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**FOR IMMEDIATE RELEASE**

**UPSHER-SMITH TO PRESENT DATA ON QUDEXY® XR (TOPIRAMATE) EXTENDED-  
RELEASE CAPSULES AND USL261 (INVESTIGATIONAL MIDAZOLAM NASAL  
SPRAY)**

**Data to be Highlighted at the 70th Annual Meeting of the American Epilepsy  
Society**

Maple Grove, MN – November 30, 2016 – [Upsher-Smith Laboratories, Inc.](http://www.upsher-smith.com) (Upsher-Smith) today announced that it will present three posters at the 70<sup>th</sup> Annual Meeting of the American Epilepsy Society (AES), including data from a Phase 1 study of USL261 (midazolam nasal spray) characterizing the pharmacokinetics and safety/tolerability in pediatric participants 2 to 13 years of age with epilepsy. Additionally, a review of the efficacy and safety of [Qudexy® XR \(topiramate\) extended-release capsules](#) and other second-generation antiepileptic drugs (AEDs) will be presented. The AES meeting will take place in Houston, TX, December 2-6, 2016.

“Upsher-Smith is committed to developing treatment options and advancing care for patients living with challenging central nervous system diseases like seizure disorders,” said William Pullman, MB, BS, BMedSc, PhD, FRACP, Chief Scientific Officer and Biotech Research Institute Division President, Upsher-Smith. “Since pediatric patients and their caregivers currently have few options for treating bouts of increased seizure activity, we are particularly pleased to be presenting Phase 1 results for USL261 that support its continued development in this important patient population.”

**Scientific posters from Upsher-Smith slated for presentation at AES include:**

*USL261*

**[Pharmacokinetics of Midazolam Nasal Spray in Pediatric Subjects with Epilepsy](#)**

*Poster 2.196; Sunday, December 4, 2016; 10 a.m. – 4 p.m. CST  
Authors to present 12 p.m. to 2 p.m.*

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**Tolerability of Midazolam Nasal Spray in Pediatric Subjects with Epilepsy**

*Poster 2.197; Sunday, December 4, 2016; 10 a.m. – 4 p.m. CST*

*Authors to present 12 p.m. to 2 p.m.*

Qudexy<sup>®</sup> XR

**Efficacy and Safety of USL255, Qudexy<sup>®</sup> XR (Topiramate) Extended-Release Capsules, and Second-Generation AEDs**

*Poster 2.198; Sunday, December 4, 2016; 10 a.m. – 4 p.m. CST*

*Authors to present 12 p.m. to 2 p.m.*

Abstracts of the poster presentations can be found online at [www.aesnet.org](http://www.aesnet.org). To schedule an interview with an investigator, please contact Andrea Preston at [apreston@klcpr.com](mailto:apreston@klcpr.com).

**About Epilepsy**

Epilepsy is a medical condition that is characterized by recurrent seizures. More than two million people in the U.S. are estimated to be affected by epilepsy, with about 150,000 new cases of epilepsy diagnosed each year.<sup>1</sup> Epilepsy can be associated with profound physical, psychological and social consequences that negatively impact people's lives.

**About Seizure Clusters**

Seizure clusters, also referred to as acute repetitive seizures, seizure flurries, crescendo seizures, cluster seizures, or bouts of increased seizure activity, consist of multiple seizures which occur over a relatively brief period of time with a pattern distinguishable from the patient's usual seizure pattern.<sup>2</sup>

Reports of seizure cluster prevalence vary depending on the population evaluated. Seizure clusters have been associated with poor seizure control.<sup>3</sup> In a study conducted in a tertiary epilepsy center in patients with a broad range of seizure control, the prevalence of seizure clusters was close to 30%.<sup>3</sup> The number of patients with epilepsy in the United States who experience seizure clusters has been estimated to be 152,000.<sup>4,5,6,7</sup>

## WHAT IS QUDEXY XR?

Qudexy® XR (topiramate) Extended-Release Capsules is a prescription medicine used to treat certain types of seizures (partial-onset seizures and primary generalized tonic-clonic seizures) and with other medicines to treat certain types of seizures (partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome) in adults and children 2 years and older.

## WHAT IMPORTANT SAFETY INFORMATION SHOULD I KNOW ABOUT QUDEXY XR?

**Qudexy® XR should not be taken by** patients with metabolic acidosis who are also taking a medicine called metformin.

### What should I tell my healthcare provider **BEFORE** starting Qudexy XR?

**Tell your healthcare provider if you take** any medicines that impair or decrease thinking, concentration, or muscle coordination; medicines used to prevent seizures; any other carbonic anhydrase inhibitors; or birth control pills. Qudexy XR may make birth control pills less effective.

### **Qudexy XR can cause serious side effects, including:**

- **Serious eye problems**, including blurred or sudden decrease in vision and increased pressure in the eye, which can lead to permanent vision loss.
- **Decreased sweating and fever**, especially in hot weather which may result in hospitalization; children are especially susceptible to these effects.
- **Increased acid level in the blood (metabolic acidosis)**, which may lead to brittle or soft bones (osteoporosis, osteomalacia, osteopenia), kidney stones, slowed rate of growth in children and fetal harm. Metabolic acidosis may or may not cause symptoms. Symptoms may include feeling tired, decreased appetite, change in heartbeat, or trouble thinking clearly.
- **High ammonia level in the blood**, which can affect mental activities, slow alertness and cause tiredness and vomiting. This can also happen when Qudexy XR is taken with a medicine called valproic acid.
- **Kidney stone formation**, which may be reduced by increasing fluid intake while taking Qudexy XR.
- **Low body temperature**. Taking Qudexy XR while taking valproic acid may cause a drop in body temperature to less than 95°F with associated symptoms of tiredness, confusion, or coma.
- **Effects on thinking and alertness**. Qudexy XR may affect thinking, and cause confusion and problems with concentration, attention, memory, or speech. Qudexy XR may cause depression or mood problems, tiredness, and sleepiness.
- **Dizziness or loss of muscle coordination**.
- **Fetal harm**. Taking Qudexy XR while pregnant increases the risk of cleft lip and cleft palate for the fetus. Alternative treatment or effective birth control should be used. Discuss with your healthcare provider.

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- **Suicidal thoughts and actions.** Like other antiepileptic drugs, Qudexy XR may cause suicidal thoughts and actions in a very small number of people, about 1 in 500. Tell your healthcare provider right away if you experience these effects, or any symptoms of depression or mood changes.

**Tell your healthcare provider right away if you have any of the above symptoms, are planning to become pregnant, or if you become pregnant while taking Qudexy XR.**

**The most common side effects of Qudexy XR include:** tingling of the arms and legs (paresthesia), not feeling hungry, weight loss, nervousness, speech problems, tiredness, dizziness, sleepiness/drowsiness, slow reactions, difficulty with memory, fever, and abnormal vision. These are not all the possible side effects of Qudexy XR. For more information, ask your healthcare provider or pharmacist.

**Before taking Qudexy XR, tell your healthcare provider about all of your medical conditions,** including if you: have had depression, mood problems, or suicidal thoughts or behavior; have kidney problems, kidney stones, or are getting kidney dialysis; have a history of metabolic acidosis (too much acid in the blood); have liver problems; have weak, brittle or soft bones (osteomalacia, osteoporosis, osteopenia, or decreased bone density); have lung or breathing problems; have eye problems, especially glaucoma; have diarrhea; have a growth problem; are on a diet high in fat and low in carbohydrates, which is called a ketogenic diet; are having surgery; are pregnant or plan to become pregnant; or if you are breastfeeding. The medicine in Qudexy XR (topiramate) passes into your breast milk. It is not known if the medicine, topiramate, that passes into breast milk can harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take Qudexy XR.

**Qudexy XR should not be taken while drinking alcohol,** as this can cause serious side effects such as severe sleepiness, dizziness, and an increase in seizures.

**Patients taking Qudexy XR should not drive, swim, climb, or operate heavy machinery until it is known how Qudexy XR affects them.** Qudexy XR can slow thinking and motor skills and may affect vision. Some patients with epilepsy taking Qudexy XR will continue to have unpredictable seizures.

**Do not stop Qudexy XR without first talking to a healthcare provider.** If you have epilepsy and you stop taking Qudexy XR suddenly, you may have seizures that do not stop.

**This is the most important information to know about Qudexy XR, but is not comprehensive. For more information, talk to your healthcare provider and read the Medication Guide for Qudexy XR. You can also visit [www.upsher-smith.com](http://www.upsher-smith.com) or call 1-888-650-3789.**

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

Qudexy is a registered trademark of Upsher-Smith Laboratories, Inc.

## About Upsher-Smith

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. As a family-owned pharmaceutical company, we are able to adapt and thrive in a dynamic healthcare environment. Our world is constantly evolving, and we are continually adapting to the ever-changing needs of patients, physicians, pharmacists, and healthcare organizations. Where there is a need, we will work to deliver solutions that simplify access to treatment, deliver better health outcomes, and enhance life. 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](http://www.upsher-smith.com).

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## References

1. Epilepsy.com. Available at: <http://www.epilepsy.com/learn/epilepsy-statistics>. Accessed October 11, 2016.
2. Dreifuss FE, Rosman NP, Cloyd JC, et al. A comparison of rectal diazepam gel and placebo for acute repetitive seizures. *N Engl J Med*. 1998;338:1869-75.
3. Haut SR, Shinnar S, and Moshe SL. Seizure Clustering: Risks and Outcomes. *Epilepsia*. 2005;46(1):146-149.
4. Kobau R, Zahran H, Thurman DJ, et al. Epilepsy Surveillance Among Adults – 19 States, Behavioral Risk Factor Surveillance System, 2005. *MMWR*. 2008;57:SS-6.
5. Kwan P, Brodie MJ. Early Identification of Refractory Epilepsy. *N Engl J Med*. 2000;342:314-319.
6. Berg AT, Vickrey BG, Testa FM, et al. How long does it take for epilepsy to become intractable? A prospective investigation. *Annals of Neurology*. 2006;60:73-79.
7. Haut SR, Lipton RB, LeValley AJ, et al. Identifying seizure clusters in patients with epilepsy. *Neurology*. 2005 October 25;65(8):1313-1315.