

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, Intrascleral and Suprachoroidal Drug Delivery**
Mark Prausnitz, PhD
- 2:55-3:10pm **Episcleral 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