ANTIEPILEPTIC
DRUG AND DEVICE TRIALS XIII

May 13-15, 2015
Turnberry Isle Miami Hotel
Aventura, Florida

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ANTIEPILEPTIC DRUG AND DEVICE TRIALS XIII

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Wednesday, May 13

7:00-9:00  Breakfast and Registration

9:00-9:15  Introduction and Welcome from the AES and ILAE
Jacqueline A. French, MD
Emilio Perucca, MD, PhD
AES - Amy Brooks-Kayal, MD

SESSION I:  PRECLINICAL DRUG DEVELOPMENT AND EARLY CLINICAL DEVELOPMENT

Moderator: Terence O’Brien

9:15-9:30  Animal Model of Newly Diagnosed Epilepsy Study
H. Steve White, PhD

9:30-9:40  The Anticonvulsant Screening Program ASP: Update
John Kehne, PhD

9:40-10:00  Preclinical Models Leading to Clinical Trials:
Update from the Translational Task Force of the ILAE
Terence J. O’Brien, MB, BS, MD

10:00-10:15  Discussion

10:15-10:35  Debate:
Preclinical Randomized Controlled Trials: Can They Increase the Likelihood of Success in Human Trials?
Terence J. O’Brien, MB, BS, MD
Michael Rogawski, MD, PhD

10:35-10:50  Discussion

10:50-11:10  Break
SESSION II: ANTIEPILEPTOGENESIS AND DISEASE MODIFICATION

Moderator: Marc Dichter

11:10-11:30 Preclinical Assessment to Screen Therapies for Disease Modification
Annamaria Vezzani, PhD

11:30-11:50 Antiepileptogenesis Biomarkers from Animals to Humans: Can They Speed Development?
Jerome Engel, MD

11:50-12:05 Discussion

12:05-1:30 Lunch (not included in registration)

1:30-1:55 Panel:
Antiepileptogenesis: When Will We Be Ready for Human Trials?
Marc A. Dichter, MD, PhD
Amy Brooks-Kayal, MD

SESSION III: NEW INITIATIVES FOR REGULATORY APPROVAL

Moderator: Emilio Perucca

1:55-2:15 Monotherapy: Unified Approval
Jacqueline A. French, MD

2:15-2:35 Monotherapy: FDA Perspective
Norman Hershkovitz, MD

2:35-2:55 Monotherapy: European Perspective
Michel Baulac, MD

2:55-3:10 Placebo in Epilepsy Trials: When and How Much is Appropriate?
Emilio Perucca, MD

3:10-3:30 Break

3:30-3:50 Time To Event Designs: Are They Ready for Prime Time?
Emilia Bagiella, PhD

3:50-4:10 New Regulatory Initiatives, Industry Perspective
Lynn Kramer, MD
Panel Discussion on new Regulatory Initiatives:  
Drs. Hershkovitz, French, Baulac, Perucca, Bagiella, Kramer, Dunn, Bastings

Thursday, May 14

SESSION IV: PEDIATRICS

Moderator: Dennis Dlugos

7:00-8:30  Breakfast

8:30-8:50  Pediatric Requirements from FDA  
Eric Bastings, MD

8:50-9:20  From Dravet Syndrome to Focal Epilepsy: Designing Trials and Counting Seizures Based on Epilepsy Syndrome  
Dennis J. Dlugos, MD, MSCE

9:20-9:40  Extrapolation of Adult Data to Children: The PEACE Effort  
O’Neill D’Cruz, MD, MBA

9:40-10:10  Panel Discussion:  
Drs. Bastings, Dlugos, D’Cruz, Dunn, Hershkovitz

SESSION V: SEIZURE COUNTING

Moderator: Dan Friedman

10:10-10:30  New Devices for Seizure Counting  
Daniel Friedman, MD

10:30-10:50  Break

10:50-11:10  Electronic Seizure Diaries: Lessons Learned from the HEP, MONEAD and WEPOD Studies  
Page B. Pennell, MD

11:10-11:30  Seizure Clusters and Trials: Birds of a Feather Flock Together  
Robert S. Fisher, MD, PhD

11:30-11:50  Discussion

11:50-1:30  Lunch (not included in registration)
SESSION VI: TRIAL METHODOLOGY

Moderator: Philippe Ryvlin

1:30-1:50 Has the Availability of the Newer AEDs Affected Patient Outcomes and Conduct of Regulatory Trials?  
*Martin Brodie, MD*

1:50-2:10 Reducing Noise in Clinical Trials: Experience with the DISCOVER Form  
*Daniel Friedman, MD*

2:10-2:30 Seizure Classification And Misclassification: What Have We Learned?  
*Jacqueline A. French, MD*

2:30-2:50 Lessons Learned on the Value of Data Sharing from NEWMEDS – Novel Methods Leading to New Medications in Depression and Schizophrenia Consortium  
*Jonathan Rabinowitz, PhD*

2:50-3:10 Discussion

3:10-3:30 Break

3:30-5:30 SHARK TANK COMPETITION

Panelists

Moderator: Jacqueline French

**Thomas Baruch, JD**  
Founding member of Formation | 8 Partners

**Gregory Bergey, MD**  
Professor of Neurology  
Director, Johns Hopkins Epilepsy Center

**Daniel Fischer**  
Founder & President, Parent Powered Innovation,  
Co-Founder, Intellimedix

**Lynn Kramer, MD**  
Corporate Officer and Chief Clinical Officer, Eisai Company Ltd.  
President, Neuroscience and General Medicine, Eisai Product Creation Systems
Page Pennell, MD
Associate Professor, Harvard Medical School
Director of Research, Division of Epilepsy
Brigham and Women's Hospital Harvard Medical School

Finalists

“Anticipated Detection of Epileptic Seizures”
Hilda Cerdeira, PhD

“Sub-Scalp Seizure Monitor for Epilepsy Patient Management”
Mark Cook

“The Safety Place Mat”
Danielle Duce

“Psychosocial Problems in Kids with Epilepsy (PIKE): A Screening Initiative”
Jana Jones, PhD

“QuiVive | Non-Invasive, Wireless EEG Seizure Alerting”
Mark Lehmkuhle, PhD

“Embrace: Learn How Stress and Sleep Impact Your Seizures”
Rosalind Picard, Sc.D., FIEEE

5:30 RECEPTION

EPILEPSY FOUNDATION 2014 LIFETIME ACCELERATOR AWARD RECIPIENT: ROGER PORTER, MD

Friday, May 15

SESSION VII: ARE GENERICS DIFFERENT FROM BRANDED DRUGS? LET'S SEE THE EVIDENCE

Moderator: Bernd Schmidt

7:00-8:00 Breakfast

8:00-8:15 Results from the Bioequivalence in Epilepsy Patients (BEEP1) Study
Tricia Ting, MD

8:15-8:30 Evidence from the Equigen Study
Michael Privitera, MD
8:30-8:45  Scaled Average Bioequivalence Approach for Narrow Therapeutic Index Drugs
Wenlei Jiang, PhD

8:45-9:00  Panel Discussion:
Drs. Tricia Ting, Michael Privitera, Wenlei Jiang, James Polli

SESSION VIII: REGULATORY ISSUES
Moderator: Russell Katz

9:00-9:20  Interactions of ILAE Regulatory TF with EMA, Report from Stockholm Meeting
Michel Baulac, MD

9:20-9:40  FDA Device Regulatory Update
Carlos Pena, PhD

9:40-10:00  FDA Regulatory Update
Billy Dunn, MD

10:00-10:20  Panel Discussion:
Drs. Baulac, Pena, Dunn, Bastings, Hershkovitz

10:20-10:40  Annual Review and Assessment of Pipeline:
What Have we Accomplished Since Last Year?
Roger Porter, MD

10:40-11:00  Break

SESSION IX: DRUG PIPELINE

PRE-CLINICAL
Moderator: Steve Schachter

11:00  SF0034; A Potent and Selective KCNQ2/3 Activator as a Potential Anti-Epileptic Drug
D. Scott Edwards, PhD, SciFluor Life Sciences LLC

11:10  Adenosine Augmentation Therapies
Detlev Boison, PhD, Legacy Research Institute

11:20  Inhaled Treatment for Refractory Epilepsy
Michael A. Rogawski, MD, PhD, EpaleX

11:30  UX007G (triheptanoin) for the Potential Treatment of Patients with GLUT1 Deficiency
(De Vivo Disease)
Sunil Agarwal, MD, Ultragenyx Pharmaceutical, Inc.
11:40  FV-082: Orally Active Broad Spectrum Anti-Epileptic IND Enabling Drug Candidate  
Malik Slassi, MSc, PhD, Fluorinov Pharma, Inc.

11:50  A Novel Drug-Device Combination Therapy….Epilepsy-An Unmet Clinical Need  
Philip Morgan, PhD, Neurolink

12:00  MTLE Mouse Model as a Screening Tool for New AEDs  
Corinne Roucard, PhD, SynapCell

12:10  NRP2945: An Exciting Candidate for Clinical Testing In Disease States of Severe Epilepsy  
Frank Sieg, PhD, CuroNZ Ltd.

12:20-1:45 Lunch (not included in registration)

**CLINICAL**

**Moderator: Jacqueline French**

1:45  GW Pharmaceuticals Cannabinoid Program in Epilepsy  
Kenneth Sommerville, MD, GW Pharmaceuticals

2:00  Ganaxolone as a Treatment for Drug-Resistant Epilepsy  
Gail M. Farfel, PhD, Marinus Pharmaceuticals, Inc.

2:10  Inhaled Alprazolam  
Jacqueline French, MD presenting for Alexza Pharmaceuticals

2:20  Biscayne Pharmaceuticals: BIS-001 for Refractory Epilepsies  
Stephen D. Collins, MD, PhD, Insero Health

2:30  ZX008-Orphan Drug for Dravet Syndrome  
Bradley Galer, MD, Zogenix, Inc.

2:40  An Introduction to Insys Therapeutics, Inc.  
Neha Parikh, Insys Therapeutics, Inc.

2:50  Sage-547 Phase ½ Trial-Final Results: New Directions, New Options in SRSE  
Steve Kanes, MD, PhD, Sage Therapeutics

3:00  Plans for Development of Transdermal Cannabadiol for the Treatment of Partial Onset  
Seizures With or Without Secondary Generalization  
Cynthia Rask, MD, presenting for Zynerba Pharmaceuticals

3:10  USL261 Midazolam Nasal Spray  
Gregory Gilmet, MD, MPH, Upsher-Smith Laboratories
UCB has requested that discussion of its investigative epilepsy compound, brivaracetam, be removed from the agenda to respect the ongoing regulatory review process at the FDA and EMEA. With their well-known heritage in epilepsy, UCB is excited about the potential of a new, innovative therapy for people living with this serious condition.

SESSION X: DEVICE PIPELINE
Moderator: Bob Fisher

3:50 Wireless EEG patch
Mark Lehmkuhle, PhD, Epitel, Inc.

4:00 Prospects for Transcranial Magnetic Stimulation in Epilepsy
Alexander Rotenberg, MD, PhD, Boston Children’s Hospital

4:10 Movement and Cardiac-Based Seizure Detection and Intervention
O’Neill D’Cruz, MD, MBA, FAAN, Cyberonics, Inc.

4:20 An Update On the Multicenter, Double-Blind Study of EMG Based Convulsive Seizure Detection and Alarming For the Home and Hospital
Luke Whitmire, PhD, Brain Sentinel

4:30 Trigeminal Nerve Stimulation
Colin Kealey, MD, NeuroSigma

4:40 Closing remarks
Roger J. Porter, M.D.

Dr. Porter is a consultant to academia and to the pharmaceutical industry, primarily in the development of anti-seizure drugs. He is also an Adjunct Professor of Neurology at the Univ. of Pennsylvania and Adjunct Professor of Pharmacology at USUHS. He has served as Chief Scientific Officer of the Epilepsy Foundation. His education includes Eckerd College (BS, 1964), Duke Univ (MD, 1968), UCalifSD (Internship, 1968-69) and UCalifSF (Residency in Neurology, 1971-74). He spent 20 years at the National Institutes of Health (NIH), in leadership positions including Chief of the Epilepsy Branch, Chief of the Medical Neurology Branch, and Deputy Director of the National Institute of Neurological Disorders and Stroke (NINDS). He left the NIH in 1992 to become Vice President, Clinical Pharmacology at Wyeth and was promoted to Vice President and Deputy Head of Clinical Research at Wyeth Research in January 1998. As VP and Deputy Head of Clinical Research, Dr. Porter had worldwide responsibility for numerous clinical programs including 200 persons in Europe, Canada, Latin America, and Asia, 65 in Worldwide Clinical Pharmacology and 40 in Global Health Outcomes Assessment. Dr. Porter retired from Wyeth in 2002. Most of Dr. Porter’s research has been in epilepsy and the study of antiepileptic drugs; he has published more than 200 articles/chapters and 13 books. His other leadership positions include Chairman of the White House Committee on Brain and Behavioral Sciences (1990-1992), President, American Epilepsy Society (1989-1990), and Secretary-General of the International League Against Epilepsy (1989-1993). He is also the past President of the American Society for Experimental NeuroTherapeutics (ASENT). He is Past-Secretary of the College of Physicians of Philadelphia and a Fellow of the American Academy of Neurology. He is the recipient of numerous awards including the Service Award from the American Epilepsy Society, the Distinguished Alumnus Award from Duke Univ. Medical Center, the USPHS Distinguished Service Medal, and Doctor of Science (Hon) from Eckerd College.
ACKNOWLEDGEMENTS

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