
Alexander Puttick
Program Director
Microbiome Movement Series

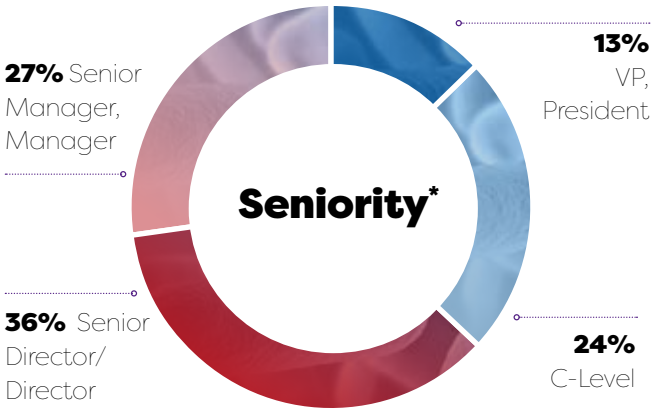
Mo Langhi
Commercial Director
Microbiome Movement Series

What's New for 2018

- **End-to-End Drug Development Focus -** MDDS Europe is carefully positioned to provide industry insight & solutions across the entire drug development value chain
- **Overcome Unique Product Development Challenges -** Integrating industry insight to help address clinical trial implications, regulatory uncertainty and CMC/ manufacturing complexities
- **Dedicated Day Focused on Microbiome's Impact within Immuno-Oncology-** Learn how the microbiome can be leveraged to improve response rates and provide a new avenue for cancer therapeutics

Typical Breakdown of Audience*





*Based on Drug Development Series 2017"

ATTENDING COMPANIES INCLUDE:*

Amrita, enterome, EPIBIOME, EVELO, FDA, MERCK, gsk, MIT, 4D pharma plc, Bristol-Myers Squibb, Pfizer, Rebiotix, SERES, SANOFI PASTEUR, Shire, Nestlé, Takeda, VEDANTA BIOSCIENCES

Expert speakers

Outi Vaarala
VP Head of Translational Biology
AstraZeneca

Travis Whitfill
Co-Founder and Chief Scientific Officer
Azitra Inc.

Assaf Oron
Chief Business Officer
BiomX

Sacha Mann
CEO
Biosys UK

Luc Sterkman
CEO
Caelus Health

Bharat Dixit
VP Bioprocessing and Manufacturing
Crestovo

Manoj Dadlani
CEO
CosmosID

Jean De Gunzburg
Chief Scientific Officer
Da Volterra

Confirmed Company
Enterome

James McIlroy
CEO
Enterobiotix

Kristin Wannerberger
Director R&D Alliance Management
Ferring Pharmaceuticals

Daniel van der Lelie
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CEO
Hervana Bio

Laurence Zitvogel
Professor
Institut Gustave Roussy

Alexander Sulakvelidze
Chief Scientific Officer
Intralytix, Inc.

Dirk Gevers
Global Head, JHMI
Janssen Research & Development

Lars Engstrand
Professor
Karolinska Institutet

Les Tillack
CEO
Luina Bio

Rita Colwell
Distinguished Professor
University of Maryland

Olga Danilchanka
Microbiome Lead, Exploratory Science Center (ESC)
Merck

Greg Sieczkiewicz
Managing Director, Chief IP Counsel
MPM Capital

Henry Haiser
Investigator III
Novartis Institutes for Biomedical Research

Lee Jones
CEO
Rebiotix

Arpita Maiti
Senior Director, ERDI I&I
Pfizer

Magali Cordaillat-Simmons
Scientific and Regulatory Affairs Director
Pharmabiotic Research Institute

Massimo Mazorati
Director, Business Development
ProDigest

Mike Frodsham
Pharmaceutical Development Manager
Quay Pharma

John Aunins
EVP of Manufacturing and Chief Technology Officer
Seres Therapeutics

David Cook
EVP of R&D and Chief Scientific Officer
Seres Therapeutics

Richard Schwartz
SVP Process Development and Manufacturing
Synlogic

Todd Parsley
Chief Scientific Officer
SynPhaGen, LLC

Christian Freguia
Director of Research
Synthetic Biologics

Gregory Lambert
CEO
TargEDys

Bruce Roberts
Chief Scientific Officer
Vedanta Biosciences

Confirmed Company
4D Pharma

WORKSHOP DAY

Monday 29th January 2018

Workshop A

Gene Therapy for the Microbiome: A Novel Therapeutic Intervention

9:00am-12:00pm

While our knowledge of how bacteria of the human body communicate and interact within the whole organism is still evolving, the ability to modify the human microbiome represents a novel way to improve human health and ameliorate diseases. Currently, fecal microbiota transplantation, the use of pre- and pro-biotics, small molecules and biologics are being developed for this intent.

By using new research in genetic engineering, it's now possible to look at the microbiome in a different way. This workshop will introduce the concepts for utilization of the commensal microbiome as a powerful mechanism for therapeutic intervention. Discussion will focus on the advantages and challenges of targeted delivery of therapeutic nucleic acids to bacteria inhabiting specific anatomical sites. A description of the microbial gene therapy platform technology being developed at SynPhaGen and potential therapeutic applications of the platform will be presented.

Join two leading researchers in industry to truly understand how gene therapy can be leveraged to help unlock the therapeutic potential of commensal microorganisms that reside in the human body.

Workshop Leader
Todd Parsley
Chief Scientific Officer
SynPhaGen, LLC

Workshop Leader
Christian Freguia
Director of Research
Synthetic Biologics

Workshop B

Harnessing the Skin Microbiome to Treat Disease

1:00pm-4:00pm

The skin microbiome plays a fundamental role in human health, protecting against pathogens and antigens while bolstering cutaneous immunity. Imbalances in the skin microbiome (i.e. "dysbiosis") are highly associated with severity of skin disease, and research shows that improving the skin microbiome may be a promising approach to treating disease.

Novel strategies have emerged to harness the skin microbiome to treat a plethora of diseases. These approaches vary and employ a plethora of techniques to beneficially modulate the skin microbiome or deliver therapeutic molecules to the skin. However, no topical microbiome-based therapy has been approved by major regulatory agencies worldwide.

Join this workshop to understand the latest in microbiome-based strategies for treating disease, key translational challenges to commercializes these approaches, and success stories in moving the needle forward in bringing new skin microbiome approaches to the market.

Workshop Leader
Travis Whitfall
Co-Founder and Chief Scientific Officer,
Azitra Inc.

CONFERENCE DAY ONE

Tuesday 30th January 2018

7.50 **Morning Coffee and Registration**

8.50 **Chairman's Opening Remarks**

Define 'Healthy Microbiome'?: Discovery Platforms that Demonstrate Causality and Identify Novel Drug Targets

Introduction and Purpose:

The microbiome has allowed researchers to look at health and disease in a unique way and are building novel discovery platforms that identify novel targets to diagnose, prevent and treat disease using microbiome-related methodology. The purpose of this theme will be to outline successful methods to tackle variability and build healthy standards.

David Cook
EVP R&D and CSO
Seres Therapeutics

9.00 **Studying Microbiome-Host Interactions to Translate Microbiome Drugs into the Clinic**

- Review of approaches to mine microbiological and functional information from human clinical trials
- Using mechanistic data and pharmacological models to design and test microbiome drugs
- Discussion of regulatory and CMC considerations for translating microbiome drugs into clinical trials

Lars Engstrand
Karolinska Institutet

9.30 **Definition of a Healthy Microbiome and If Disturbed - How to Shape It Back to Normal**

- Definition of a healthy microbiome requires prospective large-scale prospective population based studies
- Adjust for confounding factors when defining a normal cohort
- Novel approaches to shape the microbiota in clinical practise

Daniel van der Lelie
Chief Scientific Officer
Gusto Global

10.00 **State-of-the-Art Functional Analysis of Microbial Communities**

- Understanding indications through analysis of missing functionalities in the microbiome is central to therapeutic discovery
- Outlining a novel development platform that addresses missing functionalities and critical metabolic interdependencies between strains as drivers for the successful design of stable consortia
- Discussing why bioinformatics are a core competency for each stage of R&D, from early strain discoveries, isolations and characterizations through the optimization of production processes

Rita Colwell
Distinguished Professor
University of Maryland

10.30 **Microbiome in Understanding Human Biology, Disease and Diagnostics**

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Enterome

10.50 **Drugs from Bugs – Using Metagenomic Dataset Delivers Druggable Targets**

- Microbiome as a source of bioactives and novel targets
- Quantitative and functional metagenomics
- Gut-restricted therapeutics

11.20 **Morning Refreshments and Speed Networking**

Henry Haiser
Investigator III
Novartis Institutes for Biomedical Research

12.20 Microbiome Research at NIBR: Microbial Metabolites That Modulate Host Functions

- Building a pre-clinical microbiome program to uncover small molecule mediators of disease relevant microbe/host interactions
- Identifying new pharmacological targets that assimilate microbiome-derived signals
- Opening a framework that embraces external collaborations with academic and clinical researchers

Translating Pre-Clinical Results into the Clinic: From Pharmacology to Systems Biology

Introduction and Purpose:

The complexity of studying the human microbiome has slowed progress in the development of microbiome-based therapeutics. This has prompted efforts to develop predictive pre-clinical models to investigate host-microbiome interactions in specific diseases. The purpose of this theme will be to review preclinical strategies that address key safety considerations whilst guaranteeing translational and clinical success.

Luc Sterkman
CEO
Caelus Health

12.50 FMT-based discovery: from platform to product

- New insights in design of FMT-studies
- Building a platform to evaluate new leads
- Systematic in-vitro and in-vivo evaluation
- Data-mining: digging deeper pays off

Massimo Marzorati
Director, Business Development
ProDigest

1.20 Delivery, Survival, Engraftment and Activity of LBPs in the Gastrointestinal Tract

- Validated in vitro technology platforms are a key tool for the pre-clinical work in LBPs development
- The SHIME® is an enabling technology which allows an integrated simulation of the full GI tract, including lumen, mucosa and host
- The SHIME® allows to investigate the mechanism of action of LBPs in areas of the gut, which are not easily accessible, generating data complementary to in vivo studies

Clinical Trial Learnings: Preparing for Commercial Scale Microbiome Therapeutics

Introduction and Purpose:

With a number of important therapeutics entering a clinical setting, there are still major questions surrounding best practice in designing, scaling and progressing through clinical trials. The purpose of this theme will be to outline industry developments when executing clinical trials for microbiome-based therapeutics.

Lee Jones
CEO
Rebiotix

13.30 Rollercoaster Ride for the Pioneers in Microbiome Clinical Program Development

- Understand how interest and hype in the microbiome may impact clinical progress and perceptions
- Key learnings conducting clinical programs in difficult patient populations
- Hindsight is 20:20; predicting the future not so easy

14.00 Lunch and Networking

Christian Furlan Freguia
Director of Research
Synthetic Biologics

15.00 Clinical Development of Ribaxamse, an Oral-Beta Lactamase Intended to Protect the Gut Microbiome and Prevent C.Diificile

- Learning how beta-lactam antibiotics excreted in bile can damage gut microbiome
- How SYN-004 is designed to degrade residual antibiotics in the GI tract and protect the microbiome from antibiotic-mediated side effects
- Successful Phase 1 and 2a studies showing safety/efficacy and reducing risk of CDI by 71.4 %

Jean De Gunzburg
Chief Scientific Officer
Da Volterra

15.30 Preserving the Intestinal Microbiota during Antibiotic Treatments with DAV132: From Preclinical Studies in Hamsters to Phase 1 Trials in Humans

- Treatment with DAV132 severely reduces the exposure of the intestinal microbiota to co-administered antibiotics, while maintaining their systemic level
- DAV132 enables to essentially spare the intestinal microbiota from antibiotic-induced dysbiosis
- Preserving the intestinal microbiota during antibiotic treatments in hamsters prevents the development of lethal Clostridium difficile infections

Bruce Roberts
Chief Scientific Officer
Vedanta Biosciences

16.00 Clinical Considerations of Rationally Designed Live Bacterial Cocktails

16.20 Afternoon Refreshments and Networking

Approaching Regulatory Challenges in Europe and US

Introduction and Purpose:

When assessing and regulating microbiome-based therapeutics, there are still ongoing conversations regarding how international regulatory bodies classify and review these breakthrough products. The purpose of this theme will be to give an international perspective on regulating Live Biotherapeutic Products whilst addressing common challenges from industry when navigating a complex regulatory landscape.

Magali Cordaillat-Simmons
Director, Scientific and Regulatory Affairs
Pharmabiotic Research Institute

16.50 The Regulatory Challenge for Registering Live Biotherapeutic Products in Europe

- Presenting the EU regulatory Bodies in Europe regarding the pharma industry
- Discussing the regulatory status in which Probiotics were commercialized within the EU and how the landscape is evolving
- Sharing the pharmaceutical regulatory framework
- The importance to understand the system and to interact with authorities in order to clarify the regulatory framework

Lee Jones
CEO
Rebiotix

Magali Cordaillat-Simmons
Director, Scientific and Regulatory Affairs
Pharmabiotic Research Institute

Luc Sterkman
CEO
Caelus Health

Gregory Lambert
CEO
TargEDys

Kristin Wannerberger
R&D Alliance Management
Ferring Pharmaceuticals

17.20 Panel Presentation: Overcoming Regulatory Uncertainty to Accelerate Speed to Market

- How can companies work with regulatory agencies to accelerate speed to market?
- How do we overcome challenges in measuring purity, safety and product characterization when regulating microbiome-based therapeutics?
- What to consider when working with international regulaotrs to understand key design elements for seamless product development

17.50 Chair Closing Remarks

18.00 End of Conference Day 1 and Evening Drinks Reception

CONFERENCE DAY TWO

Wednesday 31st January 2018

7.50 **Morning Coffee and Registration**

8.50 **Chair's Opening Remarks**

Targeted Formulation, CMC Manufacturing & Scale-Up Strategies: How to Develop a Live Microbial Product

Introduction and Purpose:

As companies prepare to scale from early phase product development to commercial scale microbiome therapeutics, challenges around guidelines and best practice relating to formulation and CMC that ensure microbiome-based products are produced to GMP-compliant standards. The purpose of this theme will be to review the current industry thinking on manufacturing.

Bharat Dixit
VP Bioprocessing and Manufacturing
Crestovo

John Aunins
EVP Manufacturing and CTO
Seres Therapeutics

Richard Schwartz
SVP, Process Development and Manufacturing
Synlogic

9.00 **Panel Presentation: Manufacturing the Microbiome - An Industry Perspective**

- How does modality impact manufacturing approach?
- How can companies manage cost and scalability?
- How to maintain product characterization throughout the development lifecycle of a microbiome-based therapeutic?
- What are the benefits of building in-house manufacturing capabilities?

Mike Frodsham
Pharmaceutical Development Manager
Quay Pharma

10.00 **Oral Delivery of Live Bio-Therapeutics: Drug Product Development for FIM Studies**

- Key CMC considerations for the development of an LBT product
- Critical factors affecting time-lines when outsourcing GMP manufacturing activities of LBT drug products
- Incorporating 'Quality' (systems and regulations) into early phase dosage form design of LBT products

Subtractive Therapies in the Microbiome - Bacteriophages

Introduction and Purpose:

Bacteriophage-based therapies focus on using phage to target highlight specific strains of bacteria. Despite the promise, phage therapies currently lack the rigorous prod of efficacy, clinical evidence and regulatory approval in the US preventing widespread use. The purpose of this theme will be to review current practice in development bacteriophage-based therapies.

Assaf Oron
Chief Business Officer
BiomX

10.10 **Novel Approaches for Microbiome Modulation Addressing IBD, Cancer and Acne**

- Utilization of phage, either native or synthetically modified, to eradicate specific bacteria provides a promising novel therapeutic approach
- BiomX provides a novel approach to IBD through eradicating specific inflammatory enhancing, antibiotic resistant bacteria
- Demonstrating promising pre-clinical results for BX001 phage therapy for acne, expecting to enter human trials in 2018

Alexander Sulakvelidze
Chief Scientific Officer
Intralytix, Inc.

10.40 Modulating Human Microbiome: Bacteriophages and Their Practical Applications

- Bacteriophages (or phages) are bacterial viruses that are arguably the oldest (ca. 3-billion-years-old) and most ubiquitous organisms (ca. 1030-1031 phage particles/virions) on Earth
- Phages are very specific: they only attack their targeted bacterial hosts, and they cannot infect human cells or other eukaryotic cells. Moreover, phages only lyse strains or subgroups of strains of their targeted bacterial species, which makes targeted bacterial killing possible
- Lytic phages may serve as a platform technology for developing a new class of drugs (and/or nutritional supplements) for improving human health via targeted microbiome modulation

11.10 Morning Refreshments and Networking

Innovation Power-Hour: Start-Ups in the Microbiome

Introduction and Purpose:

Emerging start-ups in the human microbiome are using a variety of novel strategies to target microbial communities across different sites to treat a multitude of complex diseases. The purpose of this theme will be to showcase novel methods to target the microbiome from the companies beginning their microbiome journey.

James McIlroy
CEO
Enterobiotix

11.40 Novel Approaches to an Ancient Therapeutic Strategy

- Establishing a GMP facility for FMT-based therapeutics
- Commercialising a microbiota based medicinal product in the United Kingdom
- Development of a closed GMP-compliant processing system for enhancing faecal donations

Greg Sieczkiewicz
Managing Director, Chief IP Counsel
MPM Capital/ EverImmune

12.00 Harnessing the Human Microbiome to Influence the Development of Cancer

Sacha Mann
CEO and Director
Biosys UK

12.20 Oral Polyclonal Antibodies as Targeted Gut Microbiome Modulators

- Biosys is harnessing the power of oral polyclonal IgA therapies to modulate gut microbiome and restore host–microbial symbiosis to treat C.difficile infection
- These antibodies have specificity for multiple epitopes and can be delivered directly to the site of dysbiosys in the GI tract. They target both the spores and bacteria that cause relapse and recurrence of infection, as well as the toxins that cause clinical symptoms and disease pathologies, eliminating specific pathogens and reducing recolonization across multiple strains
- Clinical data in almost 100 patients has been published and shows evidence of both efficacy and safety in reducing relapse of CDI

Rachel Teitelbaum
CEO
Hervana Bio

12.40 Harnessing the Vaginal Microbiome in Contraceptive Development

- Vaginal Microbiome Cycle-Based Changes Can Be Exploited In Contraception
- Local Production Of Anti-Sperm Agents By Engineered Commensals Can Be Accomplished On A Cycle-By-Cycle Basis
- Preclinical Studies Demonstrate High Efficacy And Complete Reversibility

13.00 Lunch and Networking

The Large Pharma Perspective on Microbiome-based Drug Development

Introduction and Purpose:

A number of pharmaceutical companies have now committed to microbiome-based drug development whilst others remain interested. With multiple industry collaborations now announced, pharmaceutical resources may play a critical role in the success of these products. The purpose of this theme will be to review what leading pharmaceutical companies look for in this emerging space and how utilization of pharmaceutical resources may accelerate the microbiome field.

Olga Danilchanka
Microbiome Lead, Exploratory Science Center (ESC)
Merck

14.00 The Microbiome: Translating Research into Discovery

Outi Vaarala
VP Head of Translational Biology
AstraZeneca

14.30 Gut Microbiota Composition, Short-Chain Fatty Acids and Regulatory T-Cell – Are We Ready to Translate into Therapeutics?

- Understanding the role of changing gut microbiota in the development of regulatory T-cell population during the early life
- From Microbiome to therapeutics
- The use of microbiota analysis for the development of personalised treatments in allergic and respiratory diseases

James Brown
Director, Computational Biology and Senior Fellow
GSK

15.00 Respiratory Tract and Gut Microbiomes in Precision Medicine for Respiratory Diseases

- Recent studies suggest that lung microbiome dynamics plays a key role in the severity of chronic obstructive pulmonary disease (COPD)
- In this presentation, lung microbiome analyses of three large, longitudinal COPD patient cohorts (COPDMAP, BEAT and AERIS studies) will be discussed
- In addition, novel chemogenomic analysis approaches to identify potential immuno-modulator activity from gut bacterial metabolites will be described
- Collectively, these approaches are aimed at the development precision diagnostics and therapeutics for the treatment of chronic respiratory diseases

Kristin Wannerberger
Director R&D Alliance Management
Ferring Pharmaceuticals

Jim Brown
Director Computational Biology
GSK

Outi Vaarala
VP Head of Translational Biology
AstraZeneca

Olga Danilchanka
Microbiome Lead, Exploratory Science Center (ESC)
Merck

Dirk Gevers
Global Head, JHMI
Janssen Research and Development

Henry Haiser
Investigator III
Novartis Institutes for Biomedical Research

15.30 Panel Presentation: Committing to the Therapeutic Potential of the Microbiome - Resources for Results

- Discussing what scientific breakthroughs in the human microbiome are most exciting with therapeutic applications
- How can pharmaceutical companies best use their resources to accelerate the microbiome field?
- Which resources are most useful for emerging organizations?
- What are the biggest risk factors when harnessing the microbiome for therapeutic applications?

16.15 Chair's closing remarks

16.25 End of Conference Day 2

"A very well organized conference, with an optimum mix of presentations, discussions and networking breaks"

Tharaknath Rao, Head of Microbiome Clinical Development, Assembly Biosciences, Previous Attendee, Microbiome Drug Development Summit, Boston 2017

"A wonderful conference!"

Zain Kassam, Chief Medical Officer, OpenBiome, Previous Attendee, Microbiome Drug Development Summit, Boston 2017

"It was a very good conference to effectively learn the current trends in microbiome drug development around the world"-

Nanae Izumi, Senior Researcher, Daiichi Sankyo, Previous Attendee, Microbiome Drug Development Summit, Boston 2017

POST-CONFERENCE FOCUS DAY

Thursday 1st February 2018

MICROBIOME FOR IMMUNO-ONCOLOGY

In recent years, researchers have been studying the pathogenesis of disease through the context of the human microbiome. With the microbiome's impact on fundamental cell processes including metabolism and host immune response, modulation of microbiota as well microbiota-derived by products may influence the formation, progression and prevention of cancer.

This new evidence has sparked novel data that shows inter-individual differences in the microbiome may account in varying therapeutic response rates to immune-modulating therapies. The purpose of this day will be to share cutting-edge research that promotes beneficial immune responses through gut microbiome modulation that enhance the clinical response for patients treated with IO therapeutics.

Speakers Include:

Laurence Zitvogel

Arpita Maiti

Assaf Oron

4D Pharma Representative

	8.30	**Morning Coffee and Registration**
	9.30	**Chair's Opening Remarks**
 **Prof. Laurence Zitvogel** **Institut Gustave Roussey**	9.40	**The Impact of the Intestinal Microbiota in Therapeutic Responses Against Cancer** • Exploring the influence of the human microbiome in anticancer immune responses • Suggesting mechanisms of microbial mediated effects in affecting anticancer immunosurveillance and translating into clinical reality • Harnessing new research to pave the way for more effective therapies and prophylactics
	10.25	**Panel Presentation**
	11.10	**Morning Refreshments**
 **Assaf Oron** Chief Business Officer **BiomX**	11.40	**A Novel RNA Expression Based Platform for Discovery of Microbiome Modulators to Improve Response to Checkpoint Inhibitors** • BiomX novel discovery technology measures the direct dynamic response (RNA expression based) of the gut microbiome to checkpoint inhibitor administration • Providing a comprehensive approach for modulating the microbiome to improve checkpoint inhibitor response, through adding or eradicating bacteria using phage • Utilization of phage, either native or synthetically modified, to eradicate specific bacteria impacting response rate provides a promising novel therapeutic approach
 **Arpita Maiti** Senior Director, ERDI I&I **Pfizer**	12.10	**Cancer Immunotherapy and the Human Microbiome-Intersection of the Immune System and Gut Microbiota** • Why the intersection of the microbiome and immune cells could be the key to advanced mechanistic understanding of how the microbiome impacts the mobilization of immune cells • Translating research to create a source of adjunctive and combination microbiome-based therapies that could increase response to immunotherapies
	12.40	**Roundtable Discussion**
	13.10	**End of Post Conference Focus Day**

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Quay Pharma

Innovation Partner

Quay Pharma is experienced in formulation development and is one of very few companies licensed to provide clinical manufacturing materials containing live bacterial strains being targeted for delivery to, and in, the digestive, urogenital, otorhinologic and pulmonary tracts. Understanding the client dosing requirements for the live biotherapeutic, Quay can prepare a formulation development strategy to bring your live bacterial strain rapidly and effectively to First in Man studies aiming to provide a formulation with the best chance of clinical outcome.

www.quaypharma.com

ProDigest
Gastrointestinal Expertise

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

LUINABIO
BIOPHARMACEUTICAL MANUFACTURING

Innovation Partner

LuinaBio is Australia's most experienced biopharmaceutical CDMO's with 20 years' experience in our field. More specifically Luina 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

COSMOSID®

Innovation Partner

CosmosID®, based in Rockville, Maryland, is a genomics big data company focused on rapid identification of microorganisms for pharmaceutical R&D, molecular diagnostics, public health, food safety, agriculture, and environmental applications. The CosmosID platform uses proprietary sequence analysis algorithms to accurately profile all microorganisms in a metagenomic sample employing next-generation DNA sequencing.

www.cosmosid.com

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