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March 20-22, 2018 | London UK

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Complement-based Drug Development Summit *Europe*

- Expanding Complement Therapeutics beyond Orphan Diseases
- Advancing Efficacy Assessment and Complement Diagnostics
- Navigating the European Regulations Landscape

Expert Speakers Including:

Michael Holers
Scoville Professor & Head, Division of Rheumatology
University of Colorado

Paul Morgan
Professor of Immunology and Director, Systems Immunity Research Institute
Cardiff University

Eva-Maria Nichols
Head of Complement
GlaxoSmithKline

Michael Kirschfink
Professor of Immunology
University of Heidelberg

Ashley Frazer-Abel
Director
Exsera BioLabs

Frank Baas,
CSO
Complement Pharma

Anna Schubart
Investigator III
Novartis

Kai Höhlig
Senior Scientist & Project Manager
Aptarion Biotech AG

Erik Hack
CSO
Prothix

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Welcome to the Complement-based Drug Development Summit Europe

The leading industry-dedicated meeting focused on optimising clinical trial design, efficacy assessment, target identification and expansion beyond orphan diseases.

The **Complement-based Drug Development Summit Europe** brings together the leading drug developers to advance the next generation of complement therapeutics, to gain cutting-edge insight from the creme de la crème of complement researchers and aims to develop the foundation of scientific knowledge in this field.

At this meeting, achieve quality results by overcoming the current barriers in complement testing, improve clinical trial design with novel diagnostics for patient stratification and optimise the management of off-target effects.

With the first generation of complement therapeutics set to be approved in the next couple of years, this is the perfect time to look ahead to the second generation. Join the Complement-based Drug Development Summit to understand how you can treat an impressive range of broader conditions with complement therapeutics, navigate the European regulatory landscape and examine EMA guidelines with the expectations to ensure that drugs gain market approval smoothly.

Join the Complement-based Drug Development Summit and build upon the scaffold of which complement therapeutics can be expanded beyond the treatment of ultra-rare diseases.

Hear what previous attendees have to say:

"This meeting provides a unique platform for industrial, academic and clinical players in the space to share ideals, show advanced data and discuss in details"
Past CVI Summit Attendee, Aeon Therapeutics

"I can't speak highly enough about this conference, it allowed me to keep informed of the latest research and development in the field. I was also able to network with the leaders in T cell immunotherapies from both academia and the industry"
Past CVI Summit Attendee, MSKCC

Join Thought Leaders to Gain Unique Insights Into:

1. Analysing Points of Inhibition:
Assess the most effective points of complement inhibition for the treatment of individual diseases and the selection of therapeutic approaches for inhibition.

2. Optimise Clinical Trial Design:
Fine-tune clinical trial design for expansion beyond orphan diseases, advancing patient stratification, targeting, dosing, endpoints and sample handling.

3. Standardising Efficacy Assessment:
Define the next steps toward achieving standardisation of robust, functional assays in order to accurately determine treatment efficacy.

4. Advancing Safety Profiles:
Ensure patient safety by enhancing the management of off-target effects and approaches for minimising infection risk.

5. Navigating the Regulatory Landscape:
Streamline the regulatory approval process by examining guidelines and expectations, ensuring that drugs reach the market smoothly.

Expert Speakers

Anne Bruns
Executive Director
aHUS Foundation

Kai Höhlig
Senior Scientist & Project Manager
Aptarion Biotech AG

Paul Morgan
Professor of Immunology and Director, Systems Immunity Research Institute
Cardiff University

Frank Baas
CSO
Complement Pharma

Ashley Frazer-Abel
Director
Exsera BioLabs

Eva-Maria Nichols
Head of Complement
GlaxoSmithKline

Kiran Nistala
Experimental Medicine Physician
GlaxoSmithKline

Richard Smith
Director, Protein Therapeutics Laboratory
King's College London

Anna Blom
Professor of Medical Protein Chemistry
Lund University

Anna Schubart
Investigator III
Novartis

Erik Hack
CSO
Prothix

Andrea Tenner
Professor of Molecular Biology & Biochemistry
University of California

Michael Holers
Scoville Professor & Head, Division of Rheumatology
University of Colorado

Michael Kirschfink
Professor of Immunology
University of Heidelberg

Tom Mollnes
Professor of Immunology and Leader, Complement Research Group
University of Oslo

"This was an amazing meeting with a terrific turnout and engagement by industry. The advances in technology being made and the issues being addressed were extremely eye-opening."

Past CVI Summit Attendee, Prescient Healthcare

Conference Day One | Wednesday March 21st, 2018

8.00 Breakfast & Registration

Michael Holers
Scoville Professor & Head, Division of Rheumatology
University of Colorado

9.00 Chairman's Opening Remarks

Optimising Complement Efficacy Assessment & Diagnostics

Michael Kirschfink
Professor of Immunology
University of Heidelberg

9.15 Achieving Quality Results by Overcoming the Current Barriers in Complement Testing

- Recognising the importance of autoantibodies to complement proteins, C3 and C4 convertases and regulatory proteins in defining autoimmune processes and diseases based on complement dysregulation
- Extending the spectrum of diagnostic parameters and embracing new technical approaches
- Organising external quality assessment rounds, providing guidelines for modern complement analysis and standards for the development of international testing programs

Ashley Frazer-Abel
Director
Exsera Biolabs

9.45 Taking Complement Testing from Diagnostics to Drug Development: What is Well Suited for One May Not be for the Other

- The power and the short comings of the functional complement tests.
- New needs for sensitivity and consistency for all assays.
- The importance of knowing what is normal. At every stage of drug development we need to know what is a normal level of the complement tests and how it can vary over time.
- How does all this translate to post market testing? It is one thing to get a drug to market but we also need to be able to test patient post market for initial diagnostics and to follow compliance

Michael Kirschfink
Professor of Immunology
University of Heidelberg

Tom Mollnes
Professor of Immunology and Leader, Complement Research Group
University of Oslo

Ashley Frazer-Abel
Director
Exsera Biolabs

10.15 Panel: Developing a Roadmap for the Next Generation of Efficacy Assessment Techniques and Complement Diagnostics

- Assessing which aspects of complement therapeutics can benefit most from the novel application of diagnostic strategies
- Analysing the new practices that are demonstrably advancing efficacy assessment
- Implementing a plan to co-ordinate analysis of complement activity across the industry

11.00 Morning Refreshments & Networking

Expanding Complement Therapeutics Beyond Orphan Diseases

Paul Morgan
Professor of Immunology and Director, Systems Immunity Research Institute
Cardiff University

12.00 Targeting Complement in Neurological and Neuropsychiatric Diseases

- Complement's involvement in diverse neurological and neuropsychiatric diseases – from demyelination through dementia to depression
- Evidence from models, biomarkers and genetics
- Accumulating evidence that complement inhibition might provide a new therapeutic option across these many diseases
- Need to overcome problems of delivery to brain, long-term therapy and timing of intervention

Andrea Tenner
Professor of Molecular Biology & Biochemistry
University of California

12.30 Inhibition of C5aR1 Alters Microglial Polarisation and Rescues Neuron Damage and Cognitive Loss in a Mouse Model of Alzheimer's Disease

- The complement pathway is activated by fibrillar amyloid plaques in Alzheimer's disease, generating the complement activation product C5a.
- Preventing cognitive loss with genetic deletion or pharmacologic inhibition of C5aR1 in 3 different Alzheimer's disease mouse models.
- Analysis of RNA-seq data from microglia derived from mouse brain demonstrated a less inflammatory polarization state with enhanced induction of clearance pathways in AD mice that lack C5aR1 relative to those that are C5aR1 sufficient.
- Loss of neuronal complexity is prevented in the absence of C5aR1.
- Promising lack of adverse effects

Frank Baas
CSO
Complement Pharma

1.00 **The Role of the Membrane Attack Complex in Neurological Disorders**

- MAC deposition in neurological disorders
- Inhibition of MAC facilitates regeneration
- Development of MAC inhibitors
- Preclinical data in animal models

1.30 **Lunch & Networking**

Kai Höhlig
Senior Scientist & Project Manager
Aptarion Biotech AG

2.30 **Inhibition of C5a to Enhance the Efficacy of Cancer Immunotherapies**

- Contrasting roles of complement in cancer
- C5a as an emerging target in cancer
- C5a favors the generation of an immunosuppressive tumor microenvironment
- Inhibition of C5a by AON-D21 synergizes with anti-PD-1 immunotherapy in reducing tumor growth and metastasis in models of lung cancer

Kai Höhlig
Senior Scientist & Project Manager
Aptarion Biotech AG

Erik Hack
CSO
Prothix

Michael Holers
Scoville Professor & Head, Division of Rheumatology
University of Colorado

3.00 **Panel: Determining which Portion of the Complement Pathway is the Most Effective Intervention Point for Specific Diseases**

- Understanding the pathophysiology of diseases through the relationships between pathway sub-components, and how this can be leveraged to treat individual conditions
- Analysing the advantages and disadvantages of targeting on different levels

3.45 **Afternoon Refreshments & Networking**

Complement-based Drug Development Round Tables

4.15

Sessions led by
Paul Morgan
Professor of Immunology and Director, Systems Immunity Research Institute
Cardiff University

1. Meeting Dosing and Efficacy Regulatory Requirements

- What experiences have individuals had regarding PKPD and safety guidelines in the complement therapeutics space?
- How can we ensure that drugs meet the required levels of therapeutic efficacy for market approval?
- What are the biggest obstacles to getting complement-based drugs through the regulatory approval process?

2. The Future of Complement Therapeutics

- What are the most interesting emerging areas in this space that could have great potential?
- How can companies begin preparation to capitalise on emerging market trends in coming years?

3. Exploring the Micro-Landscape of Complement Related Compounds

- Which cells are responsible for the production of key compounds?
- At what rate are components cleared from cells and replenished?
- What implications do these areas have for the efficacy of complement-based drugs?

Michael Holers
Scoville Professor & Head, Division of Rheumatology
University of Colorado

5.15 **Chairman's Closing Remarks**

Conference Day Two | Thursday March 22nd, 2018

8.00 **Breakfast & Networking**

Paul Morgan
Professor of Immunology and Director, Systems Immunity Research Institute
Cardiff University

9.00 **Chairman's Opening Remarks**

Expanding Complement Therapeutics Beyond Orphan Diseases

Michael Holers
Scoville Professor & Head, Division of Rheumatology
University of Colorado

9.15 **Advances in Understanding of Disease Pathogenesis in Rheumatoid Arthritis and Systemic Lupus Erythematosus Open Up New Opportunities for Complement Therapeutics**

- Investigating the processes by which Rheumatoid Arthritis begins as a chronic mucosal inflammatory process prior to the development of clinically apparent arthritis
- Inhibition to mitigate the earliest phases of arthritis development, a process which exhibits several features of a complement system-engaging immune complex disease
- The severe glomerulonephritis that is found in patients with Systemic Lupus Erythematosus (SLE) has been ameliorated in several case reports using a complement inhibitor
- New imaging approaches to characterising and quantitating local complement activation in the lupus kidney have been developed
- Complement receptor engagement likely plays an important role in the generation of an interferon-alpha signature in lupus patients

Anna Blom
Professor of Medical Protein Chemistry
Lund University

9.45 **Therapeutically Harnessing the Role of Complement in Infection: Complement Evasion Strategies Developed by Bacterial Pathogens**

- Analysing the crucial role of complement in antimicrobial defence
- Identifying mechanisms allowing bacterial pathogens such as Streptococci to establish infection despite surveillance of the complement system
- Exploring bacterial complement evasion molecules as vaccine candidates
- Developing fusion proteins composed of complement inhibitors and fragments of immunoglobulins for treatment of infections

Tom Mollnes
Professor of Immunology and Leader, Complement Research Group
University of Oslo

10.15 **Dual Blockade of Complement C3/C5 and Tlr/Cd14 As A Novel Treatment Approach for Sepsis and Sirs.**

- Discovery of the soluble terminal complement complex (TCC) in normal human biological fluids based on a novel antibody (aE11) against activated C9
- aE11 antibody cross-reaction with pigs, paving the way for large animal studies
- Establishing a human whole blood model with an anticoagulant not interfering with the inflammatory reaction, enabling investigation of cross-talk in the inflammatory network ex vivo
- Identification of the upstream complement (C3/C5) and the TLR CD14 molecule as key "bottle neck" molecules responsible for the inflammatory reaction induced both by Gram-negative and Gram-positive bacteria, both in vitro and in vivo

10.45 **Morning Refreshments & Networking**

Applying Lessons Learned to the Next Generation of Complement Inhibitors

Anne Bruns
Executive Director
aHUS Foundation

11.45 **The Power of Complement Therapeutics: A Patient Perspective**

- Our diagnostic journey into a world of rare disease
- Research and development of therapeutic drugs creating a foundation of hope for patients and caregivers to rely on
- The power of complement therapeutic drugs and the influence they have on a rare disease community

Richard Smith
Director, Protein Therapeutics Laboratory
King's College London

12.00 Cytotopic Complement Inhibitors: Mechanisms and Insights

- Complement regulation is primarily a cell-surface phenomenon yet complement inhibitors in current development act in bulk solution
- The rise of Mirococept, an engineered fragment of CR1, Mr ~24kDa, which retains factor I cofactor and decay acceleration activities, binding to cells
- Mirococept has been manufactured on an industrial scale to cGMP and has passed relevant safety and ADME tests
- Tests in ~150 human subjects by several routes including ex-vivo perfusion of organs for transplantation and is well tolerated up to 100mg iv
- A Phase II study in renal transplantation using ex-vivo perfusion has enrolled 80 patients so far – endpoints are DGF incidence and renal function
- Several other types of agent have been cytotopically modified and are under investigation

Michael Holers
Scoville Professor & Head, Division of Rheumatology
University of Colorado

Paul Morgan
Professor of Immunology and Director, Systems Immunity Research Institute
Cardiff University

Michael Kirschfink
Professor of Immunology
University of Heidelberg

12.45 Panel: Balancing Benefits and Risks by Assessing Optimum Inhibition Levels for Key Diseases

- Identifying trends in the variance of optimum inhibition across different pathways
- Determining which animal models companies have found most and least successful
- Analyzing the strengths, limitations and potential of small molecules, monoclonal antibodies, siRNA and oligonucleotides in complement therapeutics
- Assessing the current landscape of where each approach is experiencing particular success or difficulty

1.30 Lunch & Networking

Safety Profiles, Risk and Managing Adverse Effects

Eva-Maria Nichols
Head of Complement
GlaxoSmithKline

2.30 Approaches to Computational Modelling of the Complement System

- Comparison between computational models and traditional methods
- Analysing Assumptions and limitations
- Potential application in safety assessment, target selection, patient stratification, trial simulation

Anna Schubart
Investigator III
Novartis

3.00 Details of this presentation aren't available at this stage, please check back for further details.

Paul Morgan
Professor of Immunology and Director, Systems Immunity Research Institute
Cardiff University

3.30 Chairman's Closing Remarks

3.45 Close of Summit

WORKSHOPS

Workshop Day | Tuesday March 20th, 2018

Workshop A

Optimising Complement-based Clinical Trial Design for Expansion Beyond Ultra-Rare Diseases

9:00am – 12:00pm

A number of factors in complement pathway research present barriers to producing high quality data, creating uncertainty regarding the true efficacy and safety of new therapies.

This workshop will discuss the following:

- Collecting and handling samples to avoid ex-vivo activation and improve data quality
- Advancing patient recruitment and stratification to streamline trials
- Determining the most effective clinical endpoints
- Overcoming issues surrounding dosing during trials

Leave this workshop having explored the various strategies you can implement to improve the key aspects of clinical trial design.

Workshop Leader
Eva-Maria Nichols, Head of Complement,
GlaxoSmithKline

Eva was appointed Head of Complement at GSK in 2016. The group's focus is pre-clinical target/disease validation in complement and development of novel functional assays. Eva joined GSK's C3 DPU back in 2014, working on the complement-focused early discovery pipeline.

Workshop Leader
Kiran Nistala
Experimental Medicine Physician
GlaxoSmithKline

Kiran specializes in Early Phase Clinical Trial Design and Drug Discovery Project Leadership in GSK's C3 DPU. He also leads the GSK Physician Community Global, and sits on the GSK Immunotoxicology panel and Experimental Medicine Initiative steering committee.

Workshop B

Recognising the Potential of Complement in Neurodegeneration: From Fundamental Science to Clinical Development

1:00pm – 4:00pm

In the past few years, neurodegeneration has been identified as one of the most promising new avenues for complement therapeutics, but collaboration from the academic and industry leaders is needed to advance the development of this approach.

This workshop will discuss the following:

- Looking at complement as a more proximal factor in the demise of neurons and synapses
- Analysing the available data to explore the potential of complement-based drugs in this area
- Overcoming potential pitfalls with this approach, specific to individual neurodegenerative diseases and approaches for complement inhibition
- Examining the key safety concerns associated with the use of complement-based drugs in this context

Leave this workshop having thoroughly explored the potential for complement-based drugs to treat neurodegenerative diseases.

Workshop Leader
Paul Morgan
Professor of Immunology and Director, Systems Immunity Research Institute
Cardiff University

Prof. Morgan is former Dean of Medicine at Cardiff and current Director of the Systems Immunity Research Institute and co-Director of the Hodge Centre for Neuropsychiatric Immunology. His current research focusses on roles of complement and other inflammatory pathways in disease, with a focus on neurological disease.

Topic Leader
Frank Baas
CSO
Complement Pharma

Professor Frank Baas is the CSO of Complement Pharma and head of the Laboratory of Diagnostic Genome Analysis at Leiden University Medical Center. His current research is focussed on the role of complement in neurological disease. He directs work on antibodies and anti-sense molecule MAC inhibitors, which are now under development at Complement Pharma.

SPONSOR

When pharma and biotech look to develop commercially viable complement therapeutics, are you front of mind?

Key complement-based drug developers have informed us that one of the most pressing problems in this rapidly growing field is that service providers lack knowledge and experience of the industry, forcing developers to use time and resources on work that they would rather outsource.

This summit will allow sponsors to gain a deep understanding of the most pressing concerns that the industry leaders have with CROs, CMOs and Assay Providers, and strategies for overcoming these. Partnering with us will enable you to meet with high-level representatives from a range of companies, hear exactly what criteria they use to select vendors, and act on these insights to offer the perfect products and services for complement therapeutics.

This is the perfect opportunity to demonstrate that you have the desire and capability to meet the increasing demands of this emerging field, and cement your position as the industry leader.

TECOmedical Group, Exhibitor

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The Swiss-based TECOmedical Group with subsidiaries in Germany, France and Benelux, is a leading provider of in-vitro speciality test systems in the areas of medical and veterinary diagnostic, biosafety and environmental testing. In addition we develop and evaluate new test systems in collaboration with opinion leaders or as service to pharma, CRO and research organisations.

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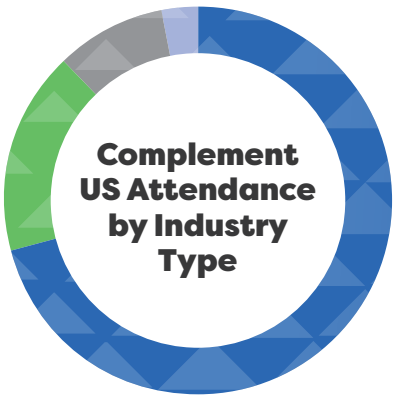
Exsera BioLabs, Exhibitor

Exsera BioLabs www.ExseraBioLabs.org

Exsera BioLabs specializes in the field of complement, immune complex and anaphylactoid testing. Our Director is a recognized expert in the field having overseen countless studies and PI reports. Combine that with a team with decades of experience in complement testing, and Exsera BioLabs has the experience to understand your unique issues or complex results. We have a commitment to providing quality and timely results with the insight and expertise that makes a difference.

www.exserabiolabs.org



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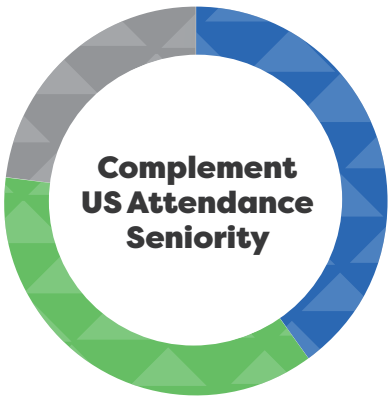

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Team Discounts*

- **10% discount** – 3 delegates
- **15% discount** – 4 delegates
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Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.

Top 3 Benefits of Attending

1. **Take** the lessons learned from ultra-rare disease trials and apply these to the expansion of complement therapeutics beyond orphan diseases.
2. **Learn** the key steps required to develop robust, functional assays in order to accurately determine treatment efficacy.
3. **Secure** the safety of patients with cutting edge approaches for minimising infection risk and managing off-target effects.

INDUSTRY PRICING		
	Register & pay by February 9th	**Standard Pricing**
Gold: Conference & 2 workshops	£2,997 **(save £200)**	£3,197
Silver: Conference & 1 workshop	£2,598 **(save £200)**	£2,798
Bronze: Conference only	£1,999 **(save £200)**	£2,199
Workshops - individual	£599	

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	Register & pay by February 9th	**Standard Pricing**
Gold: Conference & 2 workshops	£2,297 **(save £200)**	£2,497
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Bronze: Conference only	£1,499 **(save £200)**	£1,699
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