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November 14-16 2017 Boston, MA

www.complement-therapeutics.com

Complement-based Drug Development Summit 2017

- Understand the Interactions of Component Pathways in Disease
- Identify the Right Disease Indications & Targets for Complement Therapeutics
- Ensure Successful Translation of Therapeutic Targets with Optimal Clinical Trial Design

Expert Speakers Including:

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

Camille Bedrosian
CMO
Alexion Pharmaceuticals

Eva-Maria Nichols
Head of Complement
GlaxoSmithKline

Graham Parry
Senior Director of Translational Research
Bioverativ

Nader Najafian
Director of Clinical R&D
Alnylam Pharmaceuticals

Cedric Francois
CEO
Apellis Pharmaceuticals

Simon Read
CSO
Ra Pharma

Thomas Schall
President & CSO
ChemoCentryx

Ashley Frazer-Abel
Exsera BioLabs Director
University of Colorado

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Welcome to the Complement-based Drug Development Summit 2017

The first industry-dedicated meeting focused on optimizing clinical trial design, efficacy assessment, target identification, indication selection and achieving regulatory approval in the complement therapeutics space.

The complement therapeutics space is poised for a renaissance. Numerous companies have shifted their focus towards complement-based therapies in recent years, and an expanding pool of investors are funding the growth of their pipelines, creating real momentum.

The ***Complement-based Drug Development Summit*** will provide a comprehensive, end-to-end analysis of the complement-based drug research and development process. This industry-led meeting will focus on pre-clinical and clinical trial design through to gaining regulatory approval and upscaling manufacturing process to meet market demand.

Join world leaders in complement therapeutics to examine the pathophysiology of disease through the relationships between pathway sub components, and how this can be leveraged to treat individual conditions and **drive real change in drug development.**

Discussion panels, roundtable sessions and case studies from the clinic will provide the ideal platform for the field's foremost drug developers and key academics to collaborate, advancing global understanding of approaches for safe and patient-accessible complement inhibition.

Hear what previous attendees have to say:

"This meeting gathered all experts in the field to share ideas and data. It was quite an eye opener. I feel I came home with excitement and a brand new mind towards my work in the field"
Past CVI Summit Attendee, Pfizer

"Overall an excellent programme with topical presentations and great opportunities to network with leaders in the field. The fact that it was a relatively small meeting made such interactions possible and made it hugely valuable"
Past CVI Summit Attendee, Virttu Biologics

Join Thought Leaders to Gain Unique Insights into the Key Issues Facing this Industry

1.

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

2.

Optimize Clinical Trial Design: Analyze methods for improving clinical trial design with case studies in patient recruitment and stratification, targeting, dosing, endpoints and sample handling.

3.

Managing Off-Target Effects: Enhance the management of off-target effects and develop approaches for minimizing infection risk.

4.

Achieving Regulatory Approval: Learn how best to navigate the regulatory landscape, examining guidelines and expectations to ensure that drugs gain market approval smoothly.

5.

Assessing Inhibition Points: Analyze the most effective points of complement inhibition for the treatment of individual diseases and the selection of therapeutic approaches for inhibition.

Expert Speakers

David Apelian
CMO & EVP
Achillion Pharmaceuticals

Camille Bedrosian
CMO
Alexion Pharmaceuticals

Nader Najafian
Director of Clinical R&D
Alnylam Pharmaceuticals

Ted Yednock
CSO
Annexon Biosciences

Sacha Zeerleder
Professor of Immunohematology
University of Amsterdam

Cedric Francois
CEO
Apellis Pharmaceuticals

Graham Parry
Senior Director of Translational Research
Bioverativ

Christopher Horvath
SVP, PreClinical Development
bluebird bio

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University of Colorado

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

Menno van Lookeren
Principal Scientist, Immunology
Genentech

Eva-Maria Nichols
Head of Complement
GlaxoSmithKline

Rajendra Kumar-Singh
Founder & Managing Director
Hemera Biosciences

Niels Riedemann
CEO
InflaRX

Michael McCaleb
Vice President
Ionis Pharmaceuticals

Jörg Köhl
Director of the Institute for Systemic Inflammation Research
University of Lübeck

Bärbel Rohrer
Professor of Ophthalmology
Medical University of South Carolina

Kourous Rezaei
Senior Vice President of Medical Strategy
Ophthotech

Simon Read
CSO
Ra Pharma

Kishor Devalaraja
Senior Staff Scientist
Regeneron Pharmaceuticals

Conference Day One | Wednesday November 15 2017

8.00 Breakfast & Registration

Michael Holers, Scoville Professor and Head, Division of Rheumatology, **University of Colorado**

9.00 Chairman's Opening Remarks

Clinical Trial Design Optimization

Ashley Frazer-Abel, Exsera BioLabs Director **University of Colorado**

9.10 Identifying the Right Candidates – Efficacy Testing in the Era of Complement-specific Therapeutics

- Analysing the current state of complement testing
- Investigating methods for updating historic tests to meet current demands
- Overcoming the challenges confounding quality complement results
- Reviewing the international efforts to standardize complement analysis

Sacha Zeerleder, Professor of Immunohematology, **University of Amsterdam**

9.40 Enabling Confident Decision Making by Generating Powerful Data in Rare Disease Trials

- Determining effective methods for patient recruitment and experienced investigator acquisition
- Streamlining clinical trials by ensuring patient suitability - optimal patient stratification practices
- Altering clinical trial design to move beyond rare and orphan diseases into common disease areas

Ashley Frazer-Abel, Exsera BioLabs Director, **University of Colorado**

Sacha Zeerleder, Professor of Immunohematology, **University of Amsterdam**

10.10 *Panel:* Assessing Optimum Dosage, Targeting, Endpoints and Sample Handling for Clinical Trials

- Analyzing dosing requirements and site of targeting data
- Clinical endpoints – identifying powerful biomarkers
- Exploring methods for sample collection and handling to avoid ex-vivo activation

10.50 Morning Refreshments & Networking

Focus: Indication Selection and Target Identification

Michael Holers, Scoville Professor and Head, Division of Rheumatology, **University of Colorado**

11.40 Therapeutic Insights from Studies of Complement Activation Mechanisms at Local Tissue Sites

- Developing therapeutic strategies that minimize systemic inhibition of this pathway by targeting inhibition of the pathway to sites of complement activation
- Understanding which of the complement activation and amplification mechanisms play essential roles in driving local injury in a disease-specific manner
- Monitoring levels of *in vivo* complement activation in targeted tissues
- Creating a method to image fixed complement C3d in tissue sites to provide essential insights into control of complement activation in tissue sites inaccessible to biomarker assessment

Graham Parry Senior Director of Translational Research **Bioverativ**

12.10 TNT009 Prevents the Deposition of Complement Split Products on Cells & Tissues from Patients with Classical Pathway Mediated Diseases

- Identifying biomarkers to assess the pharmacodynamic effect of candidate molecules in diseases where complement activation is thought to play a pathologic role.
- Utilizing these markers of disease activity in a Phase 1 integrated trial design to evaluate monoclonal antibody TNT009's ability to inhibit C1
- Using TNT009 to treat patients with various classical pathway mediated diseases.
- Evidence of the pharmacodynamic effect of TNT009 in these diverse patient populations and supporting the clinical development of the molecule in various disease settings

Jörg Köhl, Director of the Institute for Systemic Inflammation Research, **University of Lübeck**

12.40 The Anaphylatoxins and their Receptors as Targets in Inflammatory Diseases.

- Examining the roles of C3a and C5a as effector molecules in acute and chronic inflammatory diseases through activation of their G protein-coupled receptors
- Analyzing anaphylatoxic regulation and control of innate and adaptive immune responses through intense cross-talk with immune receptor pathways.
- Assessing evidence that C5a plays an important role for the development and severity of food allergy, and the pathophysiologic role of C5a in experimental models of skin blistering diseases.
- The contribution of the C5a/C5aR1 axis for disease development, and discussing C5aR1 as an alternative or additional therapeutic option to block the inflammatory events in neurodegenerative diseases.

Menno Van Lookeren, Principal Scientist, Immunology, **Genentech**

1.10 The Role of Complement Therapeutics in the Treatment of Geographic Atrophy, the Advanced Form of Dry Age-Related Macular Degeneration

- Examining the role of complement in GA/AMD
- Inhibiting the complement system to slow or halt AMD disease progression.
- Success of the complement factor D inhibitor lampalizumab in GA phase II clinical trial.
- Investigating the contribution of complement-independent pathways to GA disease pathogenesis.

1.40 Lunch & Networking

Camille Bedrosian, CMO **Alexion Pharmaceuticals**

2.30 Terminal Complement Inhibition for Refractory Generalized Myasthenia Gravis

- An overview of the classical pathway in complement therapeutics
- Determining the role of complement in myasthenia gravis – examining animal model data
- Phase II trial of eculizumab in gMG – POC data for moving into phase III
- Phase III trial of eculizumab for refractory gMG: design, efficacy, safety results and conclusions
- Overview of eculizumab safety

Cedric Francois, CEO **Apellis Pharmaceuticals**

3.00 Therapeutic Targeting of C3 to treat PNH

- Overcoming the challenges associated with inhibiting the most abundant complement protein
- Realising the potential of C3 inhibition for disease control and modification
- Lessons learned from phase I & II compound APL-2 clinical trials

Michael Holers, Scoville Professor and Head, Division of Rheumatology, **University of Colorado**

David Apelian, CMO & EVP, **Achillion Pharmaceuticals**

Menno Van Lookeren, Principal Scientist, Immunology, **Genentech**

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

- Understanding the pathophysiology of diseases through the relationships between pathway sub-components, and how this can be leveraged to treat individual conditions
- Analyzing the advantages and disadvantages of targeting on different levels
- Discussing trends in the complement therapeutics space between points of inhibition and disease areas

4.10 Afternoon Refreshments & Networking

5.00 Complement-based Drug Development Round Tables

1. 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?

2. The Future of Complement Therapeutics

- What are the most interesting cutting edge developments in this area that could have great potential?
- How can companies begin preparation to capitalize on emerging market trends in coming years?

3. Expanding Complement Therapeutics into Common Diseases Areas

- What alterations must be made to clinical trial design in order to move beyond rare and orphan diseases?
- What implications will moving into common disease areas have for complement therapeutics – how can we begin to prepare for perceived challenges?

4. 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 revelatory approval process?

5. Preparing for Commercialization of Complement Therapies

- How can drug production processes be upscaled to meet both initial market demand and subsequent growth?
- How can logistical issues with manufacture, storage and transport of treatments be overcome?
- What future methods for treatment delivery may solve the current patient access problem?

Michael Holers, Scoville Professor and Head, Division of Rheumatology, **University of Colorado**

6.00 Chairman's Closing Remarks

Conference Day Two | Thursday November 16 2017

8.00 Breakfast & Networking

Michael Holers, Scoville Professor and Head, Division of Rheumatology, **University of Colorado**

8.50 Chairman's Opening Remarks

Focus: Therapeutic Approaches for Inhibition

Simon Read CSO **Ra Pharma**

9.00 Developing a Pipeline of Macrocyclic Peptides and Small Molecule Inhibitors For Disorders of Complement Regulation

- Macrocyclic peptide discovery for complement pathways, exemplified by Ra's Complement C5 and Factor D programs, including discovery, lead optimization and preclinical development challenges.
- Clinical Development of RA101495, a systemically administered macrocyclic peptide for PNH: Update on Phase 1 and phase 2 studies.
- Opportunities for local administration of macrocyclic Factor D inhibitors in ocular disease
- Leveraging macrocyclic peptides for small molecule discovery, with a focus on the identification of orally bioavailable 1st in class, small molecule inhibitors of Complement C5.

Nader Najafian, Director of Clinical R&D, **Alnylam Pharmaceuticals**

9.30 Utilization of si-RNAs in Treatment of Complement-Mediated Diseases

- Examining the role of siRNA and Alnylam technology to inhibit the complement pathway
- Determining the efficacy and benefits of targeting C5 by siRNA in preclinical and clinical models
- Benefits of at-source inhibition vs. peripheral inhibition

Niels Reidemann, CEO, **InflaRx**

10.00 Developing a Highly Potent and Selective First-in-Class Anti-C5a Antibody for Treatment of Inflammatory Diseases

- Overview of Terminal Complement Activation and illustration of the Extrinsic Pathway for C5a Generation
- The InflaRx technology: Making of IFX-1, a targeted highly potent and selective anti-C5a antibody
- Performance of IFX-1 in humans and in patients
- Targeted C5a-inhibition in human disease: First data of IFX-1 treatment in patients suffering from Hidradenitis Suppurativa

Rajendra Kumar-Singh, Founder and MD, **Hemera Biosciences**

10.30 Gene Therapy Targeting Complement for the Dry Form of Age-Related Macular Degeneration

- Investigating the role of complement in AMD
- Developing an inhibitor of the membrane attack complex (MAC) that can be delivered via gene therapy
- Proof of concept studies in mice, with preclinical dose and safety studies in mice and non-human primates
- Determining safety of this approach with preliminary data from the phase I clinical trial
- Examining proof of concept data for the role of complement in diabetic retinopathy

11.00 Morning Refreshments & Networking

Kourous Rezaei, Senior Vice President of Medical Strategy **Ophthotech**

12.00 The Role of MAC Inhibition in Treating Retinal Diseases

- Why MAC inhibition makes sense
- Examining MAC as a therapeutic approach for complement inhibition
- The landscape of current unmet medical need in retinal diseases
- Targeted indications for MAC Inhibition

David Apelian, CMO & EVP, **Achillion Pharmaceuticals**

12.30 Targeting Factor D of the Complement Alternative Pathway Using Small Molcules for the Treatment of C3 Glomerulopathy (C3G)

- Targeting the critical trigger point of the alternative pathway with an oral complement inhibitor program
- Benefits and Drawbacks of small molecules in complement therapeutics
- Assessing pathophysiology of C3G as a disease of excessive AP activity and ideas for further development of AP complement inhibitors

Michael McCaleb, VP, **Ionis Pharmaceuticals**

1.00 Pharmacodynamic Efficacy of the Complement Factor B (FB) Antisense Oligonucleotide, IONIS-FB-L_{RX}

- Preclinical efficacy of FB antisense oligonucleotides (ASO)
- Exploring pharmacodynamic responses to the FB ASO, IONIS-FB-L_{RX}, in a Phase 1 clinical study
- Assessing the impact of reducing plasma FB levels on systemic complement components
- Identifying opportunities for future clinical development of a FB ASO

1.30 Lunch & Networking

Menno Van Lookeren, Principal Scientist, Immunology, **Genentech**

Niels Reidemann, CEO, **InflaRx**

Michael McCaleb, VP, **Ionis Pharmaceuticals**

2.30 *Panel:* Comparing Current Approaches for Inhibition and Balancing Benefits and Risks by Assessing Optimum Inhibition Levels

- 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
- Identifying trends in the variance of optimum inhibition across different pathways
- Determining which animal models companies have found most and least successful

Focus: Safety Profiles, Risk and Managing Adverse Events

Eva-Maria Nichols, Head of Complement, **GlaxoSmithKline**

3.15 Approaches to Computational Modelling of the Complement System

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

Christopher Horvath, SVP, PreClinical Development **bluebird bio**

3.45 Complement Activation as a Mediator of Anti-Complement Product Toxicities

- Examining evidence showing that complement-directed therapies can actually activate certain complement pathways, resulting in adverse events and toxicity
- Mechanisms of this undesired activation - direct actions, class effects and immunemediated mechanisms
- Interpretation of these findings for the safety of complement-based drugs - functional assays and investigative method
- Reviewing complement pathways in an applied manner - examples of anti-complement products activating complement pathways resulting in toxicity

Michael Holers, Scoville Professor and Head, Division of Rheumatology, **University of Colorado**

4.15 Chairman's Closing Remarks

4.30 Close of Summit

*Presentation content from Cemocentryx & Regeneron currently being finalized

"A very rich environment for discussion, problem solving, and networking with all key players and up and coming players in the field. Great meeting"

Past CVI Summit Attendee, Eureka Therapeutics

WORKSHOPS

Workshop Day | Tuesday November 14 2017

Workshop A

Optimizing Complement-based Clinical Trial Design

09:00am – 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 enable you to:

- Collect and handle samples to avoid ex-vivo activation and improve data quality
- Advance patient recruitment and stratification to streamline trials, especially in rare disease research
- Gain maximum value from your trials by determining the most effective clinical endpoints
- Overcome issues surrounding dosing during trials in order to reduce risk

Leave this workshop with actionable insights that will enable you 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

Advancing Pre-Clinical Models: Development and Utilization of Effective Complement-mediated Disease Models

1:00pm – 4:00pm

Understanding the pathophysiology of complement-mediated disease through quality pre-clinical models is crucial for the development of safe and effective treatments in this space.

Join Annexon's CSO Ted Yednock and Bärbel Rohrer, an innovative leader in retinal diseases, to:

- Develop and utilize the key elements of effective disease models, preparing for a successful drug development process
- Investigate optimal approaches for treatment of complement-mediated diseases, with case studies in AMD/GA, Neurodegeneration and more
- Overcome potential pitfalls in the development of pre-clinical models, which could derail drug candidates further down the pipeline

Leave this workshop having identified the most important steps in developing and utilizing high quality pre-clinical models for a range of complement-mediated diseases.

Workshop Leader
Ted Yednock, CSO, **Annexon Biosciences**

Ted joined Annexon Biosciences as CSO in 2013. He was previously CSO at Prothena Corporation, Head of Research for Elan Pharmaceuticals and a Scientist at Athena Neurosciences. He has been the/a scientific inventor of numerous drugs treating MS, Alzheimer's, Parkinson's, rheumatoid arthritis, psoriasis and Crohn's disease.

Workshop Leader
Bärbel Rohrer, Professor and Endowed Chair, Department of Ophthalmology, **Medical University of South Carolina**

Barb's lab is investigating mechanisms of photoreceptor degeneration and neuroprotection, focusing on two areas: targeting complement activation in models of age-related macular degeneration and improving mitochondrial metabolism as a means to promote life-span in neurons.

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Exsera BioLabs, Exhibitor

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.

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Quidel's Specialty Products Group is focused on providing innovative research and diagnostic tools for identification of novel markers in autoimmune and Complement. Many of these products are unique in nature and provide researchers and clinicians valuable scientific and diagnostic information. Quidel offers products to meet biosafety testing and Complement dependent cytotoxicity testing requirements, such as normal human sera, proteins, monoclonal and polyclonal antibodies, depleted sera and Complement fragment ELISA assays.

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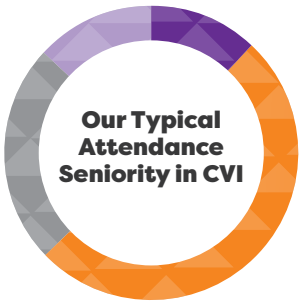
"One of the most efficient and valuable opportunities to overview the field and meet the key developers"

Past CVI Summit Attendee, AGC Business Development Americas

Are you front of mind when pharma and biotech look to develop commercially viable complement therapeutics?

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 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.

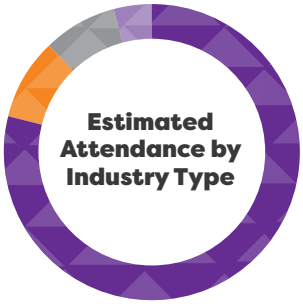


12% C-level Executives

51% Director Level and Above

24% Head of

13% Scientist



79% Drug Developers

9% Academics

8% Solution and Service Providers

4% Investors and Analysts

"A very targeted meeting filled with KOLs and industry leaders in this exciting field. The meeting was organized and run better than any other trade show I have attended"

Past CVI Summit Attendee, IntelliCyt

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Commercial Director, Cell & Viral Immunotherapy
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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. **Gain** a comprehensive understanding of what each key drug developer in this space is currently working on, and the most interesting avenues for advancement in the coming years.
2. **Meet**, network and discuss the key challenges in complement therapeutics with the field's thought leaders during interactive roundtable sessions and panel discussions.
3. **Join** senior level industry figures to analyze the most efficient changes that can be made to improve research, development and manufacturing of complement-based drugs.

INDUSTRY PRICING		
	Register & pay by September 1	**Standard Pricing**
Gold: Conference & 2 workshops	$3397 **(save $700)**	$3797 **(save $300)**
Silver: Conference & 1 workshop	$2898 **(save $500)**	$3298 **(save $100)**
Bronze: Conference only	$2299 **(save $400)**	$2699
Workshops - individual	$699	

ACADEMIC PRICING		
	Register & pay by September 1	**Standard Pricing**
Gold: Conference & 2 workshops	$2378 **(save $909)**	$2658 **(save $629)**
Silver: Conference & 1 workshop	$2030 **(save $558)**	$2310 **(save $278)**
Bronze: Conference only	$1610 **(save $279)**	$1889
Workshops - individual	$699	

VENUE

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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.

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