

RRE Advisory Committee

The Epilepsy Foundation deeply appreciates the partnership of four esteemed organizations that make up the Research Roundtable Advisory Committee: the American Epilepsy Society, Citizens United for Research in Epilepsy, the Epilepsy Leadership Council and the National Institute for Neurological Disorders and Stroke. This outstanding group, in addition to two members nominated from within the RRE, played a major role in organizing the agenda for the meeting around the chosen topic, confirming the most innovative speakers, and ensuring this years inaugural Roundtable is a success for individuals with epilepsy, their families, and all who are dedicate their professional lives to treating epilepsy patients and finding a cure. Thank you!

American Epilepsy Society

2016 RRE representative: Dr. Tracy Glauser, MD

Additional attendees:

1. Ms. Eileen Murray, MM, CAE, Executive Director
2. Dr. Cara Long, PhD, Senior Manager of Research

The American Epilepsy Society (AES) is a medical and scientific society whose members are professionals engaged in both research and clinical care for people with epilepsy. For more than 75 years, AES has provided a dynamic global forum where professionals from academia, private practice, not-for-profit, government and industry participate in interdisciplinary communication and information sharing. AES champions sound science and clinical care through the exchange of knowledge, by providing education, supporting research, and by furthering the advancement of the profession. AES is a chapter under the North American Commission of the International League Against Epilepsy.

Citizens United for Research in Epilepsy

2016 RRE representative: Dr. Tracy Dixon-Salazar, PhD, Associate Research Director

Epilepsy Leadership Council

2016 RRE representative: Dr. Christianne Heck, MD, MMM

National Institute of Neurological Disorders and Stroke

2016 RRE representative: Dr. Vicky Whittemore, PhD, Program Director, Epilepsy

Additional attendees:

1. Dr. John Kehne, PhD, Program Director; Director, Epilepsy Therapy Screening Program
2. Dr. Daniel Goldenholz, MD, NINDS Clinical Fellow

The National Institute of Neurological Disorders and Stroke (NINDS) is one of the 27 Institutes and Centers at the National Institute of Health (NIH), and since 1950 has been conducting and funding research for brain and nervous system disorders. NINDS promotes scientific discovery through basic and translational research, as well as through clinical trials that benefit patients. Initiatives like the Epilepsy Therapy Screening Program seek to pioneer new therapies for those living with seizures.

Research Roundtable Advisory Members, 2016

Each year, members of the Research Roundtable will elect two representatives to participate on the Advisory Committee. The 2016 representatives are:

1. Dr. Lynn Kramer, MD, Vice President, Chief Clinical Officer and Chief Medical Officer, Neurology Business Group, Eisai Co. Ltd.
2. Dr. Deborah Lee, MD, PhD, Vice President of Clinical Development, Insys Therapeutics

RRE Member Companies

The Epilepsy Foundation is honored to include twenty highly innovative companies in the inaugural session of its newest initiative, the Research Roundtable for Epilepsy (RRE). Participating companies, designated representatives, and a brief summary of each member company's priorities for new and improved epilepsy therapies are listed below. On behalf of the community of individuals and families living with epilepsy, the Foundation commends the Research Roundtable member companies for contributing to this altruistic and collaborative partnership to advance new therapies for the epilepsies. Thank you!

Acorda Therapeutics

2016 RRE representative: David Squillacote, MD, Executive Medical Director, Clinical Development

Acorda is a biopharmaceutical company developing and marketing therapies to restore function and improve the lives of people with neurological disorders. The company is currently studying PLUMIAZ (diazepam) Nasal Spray, in clinical trials, for the treatment of seizure clusters. This is in addition to multiple products across the neurology spectrum, including Parkinson's disease, migraine, post-stroke walking difficulty and multiple sclerosis.

Adamas Pharmaceuticals, Inc.

2016 RRE representative: Dr. Rajiv Patni, MD, Chief Medical Officer

Additional attendees:

1. Dr. David Chernoff, MD
2. Dr. Natalie McClure, PhD, Senior Vice President, Product Development

Adamas Pharmaceuticals, Inc. is driven to improve the lives of those affected by chronic disorders of the central nervous system. The company seeks to achieve this by modifying the pharmacokinetic profiles of approved drugs to create novel therapeutics for use alone and in fixed-dose combination products. Adamas is currently developing ADS-5102, its lead wholly owned product candidate, for the treatment of levodopa-induced dyskinesia associated with Parkinson's disease and for the treatment of major symptoms associated with multiple sclerosis in patients with walking impairment. The company is also evaluating ADS-4101, an extended-release version of an FDA-approved single-agent compound for the treatment of epilepsy. In addition, under a license agreement with Forest Laboratories Holdings Limited, an indirect wholly owned subsidiary of Allergan plc., the company is eligible to receive royalties from Forest on sales of Namenda XR® and

Namzanic™ beginning in June of 2018 and May of 2020, respectively. For more information, please visit www.adamaspharma.com.

(Namzanic™ is a trademark of Merz Pharma GmbH & Co. KGaA; Namenda XR® is a registered trademark of Merz Pharma GmbH & Co. KGaA.)

Alexza Pharmaceuticals

2016 RRE representative: Dr. Edwin Kamemoto, PhD, EVP, R&D, Regulatory and Quality

Additional attendees:

1. Dr. Gemma Estrada, PhD, Clinical Development Director, Ferrer

Alexza is focused on the development of novel proprietary products for acute treatment of underserved medical needs. Their commercial product and pipeline candidates are based on Alexza's proprietary Staccato® system, which vaporizes an excipient-free drug to form an orally inhaled aerosol. Their current epilepsy pipeline includes AZ-002 (*staccato* alprazolam) for use in cluster seizures.

Anavex Life Sciences Corporation

2016 RRE representative: Dr. Daniel Klamer, PhD, Senior Director of Business Development

Additional attendees:

1. Dr. Christopher Missling, PhD, Chief Executive Officer and President

Anavex Life Sciences Corp. (Anavex) is a clinical-stage biopharmaceutical company developing differentiated therapeutics for the treatment of neurodevelopmental and neurodegenerative diseases. Anavex compounds target the Sigma-1 receptor, which restore homeostasis and cell function when activated. Anavex's lead compound, ANAVEX 2-73, has demonstrated good safety, bioavailability, and tolerability in Phase 1 and Phase 2 clinical trials. In addition, data from an ongoing Phase 2a clinical trial in Alzheimer's disease demonstrates dose dependent cognitive improvements. Previously, ANAVEX 2-73 has also demonstrated significant anti-seizure, anti-anxiety and cognitive enhancement effects in several different animal models as well as a dose related and significant improvements in an array of behavioral and gait paradigms in a mouse model for Rett Syndrome. Taken together, the preclinical results, in conjunction with the clinical

data, provide a strong rationale to investigate the potential benefits of ANAVEX 2-73 in a

Phase 2 trial in patients with Rett Syndrome including seizures as an endpoint.

Dr. Reddy's Laboratories

2016 RRE representative: Dr. Sagar Munjal, MD, Senior Director, Clinical Development and Medical Affairs

Additional attendees:

1. Dr. Alix Bennett, PhD, Clinical Development and Medical Affairs
2. Dr. Elimor Brand-Schieber, PhD, Associate Director, Clinical Development

Generic medicines form the largest part of the Dr. Reddy's product offering and create a foundation for drug discovery. Their R&D philosophy for Generics has evolved along multiple dimensions – from simple, oral solid-based products to complex oral solid dosages, injectable for both neurological and dermatological products; from simple chemistry to semi-synthetic APIs, Chirals, Prostaglandins, Peptides and nano-particle based products; from established processes to advanced particle engineering solutions and complex scale-ups. The first branded product was approved recently by the FDA for episodic migraine- Sumatriptan 3mg autoinjector. Drug-device combinations are expected to have a continued focus in the future, along with nasal and fast acting oral differentiated formulations.

Eisai

2016 RRE representative: Dr. Lynn Kramer, MD, Vice President, Chief Clinical Officer and Chief Medical Officer, Neurology Business Group

A fully integrated pharmaceutical business, Eisai operates in two global business groups, oncology and neurology, of which epilepsy is a key area of therapeutic focus. The company strives to discover and develop innovative therapies based on an understanding of the emotions and realities of patients, in order to effectively address unmet medical needs. Its epilepsy products include Fycompa[®], an AMPA receptor antagonist discovered in-house; Inovelon[®]/BANZEL[®], a treatment for the rare disease Lennox-Gastaut syndrome; Zonegran[®], a treatment for partial-onset seizures that Eisai owns the rights to in Europe, the Middle East, Africa and Russia; and Zebinix[®], a treatment for partial-onset seizures that Eisai co-markets in Europe, the Middle East and Africa through a licensing agreement with the BIAL Group. To learn more about Eisai, please visit us at www.eisai.com.

GW Pharmaceuticals

2016 RRE representative: Dr. Kevan VanLandingham, MD, PhD, Senior Research Scientist

Additional attendees:

1. Dr. Tyler Story, PhD, Director, Medical Affairs
2. Dr. Xiaoting Wang, PhD, RAC, Senior Regulatory Affairs Specialist

GW's lead program is the development of a product portfolio of cannabinoid prescription medicines to meet patient needs in a wide range of therapeutic indications. Their current epilepsy pipeline includes Epidiolex® (a liquid formulation of pure plant-derived Cannabidiol) as a treatment for various orphan pediatric epilepsy syndromes and GWP42006, which features Cannabidivarin (CBDV) as the primary cannabinoid and which has shown antiepileptic properties across a range of pre-clinical models of epilepsy.

Insys Therapeutics, Inc.

2016 RRE representative: Dr. Deborah Lee, MD, PhD, Vice President of Clinical Development

Additional attendees:

1. Dr. Santosh Vetticaden, PhD, MD, MBA, Chief Medical Officer, Sr. VP Clinical Development
2. Mr. Stephen Sherman, JD, Sr. VP, Regulatory Affairs

Insys Therapeutics is a specialty pharmaceutical company that develops and commercializes innovative products that improve the quality of life of patients. Using its proprietary sublingual spray technology and its capability to develop pharmaceutical cannabinoids, the company addresses the clinical shortcomings of existing commercial products. Insys is pursuing the development of treatments for Lennox-Gastaut Syndrome and Dravet Syndrome and the potential benefits of pharmaceutical cannabidiol therapies to epilepsy patients.

Lundbeck

2016 RRE representative: Dr. Jouko Isojärvi, MD, PhD, Senior Medical Director, Medical Affairs

Additional attendees:

1. Mr. Gregg Pratt, VP, US Regulatory Affairs
2. Mr. David M. Tworek, Regional Director, MSL WEST

Lundbeck is a fully-integrated pharmaceutical company, solely devoted to the treatment of psychiatric and neurological disorders. They dedicate their R&D efforts to develop innovative drugs, and their marketed epilepsy products include Onfi (clobazam; approved in 2011 for use in Lennox-Gastaut syndrome) and Sabril (vigabatrin; approved in 2009 for use in Infantile Spasms and refractory complex-partial seizures). Their epilepsy pipeline currently includes I.V. Carbamazepine in late stage development.

Medtronic, Inc.

2016 RRE representative: Ms. Annabel Bavaud, MBA, Core Team Leader Epilepsy, Medtronic DBS

Additional attendees:

1. Ms. Kristin Lambrecht, Senior Clinical Program Manager, Medtronic DBS
2. Mr. Guy Alvarez, Clinical Affairs Manager, Medtronic Navigation

Medtronic is a medical technology development company, with the mission of alleviating pain, restoring health and extending life for people around the world. Our innovations change the lives of more than 10 million people worldwide each year. Our Brain Therapies business unit includes therapies in clinical development for the treatment of medically refractory epilepsy, including deep brain stimulation and MR-guided laser ablation.

Neurelis, Inc.

2016 RRE representative: Mr. Craig Chambliss, Chief Executive Officer and Co-founder

Additional attendees:

1. Dr. Michael Grundman, Chief Medical Officer

Neurelis is a specialty pharmaceutical company organized to license, develop, and commercialize product candidates for the treatment of central nervous system disorders. Neurelis' lead product, NRL-1 (intranasal diazepam), is being developed worldwide for pediatric, adolescent, and adult patients with epilepsy who require intermittent use of diazepam to control cluster seizures. In clinical trials, the NRL-1 nasal spray has shown high bioavailability, low patient-to-patient and dose-to-dose variability, and minimal adverse events. In November 2015, Neurelis received Orphan Drug Designation for NRL-1 in the treatment of Acute Repetitive Seizures, and it is in the final stage of clinical testing prior to submitting an NDA.

Ovid Therapeutics

2016 RRE representative: Dr. Matthew During, MD, PhD, Founder, Director, President, Chief Scientific Officer

Additional attendees:

1. Dr. Brett Abrahams, PhD, Director and Head, Pre-Clinical Biology
2. Dr. Deborah Hartman, PhD

Ovid is a biopharmaceutical company focused on developing therapies for rare and orphan diseases of the brain. Ovid is pursuing the development of OV101 (gaboxadol) in Angelman Syndrome and Fragile X Syndrome, two orphan neurological disease indications with no available treatment options, and expects to commence a Phase 2 trial for Angelman Syndrome in 2016.

Pfizer

2016 RRE representative: Dr. Lloyd Knapp, PharmD, Executive Director of Pfizer Global Research and Development

Additional attendees:

1. Dr. Rachel Gurrell, Associate Director, Pfizer Neusentis
2. Dr. Verne Pitman, PharmD, Senior Director – Pfizer Global Innovative Pharma Business, Neuroscience and Pain Clinical Sciences

Pfizer continues to explore neuroscience diseases with researchers exploring Precision Medicine approaches, rooted in human biology, neuroimaging, novel biomarkers, and a deeper understanding of brain circuitry. Neuroscience researchers are exploring the origins of central nervous system (CNS) diseases using genetics, neurophysiology, and functional brain imaging to design next generation therapeutics. Their epilepsy pipeline includes work with Lyrica (pregabalin; initially approved as adjunctive treatment for partial onset seizures in 2004 in EU), including an ongoing, comprehensive pediatric epilepsy program, as well as PF-06372865 being investigated in a photo-sensitivity epilepsy study.

Pronutria Biosciences Inc.

2016 RRE representative: Dr. Christopher Wright, MD, PhD, Senior Vice President, Chief Medical Officer

Pronutria is pioneering the development transformative medicines and nutritional supplements for patients where disrupted amino acid biology plays a central role in their disease. We do this by identifying the amino acid signature associated with their disease and using our revolutionary technologies to locate the natural protein in food that can best carry it to the affected cells where balance and health can be restored. Our vision is not a traditional pharmaceutical lock-fits-key approach but rather systems wide in scope. Our initial therapeutic candidates are focused on treating orphan diseases in muscle, liver, and neuro (including epilepsy). Our products are derived from natural proteins found in food which provides an inherent safety advantage and can be administered orally.

SAGE Therapeutics

2016 RRE representative: Dr. Amy Schacterle, PhD, Vice President Regulatory Affairs and Quality Assurance

Additional attendees:

1. Dr. Steven J. Kanés, MD, PhD, Chief Medical Officer

Sage Therapeutics is a clinical-stage biopharmaceutical company committed to developing novel medicines to transform the lives of patients with life-altering central nervous system (CNS) disorders. Sage has a portfolio of novel product candidates targeting critical CNS receptor systems. Sage's lead program, SAGE-547, is in Phase 3 clinical development for super-refractory status epilepticus, a rare and severe seizure disorder. Sage is developing its next generation modulators with a focus on acute and chronic CNS disorders, including orphan epilepsies such as Dravet syndrome and Rett syndrome.

Sunovion Pharmaceuticals Inc.

2016 RRE representative: Mr. Todd Grinnell, Director, Clinical Development and Medical Affairs

Additional attendees:

2. Dr. David Blum M.D., Executive Medical Director

Sunovion's contribution to epilepsy therapeutics is Aptiom (eslicarbazepine acetate). This agent is approved by FDA for the treatment of partial-onset seizures as monotherapy or adjunctive therapy. Other marketed agents include Latuda (for treatment of schizophrenia and bipolar depression), Brovana (for controlling symptoms of COPD), and Lunesta (for insomnia). They are developing new therapies in the areas of attention deficit disorder, schizophrenia, binge-eating disorder, motor deficit from chronic stroke, and COPD.

Supernus Pharmaceuticals, Inc.

2016 RRE representative: Dr. Gopala Krishna, PhD, VP of Preclinical Research and Development

Supernus has brought two exciting medications to the epilepsy field in recent years: Oxtellar XR (oxcarbazepine) and Trokendi XR (topiramate). They also have a dynamic pipeline in psychiatry, which is peaking interest among the neurology community due to the question of links between the two specialties.

UCB

2016 RRE representative: Mr. Mike Davis, MBA, VP, Head of Seizure Freedom Patient Value Mission

Additional attendees:

1. Dr. Konrad Werhahn, MD, PhD, Head of New Medical Solutions, Neurology
2. Dr. Elena Cleary, PhD, Vice President, Mission Lead, Epilepsy

UCB has a rich heritage in epilepsy with more than 20 years of experience in the research and development of anti-epileptic drugs. As a company with a long-term commitment to epilepsy research, UCB's goal is to create more value for patients by addressing their unmet medical needs and continuously advancing science to be able to deliver the right drug at the right time to the right patient. In Q1 2016, there were several significant achievements and pipeline updates to the epilepsy portfolio:

- Briviact[®] (brivaracetam) was approved in the EU in January 2016. In the US, the FDA approved Briviact[®] in February 2016. Briviact[®] is a controlled substance in the US and is currently undergoing scheduling by the Drug Enforcement Administration (DEA). Briviact[®] will become commercially available in the US after DEA scheduling.
- Vimpat[®] (lacosamide) as monotherapy in the treatment of adults with partial-onset seizures was filed with the European authorities in January 2016 and there are ongoing Phase III studies focused on pediatric adjunctive therapy and PGTCS. The indication for partial-onset seizures in patients 16 years and older is currently under review by Japanese authorities.
- UCB3491 (Radiprodil), an investigational treatment for epilepsy, started clinical Phase I in January 2016
- UCB0942 (PPSI) has ongoing Phase II studies in highly drug resistant epilepsy

Upsher-Smith Laboratories, Inc.

2016 RRE representative: Dr. Mark B. Halvorsen, PharmD, Medical & Scientific Affairs
Associate Vice President

Additional attendees:

1. Dr. Peter J. Van Ess, PharmD, PhD, Associate Vice President, Translational Medicine

Upsher-Smith Laboratories, Inc., founded in 1919, is a growing, fully integrated pharmaceutical company dedicated to its mission of delivering high-value, high-quality therapies and solutions which measurably improve individuals' lives. Upsher-Smith has a particular focus on developing therapies for people living with central nervous system (CNS) conditions, such as seizure disorders. For more information, visit www.upsher-smith.com.

Zogenix, Inc.

2016 RRE representative: Dr. Gail Farfel PhD, Executive Vice President and Chief Development Officer

Additional attendees:

1. Dr. Arnold Gammaitoni, PharmD, Vice President of Medical and Scientific Affairs
2. Dr. Glenn Morrison, PhD, Executive Director, Clinical Development

Zogenix, Inc. (Nasdaq: ZGNX) is a pharmaceutical company committed to developing and commercializing CNS therapies that address specific clinical needs for people living with orphan and CNS disorders who need innovative treatment alternatives to improve their daily functioning. Zogenix recently initiated Phase 3 clinical studies for its orphan drug candidate, ZX008 (low dose fenfluramine, liquid formulation) for the treatment uncontrolled seizures in children and young adults with Dravet syndrome. They work closely with support organizations such as the Dravet Syndrome Foundation, to support patients with this devastating disease and their families.