



## **EPILEPSY ORGANIZATIONS AWARD GRANTS FOR NOVEL TECHNOLOGIES WITH NEAR-TERM PROMISE FOR EPILEPSY**

### ***New Therapy Grants Program Supports Four Innovative Approaches to Treat or Detect Epilepsy***

### ***Next Grant Award Application Cycle is Now Open***

Washington, D.C., December 6, 2011 – 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, totaling more than \$1 million in funding, will support the development of four new technologies: the EpiLert V1, to alert caregivers at the onset of an epileptic seizure event; Inferior alveolar nerve stimulation (IANS) as a new surgical implantable treatment option to reduce seizures; Triheptanoin, a synthetic edible oil that has inhibited seizures in preclinical testing; and the development of develop an auto-injectable formulation for emergency administration of diazepam to treat seizures in people with epilepsy. The grant awards were announced by the Epilepsy Therapy Project and the Epilepsy Foundation during the American Epilepsy Society (AES) 65th Annual Meeting in Baltimore, MD.

“The New Therapy Grants program helps to accelerate the development of those therapies that hold near-term potential to improve the lives of those with epilepsy,” said Warren Lammert, Chairman of the Epilepsy Therapy Project. “This year we have selected four grant recipients, representative of some of the promising approaches to treat and manage epilepsy and seizure conditions. We are pleased to provide critical support along the path to commercialization.”

“Through this collaborative grant program, we hope to improve the quality of life for people living with epilepsy,” said Tony Coelho, Interim CEO of the Epilepsy Foundation. “Epilepsy affects nearly three million people in the United States and 65 million people worldwide. Even with current treatments, approximately 30 percent of people with epilepsy live with uncontrolled seizures and there remains a critical need for new treatment options.”

### **The Grant Recipients**

#### **EpiLert V1 Seizure Alert Device (BioLert, Ltd., Even Yehuda, Israel)**

- Monitoring and alert system generates warning soon after seizure onset, by detecting and identifying the specific movements associated with limb convulsions with minimal false alerts
- The EpiLert V1 and its associated computer program interfaces with My Epilepsy Diary™ via the internet and reports, in real time, an epilepsy seizure attack and the episode’s details, thus providing the capability to automatically and remotely deliver the data to physicians, caregivers and researchers

Amos Shaham, BioLert Ltd., with the Comprehensive Epilepsy Center at New York University Medical Center, received a grant to continue testing of EpiLertV1, an epilepsy alert device based on limb movement, for which a robust seizure identification algorithm is an essential element. Under a previous New Therapy Grant, BioLert developed prototypes of EpiLert V1 that include a wristwatch-like sensor unit and an alert unit the size of a cell phone. The algorithm is embedded in a dedicated microprocessor (DSP). This small package size enables the sensor to be worn both indoors and outdoors, enabling the wearer to undertake typical daily activities while under continuous monitoring. The device will be able to send an alert message or episode report to various caregivers, family members, physicians and emergency personnel. In addition, the EpiLert’s Alert unit, when connected to a computer, reports automatically and real time to all users/subscribers as part of “My Epilepsy Diary<sup>1</sup>”, a state-of-the-art, comprehensive online data-gathering and reporting tool designed to improve epilepsy care.

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<sup>1</sup> “My Epilepsy Diary” and apps are provided free of charge by the Epilepsy Therapy Project and are accessible at [www.epilepsy.com](http://www.epilepsy.com).

Under the new grant, the EpiLert V1 prototypes will be tested in hospitals in the US and Israel as part of the FDA clearance application.

### **Novel Trigeminal Nerve Stimulation Device (NuroRestore, Inc., Mansfield, MA)**

- NuroRestore has developed a novel percutaneous surgical approach to trigeminal nerve stimulation (TNS), which has been shown to reduce seizures
- By directly stimulating a deep, thick non-terminal trigeminal nerve branch, the device may have greater efficacy and tolerability compared to other TNS methods

Ming Cheng, M.D., Assistant Professor of Neurosurgery, Warren Alpert Medical School at Brown University and President, NuroRestore Inc., received a grant to develop NuroRestore's TNS device as a new treatment option for epilepsy. While vagal nerve stimulation (VNS) for epilepsy has been known for decades, trigeminal nerve stimulation has more recently garnered interest with preclinical and clinical data demonstrating significant reductions in seizures. NuroRestore has developed a novel percutaneous surgical approach to directly stimulate a deep, thick non-terminal trigeminal nerve branch with the potential for greater efficacy and fewer side effects. The NuroRestore device works like a pacemaker, but stimulates a deep branch of the trigeminal nerve. The team has successfully implanted the device in a 41 year old woman with refractory epilepsy, and her seizures lessened in frequency and severity within days of activation. With this grant, the team plans to implant more patients in clinical trials, with the hope that this will lead to a new option for epilepsy sufferers worldwide.

### **Triheptanoin as Add-on Therapy (The University of Queensland, Australia)**

- Triheptanoin, an edible oil that is being used in the clinic in patients with metabolic disorders, has demonstrated anticonvulsant properties in preclinical testing
- The proposed phase IIa clinical trial of triheptanoin aims to establish the safety and tolerability of triheptanoin as add-on treatment in adult epilepsy patients, and obtain indications for its efficacy against medically refractory seizures

Karin Borges, Ph.D., School of Biomedical Sciences, The University of Queensland, received a grant to conduct a Phase IIa clinical study of triheptanoin, a stable, edible tasteless oil that can be mixed with foods and used in cooking, and which has been studied for its activity in metabolic disorders. This Phase IIa clinical trial, which will take place at the Royal Melbourne Hospital, aims to establish the safety and tolerability of triheptanoin as add-on treatment in adult epilepsy patients, and obtain indications for its efficacy against medically refractory seizures. This treatment may be ideal for patients with epilepsy worldwide because: 1) triheptanoin does not require refrigeration and is straightforward to add to meals and 2) it is not expected to change metabolism of other drugs and require "drug monitoring" nor to have significant side effects. It is expected that the proposed research will help confirm triheptanoin's *in vivo* efficacy in humans.

### **XeriJect Diazepam for Emergency Treatment of Seizures (Xeris Pharmaceuticals, Inc., Austin, TX)**

- Current products utilizing diazepam for the treatment of seizures are difficult to administer by a non-medical professional in the midst of an emergency
- Development of a simple, ready-to-use auto-injectable diazepam would yield an emergency medication with significant advantages over the current standard of care with a presentation that is truly patient-friendly and virtually pain-free

Steven Prestrelski, Ph.D., Chief Scientific Officer, Xeris Pharmaceuticals, Inc., received a grant to develop a low volume, painless, auto-injectable formulation for the subcutaneous administration of diazepam to treat seizures in people with epilepsy, similar to the EpiPen™ for treatment of severe allergic reactions. The company's XeriJect™ formulation and delivery platform enables injection delivery of highly concentrated, non-aqueous suspension formulations of numerous drug classes, including small molecules, peptides, and proteins and offers distinct advantages over alternative delivery systems, including dosing flexibility, predictable pharmacokinetics, and a streamlined, lower risk, and lower cost regulatory pathway. The current standard of care for the treatment of cluster seizures is diazepam rectal gel, which can be complex and uncomfortable. Patients with epilepsy who would carry an emergency drug would benefit from a better solution, such as an injectable formulation of diazepam. Xeris does not yet have safety or efficacy data for a XeriJect™ diazepam formulation, but it has demonstrated the capacity of this platform with the formulation of XeriJect™ glucagon for the emergency treatment of severe hypoglycemia. The grant will be used for diazepam formulation and proof-of-concept work and the manufacture of preclinical supplies.

### **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 scientific and business advisory board members including experienced clinicians, scientists, investors and pharmaceutical and device industry executives. Awards are given based on the potential to provide substantial benefit in a timeframe relevant to those living with epilepsy today. To date, more than 50 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 March 1, 2012**

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 March 1, 2012, and applicants selected to submit full proposals have until April 12, 2012. To apply or view additional requirements, visit [http://www.epilepsy.com/etp/support\\_translational](http://www.epilepsy.com/etp/support_translational).

### **About Epilepsy**

When a person has two or more unprovoked seizures, they have epilepsy, which affects nearly 3 million people in the United States and 65 million people worldwide. This year, another 200,000 people in our country will be diagnosed with epilepsy. Despite all available treatments, 30 to 40% 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](http://www.epilepsyfoundation.org).

### **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, please visit our website, [www.epilepsy.com](http://www.epilepsy.com) or call 540.687.8077.

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Media Contacts: [Epilepsy Therapy Project](#)  
Kim Macher  
540-687-8077, ext. 100

[Epilepsy Foundation](#)  
Mimi Carter  
571-218-0951

[BCC Partners](#)  
Susan Pietropaolo  
201-923-2049