ANTIEPILEPTIC DRUG and DEVICE TRIALS XIII

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

Wednesday, May 13

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, MD

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

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: FDA Perspective
            Norman Hershkovitz, MD

2:15-2:35  Monotherapy: European Perspective
            Michel Baulac, MD

2:35-2:55  Monotherapy: Unified Approval
            Jacqueline A. French, 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

4:10-4:35  Panel Discussion on new Regulatory Initiatives:
            Drs. Hershkovitz, French, Baulac, Perucca, Bagiella, Kramer, Dunn, Bastings

Thursday, May 14

SESSION IV: PEDIATRICS

Moderator: Dennis Dlugos
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, FAAN*

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

**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

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:
Tricia Ting, Michael Privitera, Wenlei Jiang, James Polli

SESSION VIII: REGULATORY ISSUES
Moderator: Jacqueline French

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

AED Trials XIII Program (as of 1.15.15)
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  Coffee 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
  Sunil Agarwal, MD, Ultragenyx Pharmaceutical, Inc.

11:40  FV-082
  Malik Slassi, PhD, Fluorinov Pharma, Inc.

11:50  Neurolink therapy
  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

CLINICAL
Moderator: Jacqueline French
AED Trials XIII Program (as of 1.15.15)
1:45  CBD/CBDV  
Kenneth Somerville, MD, GW Pharmaceuticals

2:00  Ganaxolone  
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  Fenfluramine  
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  Transdermal Cannabadiol Gel  
Cynthia Rask, MD, presenting for Zynerba Pharmaceuticals

3:10  USL261 Midazolam Nasal Spray  
Gregory Gilmet, MD, MPH, Upsher-Smith Laboratories

3:20  Eslicarbazepine Acetate (Aptiom®) Ongoing Clinical Development and Post Marketing Requirements  
David Blum, MD, Sunovion Pharmaceuticals, Inc.

3:30  Anavex Compound  
Christopher Missling, PhD, Anavex Life Sciences Corp.

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

3:40  Wireless EEG patch  
Mark Lehmkuhle, PhD, Epitel, Inc.
3:50  Transcranial Magnetic Stimulation  
Alexander Rotenberg, MD, PhD, Boston Children’s Hospital

4:00  Movement and Cardiac-Based Seizure Detection and Intervention 
O’Neill D’Cruz, MD, MBA, FAAN, Cyberonics, Inc.

4:10  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

4:20  Trigeminal Nerve Stimulation 
Colin Kealey, MD, NeuroSigma

4:30  Closing remarks