OWP Pharmaceuticals Announces IND Approval for the First-Ever Liquid Oral Suspension Formulation of Quetiapine Fumarate for the Treatment of Schizophrenia and Bipolar Disorder

NAPERVILLE, Ill., Oct. 07, 2020 (GLOBE NEWSWIRE) -- OWP Pharmaceuticals, Inc. is a privately held, commercial-stage neuroscience specialty pharmaceutical company, dedicated to developing and commercializing novel liquid oral suspension (OS) formulations. OWP announced today that it has received approval for its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) for the first-ever liquid formulation of quetiapine fumarate. Offering an important delivery alternative for a drug often used for schizophrenia and bipolar disorder, this represents the third 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.

Quetiapine fumarate is an atypical antipsychotic and the tablets, for oral use, were first approved in the U.S. in 1997. The medication is widely prescribed by healthcare providers in psychiatry who treat adolescent and adult patients. In schizophrenia, quetiapine fumarate is indicated for treatment in adolescents aged 13 to 17 years and adults. It is also indicated for the acute treatment of manic episodes associated with bipolar I disorder, both as monotherapy and as an adjunct to lithium or divalproex, in adults, and as monotherapy in adolescent patients 10 to 17 years of age. It is also indicated as monotherapy for the acute treatment of depressive episodes in adult patients with bipolar I and bipolar II disorder. Finally, it is indicated for the maintenance treatment of bipolar I disorder, as an adjunct to lithium or divalproex in adults.[1] In tablet form, U.S. prescriptions for quetiapine fumarate are approximately 15.8 million total prescriptions annually.[2]

Scott Boyer, founder and chief executive officer of OWP stated, “Today we are pleased to have IND approval for our third liquid oral suspension which, if approved, would represent the first available for quetiapine fumarate. The potential advantage of this alternative dosage form is that it may be preferred for adult patients who experience swallowing difficulties or for adults and adolescents 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 third important therapeutic option would closely follow the releases of our oral suspensions for lamotrigine and topiramate, and continues to align 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 quetiapine fumarate 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. SEROQUEL® (quetiapine fumarate) tablets, for oral use. Full prescribing information.
2. Symphony Health Data. One year rolling average ending August 2020.