



CONTACT: Elizabeth Likly
Kovak-Likly Communications
203-762-8833, elikly@klcpr.com

FOR IMMEDIATE RELEASE

**UPSHER-SMITH RECEIVES FDA APPROVAL FOR QUDEXY™ XR (TOPIRAMATE)
EXTENDED-RELEASE CAPSULES**

**Qudexy™ XR Offers Newest Option for Managing Certain Seizure Disorders and Marks the
Company's Entrance into the Epilepsy Therapeutic Area**

Maple Grove, MN – March 12, 2014 – [Upsher-Smith Laboratories, Inc.](http://www.upsher-smith.com) (Upsher-Smith), today announced it received approval on March 11, 2014 from the U.S. Food and Drug Administration (FDA) for [Qudexy™ XR \(topiramate\) extended-release capsules](http://www.qudexyxr.com), a once-daily, broad-spectrum antiepileptic drug specifically engineered to deliver a smooth pharmacokinetic (PK) profile. Qudexy™ XR is indicated as initial monotherapy in patients 10 years of age and older with partial-onset seizures (POS) or primary generalized tonic-clonic seizures. It is also approved as adjunctive therapy in patients 2 years of age and older with POS, primary generalized tonic-clonic seizures and seizures associated with Lennox-Gastaut syndrome. Qudexy™ XR will be available to patients in the second quarter of 2014. More information is available at www.qudexyxr.com.

As many as two out of three patients treated for epilepsy have seizures that are refractory to therapy, either because they have incomplete control of their seizures or they experience treatment-related side effects that interfere with their quality of life.¹ Results from Upsher-Smith's Phase 3 trial (PREVAIL) of Qudexy™ XR demonstrated that the drug is effective and generally well-tolerated. Additionally, Qudexy™ XR offers patients flexibility. All strengths of Qudexy™ XR may be swallowed whole or administered by carefully opening the capsule and sprinkling the entire contents on a spoonful of soft food. This makes it the only approved extended-release topiramate product for patients who experience challenges swallowing whole capsules or tablets.

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“Upsher-Smith is pleased by the FDA’s approval of Qudexy™ XR,” said Mark Evenstad, President and Chief Executive Officer of Upsher-Smith. “Today’s approval is a major milestone in Upsher-Smith’s history, as Qudexy™ XR is the first branded product in our central nervous system portfolio. At Upsher-Smith, our mission is to make a measurable improvement in people’s lives by focusing on the patient.”

“PREVAIL demonstrated that Qudexy™ XR was efficacious and generally well-tolerated, particularly with respect to the incidence of cognitive side effects,” said Steve Chung, M.D., Professor of Neurology at the Barrow Neurological Institute in Phoenix and trial investigator. “As a physician, I’m encouraged that Qudexy™ XR will be an available treatment option for many patients.”

Qudexy™ XR is available in 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg extended-release capsules.

About Upsher-Smith’s Phase 3 (PREVAIL) Clinical Trial

The global Phase 3 (PREVAIL) trial was a randomized, multicenter, double-blind, placebo-controlled, parallel-group study designed to evaluate the efficacy and safety of Qudexy™ XR as adjunctive therapy in patients with refractory POS. The study enrolled 249 adult patients worldwide at 66 centers.

Results from the PREVAIL study showed that the drug met its endpoints for efficacy and demonstrated favorable safety and tolerability in epilepsy patients with refractory POS. The findings demonstrated that Qudexy™ XR was associated with a significantly greater median percent reduction from baseline in POS frequency compared with placebo (39.5% vs 21.7%, $P < 0.001$) after 11 weeks of treatment.

INDICATIONS

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) in adults and children 10 years of age and older,
- 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.

IMPORTANT SAFETY INFORMATION

Do not take Qudexy™ XR if you have metabolic acidosis and are also taking metformin (e.g., Glucophage®).

Qudexy XR can cause serious side effects, including: Eye problems. Serious eye problems include blurred vision, sudden decrease in vision with or without eye pain and redness, and a blockage of fluid that may cause increased pressure in the eye (secondary angle closure glaucoma). **Decreased sweating and increased body temperature (fever).** People, especially children, should be watched for signs of decreased sweating and fever, especially in hot temperatures. Some people may need to be hospitalized for this condition. **Increased acid level in your blood (metabolic acidosis).** This may or may not cause symptoms. Symptoms may include feeling tired, decreased appetite, change in heartbeat, or trouble thinking clearly. If left untreated, metabolic acidosis can cause brittle or soft bones (osteoporosis, osteomalacia, osteopenia), kidney stones, can slow the rate of growth in children, and may harm your baby if you are pregnant. **High blood ammonia levels.** High ammonia in the blood can affect mental activities, slow alertness, cause tiredness, or cause vomiting. This has happened when Qudexy XR is taken with a medicine called valproic acid (e.g., Depakene® and Depakote®). **Kidney stones.** Drink plenty of fluids when taking Qudexy XR to decrease your chances of getting kidney stones. **Low body temperature.** Taking Qudexy XR when you are also taking valproic acid may cause a drop in body temperature to less than 95°F, tiredness, confusion, or coma. **Effects on thinking and alertness.** Qudexy XR may affect how you think, and can 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.** Call your healthcare provider right away if you have any of the above symptoms.

The most common side effects include tingling of the arms and legs (paresthesia), irregular movements of the eyes (nystagmus), loss of appetite, nausea or indigestion, a change in the way foods taste, diarrhea, weight loss, nervousness, and upper respiratory tract infection. These are not all the possible side effects of Qudexy XR. For more information, ask your healthcare provider or pharmacist.

Like other antiepileptic drugs, Qudexy XR may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Before you take Qudexy XR, tell your healthcare provider if you have or have had depression, mood problems, or suicidal thoughts or behavior. Call a healthcare provider right away if you have thoughts about suicide or dying; have attempted to commit suicide; have new or worsening depression or anxiety; feel agitated or restless; experience panic attacks, trouble sleeping (insomnia), or new or worsening irritability; feel or act aggressive, angry, or violent; act on dangerous impulses; have an extreme increase in activity and talking (mania); or experience other unusual changes in behavior or mood.

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Before taking Qudexy XR, tell your healthcare provider about any other 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. Qudexy XR passes into your breast milk. It is not known if the Qudexy XR 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 can harm your unborn baby. All women of childbearing age should talk to their healthcare providers about possible alternative treatments. If you take Qudexy XR during pregnancy, your baby has a higher risk for birth defects called cleft lip and cleft palate. These defects can begin early in pregnancy, even before you know you are pregnant. If the decision is made to use Qudexy XR, you should use effective birth control (contraception) unless you are planning to become pregnant. Tell your healthcare provider right away if you become pregnant while taking Qudexy XR.

Tell your healthcare provider about any other medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Qudexy XR and other medicines may affect each other causing side effects. Especially tell your healthcare provider if you take metformin (e.g., Glucophage®); valproic acid (e.g., Depakene or Depakote); any medicines that impair or decrease your thinking, concentration, or muscle coordination; birth control pills; medicines used to prevent seizures; or any other carbonic anhydrase inhibitors. Qudexy XR may make your birth control pills less effective.

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. Your healthcare provider will tell you how to stop taking Qudexy XR slowly.

Do not drink alcohol while taking Qudexy XR. Qudexy XR and alcohol can cause serious side effects such as severe sleepiness and dizziness and an increase in seizures.

Do not drive a car, swim, climb, or operate heavy machinery until you know how Qudexy XR affects you. Qudexy XR can slow your thinking and motor skills, and may affect vision. Even when taking Qudexy XR, some patients with epilepsy will continue to have unpredictable seizures.

If you are unable to swallow QUDEXY XR capsules whole, the medicine may be sprinkled on a spoonful of soft food like applesauce. Do not store the food and medicine mixture to use later or crush or chew the food and medicine mixture before swallowing.

This safety information is not all-inclusive. For additional important information, talk to your healthcare provider and read the Medication Guide for Qudexy XR. You can also visit 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, or call 1-800-FDA-1088.

Please see Full Prescribing Information at www.upsher-smith.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 200,000 new cases of epilepsy diagnosed each year.² Epilepsy can be associated with profound physical, psychological and social consequences that negatively impact people's lives.

Upsher-Smith's Epilepsy Pipeline

In addition to the recently-approved Qudexy™ XR, Upsher-Smith's clinical development pipeline includes two investigational drugs that are being studied for the management of seizure disorders. The pipeline includes USL261, an investigational intranasal midazolam for the rescue treatment of seizures in patients who require control of intermittent bouts of increased seizure activity, often called seizure clusters, which is the subject of an ongoing international Phase 3 clinical trial (ARTEMIS1) with an open-label safety extension study. In addition, USL260 (tonabersat) is in early clinical development as a potential first-in-class neuronal gap junction modulator.

About Upsher-Smith

Upsher-Smith Laboratories, Inc., founded in 1919, is a growing pharmaceutical company dedicated to its mission of *Advancing Pharmacotherapy. Improving Life™*. With capabilities ranging from early-stage research to delivering on-market products, Upsher-Smith is committed to offering quality products that enable people to live life to its greatest potential. Upsher-Smith's approach to product development and partnering has resulted in a broad range of both branded and generic therapeutic solutions to address patients' needs. The Company has a particular focus on developing therapies for people living with central nervous system (CNS)

conditions, such as seizure disorders, and has a robust pipeline of promising CNS compounds in various stages of development. For more information, visit www.upsheer-smith.com. For more information about Qudexy™ XR, visit www.qudexyxr.com.

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References

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2. Epilepsy Foundation. Available at: <http://www.epilepsyfoundation.org>. Accessed February 24, 2014.