EPILEPSY THERAPIES AND DIAGNOSTICS DEVELOPMENT XVII

May 31-June 2, 2023 JW Marriott Miami Turnberry Aventura, Florida

Wednesday, May 31

7:00-8:00	Breakfast and Registration
8:00-8:25	Introduction and Welcome from the AES, EF and ILAE Jacqueline French, MD, President, Epilepsy Study Consortium, Inc. Manisha Patel, PhD, President, AES Brandy Fureman, PhD, Chief Outcomes Officer, EF Helen Cross, MD, PhD, President, ILAE

SESSION I: EPILEPSY RESEARCH ROUNDTABLE UPDATE: 2022/2023

Ia: ANTI-EPILEPTOGENESIS and DISEASE MODIFICATION

Moderator:	Jacqueline French, MD
8:25-8:30	Patient/Caregiver Perspective Traci Abeyta
8:30-8:50	Disease Modification and Antiepileptogenesis: Community, Industry and Regulatory Definitions Konrad Werhahn, MD, PhD
8:50-9:10	Disease Modification Trial Designs: Measuring the Things That Matter Nathan Fountain, MD
9:10-9:30	Can we Prevent Epilepsy: The Promise of the PREVENT Trial and Beyond Martina Bebin, MD
9:30-9:50	From Success to Success: What can be Learned from Acquired/TSC Epilepsy Trials That Can Inform Prevention/PTE Trials? Pavel Klein, MD
9:50-10:10	Discussion
10:10-10:30	Break

Ib: BIOMARKERS

Moderator: Caitlin Grzeskowiak, PhD

10:30-10:35 Patient/Caregiver Perspective

JayEtta Hecker, MS

10:35-10:55 What Biomarkers are Most Promising for Epilepsy Development?

Sudha Kessler, MD, MSCE

10:55-11:15 Can We Use Biomarkers (EEG, other) as Outcome Measures and to Optimize

Patient Recruitment into Trials?

Jay Pathmanathan, MD, PhD

11:15-11:35 Discussion

SESSION II: PRECLINICAL

Moderator: Marc Dichter, MD, PhD

11:35-11:40 Patient/Caregiver Perspective

Veronica Hood, PhD

11:40-12:00 Seizures in Animal Models During Safety Studies: Do They Predict Seizure

Worsening in Humans?

Steve White, PhD, and Michelle Guignet, PhD

12:00-1:15 Lunch (Not included in registration)

SESSION II: PRECLINICAL (CONTINUED)

1:15-1:35 From Science Fiction to Science-What Pre-Clinical Concepts Will be the Next to

Make it to the Clinic?

Manisha Patel, PhD

1:35-1:55 Update on the Anticonvulsant Drug Development (ADD) Program

Cameron Metcalf, PhD

1:55-2:15 **Discussion**

SESSION III: CLINICAL TRIAL DESIGN ISSUES

Moderator: Kamil Detyniecki, MD

2:15-2:20 Patient/Caregiver Perspective

Heather Longo

2:20-2:40 Time to Event Designs

Wesley Kerr, MD, PhD

2:40-3:00	Panel: Where Have all the Patients Gone? Difficult Recruitment into Focal Epilepsy Studies and What We Can do About it Daniel Friedman, MD, and Michael Sperling, MD
3:00-3:20	Break
3:20-3:40	Debate: Open Label Extension After Double Blind-Nice to Have or Must Have <i>Michael Sperling, MD vs Jacqueline French, MD</i>
3:40-4:00	Design of Long-term Outcome Measures for Disease Modifying Therapies to Assess Co-morbidities JayEtta Hecker, MS and Natasha Ludwig, PhD
4:00-4:20	Clinical Endpoint for Hard to Identify and Count Seizures (e.g., Absence, Myoclonus) Dennis Dlugos, MD
4:20-4:40	Discussion
4:40-5:10	Panel: The Impact of CROs on Clinical Trials in 2023 Nathan Fountain, MD, David Vossler, MD, Sudha Kessler, MD, MSCE, Lilly Frohlich, MPH, and Jennie Minnick
5:10-5:30	Discussion
Thursday, June 1	
7:00-8:00	Breakfast and Registration
SESSION IV	: BEYOND SEIZURES
Moderator:	Andres Kanner, MD
8:00-8:05	Patient/Caregiver Perspective Skylar Economy
8:05-8:25	Cardiovascular Risk in Epilepsy: Are our ASMs the Cause or the Prevention? Colin Josephson, MD
8:25-8:45	Can We Treat Co-morbidities? Treatments for Memory and Cognition Issues in People with Epilepsy Kimford Meador, MD
8:45-9:05	Selection and Validation of Non-Seizure Endpoints in Epilepsy Clinical Trials Kimberly Parkerson, MD, PhD
9:05-9:25	Discussion

SESSION V: DEVICES

Moderator: Brandy Fureman, PhD

9:25-9:30 Patient/Caregiver Perspective

Ryan DeLoughry

9:30-9:50 Use of Seizure Detection Devices as Endpoints in Clinical Trials-Ready for

Prime Time?

Daniel Friedman, MD

9:50-10:10 Break

10:10-10:30 Trials and Tribulations of Electronic Seizure Diaries

Gail Farfel, PhD

10:30-10:50 Optimizing Stimulation Devices: Are we Making any Progress?

Michael Sperling, MD

10:50-11:10 Discussion

SESSION VI: RARE EPILEPSIES

Moderator: Kelly Knupp, MD

11:10-11:15 Patient/Caregiver Perspective

Tracy Dixon-Salazar, PhD

11:15-11:35 When Does a Gene Become a Disease: ICD-10 Codes for Genetic Epilepsies:

How to get Them and Why do we Need Them?

David Vossler, MD

11:35-11:55 ASOs and Gene Therapies: What are the Risk Tradeoffs and How Far Will

Families be Willing to go?

Gregory Krauss, MD

11:55-12:15 Discussion

12:15-1:45 Lunch (Not included in registration)

1:45-5:00 SHARK TANK COMPETITION

1:45-1:50 Shark Tank Welcome

Caitlin Grzeskowiak, PhD

1:50-2:00 Epipal: For Epilepsy Families Update

Amir Helmy, CEO, Epipal

2:00-2:10 An Update on Neuraura's Electrodes to Improve Brain Mapping

Pierre Wijdenes, MEng, PhD, CPO & Co-founder, Neuraura

Moderator: Jacqueline French, MD

Sharks:

Carter Caldwell, MBA, Penn Medicine Co-Investment Program

Elizabeth Corbett, Board of Directors, Epilepsy Foundation

Sudha Kessler, MD, MSCE, Children's Hospital of Philadelphia

Lidia Moura, MD, PhD, MPH, Harvard Medical School

Mark Theeuwes, CEO, Receptor Life Science

Shark Tank Finalists:

All Hands Life Signature Mat: Safer Spaces for a More Joyful Life Shana Bairrington, Founder Allhands Life

EnCompass: A Personalized Companion for Precision Epilepsy Surgery Nitin Tandon, MD, FAANS, BrainDynamics, Inc.

Clinical Decision Support Platform for Epilepsy Surgical Planning Noam Peled, CEO and Co-founder, FIND Neuro

Modernize Childhood Absence Epilepsy Care with a Time-Tested Tool Rachel Kuperman, MD, Eysz

EASEE® - Stimulating the Brain, Reducing Epileptic Seizures Angela Liedler, MD, CEO, Precisis GmbH

Easy Brain DiagnosticsPaul Loomis, CCO, BrainCapture

6:00 DINNER RECEPTION

2023 EPILEPSY FOUNDATION LIFETIME ACCELERATOR AWARD

RECIPIENT: JACQUELINE A. FRENCH, MD

Friday, June 2

7:00-8:00	Breakfast and Registration
8:00-8:20	Epilepsy Study Consortium, Inc. Jacqueline French, MD
8:20-8:40	Update on NINDS Funding for Therapy and Device Development in Epilepsy Brian Klein, PhD and Brooks Gross, PhD
8:40-8:50	Discussion
SESSION VI	I: DRUG PIPELINE—PRE-CLINICAL
Moderator:	Roger Porter, MD
8:50-9:00	Preclinical Data Supporting the Efficacy of OV329, A Next Generation GABA Aminotransferase Inhibitor, Against Seizures Julia Tsai, PhD, Ovid Therapeutics
9:00-9:10	Discovery and Characterisation of ETX-123: a Novel Kv7.2/3 Opener Manuela Cerina, PhD, Eliem Therapeutics
9:10-9:20	Disease Modifying RNA Therapy for Treatment of Epilepsy Stine N. Hansen, PhD, NEUmiRNA Therapeutics
9:20-9:30	From Oil to Tablet: The New Platform of Cannabidiol Medicine Abdel-Rahman Lawendy, MD, PhD, London Research & Pharmaceuticals
9:30-9:40	PrevEp Update: Network Pharmacology to Prevent Acquired Epilepsy, and New Portfolio Developments Pavel Klein, MD, PrevEp Inc.
9:40-9:50	CUE® Platform by SynapCell: an EEG-Based Preclinical Platform Dedicated to ASMs, from Small Molecules to Gene Therapies Corinne Roucard, PhD, SynapCell SAS
9:50-10:00	AMT-260, a Novel AAV9-MicroRNA Based Therapy for the Treatment of Refractory Temporal Lobe Epilepsy Andreas Borta, uniQure
10:00-10:10	Next Gen AAV Therapeutics for Treatment of Genetic Epilepsy Caused by Mutations in the STXBP1 Gene Nicholas Flytzanis, PhD, Capsida Biotherapeutics

SESSION VIII: DRUG AND DRUG DEVICE PIPELINE—CLINICAL

Moderator:	Daniel Friedman, MD
10:10-10:20	Importance of Intracerebroventricular ROA: Route of Access Daniel Abrams, MD, Cerebral Therapeutics
10:20-10:30	A Phase I/II Clinical Trial of NRTX-1001: Human Stem Cell-Derived Inhibitory Neurons for Chronic Focal Epilepsy Cory Nicholas, PhD, Neurona Therapeutics
10:30-10:40	Soticlestat (TAK-935) Development for Treatment of Dravet Syndrome and Lennox-Gastaut Syndrome Mahnaz Asgharnejad, PharmD, Takeda Pharmaceuticals
10:40-11:00	Break
11:00-11:10	XEN1101, a Potent, Differentiated KV7 Potassium Channel Opener in Development for the Treatment Epilepsy Christopher Kenney, MD, Xenon Therapeutics
11:10-11:20	Radiprodil a Candidate Drug in Early-Stage Clinical Development for GRIN Related Disorders Michael Panzara, MD, GRIN Therapeutics
11:20-11:30	Update on the Clinical Development of LP352, a 5HT2C Superagonist for the Treatment of Seizures in Developmental and Epileptic Encephalopathies Randall Kaye, MD, Longboard Pharmaceuticals
11:30-11:40	A Novel Antibody-Enzyme Fusion (VAL-1221; FAB-GAA) Clinical Candidate for Clearing Aggregated Polyglucosan Buildup and Treating Lafora Epilepsy Dustin Armstrong, PhD, Parasail LLC
11:40-11:50	BHV-7000: A Novel Clinical-Stage Kv7.2/7.3 Activator for the Treatment of Epilepsy Jason Lerner, MD, Biohaven Pharmaceuticals
11:50-12:00	NBI-921352: A Selective NaV1.6 Inhibitor for the Treatment of Focal Onset Seizures Svetlana Shore, PhD, Neurocrine Biosciences, Inc.
12:00-12:10	Basimglurant- A Novel Approach in Treatment of Seizures in TSC? Renata Lazarova, MD, Noema Pharma
12:10-1:25	Lunch (Not included in registration)
1:25-1:40	UCB Development Updates Brian Moseley, MD, UCB

1.10 1.50	Welton O'Neal Jr., PharmD, Supernus Pharmaceuticals
1:50-2:00	Ganaxolone Development Update Joseph Hulihan, MD, Marinus Pharmaceuticals, Inc.
2:00-2:10	BL-001, a First-in-Class LBP Being Developed for Rare Developmental Epilepsies Paolo Baroldi, MD, PhD, Bloom Science
SESSION IX:	DEVICE/DIGITAL HEALTH
Moderator:	David Squillacote, MD
2:10-2:20	Integrating Seizure Detection and Alerting Into a Remote Patient Monitoring Platform: a Novel Example from EmbracePlus Matteo Lai, Empatica Inc.
2:20-2:30	Seizure Diary: Electronic Templates Optimized for Data Capture Manuela Bossi, PhD, Signant Health
2:30-2:40	A Novel Approach to Seizure eDiary Development and Implementation Shelly Steele, WCG Clinical Endpoint Solutions
2:40-2:50	EpiCare@Home: An End-to-End Epileptic Activity and Seizure Monitoring Service for Clinical Care and Drug Development Julie Nys, PhD, Byteflies
2:50-3:00	Evolving EEG Monitoring with REMI Mark Lehmkuhle, PhD, Epitel, Inc.
3:00-3:10	Seizure Cycles: Implications for New Therapies John Hixson, MD, on behalf of Seer Medical
3:10-3:20	AWARE - Automated Awareness Testing in AE & Taking on Rare Epilepsies, 1 Seizure at a Time Tim Buckinx, Epihunter
3:20-3:30	Multichannel Transcranial Direct Current Stimulation (tDCS) for Medication-Resistant Focal Epilepsy (with Potential to Treat Depression) Alexander Rotenberg, MD, PhD, Neuroelectrics
3:30	Closing Remarks

SPN-817 in Treatment-Resistant Focal Epilepsy – Clinical Program Update

1:40-1:50