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
10:30-10:45am  The Effect of Vitreous Syneresis on Drug Transport  
Susan Lee, MS

10:45-11:00am  Corticosteroid Delivery Systems in the Vitreous: Is Location Important?  
Uday Kompella, PhD

11:00- 11:15am  Computer Simulation of Convective and Diffusive Transport of Controlled-release Drugs in the Vitreous Humor  
Patrick Hughes, PhD

11:15-11:25am  Effects Of Vitreous Liquefaction on the Intravitreal Distribution of Sodium Fluorescein, Fluorescein Dextran and Fluorescent Microparticles  
Lay Ean Tan, MPharm

11:25-11:35am  Interactive Round Table discussion

Session 3: Intravitreal Drug Delivery  
Moderators: Barry Kupperman, MD, PhD and Karl Csaky, MD, PhD

11:35-11:50am  Development of a Sustained Delivery System to the Posterior Segment: Retisert, The Early Story  
Kay Rittenhouse, PhD

11:50-12:05pm  Review of Corticosteroid Implants/ Formulations (I-Vation, Medidur, Posurdex, Retisert, Trivaris)  
Barry Kupperman, MD, PhD

12:05-12:20pm  Development of Encapsulated Cell Technology for Retinal Degenerative Diseases  
Weng Tao, MD, PhD

12:20-12:30pm  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  
Vernon Wong, MD

12:30-12:40  Antibody Tissue-tablet for Prolonged Local Ocular Delivery  
Ashkan Khalili, MD

12:40-12:50pm  Interactive Round Table discussion

12:50- 1:30pm  Lunch

1:15-2:15pm  Poster Viewing

2:15- 2:25pm  Afternoon Session Remarks  
Cheryl Rowe-Rendleman, PhD

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, Intrasceral 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