UPSHER-SMITH SUCCESSFULLY COMPLETES PHASE III STUDY OF USL255 (EXTENDED-RELEASE TOPIRAMATE) FOR ADJUNCTIVE TREATMENT OF EPILEPSY IN PATIENTS WITH REFRACTORY PARTIAL-ONSET SEIZURES

Global Study Advances Upsher-Smith’s CNS Pipeline

Maple Grove, MN – May 22, 2013 – Upsher-Smith Laboratories, Inc. today announced the successful completion of its global Phase III clinical trial for USL255 (extended-release topiramate), an internally developed program for the management of epilepsy in adults, using the company’s proprietary formulation technology. USL255 is specifically engineered to provide convenient once-daily dosing and reduce fluctuations in topiramate blood levels observed with currently available treatment options. Upsher-Smith’s New Drug Application for USL255 has been accepted for review by the U.S. Food and Drug Administration (FDA) with an anticipated target review date under the Prescription Drug User Fee Act (PDUFA) of December 2013.

In the study, USL255 demonstrated a positive treatment effect as adjunctive therapy in patients with refractory partial-onset seizures (POS) compared with placebo. USL255 had a statistically significant reduction from baseline in weekly POS frequency during the titration plus maintenance phase compared to placebo (p<0.001). Preliminary findings from the Phase III trial will be submitted for presentation at the 2013 Annual Meeting of the American Epilepsy Society, December 6-10 in Washington, D.C.

“We are very excited by the preliminary findings from this well-executed global trial. Sixty-nine centers enrolled more than 200 patients to evaluate the safety and efficacy of USL255, a uniquely designed extended-release formulation of topiramate,” said Steve Chung, M.D., Professor of Neurology at the Barrow Neurological Institute, Phoenix and trial investigator. “This study provides strong evidence suggesting that once-daily USL255 may be a therapeutic option for patients suffering from partial-onset seizures.”

“The successful completion of the Phase III clinical trial of USL255 marks an exciting milestone in Upsher-Smith’s focused strategy to develop and deliver therapies to address central nervous system disorders,” said Mark Evenstad, President and CEO of Upsher-Smith. “Underpinning this strategy is our commitment to advancing pharmacotherapy to improve lives.”

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About the Trial

The Phase III (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 (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.

About Epilepsy

Epilepsy is a medical condition that causes seizures affecting a variety of cognitive and physical functions. 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.¹ For many people with epilepsy, medication will prevent seizures if taken regularly, but some people continue to have seizures.¹ 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.²

Upsher-Smith’s Epilepsy Pipeline

Upsher-Smith’s clinical development pipeline includes three investigational drugs that are being studied for the management of epilepsy. 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 who require control of intermittent bouts of increased seizure activity, often called seizure clusters, which is the subject of an ongoing international Phase III 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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References