Ocular Toxicology
Pharmacology and Drug Delivery: An Eye on the Future

SOT | CONTEMPORARY CONCEPTS in TOXICOLOGY

June 27–28, 2016
South San Francisco, California
Genentech Campus

PROGRAM
Organizing Committee

Evan Thackaberry
Chair
Genentech, South San Francisco, California

Christopher Somps
Chair
Pfizer, Groton, Connecticut

Vladimir Bantseev
Genentech, South San Francisco, California

Edward Chow
Allergan, Irvine, California

Brian Christian
Covance, Madison, Wisconsin

Donald Fox
University of Houston, Houston, Texas

Alan Katz
ToXcel, Gainesville, Virginia

Ron Newton
Novartis, Cambridge, Massachusetts

James Render
NAMSA, Northwood, Ohio

Melva Rios-Blanco
Allergan, Irvine, California

JoAnn Schuh
JCL Schuh PLLC, Bainbridge Island, Washington
President’s Letter

Dear Colleagues,

The *Ocular Toxicology, Pharmacology and Drug Delivery: An Eye on the Future—Contemporary Concepts in Toxicology Meeting* incorporates novel lectures and presentations on scientific research related to the rapid expansion of ocular drug development; as well as a unique opportunity to network and establish collaborations with scientists conducting similar research around the world. This meeting brings together toxicologists, pathologists, clinicians, pharmacologists, and basic scientists all working in the field of ocular drug development.

This exemplary two-day scientific program features scientific lectures on current research advancing the field of ocular drug development. The program is designed to improve our understanding of ocular toxicology, pharmacology, and safety assessment and to increase our understanding of the challenges associated with development of the next generation of ocular drugs and devices. Through these endeavors we work towards fulfilling our mission of creating a safer and healthier world by advancing the science and increasing the impact of toxicology.

The welcome reception on Monday is an opportunity to network and become better acquainted with your colleagues.

Enjoy the meeting!

Sincerely,

John B. Morris, PhD, ATS
SOT President
Program

Monday, June 27, 2016

Day 1: Ocular and Retinal Toxicology and Pharmacology

8:00 AM–9:45 AM
SESSION I: Ocular Toxicology: Preclinical Models and Specialized Endpoints
Chair: Evan Thackaberry, Genentech, South San Francisco, CA

Welcome and Overview
Evan Thackaberry, Genentech, South San Francisco, CA

The Function Morphology of the Vertebrate Eye
Christopher Murphy, University of California Davis, Davis, CA

Electroretinography in Preclinical Studies
Jim Ver Hoeve, University of Wisconsin, Madison, WI

State-of-the-Art Ocular Imaging Techniques
Michael Twa, University of Alabama Birmingham, Birmingham, AL

9:45 AM–10:15 AM
BREAK

10:15 AM–11:45 AM
SESSION II: Advances in the Development of Protein-Based Intravitreal Therapies
Chair: Edward Chow, Allergan, Irvine, CA

Nonclinical Safety Assessment of Lucentis® and Clinical Translatability
Florence Lorget, Genentech, South San Francisco, CA

In Vitro Tools to Control Product Quality Attributes Related Risk Assessments for Ocular Biologic Drugs
Swati Gupta and Joe Zhou, Allergan, Irvine, CA

Unexpected Toxicity with a Novel Bispecific Fab for Intravitreal Administration: Pharmacology or Immunogenicity?
Evan Thackaberry, Genentech, South San Francisco, CA

11:45 AM–12:45 PM
LUNCH

12:45 PM–2:15 PM
SESSION III: The Emerging Role of Ocular Immunology and Immunomodulation in Ocular Disease and Drug Development
Chair: JoAnn Schuh, JCL Schuh Consulting PLLC, Bainbridge Island, WA

Immunomodulation of Diseases at Ocular Surfaces
Neal Barney, University of Wisconsin, Madison, WI

Glial Reactivity: Key Roles in Inner Retinal Neurovascular Disease
Jeremy Sivak, Toronto Western Research Institute, Toronto, ON, Canada

Toll-Like Receptors and Ocular Immunotoxicology
Curtis Brandt, University of Wisconsin, Madison, WI

2:15 PM–2:30 PM
BREAK
Tuesday, June 28, 2016

Day 2: Toxicology of Novel Ocular Drug Delivery Systems

8:00 AM–9:30 AM
SESSION V: Regulatory Challenges for Developing Novel Ocular Therapies
Chair: Evan Thackaberry, Genentech, South San Francisco, CA

Regulatory Considerations for Preclinical Ocular Programs in Support of Clinical Trials
Mark Vezina, Charles River, Senneville, QC, Canada

Regulatory Challenges for Novel Ophthalmic Drug Delivery
Gary Novack, PharmaLogic, San Rafael, CA

Safety Assessment and Regulatory Strategies and Challenges for Developing an Intravitreal Drug/Device Combination
Vladimir Bantseev, Genentech, South San Francisco, CA

9:30 AM–10:00 AM
BREAK

10:00 AM–11:30 AM
SESSION VI: Next Generation Biomarkers to Assess Ocular Injury
Chair: Melva Rios-Blanco, Allergan, Irvine, CA

MiRNAs As Potential Predictors of Retinal Toxicity
Qinghai Peng, Pfizer, San Diego, CA

E2012-Induced Cataract and Its Predictive Biomarkers
Kyoko Nakano, Eisai, Tsukuba, Japan
11:30 AM–12:30 PM
LUNCH

3:00 PM–4:30 PM
SESSION VIII: Developing the Future: Safety Assessment of Gene and Stem Cell Therapies

Chairs: Ewa Budzynski, Covance, Madison, WI; and Ron Newton, Novartis, Cambridge, MA

IND-Enabling Preclinical Toxicity and Efficacy Studies for an RPE-Patch Developed from AMD-Patient-Specific iPS Cells
Kapil Bharti, NEI-NIH, Bethesda, MD

Development of Subretinal Gene Therapies for Retinitis Pigmentosa
Mark Milton, Novartis, Cambridge, MA

Safety and Efficacy of an AAV-Vector Following Subretinal Injection in Mouse Model of Achromatopsia
Ewa Budzynski, Covance, Madison, WI

12:30 PM–2:30 PM
SESSION VII: Toxicology Assessment of Novel Slow Release Ophthalmologic Formulations

Chairs: Christopher Somps, Pfizer, Groton, CT; and Evan Thackaberry, Genentech, South San Francisco, CA

Drug Delivery to the Eye Overview
Uday Kompella, University of Colorado, Denver, CO

Slow-Release Formulations and Ocular Immunology: Microscopic Observations
Vito Sasseville, Novartis, Cambridge, MA

Vitreal/Peptide Deposits As a Slow Release Formulation
Margaret Collins, Charles River, Reno, NV

Challenges of Slow-Release Intravitreal Therapeutics for Age-Related Macular Degeneration
James Chastain, Alcon, Fort Worth, TX

2:30 PM–3:00 PM
BREAK
Vision and Background

Over the last ten years, the landscape for ocular drug development has changed significantly. Longer life expectancy and increased incidence of diabetes have resulted in rapidly increasing incidence of the major eye diseases, such as age-related macular degeneration and glaucoma (30% increase expected by 2020) and diabetic eye disease (69% increase expected by 2030). As a result, interest in the treatment of eye diseases has grown considerably. The rapid expansion of ocular drug development has revealed significant challenges for ocular toxicology, pharmacology, and drug delivery. Moreover, there is increasing evidence of retinotoxicity resulting from off-target drug effects and neurotoxicants. All of these factors led to the creation of the Society of Toxicology (SOT) Ocular Toxicology Specialty Section (OTSS) in 2009. Since then, OTSS membership has grown rapidly to more than 100 members.

This conference will provide a forum for communication and interactions between toxicologists, pathologists, clinicians, pharmacologists, basic scientists, and other professionals working in the field of ocular toxicology. The main focus will be two-fold: to improve our understanding of ocular toxicology, pharmacology, and safety assessment and to increase our understanding of the challenges associated with development of the next generation of ocular drugs and devices. In particular, the committee has focused on the two challenges which were considered to be of the highest importance in the field. The first is immunogenicity of intravitreal therapeutics, which has become a significant issue across the industry as more intravitreal protein (or protein/polymer combination) therapeutics advance to clinical trials. Immunogenicity of these therapeutics is a significant confounding factor and often makes nonclinical risk assessment difficult. The second key issue is the development of locally-administered complex long-acting delivery technologies, including polymer, device, gene, and/or cell-based therapies. The development of these technologies is complicated by their complex and novel composition, the local cellular response often observed against these systems within the eye, and a lack of clear regulatory guidance in the field.

Online Material
Access materials online www.toxicology.org/ocular
Speaker Presentation Abstracts • Program • Attendee List

Food and Beverage Breaks
Beverages and snacks will be provided during the sessions breaks.
Lunch is provided for attendees.