OWP Pharmaceuticals Announces Patent Application for the First-Ever Oral Liquid Formulation of Atomoxetine Hydrochloride for the Treatment of Attention Deficit Hyperactivity Disorder

NAPERVILLE, Ill., April 22, 2021 (GLOBE NEWSWIRE) -- OWP Pharmaceuticals, Inc. is a privately held, commercial-stage neuroscience specialty pharmaceutical company, dedicated to developing and commercializing novel oral liquid formulations. OWP announced today that it has submitted for U.S. patent protection, for the first-ever oral suspension of atomoxetine hydrochloride. Offering an important delivery alternative for a drug often used for attention deficit hyperactivity disorder (ADHD), this represents the fifth of several oral liquid medications 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.

Atomoxetine hydrochloride is a selective norepinephrine reuptake inhibitor and the capsules, for oral use, were first approved in the U.S. in 2002. The medication is widely prescribed by healthcare providers in psychiatry for ADHD, and it is indicated for treatment in children 6 years and older and adults. The efficacy of atomoxetine hydrochloride capsules was established in seven clinical trials in outpatients with ADHD: four 6 to 9-week trials in pediatric patients (ages 6 to 18), two 10-week trials in adults (age 18 and older), and one maintenance trial in pediatrics (ages 6 to 15).[1] In capsule form, U.S. prescriptions for atomoxetine hydrochloride are approximately 2.9 million total prescriptions annually.[2]

The term “attention deficit hyperactivity disorder” or “ADHD” refers to a neurodevelopmental disorder characterized by inattention, or excessive activity and impulsivity, which are otherwise not appropriate for a person's age. Some individuals with ADHD also display difficulty regulating emotions or problems with executive function. For a diagnosis, the symptoms should appear before a person is 12 years old, be present for more than six months, and cause problems in at least two settings (such as school, home, or recreational activities). In children, problems paying attention may result in poor school performance. Additionally, it is associated with other mental disorders and substance misuse. Although it causes impairment, particularly in modern society, many people with ADHD can have sustained attention for tasks they find interesting or rewarding (known as hyperfocus).

Scott Boyer, founder and chief executive officer of OWP stated, “Today we are pleased to have filed a patent which will lead to the potential introduction of our fifth unique formulation of another drug widely used in neuroscience for patients who are 6 years and older and challenged with ADHD. As with our other potential entrants, this alternative dosage form may be preferred by patients of many ages who have trouble swallowing tablets or capsules or who experience swallowing difficulties. Healthcare providers may also find that in this form, the dosage may be easier to titrate and adjust. This fifth important strategic initiative, closely following the releases of our oral liquid formulations for lamotrigine, topiramate, quetiapine, and duloxetine, 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 atomoxetine hydrochloride 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. STRATTERA® (atomoxetine hydrochloride) capsules, for oral use. Full prescribing information. https://uspl.lilly.com/strattera/strattera.html#pi. Accessed April 19, 2021.

2. Symphony Health Data. One year rolling average ending March 2020.