March 26-28, 2019 | Boston, USA

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2nd Antigen-Specific Immune Tolerance Drug Development

Optimize Antigen-Specific Immune Tolerance Induction Strategies, Accelerate Safe and Effective Translation into the Clinic & Expand Opportunities Through Combination Therapies

Expert Speakers Including:

Amy Rosenberg
Supervisory Medical Officer and Division Director, Office of Biotechnology Products
CDER/FDA

Carla Greenbaum
Director- Diabetes Program
Benaroya Research Institute

Gerald (Jerry) Nepom
Director
Immune Tolerance Network

Anne De Groot
CEO & CSO
EpiVax

Matthias von Herrath
Professor at the La Jolla Institute for Allergy & Immunology; VP of T1D R&D Center Seattle
Novo Nordisk

Robert (Bob) Anderson
CSO
ImmusanT

Jack Ragheb
Senior Medical Fellow for Immunology- Global Patient Safety
Eli Lilly

Michael Boyne
VP of Product Development & Analytics
Cour Pharmaceuticals

Kei Kishimoto
CSO
Selecta Biosciences

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2nd Antigen-Specific Immune Tolerance Drug Development Summit 2019

Successfully Improve the Discovery of Novel Antigens, Optimize the Tolerance Delivery Systems & Accelerate the Translation of Safe & Effective Immune Tolerance Therapies into the Clinic with Solution Led Insights from the Fields of Allergy & Autoimmunity

As the race to generate compelling clinical data to prove the concept of antigen-specific immunotherapies gains momentum, the **2nd Antigen-Specific Immune Tolerance Drug Development Summit** returns to Boston in 2019 to help large pharma, biotech and academic researchers overcome the complexity of auto-immune mediated disorders, expand opportunities through combination strategies and undertake a more precise and antigen-specific approach to novel drug development.

Join your peers at the **2nd Antigen-Specific Immune Tolerance Drug Development Summit 2019** and become central to leading industry conversations dedicated to overcoming the challenge of **discovering and defining monogenic and multigenic antigens** present in very complex diseases that do not replicate well in animal models and **improving tolerance delivery systems** in order to robustly **translate and generate human clinical data** to develop effective therapies for the unmet fields of allergy, transplantation and autoimmunity.

Why our speakers are looking forward to this summit?

"I look forward to presenting our new, unpublished research on Tregitopes to a gathering of my peers"

Anne De Groot, CEO & CSO, EpiVax

"Pulling together speakers from across the field of antigen-specific tolerance translation into a single focussed meeting is what excites me about this summit"

Ranjeny Thomas, Professor of Rheumatology at University of Queensland; Director, Dendright

100+ Attendees

7+ Hours of Networking

3 Interactive Workshops

23+ Real World Case Studies

Why Attend the 2nd Antigen-Specific Immune Tolerance Drug Development Summit 2019?

1. Benchmark against the latest understandings of antigen-specific immune tolerance strategies as therapeutic targets in allergy and autoimmune diseases with insights from **Immune Tolerance Network, Eli Lilly & Dendright**

2. Widen your expertise on identification & validation of novel targets & mechanism of actions for effective antigen-specific immune tolerance induction with insights from **GSK, EpiVax & University of Zurich**

3. Overcome key design and optimization challenges of antigen-specific delivery systems with insights from **Topas Therapeutics, SQZ Biotechnologies & Northwestern University**

4. Increase your translational success rate with case studies on how to overcome challenges of animal model studies and identification/ validation of human biomarkers from **Novo Nordisk, ImmusanT & Akston Biosciences**

5. Optimize your clinical trial strategy by hearing the latest insights from patient data of the most advanced antigen-specific immune tolerance clinical programs from **Selecta Biosciences, Cour Pharmaceuticals & ImmusanT**

6. Join the momentum to re-define the antigen-specific immune tolerance induction strategies & widen the opportunities through combination therapies with insights from **FDA, Provention Bio & ActoBio Therapeutics**

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YOUR EXPERT SPEAKERS

Carla Greenbaum
Director- Diabetes Program
Benaroya Research Institute

Gerald (Jerry) Nepom
Director
Immune Tolerance Network

David Wraith
Institute Director of Immunology & Immunotherapy and Professor of Immunology
University of Birmingham

Amy Rosenberg
Supervisory Medical Officer and Division Director, Office of Biotechnology Products
CDER/FDA

Ranjeny Thomas
Professor of Rheumatology at University of Queensland; Director
Dendright

Erika von Mutius
Professor of Pediatric Allergology
Dr. von Hauner Children's Hospital

Jack Ragheb
Senior Medical Fellow for Immunology- Global Patient Safety
Eli Lilly

Robert (Bob) Anderson
CSO
ImmusanT

Michael Boyne
VP of Product Development & Analytics
Cour Pharmaceuticals

Stephan Kontos
Co-founder & CSO
Anokion

Anne De Groot
CEO & CSO
EpiVax

Lotta Jansson
Chief Research Officer
Apitope

Timm Jessen
CEO
Topas Therapeutics

Roland Martin
Head- Department of Neuroimmunology & Multiple Sclerosis Research Neurology Clinic
University Hospital Zurich, University of Zurich

Charlotte Fribert
CEO
Toleranzi AB

Kei Kishimoto
CSO
Selecta Biosciences

Stephen Miller
Co-founder of Cour Pharmaceuticals; Professor of Microbiology-Immunology
Northwestern University Medical School

Francisco Leon
CSO
Provention Bio

Pieter Rottiers
CEO
ActoBio Therapeutics

Finola Moore
Associate Director of Immune Tolerance
SQZ Biotechnologies

Matthias von Herrath
Professor at the La Jolla Institute for Allergy & Immunology; VP of T1D R&D Center Seattle
Novo Nordisk

David Alleva
Executive Director- Immunotherapeutics
Akston Biosciences

Joshua Sestak
President & CSO
Orion BioScience

Simi Ahmed
Director, Research
JDRF

Yoav Messinger
Medical Director- Cancer and Blood Disorders
Children's Hospitals and Clinics of Minnesota

Xunrong Luo
Director-Translational Research
Duke Transplant Center, Duke University

Andreas Lutterotti
MD; Assistant Professor- Experimental Therapy Research in Multiple Sclerosis
University of Zurich

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WHY ARE OUR EXPERT SPEAKERS GETTING INVOLVED AT THE SUMMIT?

"I look forward to further exchanges with specialists in the field of Antigen-Specific Immune Tolerance, to deepen and broaden dialog started at the first Antigen-Specific Immune Tolerance Summit in Boston, which was quite illuminating"

Charlotte Fribert
CEO
Toleranzi AB

"This meeting is an ideal opportunity to gain insight into new tolerance strategies and obtain an overview of the existing field"

Jack Ragheb
Senior Medical Fellow for Immunology- Global Patient Safety
Eli Lilly

"I look forward to exchanging ideas and concepts on immune tolerance across the different perspectives from academia, biotech and pharma"

Andreas Lutterotti
MD; Assistant Professor- Experimental Therapy Research in Multiple Sclerosis
University of Zurich

"This meeting will provide opportunities to network with key scientists, hear about the latest developments and state-of-the-art science in the field of immune tolerance"

Antoon Van Oosterhout
VP & Head Allergic Inflammation Discovery Performance Unit
GSK

"I look forward to participating at this summit as cross-disease and cross-discipline exchanges are critical if we are to make disease-modifying therapy a reality in type 1 diabetes"

Carla Greenbaum
Director- Diabetes Program
Benaroya Research Institute

"The meeting is an excellent event for networking but also an opinion generator/former for developing these novel therapeutics clinically in the exciting field of antigen-specific immune tolerance induction"

Timm Jessen
CEO
Topas Therapeutics

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CONFERENCE DAY ONE
WEDNESDAY, MARCH 27, 2019

8.00 Registration & Networking Breakfast

8.50 Chair's Opening Remarks

Carla Greenbaum
Director- Diabetes Program
Benaroya Research Institute

Addressing Knowledge Gap in Immune Tolerance Induction by Connecting the Dots Between Transplantation, Allergies & Autoimmune Diseases

Gerald (Jerry) Nepom
Director
Immune Tolerance Network

9.00 Antigen-Specific T Cell Profiles as Therapeutic Targets in Allergy and Autoimmune Disease

- High-dimensional phenotyping identifies distinct antigen-specific T cell profiles using peripheral blood from patients with allergy and autoimmune disease
- Deletion, deviation, anergy, and exhaustion are potential tolerogenic outcomes of therapy
- Tracking antigen-specific T cells during therapy may be a surrogate for clinical response

David Wraith
Institute Director of Immunology & Immunotherapy and Professor of Immunology
University of Birmingham

9.30 Antigen-Specific Immunotherapy for Treatment of Autoimmune Diseases

- A review of different approaches for induction of antigen-specific immunotherapy
- A report on recent clinical trials of the approach for immunotherapy of autoimmune diseases
- A discussion on the potential for combination approaches to promote antigen-specific immunotherapy

Michael Boyne
VP of Product Development & Analytics
Cour Pharmaceuticals

10.00 Antigen Specific Approaches to Food Allergy & Immunogenicity

- Inducing tolerance without immune suppression by harnessing nanoparticle technology
- Proof of principle data for Peanut Allergy
- Proof of principle data for Recombinant Proteins

10.30 Speed Networking & Morning Refreshments

Erika von Mutius
Professor of Pediatric Allergology
Dr. von Hauner Children's Hospital

11.30 Protection from Childhood Allergies & Inflammatory Bowel Disease

- Prevention of allergic and autoimmune diseases in environment rich microbial exposure
- Potential mechanisms of preventive approach
- Translational aspects and considerations

Jack Ragheb
Senior Medical Fellow for Immunology-Global Patient Safety
Eli Lilly

12.00 Anti-Drug Antibody Responses: Past, Present & Future

- Review the history of ADA responses
- Review the present state of ADA responses
- Discuss the future state of ADA responses

Xunrong Luo
Director-Translational Research
Duke Transplant Center, Duke University

12.30 Antigen-Specific Tolerance for Transplantation

- A top-down approach can be used to overcome the complexity of alloantigens for transplantation tolerance
- Multiple parallel mechanisms involving both innate and adaptive immune cells are implicated for transplantation tolerance
- B cells play a critical role in tolerance resistance in pre-sensitized hosts

13.00 Networking Lunch

Identification & Validation of Novel Targets & Mechanism of Actions for Antigen-Specific Immune Tolerance Induction

Stephan Kontos
Co-founder & CSO
Anokion

14.00 Targeted Antigen Delivery to the Liver via Synthetic Glycosylation Induces Robust Antigen-Specific Tolerance

- Active targeting domains deliver antigen to tolerogenic pathways in the liver, and induce robust antigen-specific tolerance in both mouse and non-human primate models of immunity
- Our technologies are translational, in that the mechanisms induced are consistent with unmet clinical needs, and our molecules are developable
- Discuss potential approaches to de-risk MoA's in higher-order species, and consider their value

Ranjeny Thomas
Professor of Rheumatology at University of Queensland; Director
Dendright

14.30 Antigen-Specific Tolerance Induction in Rheumatoid Arthritis

- What are the opportunities and challenges of antigen-specific tolerance induction in a systemic inflammatory autoimmune disease?
- How does the autoimmune induction phase differ from the inflammatory effector phase in rheumatoid arthritis and what are the implications for therapeutic tolerising strategies?
- What type of immunomonitoring could contribute to evaluation of the outcome of tolerising strategies in rheumatoid arthritis?

Roland Martin
Head- Department of Neuroimmunology & Multiple Sclerosis Research Neurology Clinic
University Hospital Zurich, University of Zurich

15.00 Target Identification in Immune-Mediated Disorders Including Autoimmune Diseases, Allergies, Anti-Drug Responses & Tumor Immunology

- Unbiased and systematic identification of target antigens for T cells using combinatorial chemistry and bioinformatics
- Identification of disease-relevant T cells in autoimmune diseases
- How does the autoimmune T cell response relate to recognition of foreign antigens as triggers?

15.30 Afternoon Refreshments & Poster Session

Advancing Pre-Clinical Development of Novel Antigen-Specific Immune Tolerance Therapies

Charlotte Fribert
CEO
Toleranzi AB

16.00 TOL2: An Antigen Specific Tolerogenic Therapy for the Treatment of Myasthenia Gravis

- TOL2 treatment modalities
- Tolerance induction and maintenance using TOL2
- Preclinical development of TOL2

Finola Moore
Associate Director of Immune Tolerance
SQZ Biotechnologies

16.30 Engineering Red Blood Cells for Immune Tolerance Using Cell Squeeze® Technology

- The SQZ process efficiently delivers antigen into red blood cells (RBCs) and primes cells for rapid clearance in the liver and spleen
- SQZ'd RBCs reduce CD4+ and CD8+ T cell responses against model antigens and human autoantigens
- SQZ'd RBCs delay or prevent onset of T1D in adoptive transfer model

17.00 Panel Discussion: How to Identify & Prioritize the Route to Success for Antigen-Specific Immune Tolerance Induction Strategies?

- What does it take to achieve a robust proof-of-concept for antigen-specific immune tolerance induction strategies in complex auto-immune mediated diseases?
- Delivering on the hype and investment thus far – how to translate promising science and clear opportunity into safe and effective antigen-specific tolerance inducing therapeutics?
- The most promising route to funding: how to secure funding, through cross-industry collaborations, to fuel early clinical trial studies and beyond?

Moderator:

Charlotte Fribert
CEO
Toleranzi AB

Panelists:

Matthias von Herrath
Professor at the La Jolla Institute for Allergy & Immunology; VP of T1D R&D Center Seattle
Novo Nordisk

David Alleva
Executive Director-Immuno-therapeutics
Akston Biosciences

Joshua Sestak
President & CSO
Orion BioScience

Lotta Jansson
Chief Research Officer
Apitope

17.30 Chair's Closing Remarks & End of Day One

"Progress in immune tolerance therapies transcends individual diseases or single therapeutic platforms. We can share ideas and learn from eachother in order to move forward with optimized clinical strategies and trials"

Gerald (Jerry) Nepom, Director, Immune Tolerance Network

CONFERENCE DAY TWO
THURSDAY, MARCH 28, 2019

8.00 Breakfast & Networking

8.25 Chair's Opening Remarks

Jack Ragheb
Senior Medical Fellow for Immunology- Global Patient Safety
Eli Lilly

Optimization of Tolerance Delivery Systems & Translation of Antigen-Specific Tolerance Strategies into Clinic

Stephen Miller
Co-founder of Cour Pharmaceuticals; Professor of Microbiology-Immunology
Northwestern University Medical School

8.30 Mechanisms Underlying Tolerance Induction with Antigen-Encapsulating PLG Nanoparticles

- Tolerance induction using antigen-encapsulating PLG nanoparticles (Ag-PLG) recapitulates how self-tolerance is maintained in the hematopoietic system
- Ag-PLG uptake by splenic and liver APCs confers a tolerogenic phenotype
- Ag-PLG induces the induction of CD4+Foxp3+ and CD8+CD122+ regulatory T cells

David Alleva
Executive Director-Immunotherapeutics
Akston Biosciences

9.00 Antigen-Specific Targeting of B Cells in Type 1 Diabetes

- Insulin-specific B cells promote T1D pathogenesis by acting as antigen-presenting cells (APCs) that activate pathogenic effector T cells
- Antigen-specific deletion of such B cells has not yet been successful, mainly because of the requirement of a fully-conformational antigen that contains a deletional mechanism. Akston has created such a therapeutic, AKS-107
- The presence of autoantibodies produced by autoreactive B cells allows for feasible clinical biomarker assays for both entry criteria (patient stratification) and therapeutic response monitoring

Joshua Sestak
President & CSO
Orion BioScience

9.30 Soluble Antigen Arrays' Mimic Peripheral Tolerance to Intercept Autoimmune Disease and Restore Health

- The importance of restoring tolerance mechanisms after an autoimmune break
- The role of physiochemical as well as molecular properties in therapeutic design
- The value of leveraging safety in early stage or adolescent autoimmune disease patients

10.00 Morning Refreshments & Networking

Timm Jessen
CEO
Topas Therapeutics

10.30 Preparation of Liver-Targeting Nanoparticles for Clinical Trials

- The liver as tolerance mediator
- Nanoparticles as therapeutic agents
- Regulatory aspects of nanomedicine

Matthias von Herrath
Professor at the La Jolla Institute for Allergy & Immunology; VP of T1D R&D Center Seattle
Novo Nordisk

11.00 Obstacles for Bringing Antigenic Tolerance Induction to the Clinic

- Front runners can be chosen with smart in vivo and in vitro comparative assays
- A key obstacle for clinical development of antigenic tolerance induction is the lack of human biomarkers as surrogate endpoint in safety/dosing trials
- We do not understand how tolerance is optimally achieved in humans (regulation versus exhaustion versus anergy versus deletion)?

11.30 Networking Lunch

Fulfilling the Future of Tolerance Clinical Development with Insights from Patient Data

Kei Kishimoto
CSO
Selecta Biosciences

12.30 Preclinical & Clinical Development of Tolerogenic Nanoparticles to Mitigate Immunogenicity of Biotherapeutics

- Immunogenicity is a major cause of treatment failure for many biologic therapies
- Selecta Biosceinces has developed rapamycin-carrying nanoparticles to mitigate immunogenicity to a wide variety of biologics
- An update on preclinical applications, including gene therapy, and early clinical data from a Phase 2 trial with an enzyme therapy for the treatment of severe gout

Robert (Bob) Anderson
CSO
ImmusanT

13.00 Immunotherapy for Celiac Disease Using Immuno-Dominant Gluten Epitopes (Nexvax2®) – Discovery to Phase 2

- Celiac disease, as both a food hypersensitivity and autoimmune disease, facilitates antigen challenge in patients that is enabling for epitope identification, biomarker discovery, and efficacy assessment
- The first dose effect observed when immuno-dominant gluten epitopes are administered systemically recapitulates cytokine release and symptoms caused by gluten ingestion in celiac disease
- Stepwise updosing allows immuno-dominant gluten epitopes to be administered in a standardized regimen that uniformly achieves immune non-responsiveness to dose levels that are well above the MTD for single dose exposure

Carla Greenbaum
Director- Diabetes Program
Benaroya Research Institute

13.30 Lessons Learned from Multi-Center Trials of Antigen Therapy in T1D

- What are the specific clinical trial design considerations for multi-center trials of antigen therapy in T1D?
- How to get around the practical problems of running a multi-center GCP clinical trial?
- TrialNet observations as a solution led case study

Yoav Messinger
Medical Director- Cancer and Blood Disorders
Children's Hospitals and Clinics of Minnesota

14.00 Long-Term Consequences of Tolerance Induction Strategies Using Anti-B-Cell (Rituximab), Especially to the Growing Child: Lessons Learned from Oncology & Pompe Disease

- If immune modulation includes anti-B-cell agents, a proportion of patients exposed to Rituximab develop long-term B-cell dysfunction
- Successful tolerance induction to enzyme replacement (ERT) for infantile Pompe disease includes rituximab. However, some patients are left with ongoing IVIG requirement and long-term B-cell dysfunction
- Monitoring guidelines are suggested

14.30 Afternoon Refreshments & Networking

The Future Landscape of Antigen-Specific Immune Tolerance Therapies: The Promise of Combination Strategies

Gerald (Jerry) Nepom
Director
Immune Tolerance Network

15.00 Combining Induction with Consolidation Therapy in ITN Clinical Trials for Autoimmunity

- Induction therapy targets persistent effector cells that are a barrier to durable response
- Consolidation therapy allows homeostatic and regulatory mechanisms to mature
- Sequential combinations of induction and consolidation offer prospects for tolerogenic outcomes

Anne De Groot
CEO & CSO
EpiVax

15.30 Tregitopes Induce Active Tolerance in Autoimmune Diabetes & Allergy

- Tregitopes (natural T cell epitopes derived from IgG) that (a) bind to multiple MHC class II molecules, (b) suppress effector T cell responses to co-delivered antigen, and (c) up-regulate Treg-associated cytokines and chemokines
- Tregitopes promote tolerance by activating Regulatory T cell (Treg) activity and expanding Tregs in vitro and in vivo
- Tregitopes provide an explanation for the mechanism of action IVIg on DC and T-cells and may ultimately provide a safe alternative to plasma-based immune regulation therapies
- Case study on combination of Tregitope-albumin fusions and PPI peptides (T1D ASATI): Antigen-specific adaptive tolerance induction (ASATI) is induced when antigens are administered in combination with Tregitopes

Francisco Leon
CSO
Provention Bio

16.00 Immune Modulation + Antigen Specificity: Exploring Combination Approaches for Tolerance Induction & Maintenance in Autoimmunity & Immunogenicity

- The combination of immune-modulatory agents and antigen-specific approaches may yield superior efficacy in the induction and maintenance of immune tolerance
- A review of the unmet need in autoimmunity and in the immunogenicity of therapeutic agents, as well as current attempts to address the issue
- The combination of a T cell modulator (teplizumab) and a B cell inhibitor (PRV-3279) with antigen-specific approaches will be presented as examples

16.30 Panel Discussion: Evaluation of Combination Therapies to Address Unmet Clinical Needs

- What are the translational challenges of combination therapies in the context of disease complexity and mechanism of action?
- What are the regulatory guidelines and considerations for combining two unapproved drugs as a combination strategy?
- What is the expected value-split between the stakeholders?

Moderator:

Finola Moore
Associate Director of Immune Tolerance
SQZ Biotechnologies

Lotta Jansson
Chief Research Officer
Apitope

Panelists:

Amy Rosenberg
Supervisory Medical Officer and Division Director, Office of Biotechnology Products
CDER/FDA

Pieter Rottiers
CEO
ActoBio Therapeutics

17.00 Chair's Closing Remarks & Close of 2nd Antigen-Specific Immune Tolerance Drug Development Summit 2019

Don't miss out on the technical workshop day on next page!

PRE-CONFERENCE WORKSHOP DAY
TUESDAY, MARCH 26, 2019

Workshop A

8:30am – 11:00am

Improving the Translation of Antigen Specific Therapies into the Clinic Across Disease Indications

The purpose of this workshop is to bring together experts across autoimmune fields to discuss common challenges facing clinical translation of antigen specific therapies. Topics of key relevance include defining a late stage preclinical development path of therapeutic candidates, common cross disease challenges in identifying reliable mechanistic markers of immune effects of antigen specific therapies, possible need for de-bulking therapies or other combinations to ensure success of these types of therapies, and how multiple stakeholders might come together in public-private partnership to overcome common hurdles.

Hear & Discuss About:

- Need for harmonized approaches in this space and novel ways to address them
- Blood mechanistic markers to evaluate treatment and therapeutic response of antigen specific therapies
- Improving the predictability and effective utilization of preclinical models as pre-requisites for clinical testing
- Lessons learnt from successful clinical testing of antigen specific therapies across diseases

Workshop Leaders

Matthias von Herrath
Professor at the La Jolla Institute for Allergy & Immunology; VP of T1D R&D Center Seattle
Novo Nordisk

Matthias is a Vice President at novoNordisk since 2012 and responsible for type 1 and kidney complications R&D strategy. Professor at La Jolla institute (part time), MD from Freiburg medical school and postdoc in Virology at Scripps. He received 2006 ADA Outstanding scientific achievement award and 2014 German Langerhans Preis.

Simi Ahmed
Director, Research
JDRF

Simi Ahmed is a Director of Research and lead of the Immune Therapies Program at JDRF. She is responsible for creating and implementing the vision and strategy of this program, with core emphasis on the establishment of effective disease modifying immunotherapies for T1D.

Workshop B

11:30am – 14:00pm

Antigen-Specific Tolerance Induction: Robust Strategies to Improve Clinical Trials Efficacy & Success Rate

This interactive workshop session will delve deep into the challenges associated with the lack of robustness in terms of proof of concept in the field of antigen-specific immune tolerance induction, clinical efficacy in relation to mechanism of action and strategic considerations for developing clinical trial protocols to optimize successful translation into and through different phases of clinical trials.

Hear & Discuss About:

- How to document clinical efficacy in relation to mechanism of action?
- Outcome measure
- Clinical trial protocols and critical steps to consider (phase IIa as PoC component)
- Regulatory issues (advanced therapy medicinal products (ATMP) versus biological, nanoparticle)

Workshop Leader

Andreas Lutterotti
MD; Assistant Professor- Experimental Therapy Research in Multiple Sclerosis
University of Zurich

Andreas Lutterotti is Assistant Professor for "Experimental Therapy Research in Multiple Sclerosis and Other Neurological Diseases" at the University of Zurich since August 2014. His core expertise is the development and implementation of experimental therapies in the field of multiple sclerosis and other autoimmune diseases. He is Co-Founder of Cellerys AG, a company developing a cell based therapy to induce immune tolerance in MS.

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Workshop C

14:30pm – 17:00pm

Considerations for Combination Strategies for Tolerizing Immunotherapies

This informative workshop highlights potential regulatory and R&D strategies to combine antigen-specific immune tolerance approaches with other therapies in order to open up the potentials to address a wider unmet patient need across various therapeutic areas.

Hear & Discuss About:

- When might combination strategies be applicable to treatment of autoimmune disease?
- What types of combination strategies might be used in autoimmune disease and is there evidence from the clinic already?
- Does combination always mean simultaneous?
- How could immunomonitoring be applied to trials of combination tolerising therapies?
- Considerations for clinical trial design
- How does the regulatory landscape change if developing a combination therapy based on two unapproved drugs?

Workshop Leaders

Amy Rosenberg
Supervisory Medical Officer and Division Director, Office of Biotechnology Products
CDER/FDA

Amy Rosenberg received her MD from Albert Einstein College of Medicine and is Board Certified in Internal Medicine. She joined CBER, FDA in 1988, becoming Director of the Division of Therapeutic Proteins, CBER/CDER in 2000 (now DBRR3 in the Office of Biotechnology Products, CDER). She has been a driving force in risk evaluation and mitigation pertaining to the immunogenicity of therapeutic proteins and in the elucidation and implementation of immune tolerance induction protocols in clinical settings.

Ranjeny Thomas
Professor of Rheumatology at University of Queensland; Director
Dendright

Ranjeny Thomas is Professor of Rheumatology at University of Queensland as well as founder and a director of the spin-off company, Dendright, which is developing immunotherapy for autoimmune diseases. Her research seeks to understand autoimmune disease and restoration of immune tolerance. Through this work, she developed and tested the first rheumatoid arthritis vaccine.

> "The development of antigen-specific tolerization is currently taking important steps, but critical questions have remained open. I see this conference as an excellent venue to exchange ideas with other investigators in this field"
>
> **Roland Martin, Head- Department of Neuroimmunology & Multiple Sclerosis Research, Neurology Clinic University Hospital Zurich, University of Zurich**

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Innovation Partner

Anokion is a leading immune tolerance company advancing novel, antigen-specific treatments for people living with the devastating effects of autoimmune disease. Anokion is strategically progressing its development pipeline based on an industry-leading, novel platform that harnesses the body's natural tolerance pathways. Initially formed as a spin-off from the Ecole Polytechnique Fédérale de Lausanne (EPFL), the company is funded by leading investors, including Versant Ventures, Novo Ventures, and Novartis Venture Fund. For more information, please visit

www.anokion.com

Brand Partner

Topas Therapeutics (Hamburg, Germany) is focused on developing products in areas of major unmet need, including autoimmune diseases, allergies and anti-drug antibodies. Topas' technology induces antigen-specific regulatory T cells in the liver by mimicking bloodborne antigens via the Company´s proprietary peptide-loaded nanoparticles. Topas has programs in MS, T1D and an orphan indication, which is planned to enter the clinic in 2019. The Company has collaborations with Eli Lilly and Company and with Evotec.

www.topas-therapeutics.com

Brand Partner

Orion BioScience Inc. is a preclinical stage biotechnology company focused on developing our "Soluble Antigen Array' (or SAgA) technology to intercept and prevent the onset of autoimmune diseases in at risk and early stage patients. Our research into treating multiple sclerosis, neuromyelitis optica, and type-1 diabetes has shown that Orion can develop disease specific immunotherapeutics that can re-tolerize and restore the healthy immune state. The Orion team leverages extensive development experience, and strong clinical relationships, to rapidly progress first-in-class, blockbuster treatments for NMO and T1D into the clinic

www.orionbioscience.com

Brand Partner

Nektar Therapeutics is a research-based development stage biopharmaceutical company whose mission is to discover and develop innovative medicines to address the unmet medical needs of patients. Our R&D pipeline of new investigational medicines includes treatments for cancer, autoimmune disease and chronic pain. We leverage Nektar's proprietary and proven chemistry platform in the discovery and design of our new therapeutic candidates.

www.nektar.com

Event Partner

Selecta Biosciences, Inc. is a clinical-stage biotechnology company focused on unlocking the full potential of biologic therapies based on its immune tolerance technology (ImmTOR) platform. Selecta plans to combine ImmTOR with a range of biologic therapies for rare and serious diseases that require new treatment options due to high immunogenicity. The company's current proprietary pipeline includes ImmTOR-powered therapeutic enzyme and gene therapy product candidates.

www.selectabio.com

GET INVOLVED

Bashir Langhi
Partnerships Manager
Tel: +44 (0)2031418797
Email: Bashir.Langhi@hansonwade.com

READY TO REGISTER?

3 EASY WAYS TO BOOK

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- **15% discount – 4 delegates**
- **20% discount – 5 or more delegates**

Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.

Contact: register@hansonwade.com

1. Discuss and learn more about antigen-specific tolerance induction strategies with cross-disciplinary insights from the fields of transplantation, allergy and autoimmunity
2. Overcome challenges of delivery system optimization and robust translation into clinic through case studies focused on improvement of animal models, biomarker identification/validation studies and early clinical trial considerations
3. Define future scientific and strategic trends of the field with insights from clinical patient data to ensure successful antigen-specific immune tolerance drug development, both as a stand-alone approach or in combination with other strategies

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