

OWP Pharmaceuticals Announces IND Approval and Patent Application for the First-Ever Liquid Oral Suspension Formulation of Topiramate for the Treatment of Epilepsy and Migraine

NAPERVILLE, Ill., Nov. 20, 2019 (GLOBE NEWSWIRE) -- OWP Pharmaceuticals, Inc., a privately-held, commercial-stage neuroscience specialty pharmaceutical company, dedicated to developing and commercializing novel liquid oral suspension (OS) formulations, announced today that it has received Investigational New Drug (IND) approval from the U.S. Food and Drug Administration (FDA), and has submitted for U.S. patent protection, for the first-ever liquid formulation of topiramate. Offering an important delivery alternative for a drug often used for epilepsy and migraine, this represents the first of several oral suspensions in neuroscience that the company hopes to commercialize over the next several years via a 505(b)(2) application, in keeping with its pipeline of reformulated, approved therapeutics with no currently available liquid formulation.

Topiramate tablets, for oral use, were first approved in the U.S. in 1996 and the medication is widely prescribed by pediatric and adult healthcare providers in neurology and internal medicine. In epilepsy, topiramate is indicated as initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older and adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older. It is also indicated for the preventive treatment of migraine in patients 12 years of age and older.¹ In oral tablet or capsule form, U.S. prescriptions for topiramate are approximately 12 million total prescriptions annually.²

Scott Boyer, founder and chief executive officer of OWP stated, "We believe that clinicians who regularly treat young patients with epilepsy, who often have trouble with or are afraid of swallowing tablets, could benefit from the availability of a liquid formulation of topiramate for which the dose can be fine-tuned and precise. Some parents, who are already troubled with their child's diagnosis, have challenges with administration of tablets to their children."

He added, "Today marks the achievement of a key milestone in the development of our company's first liquid oral suspension, which, if approved, would represent the first available oral suspension of topiramate. Given that there are no currently available liquid formulations for many drugs in neuroscience that are widely prescribed, we are very excited to have the potential to bring our first suspension for a significant unmet need to the pediatric community, and possibly to other clinicians who have patients that struggle with swallowing tablets, such as in older populations."

About OWP Pharmaceuticals

Established in 2014, OWP Pharmaceuticals (www.owppharma.com) delivers quality branded and generic neuroscience medications. Its strategic focus is to support neurologists, psychiatrists, and patients in the U.S. with commonly used products and to donate a significant portion of the profits to the ROW Foundation (www.rowpharma.org), so that the foundation can provide resources for those living with epilepsy and associated psychiatric disorders in under-resourced areas of the world.

Cautionary Note Regarding Forward-Looking Statements

This news release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve substantial risks and uncertainties, including statements that are based on the current expectations and assumptions of the Company's management. All statements, other than statements of historical facts, included in this press release, including the Company's belief of the clinical efficacy and safety of topiramate oral suspension and its ability to improve upon existing treatment options, are forward-looking statements. You should not place undue reliance on the Company's forward-looking statements. Various important factors could cause actual results or events to differ materially from those that may be expressed or implied by our forward-looking statements. The forward-looking statements are made as of this date and the Company does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

For further information, contact Scott Boyer, the Chief Executive Officer at Scott.Boyer@owppharma.com.

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1. TOPAMAX® (topiramate) TABLETS, for oral use and TOPAMAX® (topiramate capsules) SPRINKLE CAPSULES, for oral use. Full prescribing information. <http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TOPAMAX-pi.pdf>. Accessed October 30, 2019.
2. Symphony Health Data. September 2019.