Phase I Research of Extended-Release Topiramate Shows Less Fluctuation in Plasma Levels

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MAPLE GROVE, Minn., April 11, 2011 /PRNewswire/ -- Upsher-Smith Laboratories today announced the presentation of data indicating that once daily administration of USL255, a proprietary extended-release (ER) formulation of the epilepsy medication topiramate, was associated with less fluctuation in topiramate plasma levels compared to immediate-release (IR) topiramate administered twice daily in healthy volunteers.

These data were presented Monday, April 11 at the American Academy of Neurology's (AAN) 2011 Annual Meeting in Honolulu, HI, and marked another milestone in Upsher-Smith's commitment to addressing unmet patient needs in epilepsy and other central nervous system diseases.

USL255 is being developed for the treatment of adults with partial-onset seizures and is the subject of a Phase III clinical trial (PREVAIL). This proprietary extended-release formulation is designed to provide convenient once-daily dosing with reduced fluctuation in topiramate plasma levels versus traditional IR dosage forms.

"Fluctuations in plasma levels with certain antiepileptic drugs have the potential to cause challenges for patients with epilepsy. There is concern that some individuals may experience increased side effects during peak concentrations, or suffer break-through seizures if plasma levels fall too low. We are excited to share this Phase I data about USL255 and its encouraging pharmacokinetic profile with clinicians at AAN," said Mark Halvorsen, Pharm.D., Senior Director, Clinical Development at Upsher-Smith.

Abstracts of the poster presentations can be found online at www.aan.com [1]. Titles and authors are:

- "Development and Optimization of Extended-Release Formulations of Topiramate." *Authors: Lawrence J. Lambrecht, Wesley M. Todd, John A. Carrithers, Mark B. Halvorsen.*
- "Pharmacokinetic Equivalence Between Immediate-Release Topiramate and USL255 (A Novel
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SOURCE [2]

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Links:
[1] http://www.aan.com
[2] http://www.bio-medicine.org/medicine-technology-1/Phase-I-Research-of-Extended-Release-Topiramate-Shows-Less-Fluctuation-in-Plasma-Levels-16240-1/