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UPSHER-SMITH ANNOUNCES PATIENT ENROLLMENT IN OPEN-LABEL SAFETY STUDY OF USL261 (INTRANASAL MIDAZOLAM) FOR RESCUE TREATMENT OF SEIZURE CLUSTERS IN EPILEPSY

Extension Study Offers Patients Experiencing Seizure Clusters Continued Access to USL261

Maple Grove, MN – June 24, 2013 – Upsher-Smith Laboratories, Inc., (Upsher-Smith) today announced that it is enrolling patients in its open-label safety extension study to ARTEMIS1 (**A**cute **R**escue **T**herapy in **E**pilepsy with **M**idazolam **I**ntranasal **S**pray), a global Phase III clinical trial for USL261, a novel, investigational formulation of the benzodiazepine midazolam. USL261 is delivered intranasally for the rescue treatment of seizures in patients who require control of intermittent bouts of increased seizure activity, often called seizure clusters or acute repetitive seizures. The open-label, multicenter study will evaluate the long-term safety and tolerability of USL261 in the treatment of seizure clusters. USL261 has been granted orphan drug designation for this use by the Food and Drug Administration (FDA) and Upsher-Smith will be seeking approval for this indication.

More information about the open-label extension study, including key eligibility requirements, is available at www.clinicaltrials.gov (NCT# 01529034).

"At Upsher-Smith, we are dedicated to researching new treatment options for people living with challenging central nervous system conditions like epilepsy," said William Pullman, MB BS, BMedSc, PhD, FRACP, Chief Scientific Officer, Upsher-Smith. "In this open-label safety extension study, patients receiving both placebo and study medication in ARTEMIS1 will have the opportunity to utilize USL261 for the rescue treatment of seizure clusters. We are pleased to offer eligible patients access to USL261 during this study period as this will help to inform the safety profile of the product."

"Seizure emergencies, such as repetitive seizures and seizure clusters, are serious medical events requiring immediate treatment to reduce the risk of morbidity and mortality," said Robert T. Wechsler, MD, PhD, FAAN, Medical Director, Idaho Comprehensive Epilepsy Center. "There is a

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significant need for new therapies to treat seizure clusters. Currently, only one medication is FDA-approved for intermittent bouts of increased seizure activity outside of the hospital setting, and it must be delivered rectally, which may be undesirable to some individuals."

Favorable Phase I data for USL261 in healthy volunteers were recently presented at the Annual Meeting of the American Academy of Neurology in March 2013. The results demonstrated that peak midazolam plasma concentrations were rapidly achieved (10-15 min) after dosing with USL261. USL261 also demonstrated increased absorption with an improved bioavailability compared to an equivalent dose of injectable midazolam delivered intranasally. Single doses of USL261 up to 7.5 mg were generally well tolerated.

About ARTEMIS1

ARTEMIS1, a Phase III randomized, double-blind, placebo-controlled study, is designed to assess the efficacy, safety and tolerability of USL261 in males and females ages 14 to 65 years with seizure clusters. Study medication is administered intranasally without active inhalation by the patient.

The primary efficacy endpoint of the study is Treatment Success, which is defined as achieving both of the following: 1) termination of seizure(s) within 10 minutes after study drug administration, and 2) no recurrence of seizure(s) within four hours after study drug administration.

To be eligible for the trial, participants must have a diagnosis of epilepsy, a history of seizure clusters and an adult caregiver who can recognize, observe and record seizure cluster episodes.

More information about the ARTEMIS1 trial, including key eligibility requirements, is available at www.clinicaltrials.gov (NCT# 01390220) and at www.seizureclusterstudy.com.

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]

About Seizure Clusters

Seizure clusters, also referred to as acute repetitive seizures or increased bouts of seizure activity, are multiple seizures which occur over a relatively brief period of time with a pattern distinguishable from the usual seizure pattern.[2] Typically, there is recovery between seizures.[3]

Reports of seizure cluster prevalence vary, but it has been estimated that approximately 22% of the intractable epilepsy population (approximately 152,000 people) experience them. [4,5,6,7]

Inadequate treatment of seizure clusters may potentially impact the safety of an epilepsy patient, may result in emergency room visits, and/or may evolve into status epilepticus, a potentially life-threatening condition.[8,9,10] Benzodiazepines are the treatment of choice for management of acute seizures.[2] Prehospital treatment with benzodiazepines has been shown to reduce seizure activity significantly compared with seizures that remain untreated until the patient reaches the emergency department; however, currently available options are underused.[2,11,12] It is important to treat seizure emergencies early for many reasons, including findings that patients treated within 30 minutes of seizure onset are more responsive to first-line treatment.[13]

Market research has shown that patients and caregivers would prefer a rescue medication for seizure clusters that could be administered in any setting and that provides effective and rapid seizure termination in an easy-to-use, non-invasive form of administration.[14] Physicians, much like patients and caregivers, have expressed interest in a non-invasive rescue therapy for use outside of the hospital.[15]

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 providing 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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