Epilepsy Organizations Award Funding for New Devices to Treat, Detect, and Monitor Epilepsy Conditions

The Epilepsy Therapy Project (ETP) and the Epilepsy Foundation (EF) today announced the latest grant recipients of their New Therapy Grants Program, a unique joint venture of the two non-profit epilepsy organizations to advance clinical development and commercialization of promising epilepsy therapies. The grant awards will support the development of four important new technologies:

- High definition transcranial direct current stimulation (HD-tDCS) for the treatment of intractable focal status epilepticus;
- Optogenetic functional MRI (ofMRI), a revolutionary technology and proprietary mouse model that directly visualizes in vivo the actual spread of seizure activity through brain networks and assesses drug effects;
- A dry electrode headset that records brain waves (EEG) without requiring extensive, time-consuming and uncomfortable patient preparation, potentially offering significant improvements in care and outcomes for patients in emergency and intensive care units; and
- A wireless EEG device designed as a dermal “patch” applied to the scalp to unobtrusively track seizure activity in patients with epilepsy over a period of time.

“We are continuing to support new technologies to detect, monitor and treat epilepsy through the New Therapy Grants award program,” said Warren Lammert, Chairman of the Epilepsy Therapy Project. “In this grant cycle, we have selected four projects that may prove critical to managing and treating epilepsy and to accelerating the development of future new therapies. With these grants and the support and guidance our organizations can offer, we are advancing important new products to market and so to people with epilepsy.”

For a comprehensive list of all epilepsy therapies in development including past projects supported by the New Therapy Grants program, please visit http://www.epilepsy.com/etp/pipeline_new_therapies [1]. The epilepsy pipeline identifies the most promising products from early-stage development to commercial-stage, and whether a product is currently available in the US or internationally.

“The mission of this collaborative grant program is to improve the quality of life for people living with epilepsy in their lifetimes,” said Sandy Finucane, Executive Vice President of the Epilepsy Foundation. “Epilepsy affects nearly three million people in the United States and 65 million people worldwide. Even with current treatments, close to one third of people with epilepsy live with uncontrolled seizures and there remains an overwhelming need for new treatment options.”

The Grant Recipients

High Definition Cathodal Transcranial Direct Current for Treatment of Focal Status Epilepticus (Soterix Medical Inc., New York, NY):

- Phase 1 testing of a novel application of high-definition transcranial direct current stimulation (HD-tDCS) - technology with demonstrated ability to limit cortical excitability and suppress ongoing seizures in preclinical testing as a new approach to treat intractable and/or ongoing focal seizures
- Awarded to Alexander Rotenberg, M.D., Ph.D., Assistant Professor of Neurology, Children’s Hospital Boston

Dr. Rotenberg and his team are developing a novel, non-invasive form of cathodal transcranial direct current (tDCS), a painless and safe method for focal brain stimulation. Despite its favorable safety profile and a proven capacity to modulate cortical excitability, conventional tDCS technology has not successfully been applied to the treatment of focal status epilepticus (FSE), in part due to the poor spatial targeting. The research team proposes to overcome this limitation with High Definition (HD)-tDCS and hypothesizes that HD-tDCS can safely reduce seizure burden in patients with FSE. FSE is characterized by repetitive discrete seizures often lasting more than an hour (at times as long as days or weeks). Unfortunately, drug treatments are often ineffective.

HD-tDCS devices are lightweight, inexpensive and can be applied in minutes with minimal training. The proposed HD-tDCS platform is the only neuromodulation technology capable of highly focused DC stimulation of identified cortical targets, an essential safety feature for populations such as children with epilepsy. Favorable data from the proposed studies may enable larger trials of cathodal HD-tDCS in emergency seizure settings. Of note, clinical applications for additional use of this technology in the management of mood disorder and chronic pain are also in progress.

Direct Network Visualization of Drug Efficacy Using of MRI (Stanford University, CA)

- Preclinical evaluation of optogenic functional MRI (ofMRI) - an innovative technology to assess the potential of new epilepsy therapies and their effect on seizures through visualization of brain networks
- Awarded to Jin Hyung Lee, Ph.D., Assistant Professor, Neurology and Neurological Sciences, Bioengineering, Stanford University

Dr. Lee and her research team have utilized a revolutionary technology, optogenic functional MRI (ofMRI), to directly visualize--in vivo--the actual spread of seizure activity through brain networks as well as drug effects on this seizure activity. The approach is to create an optogenic seizure rat model by implanting a fiber-optic light source that can create seizures on demand. The ofMRI imaging techniques would then display the specific brain networks activated by the seizures, enabling precise knowledge about which areas of the brain are affected. The technology may be used to expedite preliminary evaluation of drugs and their potential value in neurological disease. More specifically, with the potential to better visualize brain

region involvement and response, ofMRI may expedite drug screening and reduce clinical trial costs by allowing better drug selection. The funding will be applied to testing several drugs in two proprietary animal models with the objective of accelerating the development of new neuroactive drugs and treatments for epilepsy.

Validation of the ANI-SI Dry EEG Headset in Time-Critical Applications (Advanced Neurometrics, Inc., San Diego, CA)

- Clinical testing and validation of Advanced Neurometrics' electroencephalogram system (ANI-SI EEG) - a non-invasive dry electrode headset that rapidly records EEG data with a minimum of patient preparation which would offer particular value in the ER and intensive care settings where rapid diagnoses and prompt treatment can result in faster seizure control.
- Awarded to Wendy Catharina Ziai, M.D., M.P.H., Assistant Professor, Neurology, Anesthesiology and Critical Care Medicine, Johns Hopkins University School of Medicine

Dr. Ziai and her team with participating institution University of California, San Francisco, will test Advanced Neurometrics' ANI-SI EEG system in ER and intensive care units to evaluate how the device performs in the measurement and characterization of seizures and other causes of altered mental states compared to standard EEG. The ANI-SI EEG system is a dry electrode headset that records EEG without requiring extensive and time-consuming patient skin preparation, head measurements or gels. Timely identification of the presence or absence of ongoing electrographic seizures is critical for appropriate clinical care; delays in diagnosis may result in a worse neurologic outcome. Most emergency rooms and hospitals lack the capability for emergency EEG, which may be the only way to confirm if a patient is experiencing a seizure or if decreased alertness is due to another condition. The ANI-SI EEG system has thus far proven to record EEG signals with high fidelity and has demonstrated significant promise in reducing time to interpretable EEG data compared to wet electrode conventional EEG.

Wireless EEG Seizure Patch (Epitel, Inc., Salt Lake City, Utah)

- Phase 1 testing of Epitel, Inc.'s novel EEG device - a dermal patch device that can wirelessly transmit EEG activity for approximately 12 days as a means of augmenting seizure reporting and measurement
- Designed to transmit when seizures are occurring, the device provides high-quality data and long-term seizure monitoring that will drive patient care, such as the selection of specific antiepileptic (AED) therapies and regimens
- Awarded to Mark Lehmkuhle, Ph.D., Chief Executive Officer, Chief Technology Officer, Epitel, Inc.

Dr. Lehmkuhle and his team are conducting an expanded Phase 1 clinical study of a novel EEG device with potential to track the frequency of drug-refractory epileptic

seizures. Designed as an affordable wireless patch, the device is small enough to be placed on the scalp for the identification of abnormal brain activity in neonates, children and adults without requiring the use of protective head gear or electrode wires. The low-power transmitter signal is received by a USB sensor attached to a conventional smart phone, which is used to verify signal quality. The device can log EEG activity for approximately12 days permitting users to proceed with their daily routines. In contrast to current ambulatory EEG technology, this patch technology is small and discrete, easy to conceal, and eliminates the social stigma associated with ambulatory and outpatient monitoring.

The Epitel wireless EEG transmitter with data logger is the first device designed to yield long-term data on seizure frequency for patients whose seizures involve both hemispheres, such as patients with complex partial seizures. The grant will support feasibility studies for tracking seizures in patients with refractory epilepsy based on this relatively low-cost, unobtrusive and patient-sensitive advanced technology. With improved and high-quality access to quantitative data of seizure frequency and pattern and seizure history, the Epitel wireless device has the promise of better treatment outcomes and may serve as a valuable screening tool for clinical trials.

About The New Therapy Grants Program
The New Therapy Grants Program is a unique joint venture between two non-profit epilepsy organizations, The Epilepsy Therapy Project and the Epilepsy Foundation. Grants are awarded to support programs that demonstrate promise as new treatments through critical early clinical milestones and readiness for further investment and development. Applications are evaluated by professional scientific and business advisory board members. Awards are given based on the potential to provide substantial benefit in a timeframe relevant to those living with epilepsy today. To date, close to 60 grants have been awarded for the advancement of new therapeutics and devices that have demonstrated a more rapid path to benefitting patients and future commercialization.

Upcoming Grant Applicants: Note Deadline for Letter of Intent is August 9, 2013
The New Therapy Grants Program is requesting proposals from scientific and clinical investigators pursuing innovative projects that demonstrate a clear path to commercialization. The program accepts the submission of proposals ranging from $50,000 to $500,000. The deadline to submit a Letter of Intent (LOI) is August 9, 2013. If LOI is selected for full proposal, submissions are due September 25, 2013. To apply or view additional requirements, visit http://www.epilepsy.com/etp/support_translational [2].

About Epilepsy
When a person has two or more unprovoked seizures, they have epilepsy. Epilepsy conditions affect nearly three million people in the United States and 65 million people worldwide. This year, another 200,000 people in the U.S. will be diagnosed with epilepsy. Despite all available treatments, 30 to 40 percent of people with epilepsy continue to experience seizures.

About the Epilepsy Foundation
The Epilepsy Foundation, a national nonprofit with affiliated organizations

throughout the United States, has led the fight against epilepsy since 1968. The Foundation's mission is to stop seizures, find cures and overcome the challenges created by epilepsy. For additional information, please visit www.epilepsyfoundation.org [3].

About the Epilepsy Therapy Project
The Epilepsy Therapy Project is a 501(c) (3) non-profit organization whose mission is to accelerate ideas into therapies for people living with epilepsy and seizures. Founded in 2002 by a group of parents, distinguished physicians, and researchers, the Epilepsy Therapy Project supports the commercialization of new therapies through direct grants and investments in promising academic and commercial projects. For more information about epilepsy, epilepsy treatment and the epilepsy pipeline, or to donate, please visit our website, www.epilepsy.com [4] or call 540.687.8077.

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[1] http://www.epilepsy.com/etp/pipeline_new_therapies
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