OWP Pharmaceuticals Announces Patent Application for the First-Ever Powder for Oral Liquid Formulation of Duloxetine Hydrochloride for the Treatment of Major Depressive and Generalized Anxiety Disorder

NAPERVILLE, Ill., July 08, 2020 (GLOBE NEWSWIRE) -- OWP Pharmaceuticals, Inc., a privately-held, commercial-stage neuroscience specialty pharmaceutical company, dedicated to developing and commercializing novel oral liquid formulations, announced today that it has submitted for U.S. patent protection, for the first-ever powder for oral liquid formulation of duloxetine hydrochloride. Offering an important delivery alternative for a drug often used for major depressive and generalized anxiety disorder, this represents the fourth of several oral liquid options in neuroscience that the company hopes to commercialize over the next several years via 505(b)(2) applications, in keeping with its pipeline of reformulated, approved therapeutics with no currently available liquid formulation.

Duloxetine hydrochloride is a serotonin and norepinephrine reuptake inhibitor (SNRI) and the delayed-release capsules, for oral use, were first approved in the U.S. in 2004. The medication is widely prescribed by healthcare providers in psychiatry. In major depressive and generalized anxiety disorders, duloxetine hydrochloride is indicated for treatment in adults. It is also indicated in adults for the management of neuropathic pain (DPNP) associated with diabetic peripheral neuropathy, fibromyalgia (FM), and chronic musculoskeletal pain, established in studies in patients with chronic low back pain and chronic pain due to osteoarthritis.[1] In delayed-release capsule form, U.S. prescriptions for duloxetine hydrochloride are over 24 million total prescriptions annually.[2]

Scott Boyer, founder and chief executive officer of OWP stated, “Today we have marked yet another key milestone for our company with the potential introduction of our fourth unique formulation of another drug widely used in neuroscience. If approved, this would represent the first-ever powder for oral liquid formulation available for duloxetine hydrochloride. As with our other potential entrants, this alternative dosage form may be preferred by adult patients who experience swallowing difficulties or who have trouble swallowing tablets or capsules. Healthcare providers may also find that in this form, the dosage may be easier to titrate and adjust. This fourth important strategic initiative, closely following the releases of our oral liquids for lamotrigine, topiramate, and quetiapine, aligns well with our goal of expanding our business model of single source and multisource generics to include more complex 505(b)(2) branded 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 duloxetine hydrochloride powder for oral liquid formulation 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. CYMBALTA® (duloxetine hydrochloride) Delayed-Release Capsules for Oral Use. Full prescribing information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022516lbl.pdf. Accessed June 28, 2020.
2. Symphony Health Data. One year rolling average ending April 2020.