Ophthalmic Drug Delivery Systems for the Treatment of Retinal Diseases: Basic Research to Clinical Application

July 31 – August 1, 2009

Bethesda, MD

Friday, July 31, 2009

7:00 – 8:00am  Registration and Continental Breakfast

8:00- 8:05am  Welcome and Opening Remarks
Henry Edelhauser, PhD

8:05-8:15am  Introduction
Paul Sieving, MD, PhD, Director, National Eye Institute

8:15:8:35am  Keys to Success in Translational Research in Ophthalmology
Jerry Chader, PhD

Session 1: Eye Anatomy, Ocular Barriers to Drug Transport
Moderators: Kay Rittenhouse, PhD and Hans E. Grossniklaus, MD

8:35-8:50am  Drug Delivery for Posterior Segment: Clinicopathologic Considerations
Hans E. Grossniklaus, MD

8:50 – 9:05am  Barriers to Intravitreal Drug Delivery to the Retina
Clive Wilson, PhD

9:05- 9:20am  Barriers to Transscleral Drug Delivery to the Retina
Michael Robinson, MD

9:20-9:30am  The Ciliary Muscle: A Bioreactor for the Sustained Release of Therapeutic Proteins for the Treatment of Retinal Diseases
Francine Behar-Cohen, MD, PhD

9:30-9:40am  Novel Treatment Strategy for Amd and Dr: Retinal Drug Delivery from Topical Aqueous Drops
Ashim Mitra, PhD

9:40-9:50am  Interactive Round Table discussion

9:50-10:15am  Coffee Break

Session 2: The Vitreous Humor in Drug Delivery
Moderators:  David Weber, PhD and Clive G. Wilson, PhD

10:15-10:30am  Tracing of Intravitreally Injected Labeled Drugs and Nanoparticles in Human Vitreous and Retina Using a Liquid Nitrogen Snap-freeze Thaw Technique
Lennart Berglin, MD, PhD
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<tr>
<th>Time</th>
<th>Topic</th>
<th>Presenter</th>
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<tbody>
<tr>
<td>10:30-10:45am</td>
<td><strong>The Effect of Vitreous Syneresis on Drug Transport</strong></td>
<td>Susan Lee, MS</td>
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<td>10:45-11:00am</td>
<td><strong>Corticosteroid Delivery Systems in the Vitreous: Is Location Important?</strong></td>
<td>Uday Kompella, PhD</td>
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<td>11:00-11:15am</td>
<td><strong>Computer Simulation of Convective and Diffusive Transport of Controlled-release Drugs in the Vitreous Humor</strong></td>
<td>Patrick Hughes, PhD</td>
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<td>11:15-11:25am</td>
<td><strong>Effects Of Vitreous Liquefaction on the Intravitreal Distribution of Sodium Fluorescein, Fluorescein Dextran and Fluorescent Microparticles</strong></td>
<td>Lay Ean Tan, MPharm</td>
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<td>11:25-11:35am</td>
<td><strong>Interactive Round Table discussion</strong></td>
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**Session 3: Intravitreal Drug Delivery**
Moderators: Barry Kupperman, MD, PhD and Karl Csaky, MD, PhD

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<tr>
<td>11:35-11:50am</td>
<td><strong>Development of a Sustained Delivery System to the Posterior Segment: Retisert, The Early Story</strong></td>
<td>Kay Rittenhouse, PhD</td>
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<td>11:50-12:05pm</td>
<td><strong>Review of Corticosteroid Implants/ Formulations (I-Vation, Medidur, Posurdex, Retisert, Trivaris)</strong></td>
<td>Barry Kupperman, MD, PhD</td>
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<td>12:05-12:20pm</td>
<td><strong>Development of Encapsulated Cell Technology for Retinal Degenerative Diseases</strong></td>
<td>Weng Tao, MD, PhD</td>
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<td>12:20-12:30pm</td>
<td><strong>A Phase 1 Study Evaluating the Safety and Evidence of Efficacy of Ibi-20089, a Triamcinolone Intravitreal Injection Formulated with the Verisome™ Drug Delivery Technology, in Patients with Cystoid Macular Edema</strong></td>
<td>Vernon Wong, MD</td>
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<td>12:30-12:40</td>
<td><strong>Antibody Tissue-tablet for Prolonged Local Ocular Delivery</strong></td>
<td>Ashkan Khalili, MD</td>
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<td>12:40-12:50pm</td>
<td><strong>Interactive Round Table discussion</strong></td>
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<td>12:50-1:30pm</td>
<td><strong>Lunch</strong></td>
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<td>1:15-2:15pm</td>
<td><strong>Poster Viewing</strong></td>
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<td>2:15-2:25pm</td>
<td><strong>Afternoon Session Remarks</strong></td>
<td>Cheryl Rowe-Rendleman, PhD</td>
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**Session 4: Transscleral Drug Delivery for Retinal Diseases**
Moderators: Timothy W. Olsen, MD and Uday Kompella, PhD
2:25- 2:40pm  
**Formulations Designed for Transscleral Drug Delivery**  
Thierry Nivaggioli, PhD

2:40-2:55pm  
**Microneedles for Intracorneal, Intrascleeral and Suprachoroidal Drug Delivery**  
Mark Prausnitz, PhD

2:55-3:10pm  
**Episceral Drug Reservoirs**  
A. Linn Murphree, MD

3:10-3:25pm  
**Cannulation of the Suprachoroidal Space for Drug Delivery**  
Timothy W. Olsen, MD

3:25-3:35pm  
**Low Dose Subconjunctival Insulin Treats Retinal Dysfunction in Early Diabetic Retinopathy**  
Ravi Singh, MD

3:35-3:45pm  
**Interactive Round Table discussion**

3:45-4:05pm  
**Coffee Break**

**Session 5: Preclinical Benchmarks for Retinal Drug Therapy**  
Moderators: V. Michael Holers, MD and Greg Hageman, PhD

4:05-4:20pm  
**Retinal Degeneration in the Spectrum of Systemic Diseases – Rationale for Target Selection**  
V. Michael Holers, MD

4:20-4:35pm  
**Targeted Complement Delivery for RPE Damage**  
Bärbel Rohrer, PhD

4:35- 4:50pm  
**Systemic vs. Local Delivery of Therapeutic Drugs for Retinal Disease**  
Anthony Adamis, MD

4:50-5:05pm  
**Computer Modeling of Pharmacokinetics from Ocular Drug Delivery**  
Paul Missel, PhD

5:05-5:15pm  
**A Novel Experimental Platform for Systemic Drug Delivery to the Retina**  
Matthew Campbell, BSc

5:15-5:30pm  
**Interactive Round Table discussion**

**Saturday, August 1, 2009**

7:00-8:00am  
Continental Breakfast

8:00- 8:10am  
Welcome and Opening Remarks  
Michael R. Robinson, MD

8:10-8:20am  
Introduction  
Lisa Neuhold, PhD, Director, Retinal Disease, National Eye Institute
Session 6: Animal Models to Evaluate Drug Delivery Systems  
Moderators: Brian Gilger, DVM and Peter A. Campochiaro, MD

8:20-8:35am  Models of Choroidal Neovascularization  
Hans Grossniklaus, MD

8:35-8:50am  Models of Dry Age Related Macular Degeneration  
Chi-Chao Chan, MD

8:50-9:05am  Models of Retinal Degeneration  
Gustavo Aguirre, VMD, PhD

9:05-9:20am  Animal Models of Uveitis and Drug Delivery  
Brian Gilger, DVM

9:20-9:30am  Delivery of SAR 1118 to the Retina via Ophthalmic Drops and its Effect in the Reduction of Retinal Leukocyte Adhesion and Vascular Leakiness in the Rat Streptozotocin (STZ) Model of Diabetic Retinopathy (DR)  
Tom Gadek, PhD

9:30-9:40am  Interactive Round Table discussion

9:40-10:00am  Coffee Break

Session 7: Topical Therapy for Retinal Diseases  
Moderators: Patrick Hughes, PhD and Cheryl Rowe-Rendleman, PhD

10:00-10:20am  Topical Delivery of Drugs for Retinal and Choroidal Diseases  
Peter Campochiaro, MD

10:20-10:45am  A Review of Topical Delivery to the Retina  
Patrick Hughes, PhD

10:45-11:00am  Application of Iontophoresis for Treating Ocular Diseases  
Jean-Marie Parel, PhD

11:00-11:20am  Commercializing an Iontophoretic Drug Delivery System for Ophthalmic Disease  
Mike Patane, PhD

11:20-11:30am  In Vitro Optimization and In Vivo Validation of Anti-inflammatory Nanoliposomes for Treatment of Retinal Disease  
Mark Kester, PhD

11:30-11:40am  Interactive Round Table discussion

11:40-12:30pm  Lunch

12:30-1:30pm  Poster Viewing

1:30-1:40pm  Afternoon Session Remarks  
Henry Edelhauser, PhD
1:40-2:40pm  **Rapid-Fire Poster Discussion**  
Moderators: Scott Whitcup, MD and Greg Hageman, PhD

**Session 8: Clinical Trials 1**  
Moderators: Scott Whitcup, MD and Wai Wong, MD, PhD

2:40-2:55pm  **Early Phase Clinical Trials Development in Ophthalmology**  
Emily Chew, MD

2:55-3:10pm  **Pitfalls in Clinical Trial Development**  
Curtis Meinert, PhD

3:10-3:25pm  **Impact of the NEI/FDA Retina Endpoints Symposium**  
Karl Csaky, MD, PhD

3:25-3:40pm  **The Evolving Role of the CMS in Assessment of Therapies for the Eye**  
Ross Brechner, MD

3:40-4:00pm  **Coffee Break**

4:00-4:10pm  **How to Obtain the Strongest Patent Coverage for your New Ocular Drug Delivery Invention**  
Philip Reilly, JD, PhD

4:10-4:20pm  **Interactive Round Table discussion**

**Session 9: From Abstracts**  
Moderators: Cheryl Rowe-Rendleman, PhD and Michael Robinson, MD

4:20-4:30pm  **A Phase 2 Study of Encapsulated CNTF Secreting Cell Implant (NT-501) in Patients with Geographic Atrophy Associated with Dry AMD**  
Kang Zhang, MD, PhD

4:30-4:40pm  **A Topical Application Device for Transscleral Passive Drug Delivery: A Possible Option in Non-invasive Treatment of Intermediate and Posterior Segment Eye Diseases**  
Kongnara Papangkorn, PhD

4:40-5:30pm  **Interactive Round Table discussion**

5:30-6:00pm  **Meeting Wrap-up**  
Henry Edelhauser, PhD