UPSHER-SMITH TO PRESENT NEW RESEARCH ON USL255 (EXTENDED-RELEASE
TOPIRAMATE) AT 2013 AMERICAN EPILEPSY SOCIETY ANNUAL MEETING

Multiple Presentations Highlight Findings from Phase 3 Trial Investigating USL255 for
Adjunctive Treatment of Epilepsy in Patients with Refractory Partial-Onset Seizures

Maple Grove, MN – November 18, 2013 – Upsher-Smith Laboratories, Inc. (Upsher-Smith),
today announced that it will present new research from its epilepsy clinical development
program for USL255 (extended-release topiramate) during the American Epilepsy Society’s
(AES) 67th Annual Meeting in Washington, DC, December 6-10, 2013.

Seven presentations will highlight results from the PREVAIL clinical trial, the first of its
kind conducted on an extended-release formulation of topiramate. The global Phase 3 study
enrolled more than 200 patients and assessed the efficacy and safety of USL255 as an
adjunctive treatment of epilepsy in patients with refractory partial-onset seizures (POS). In
addition, two presentations will feature Phase 1 findings including the pharmacokinetics of
USL255 when sprinkled onto food or swallowed intact and the impact of delayed-dose
administration of USL255.

USL255 is a once-daily, broad-spectrum antiepileptic drug specifically engineered to
deliver a smooth pharmacokinetic profile. It is being developed by Upsher-Smith for the
management of seizure disorders. Upsher-Smith’s New Drug Application for USL255 has been
accepted for review by the U.S. Food and Drug Administration (FDA).

“This year’s AES meeting marks the first time the findings from our Phase 3 trial will be
presented publicly,” said William Pullman, MB BS, BMedSc, PhD, FRACP, Chief Scientific
Officer, Upsher-Smith. “We look forward to sharing data from the first global Phase 3 clinical
trial of an extended-release formulation of topiramate with the epilepsy community at this year’s
Annual Meeting.”

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Poster Presentations
PREVAIL Phase 3 Clinical Trial

• **USL255, a Once-Daily, Extended-Release Topiramate, is Efficacious as an Adjunctive Therapy for Refractory Partial-Onset Seizures: Results from the Randomized Phase 3 PREVAIL Clinical Trial**
  Poster 1.221; Saturday, December 7, 2013; 12 p.m. – 6 p.m. EST; Authors Present 12 p.m. – 2 p.m.

• **USL255 is Efficacious Across all Partial-Onset Seizure Types and with a Variety of Concomitant Antiepileptic Drugs: Results from Subgroup Analyses of the Phase 3 PREVAIL Clinical Trial**
  Poster 2.116; Sunday, December 8, 2013; 8 a.m. – 5 p.m. EST; Authors Present 12 p.m. – 2 p.m.

• **Time to Onset of Efficacy and Sustained Treatment Effects of USL255: Results from the Phase 3 PREVAIL Clinical Trial**
  Poster 1.222; Saturday, December 7, 2013; 12 p.m. – 6 p.m. EST; Authors Present 12 p.m. – 2 p.m.

• **Safety and Tolerability of USL255 in Subjects with Refractory Partial-Onset Seizures: Results from the Randomized, Phase 3 PREVAIL Clinical Trial**
  Poster 1.219; Saturday, December 7, 2013; 12 p.m. – 6 p.m. EST; Authors Present 12 p.m. – 2 p.m.

• **USL255, a Once-Daily, Extended-Release Topiramate, has Positive Effects on Clinical Outcomes and Quality of Life: Results from the Phase 3 PREVAIL Clinical Trial**
  Poster 1.223; Saturday, December 7, 2013; 12 p.m. – 6 p.m. EST; Authors Present 12 p.m. – 2 p.m.

• **Long-Term Open-Label Extension (OLE) Study Evaluating the Safety and Efficacy of USL255, Once-Daily Extended-Release Topiramate, in Patients with Partial-Onset Seizures: Interim Analysis from PREVAIL OLE**
  Poster 2.117; Sunday, December 8, 2013; 8 a.m. – 5 p.m. EST; Authors Present 12 p.m. – 2 p.m.
• **Use of Investigator Training to Improve Seizure Classification in PREVAIL – a Phase 3, Global Study Evaluating USL255, Once-Daily Extended-Release Topiramate, in Adults with Partial-Onset Seizures**

  *Poster 3.214; Monday, December 9, 2013; 8 a.m. – 3:30 p.m. EST; Authors Present 12 p.m. – 2 p.m.*

**USL255 Phase 1**

• **Comparison of the Pharmacokinetics of USL255, an Extended-Release Topiramate, when Sprinkled onto Food or Swallowed Intact**

  *Poster 1.220; Saturday, December 7, 2013; 12 p.m. – 6 p.m. EST; Authors Present 12 p.m. – 2 p.m.*

• **Impact of Delayed-Dose Administration of USL255, an Extended-Release Topiramate Formulation**

  *Poster 2.157; Sunday, December 8, 2013; 8 a.m. – 5 p.m. EST; Authors Present 12 p.m. – 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 Elizabeth Likly at elikly@klcpr.com.

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

The PREVAIL trial was a randomized, multicenter, double-blind, placebo-controlled, parallel-group study designed to evaluate the efficacy and safety of USL255 as adjunctive therapy in patients with refractory POS.

PREVAIL was conducted under a Special Protocol Assessment (SPA) agreement with the FDA. More information about the trial is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT01142193).

An open-label extension study to evaluate the safety of USL255 as adjunctive therapy in patients with refractory POS who had participated in PREVAIL is ongoing. The open-label extension study can be found by searching NCT01191086 on [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

**Upsher-Smith’s Epilepsy Pipeline**

Upsher-Smith’s clinical development pipeline includes three investigational drugs that are being studied for the management of seizure disorders. USL255 is an investigational once-daily, extended-release topiramate for the management of epilepsy. The pipeline also includes USL261, an investigational intranasal midazolam for the rescue treatment of seizures in patients with epilepsy.
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, founded in 1919, is an independent and privately-owned specialty pharmaceutical company headquartered in Maple Grove, Minnesota that focuses on product growth and innovation for branded and generic pharmaceuticals. Upsher-Smith has a particular focus on developing therapies to assist people suffering from central nervous system diseases and also markets products relating to cardiology, dermatology, and women’s health. For more information, visit www.upsher-smith.com.

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