OWP Pharmaceuticals Announces a Second IND Approval and Patent Application: The First-Ever Liquid Oral Suspension Formulation of Lamotrigine for the Treatment of Epilepsy and Bipolar Disorder

NAPERVILLE, Ill., Dec. 03, 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 lamotrigine. Offering an important delivery alternative for a drug often used for epilepsy and bipolar disorder, this represents the second 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.

Lamotrigine tablets, for oral use, were first approved in the U.S. in 1994 and the medication is widely prescribed by pediatric and adult healthcare providers in neurology and psychiatry. In epilepsy, lamotrigine is indicated for adjunctive therapy in patients aged 2 years and older who have partial onset seizures, primary generalized tonic-clonic seizures, and generalized seizures of Lennox-Gastaut syndrome. It is also indicated for conversion to monotherapy in patients aged 16 years and older with partial-onset seizures who are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single antiepileptic drug (AED). Finally, it is indicated for maintenance treatment of bipolar 1 disorder in patients who are 18 years of age or older.[1] In oral solid form, U.S. prescriptions for lamotrigine are 10.9 million total prescriptions annually.[2]

Scott Boyer, founder and chief executive officer of OWP stated, “Pediatric clinicians who regularly treat children and adolescents with epilepsy often find that their patients have trouble with or are afraid of swallowing tablets. We believe that the availability of a liquid formulation of lamotrigine for which parents can easily manage the dose, could be helpful to their practices and their patients.”

Mr. Boyer added, “Today we have marked another key milestone for our company with the potential introduction of our second liquid oral suspension, which, if approved, would represent the first available oral suspension of lamotrigine. With the development of an oral suspension of lamotrigine, as well as our oral suspension of topiramate, we hope to establish a leadership position in the creation of novel formulations for patients with neuroscience disorders. We have built a solid platform to offer even more commonly used neuroscience liquid formulations in the future, all of which will address important unmet needs. This second important strategic initiative aligns well with our goal of expanding our business model of single source and multisource generics to include more complex 505(b)(2) products in our pipeline.”

About OWP

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 lamotrigine 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.

SOURCE OWP Pharmaceuticals, Inc.

1. LAMICTAL (lamotrigine) tablets, for oral use; LAMICTAL (lamotrigine) chewable dispersible tablets, for oral use; LAMICTAL ODT (lamotrigine) orally disintegrating tablets, for oral use. Full prescribing information. https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Lamictal/pdf/LAMICTAL-PI-MG.PDF. Accessed October 29, 2019.
2. Symphony Health Data. September 2019.