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**FOR IMMEDIATE RELEASE**

**Xeris Pharmaceuticals Awarded Phase I-II NIH SBIR Fast Track Grant to Advance a Stable, Non-Aqueous Diazepam, Subcutaneous Injection for Treatment of Acute Repetitive Seizures in Patients with Epilepsy**

**AUSTIN, Texas – October 1, 2015** - Xeris Pharmaceuticals, Inc. (“Xeris”), an Austin-based, emerging biopharmaceutical company developing patient-friendly injectable treatments, was awarded a Small Business Innovation Research (SBIR) Phase I grant for \$514,129 to advance the company's stable, non-aqueous diazepam formulation for the treatment of acute repetitive seizures (ARS) and seizure clusters in patients with epilepsy. The grant is the initial installment of a Phase I-II Fast Track SBIR grant, with the potential for a total funding of over \$2 million with Phase II funding. The grant was awarded on September 25, 2015 by the National Institute of Neurological Disorders and Stroke (NINDS), an institute of the National Institutes of Health (NIH), which supports research to reduce the burden of neurological disease.

The grant will support further formulation development, manufacture of drug supplies for non-clinical studies, regulatory development, and manufacturing of clinical supplies. The target population for XeriSol™ diazepam, subcutaneous injection is patients with epilepsy taking anti-seizure medications who experience periodic seizure clusters or ARS. Adverse effects and co-morbidities in these pharmacoresistant patients include sudden unexpected death, potential for injury, costly emergency department and hospital admissions, absence from work or school, and diminished quality of life, stigma and social exclusion and most importantly, the repercussions on their families.

“Working with the NINDS and James Cloyd, PharmD, a professor at the University of Minnesota, College of Pharmacy, Xeris will develop an innovative rescue medication for ARS. The product will consist of a highly concentrated, non-aqueous diazepam solution that is coupled with a caregiver-friendly, auto-injector designed for subcutaneous administration.” said Dr. John Kinzell, EVP of Corporate Development for Xeris Pharmaceuticals and Principal Investigator. “This is a significant unmet medical need and the SBIR funding will help advance our novel formulation and delivery system for diazepam.”

“The current therapy for ARS and cluster seizures is rectal administration of diazepam. Many patients and caregivers find this route objectionable or circumstances such as location make it, in some cases, difficult to administer. Combining diazepam, a proven effective therapy for ARS, with an auto-injector intended for subcutaneous administration that is quickly and easily administered offers the potential for complete, consistent drug absorption and rapid onset of effect. Such a product would be an important addition to the rescue therapy tool chest for patients with epilepsy.” according to Dr. Cloyd.

**Grant Number:** 1R44NS086229-01A1

**Project Name:** Auto-Injectable Diazepam Formulation for Rapid Treatment of Uncontrolled Seizures

### **About Acute Repetitive Seizures**

Acute repetitive seizures, seizure clusters, or serial seizures describe a condition characterized by rapidly recurring seizures in patients with epilepsy. They occur over a relatively brief period of time, generally within 24 hours. Rescue intervention with benzodiazepines, such as diazepam can abort such episodes and decrease adverse outcomes. The prevalence of epilepsy in the US is 2 - 2.5 million individuals of which about 30% are refractory to medical management or 600,000 to 700,000 adults and children. Total indirect and direct costs of epilepsy are estimated at \$16 billion annually (Centers for Disease Control, 2012).

### **About Diazepam**

Diazepam is a medication belonging to a pharmaceutical chemistry group called benzodiazepines. First marketed in 1963, as Valium and is used to treat a variety of conditions including anxiety, alcohol withdrawal syndrome, muscle spasms, seizures, insomnia and restless leg syndrome. In 1997, diazepam as a rectal gel product, DIASTAT® AcuDial™, was approved by the FDA as a medication for the management of seizures in patients over the age of 2 years with epilepsy on stable regimens of anti-seizure drugs, requiring intermittent use of diazepam to control bouts of increased seizure activity.

### **About Xeris Pharmaceuticals, Inc.**

Xeris is an Austin, Texas-based, specialty biopharmaceutical company developing improved and differentiated, injectable therapeutics for multiple indications including epilepsy. The company's proprietary, non-aqueous formulation technologies allow for the delivery of highly concentrated, non-aqueous, ready-to-inject suspension and solution formulations of peptides, proteins, antibodies and small molecules. Xeris' proprietary formulation approach offers distinct advantages over existing products and formulations including: up to 1000-fold lower injection volumes, eliminating the need for reconstitution and refrigeration, with extended room temperature shelf-life stability, all of which can lead to products that are easier to use by patients, caregivers, health practitioners, and that can reduce costs for payers and the healthcare system. For more information, please visit the Xeris website at: [www.xerispharma.com](http://www.xerispharma.com)

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