



**Saturday, June 16**

9:00 AM–4:30 PM

**NTP Satellite Symposium: Pathology Potpourri**

*Chair: Susan A. Elmore, MS, DVM, DABT, FIATP, DACVP, NTP and NIEHS, Research Triangle Park, NC*

The objective of this interactive symposium is to provide continuing education on interpreting pathology slides, to generate lively and productive conversation, and to have a good time. During each talk, the speakers will project a series of images of lesions on one screen with a choice of diagnoses/answers on a separate screen. The members of the audience will then vote using wireless keypads and the results will be displayed on the screen. Time is allowed for discussion after each voting session.

**Sunday, June 17**

**Career Development Session (Sunday AM)**

8:00 AM–12:00 Noon

**Practical Strategies for Navigating Toxicologic Pathology in One's Early Career...and Beyond!**

*Co-Chairs: Vinicius Carreira, DVM, PhD, DACVP, DABT, Janssen R&D—Johnson & Johnson, La Jolla, CA; and Gopinath Palanisamy, BVSc, MS, PhD, DACVP, Genentech, South San Francisco, CA*

Toxicologic Pathology is a unique and exciting field with an ever-increasing demand for professionals. But what exactly do toxicologic pathologists bring to the table, where do they work, and how do you function effectively as one? These questions and more shall be answered in this session, complete with overviews of career preparation, roles in various sectors of the industry, bases of safety toxicology, logistics of GLP work, anatomic and clinical pathology data analysis, and a discussion of the scientific tools available to support the toxicologic pathologist in his or her journey.

**CE 1 (Sunday AM)**

8:00 AM–12:00 Noon

**Clinical Pathology of Biotherapeutics**

*Co-Chairs: Allison Vitsky, BS, DVM, DACVP, Pfizer Global Research and Development, San Diego, CA; and Tara P. Arndt, DVM, DACVP, Covance, Madison, WI*

Biologic drug modalities are rapidly expanding in number and complexity, and this expansion has been accompanied by the observation of equally complex effects, both expected and unexpected, in nonclinical safety studies. The increasing emphasis on immunotherapeutic agents has further complicated matters, such that interpreting clinical pathology data has become a challenging endeavor requiring heightened comprehension of immunology, and a working understanding of responses which may be qualitatively

or quantitatively different between species. This session will cover clinical pathology alterations common to various biotherapeutics, using didactic presentations, mechanistic discussions, and case examples to deliver a comprehensive discourse on this challenging topic.

8:00 AM–8:05 AM

**Introduction**

8:05 AM–8:55 AM

**Effects of Biologic Drug Modalities on Peripheral Blood Cells**

*Nancy E. Everds, DVM, DACVP, Seattle Genetics, Bothell, WA*

8:55 AM–9:45 AM

**Immunogenicity and Immune Complex Disease in Preclinical Safety Assessment Studies: Challenges for Assessing Human Safety**

*John L. Vahle, DVM, PhD, DACVP, Eli Lilly & Company, Indianapolis, IN*

9:45 AM–10:15 AM

**Break**

10:15 AM–11:05 AM

**Complement Activation, Cause and Effect**

*William Siska, DVM, MS, DACVP, Charles River Laboratories, Reno, NV*

11:05 AM–11:55 AM

**Immunophenotyping and Cytokines, Considerations and Case Examples**

*Ellen W. Evans, DVM, PhD, DACVP, Pfizer, Inc., Groton, CT*

11:55 AM–12:00 Noon

**Panel Discussion**

**CE 2 (Sunday AM)**

8:00 AM–12:00 Noon

**Scientific and Regulatory Considerations in Safety Evaluation of Gene Therapy Products in Preclinical Studies**

*Co-Chairs: Basel T. Assaf, BVSc, PhD, DACVP, Pfizer, Inc., Andover, MA; and Laurence O. Whiteley, DVM, PhD, DACVP, Pfizer, Inc., Andover, MA*

Progress in understanding the molecular bases of human health and disease in recent decades has flourished the field of Gene Therapy (GT) to offer new possibilities for treating, and even curing, a plethora of medical conditions such as monogenic disorders and metabolic diseases. GT is a therapeutic intervention to genetically alter or modify living cells by means of gene delivery achieved using either viral vectors or non-viral vectors, with the former constituting market share majority. Although gene therapy is conceptually attractive, adverse and even fatal iatrogenic complications have marred the initial enthusiasm of clinical successes. The properties of investigational viral vector-based

gene therapy product (VGTP), such as their integration potentials, pose safety concerns unique from those of small molecule drugs and other macromolecule biologics. These products carry risks associated with ectopic or unregulated expression of the transgene, genotoxicity and cell transformation associated with integrative vectors, immunogenicity and inflammatory host tissue responses, long term persistence, and off-target distribution. These risks are generally evaluated in preclinical studies as part of a comprehensive preclinical safety program prior to administration in humans. However, safety assessment for these products can be challenging due to the lack of standardized approaches. A primary goal of this session is to introduce this product class to the toxicologic pathology community and provide a forum for discussion of the scientific and the regulatory considerations in the evaluation of host responses to GT products.

8:00 AM–8:05 AM

## Introduction

8:05 AM–8:40 AM

## Gene Therapy: From Discovery to Translational Research

*Guangping Gao, PhD, University of Massachusetts Medical School, Worcester, MA*

8:40 AM–9:15 AM

## A Pathologist's Approach to Characterizing the Safety Profile of AAV-Based Gene Therapy

*Laurence O. Whiteley, DVM, PhD, DACVP, Pfizer, Inc., Andover, MA*

9:15 AM–9:50 AM

## US FDA/CBER Regulatory Considerations in the Preclinical Evaluation of GT Products

*Sandhya Sanduja, PhD, US FDA/CBER, Silver Spring, MD*

9:50 AM–10:20 AM

## Break

10:20 AM–10:55 AM

## Animal Models to Assess the Immunogenicity of AAV Vectors

*Hildegund C.J. Ertl, MD, The Wistar Institute, Philadelphia, PA*

10:55 AM–11:30 AM

## Advancing GT into the Clinic; In-Depth Experience on the Interaction with Regulatory Agencies and the Advancement to Clinical Trials of GT Products

*Katherine A. High, MD, Spark Therapeutics, Philadelphia, PA*

11:30 AM–12:00 Noon

## Panel Discussion

## CE 3 (Sunday PM)

1:30 PM–5:30 PM

## Toxicologic Pathology of the Peripheral Nervous System

*Co-Chairs: Ingrid D. Pardo, DVM, MS, DACVP, Pfizer, Inc., Gales Ferry, CT; and Deepa B. Rao, BVSc, MS, PhD, DABT, DACVP, US FDA, Silver Spring, MD*

Peripheral Nervous System (PNS) toxicity evaluation is relatively less well-defined compared to Central Nervous System (CNS) toxicity evaluation in routine animal toxicology studies. PNS toxicity is often encountered in patients treated with therapeutic agents (e.g., cancer chemotherapeutics), or, as a result of exposure to environmental chemicals (e.g., industrial solvents). Available literature, guidance, and translation between animal studies to human risk assessment is generally limited. This half-day course is designed to familiarize participants with PNS toxicologic histopathology. Topics will include an overview of PNS biology, classic methods, and current best practices for PNS sampling, preparation, and evaluation, commonly observed lesions and artifacts in the PNS, and, examples and mechanisms of PNS toxicity. A final presentation of three case studies will conclude into a platform session with the audience for an open discussion with all speakers.

1:30 PM–1:35 PM

## Introduction

1:35 PM–1:45 PM

## Biology of the PNS

*Brad Bolon, DVM, MS, PhD, DACVP, DABT, ATS, FIATP, GEMpath, Inc., Longmont, CO*

1:45 PM–2:20 PM

## Anatomic Assessment and Review of Best Practices

*Mark Butt, DVM, Tox Path Specialists, LLC, Frederick, MD*

2:20 PM–2:35 PM

## Common Structural Lesions and Artifacts in the PNS

*Bernie Jortner, VMD, Virginia Tech, Blacksburg, VA*

2:35 PM–3:05 PM

## Break

3:05 PM–3:40 PM

## Peripheral Neurotoxicants: Agents and Mechanisms

*William M. Valentine, DVM, PhD, DABT, DABVT, Vanderbilt University Medical Center, Nashville, TN*

3:40 PM–4:15 PM

## Electrophysiological Methods for Evaluating the PNS

*Joseph C. Arezzo, PhD, Albert Einstein College of Medicine, Bronx, NY*

4:15 PM–5:10 PM

## Case Studies in PNS Neurotoxicity

*Ingrid D. Pardo, DVM, MS, DACVP, Pfizer, Inc., Gales Ferry, CT; Deepa B. Rao BVSc, MS, PhD, DABT, DACVP, US FDA, Silver Spring, MD; and Alok K. Sharma, BVSc, MVSc, MS, PhD, DACVP, DABT, Covance Laboratories Inc., Madison, WI*

5:10 PM–5:30 PM

## Panel Discussion

**CE 4 (Sunday PM)**

1:30 PM–5:30 PM

**The Breakthrough of Oligonucleotide Therapeutics: What Is Happening in between Small and Large Molecules?***Sponsored by the American College of Toxicology (ACT)*

**Co-Chairs: Sven Korte, PhD**, Covance Preclinical Services GmbH, Münster, Germany; and **Brian Vuilleminot, PhD, DABT**, Adverum Biotechnologies, Inc., Menlo Park, CA

The course is aimed for toxicologists and pathologists, but equally provides a great summary for pharmaceutical and regulatory experts. This is a rare chance to get guided through this field by a variety of world leading experts. This CE course will define different classes of oligonucleotide-based therapeutics on the basis of mechanism of action and summarize the history of this compound class. Furthermore, characterization of the pharmacokinetics and toxicology of Antisense Oligonucleotide (ASO) therapeutics will be presented and it will be described how toxicology testing strategies might differ from typical small molecule development. This course will also provide in-depth knowledge to conduct intrathecal screening and chronic lumbar or port catheter studies in juvenile and mature cynomolgus monkeys. Finally, the session will help you to understand the clinical relevance of toxicity findings, pathologic alterations that may be seen in nonhuman primates given repeated subcutaneous or intrathecal doses of single stranded antisense oligonucleotides and discuss recent advancements in the antisense field, allowing a look into the future of this technology platform.

1:30 PM–1:45 PM

**Introduction**

1:45 PM–2:25 PM

**Oligonucleotide Therapeutics: A Historical Perspective***Laurence O. Whiteley, DVM, PhD, DACVP, Pfizer, Inc., Andover, MA*

2:25 PM–3:15 PM

**US Regulatory Experience with Oligonucleotide-Based Therapeutics***Ronald L. Wange, BS, PhD, US FDA, Silver Spring, MD*

3:15 PM–3:45 PM

**Break**

3:45 PM–4:20 PM

**Toxicopathology of Single Stranded Antisense Oligonucleotides***Jeffery A. Engelhardt, DVM, PhD, Ionis Pharmaceuticals, Carlsbad, CA*

4:20 PM–4:55 PM

**Conduct and Design of NHP Studies for First-in-Man Studies***Sven Korte, PhD, Covance Preclinical Services GmbH, Münster, Germany*

4:55 PM–5:30 PM

**When Your Cup Runneth Over: Advances in Antisense Chemistry, Targeting, and Mechanisms***Scott P. Henry, PhD, Ionis Pharmaceuticals, Carlsbad, CA***Monday, June 18**

8:00 AM–8:10 AM

**Symposium Welcome**

8:10 AM–8:25 AM

**Fundamentals of Glomerular Anatomy and Physiology***Kendall Frazier, DVM, PhD, DACVP, DABT, GlaxoSmithKline, King of Prussia, PA*

8:25 AM–9:25 AM

**Keynote Address: Glomerulonephritis***J. Charles Jennette, MD, UNC Hospitals, Chapel Hill, NC***Session 1**

9:25 AM–12:00 Noon

**Glomerular Grab Bag****Co-Chairs: Kendall Frazier, DVM, PhD, DACVP, DABT,***GlaxoSmithKline, King of Prussia, PA; and Rachel Cianciolo, VMD, PhD, DACVP, The Ohio State University, Columbus, OH*

The Monday morning session entitled “Glomerular Grab Bag” begins with a short introduction on “Glomerular Anatomy and Physiology” by Dr. Ken Frazier of GSK, which is followed by the plenary session on “Glomerulonephritis” by renowned nephrologist and researcher Dr. J. Charles Jennette from the University of North Carolina hospital at Chapel Hill. The plenary is followed by a talk on “Integrated Diagnostic Approach as a Basis for Nonclinical to Clinical Translation and Biomarkers” by Dr. Rachel Cianciolo of The Ohio State University. Following the break, Dr. Frazier gives another seminar on drug-induced glomerulonephritis entitled “The Problem of Biotherapeutic and Antisense Oligonucleotide Immune Activation in the Kidney”, and the session closes with an interesting translational lecture by Dr. Brad Rovin of The Ohio State University on “Lupus Nephritis, a Clinician’s Experience”.

9:25 AM–10:00 AM

**Integrated Diagnostic Approach As a Basis for Nonclinical to Clinical Translation and Biomarkers***Rachel Cianciolo, VMD, PhD, DACVP, The Ohio State University, Columbus, OH*

10:00 AM–10:30 AM

**Break**

10:30 AM–11:10 AM

**The Problem of Biotherapeutic and Antisense Oligonucleotide Immune Activation in the Kidney***Kendall Frazier, DVM, PhD, DACVP, DABT, GlaxoSmithKline, King of Prussia, PA*

11:10 AM–12:00 Noon

**Lupus Nephritis, a Clinician’s Experience***Brad Rovin, MD, The Ohio State University, Columbus, OH*

## Career Development Lunchtime Session

12:30 PM–1:30 PM

### The Standard for the Exchange of Nonclinical Data (SEND): Challenges and Promise

**Co-Chairs:** *Kimberly Maratea, DVM, PhD DACVP, AstraZeneca, Waltham, MA; and Shambhunath Choudhary, BVSc, PhD, DACVP, Charles River Laboratories, Spencerville, OH*

SEND is an implementation of the Study Data Tabulation Model (SDTM) for nonclinical studies that enables the US FDA to modernize and streamline the review process. In this session, a panel of experts including pathologists, IT professionals familiar with the SEND submission process, and US FDA reviewers will discuss obstacles that challenge implementation of SEND in routine submissions to US FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER). Panelists and audience members will also have an opportunity to discuss the benefits of standardization and how they outweigh the perceived disadvantages. The goal of the panel discussion will be to create greater familiarity among STP members about SEND, including the steps, obstacles, and mistakes to avoid in its implementation during routine submissions.

## Session 2

1:15 PM–5:00 PM

### Acute Kidney Injury (AKI): Toxicologic Pathologist's Constant Companion

**Co-Chairs:** *Torrie A. Crabbs, DVM, DACVP, Experimental Pathology Laboratories, Inc., Research Triangle Park, NC; and Zaher A. Radi, DVM, MSc, MBA, PhD, DABT, DACVP, Pfizer Inc., Andover, MA*

Acute Kidney Injury (AKI): The Toxicologic Pathologist's Constant Companion is the theme of Session 2, which will commence on Monday afternoon by covering the fundamentals of tubule and interstitial anatomy and physiology by Dr. Kevin McDorman of Charles River. This will be followed by a review of DIKI, INHAND, and SEND nomenclature in the renal arena which will be co-presented by Dr. Torrie Crabbs of EPL and Dr. Zaher Radi of Pfizer. As a leading expert in AKI pathogenesis, Dr. Bruce Molitoris from Indiana University, will then give a talk on "Renal Hemodynamics, Microcirculation, and Tubular Ischemia: It's All about the Blood Flow." Dr. Brad Rovin, The Ohio State University, will give a seminar after the break that will discuss "Advances and Challenges on New Therapies and Clinical Targets of AKI." Session 2 will close with a seminar by Dr. Radi on "Immunopathologic Responses in AKI."

1:15 PM–1:20 PM

#### Introduction

1:20 PM–1:40 PM

#### Fundamentals of Tubule and Interstitial Anatomy and Physiology

*Kevin S. McDorman, DVM, PhD, DACVP, Charles River, Frederick, MD*

1:40 PM–2:10 PM

#### DIKI and INHAND and SEND Nomenclature Review

*Torrie A. Crabbs, DVM, DACVP, Experimental Pathology Laboratories, Inc., Research Triangle Park, NC; and Zaher A. Radi, DVM, MSc, MBA, PhD, DABT, DACVP, Pfizer Inc., Andover, MA*

2:10 PM–3:00 PM

#### Renal Hemodynamics, Microcirculation, and Tubular Ischemia: It's All about the Blood Flow

*Bruce A. Molitoris, MD, Indiana University, Indianapolis, IN*

3:00 PM–3:30 PM

#### Break

3:30 PM–4:20 PM

#### Advances and Challenges on New Therapies and Clinical Targets of AKI

*Brad Rovin, MD, The Ohio State University, Columbus, OH*

4:20 PM–5:00 PM

#### Immunopathologic Responses in AKI

*Zaher A. Radi, DVM, MSc, MBA, PhD, DABT, DACVP, Pfizer Inc., Andover, MA*

5:30 PM–6:30 PM

## Town Hall

**Tuesday, June 19**

## Session 3

8:00 AM–12:00 Noon

### Chronic Kidney Disease: Mechanisms and Progression

**Co-Chairs:** *Gordon Hard, BVSc, PhD, DSc, ATS, Tairu, New Zealand; and Kevin S. McDorman, DVM, PhD, DACVP, Charles River, Frederick, MD*

The Tuesday morning scientific session will build on the information presented earlier in the meeting on acute kidney injury, and will focus on chronic kidney disease progression. Mechanisms of chronic kidney disease will be presented by Dr. Agnes B. Fogo, Professor and John L. Shapiro Chair of Pathology at Vanderbilt University Medical Center, and an expert in glomerulosclerosis with and author of 280 research articles and reviews as well as two textbooks on renal pathology. Dr. Samuel M. Cohen, Professor and Havlik-Wall Professor of Oncology at the University of Nebraska Medical Center, will then discuss the relationship between crystalluria and chronic kidney disease. Following a break providing the opportunity for networking and visiting the exhibit hall, Dr. Charles Wood, Research Biologist and Pathologist at the United States Environmental Protection Agency, will present chronic kidney disease associated with environmental toxins and exposures. The concluding talk of the session will be a current state and understanding of renal carcinogenesis mechanisms in rodents delivered by Dr. Gordon Hard, renowned expert renal pathology consultant with over 40 years of experience in chemical carcinogenesis and toxicology research, specializing in renal toxicologic pathology.

8:00 AM–8:10 AM

**Introduction**

8:10 AM–9:10 AM

**Mechanisms of Chronic Kidney Disease Progression***Agnes Fogo, MD, Vanderbilt University, Nashville, TN*

9:10 AM–9:55 AM

**Chronic Kidney Disease: Mechanisms and Progression***Samuel D. Cohen, MD, PhD, University of Nebraska Medical Center, Omaha, NE*

9:55 AM–10:25 AM

**Break**

10:25 AM–11:15 AM

**Chronic Kidney Disease Associated with Environmental Toxins and Exposures***Charles Wood, DVM, PhD, DACVP, US EPA, Research Triangle Park, NC*

11:15 AM–12:00 Noon

**Renal Carcinogenesis Mechanisms***Gordon Hard, BVSc, PhD, DSc, ATS, Tairu, New Zealand*

12:30 PM–1:30 PM

**Lunchtime Talk***Speaker: Mark D. Seaton, US FDA, Silver Spring, MD***Afternoon  
Free Time**

7:00 PM–9:00 PM

**Mystery Slide Session***Sponsored by HistoTox Labs***Renal: Mystery Renal Slide Session***Chair: Jerrold M. Ward, DVM, PhD, DACVP, Global Vet Pathology, Montgomery Village, MD***Wednesday, June 20****Session 4**

8:00 AM–12:00 Noon

**Animal Models of Kidney Disease: Literal Translation or Lateral Transgression***Co-Chairs: Kathleen Heinz-Taheny, DVM, PhD, DACVP, DABT, Eli Lilly & Company, Indianapolis, IN; and Bruce L. Homer, DVM, PhD, DACVP, Consultant, Ashburn, VA*

The Wednesday morning session explores animal models and translation to the human condition, entitled “Animal Models of Kidney Disease: Literal Translation or Lateral Transgression”. Session co-chairs, Drs. Katie Heinz-Taheny of Eli Lilly and Bruce Homer, consultant, will co-present “Sweet! Diabetic Kidney Disease Models” focusing on rodent DKD models. Renowned nephrologist Dr. Stuart Shankland of the Kidney Research Institute will present “Can We Get to the Clinic Using Mice and Organoids as Preclinical

Models of Kidney Diseases” focusing on the benefits of these models in understanding the mechanisms of disease, potential targets for therapy, and candidate therapies as a critical step towards the patient in the clinic. Dr. Eric McDuffie of Janssen, will follow with “Assessment of Compound-Induced Acute Kidney Injury Using Animal Models and *In Vitro* Platforms”. After a short break, internationally recognized nephrologist Dr. Agnes Fogo of Vanderbilt University will present “From Mice to Humans—Kidney Disease Challenges”. The session will conclude with Dr. Shannon Harlan presenting “Similarity of Animal Models to Human Diseases Based on Microarray mRNA”.

8:00 AM–8:05 AM

**Introduction**

8:05 AM–8:45 AM

**Sweet! Diabetic Kidney Disease Models***Kathleen Heinz-Taheny, DVM, PhD, DACVP, DABT, Eli Lilly & Company, Indianapolis, IN; and Bruce L. Homer, DVM, PhD, DACVP, Consultant, Ashburn, VA*

8:45 AM–9:25 AM

**Can We Get to the Clinic Using Mice and Organoids As Preclinical Models of Kidney Diseases***Stuart J. Shankland, MD, MBA, FRCP, University of Washington, Seattle, WA*

9:25 AM–10:00 AM

**Assessment of Compound-Induced Acute Kidney Injury Using Animal Models and *In Vitro* Platforms***J. Eric Duffie, BS, PhD, MBA, Janssen Pharmaceutical Companies of Johnson & Johnson, San Diego, CA*

10:00 AM–10:15 AM

**Student Speaker**

10:15 AM–10:45 AM

**Break**

10:45 AM–11:30 AM

**From Mice to Humans—Kidney Disease Challenges***Agnes Fogo, MD, Vanderbilt University, Nashville, TN*

11:30 AM–12:00 Noon

**Similarity of Animal Models to Human Diseases Based on Microarray mRNA***Shannon M. Harlan, PhD, Eli Lilly & Company, Indianapolis, IN*

12:30 PM–1:30 PM

**Evaluation of Stem Cell-Derived Cellular Therapy Products***Sponsored by IATP and STP**Co-Chairs: Darlene Dixon, DVM, PhD, DACVP, FIATP, NIEHS/NTP, Research Triangle Park, NC; and Robert R. Maronpot, DVM, MS, MPH, DACVP, DABT, FIATP, Maronpot Consulting, LLC, Raleigh, NC**Speaker: Alys Bradley, BSc, BVSc, MAnimSc, DipRCPath, FRIPH, MRCVS, FRCPath, FIATP, Charles River Laboratories, Edinburgh, United Kingdom*

## Session 5

1:15 PM–5:00 PM

### Bridging Nonclinical to Clinical Translation Using Emerging Science

**Co-Chairs:** *Shashi Ramaiah, DVM, MVSc, PhD, DACVP, DABT, Pfizer Global Research and Development, Cambridge, MA; and Paul W. Snyder, DVM, PhD, DACVP, FIATP, EPL, Inc., West Lafayette, IN*

The Wednesday afternoon session “Bridging Nonclinical to Clinical Translation Using Emerging Science” will be co-chaired by Shashi Ramaiah from Pfizer and Paul Snyder from EPL Inc. The session begins with a brief overview on “Traditional Renal Biomarkers and New Approaches to Diagnostics” by Dr. Mary Nabity from Texas A&M University followed by a talk from Dr. Mireia Fernandez Ocana from Pfizer on “Emerging Mass Spectrometry Analytical Approach to Assess Glomerular Injury”. After the break, there will be a student presentation followed by a talk from Dr. Vishal Vaidya from Pfizer on “High-Throughput *In Vitro* Screening Approach to Detect Nephrotoxics”. The session closes with an emerging therapeutic modality topic by Dr. Jessica Quimby from The Ohio State University on “Stem Cell Therapy for Chronic Kidney Disease in Cats”.

1:15 PM–1:20 PM

#### Introduction

1:20 PM–2:15 PM

#### Traditional Renal Biomarkers and New Approaches to Diagnostics

*Mary Nabity, DVM, PhD, DACVP, Texas A&M University, College Station, TX*

2:15 PM–3:00 PM

#### Emerging Mass Spectrometry Analytical Approach to Assess Glomerular Injury

*Mireia Fernandez Ocana, PhD, Pfizer Inc., Andover, MA*

3:00 PM–3:30 PM

#### Break

3:30 PM–3:45 PM

#### Student Speaker

3:45 PM–4:25 PM

#### High-Throughput *In Vitro* Screening Approach to Detect Nephrotoxics

*Vishal S. Vaidya, PhD, Pfizer, Boston, MA*

4:25 PM–5:00 PM

#### Stem Cell Therapy for Chronic Kidney Disease in Cats

*Jessica M. Quimby, DVM, PhD, DACVIM, The Ohio State University, Columbus, OH*

## Thursday, June 21

## Session 6

8:00 AM–12:00 Noon

### New Frontiers: Approaches to Understand the Mechanistic Basis of Renal Toxicity

**Co-Chairs:** *Mary Nabity, DVM, PhD, DACVP, Texas A&M University, College Station, TX; and Warren E. Glaab, PhD, Merck Research Laboratories, West Point, PA*

The Thursday morning session entitled “New Frontiers: Approaches to Understand the Mechanistic Basis of Renal Toxicity” begins with a presentation on urinary miRNAs to monitor kidney injury and the potential to provide mechanistic insight of such injury by Dr. Vishal Vaidya from Pfizer, followed by a presentation by Dr. Joseph Polli from GSK on the role and impact of kidney membrane transporters in drug-induced kidney toxicity. The third presentation from Dr. Angela Hughes-Earle will present the use of MALDI imaging mass spectrometry to quantify drug distribution in the kidney and the relationship of this distribution to drug-induced kidney injury. Following the break, Dr. Andrzej Krolewski will give the final presentation of the session on monitoring progressive kidney injury in diabetic nephropathy.

8:00 AM–8:05 AM

#### Introduction

8:05 AM–9:05 AM

#### Urinary miRNAs As Biomarkers of Kidney Toxicity to Provide Mechanistic Insight into the Location of Induced Injury

*Vishal S. Vaidya, PhD, Pfizer, Boston, MA*

9:05 AM–10:05 AM

#### The Role of Kidney Membrane Transporters in Drug Development and Impact on Drug-Induced Kidney Toxicity

*Joseph W. Polli, GlaxoSmithKline, Research Triangle Park, NC*

10:05 AM–10:35 AM

#### Using MALDI Imaging Mass Spectrometry to Quantify Drug Distribution in Kidney and Relationship to Drug-Induced Kidney Injury

*Angela R. Hughes-Earle, DVM, GlaxoSmithKline, King of Prussia, PA*

10:35 AM–11:05 AM

#### Break

11:05 AM–12:00 Noon

#### Monitoring Progressive Kidney Injury in Diabetic Nephropathy

*Andrzej S. Krolewski, MD, PhD, Joslin Diabetes Center, Boston, MA*

12:00 Noon

#### Meeting Adjourned