OWP Pharmaceuticals Announces IND Authorization for First Oral Liquid Formulation of Trazodone for Treatment of MDD

NAPERVILLE, ILLINOIS, UNITED STATES, August 1, 2023 /EINPresswire.com/ -- 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 received IND authorization from the FDA for the first-ever oral solution of trazodone hydrochloride. Offering an important delivery alternative for a drug indicated for the treatment of major depressive disorder (MDD) in adults, this represents the sixth 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.

Trazodone hydrochloride is a selective serotonin reuptake inhibitor and the tablets, for oral use, were first approved in the U.S. in 1981. The medication is widely prescribed by healthcare providers in psychiatry for MDD, and it is indicated for treatment in adults. The efficacy and safety of trazodone hydrochloride were established from inpatient and outpatient trials of the trazodone immediate release formulation in the treatment of major depressive disorder. In tablet form, U.S. prescriptions for trazodone hydrochloride are approximately 43 million total prescriptions annually.

Major depressive disorder (MDD) has been ranked as the third cause of the burden of disease worldwide in 2008 by WHO, which has projected that this disease will rank first by 2030. It is diagnosed when an individual has a persistently low or depressed mood, anhedonia or decreased interest in pleasurable activities, feelings of guilt or worthlessness, lack of energy, poor concentration, appetite changes, psychomotor retardation or agitation, sleep disturbances, or suicidal thoughts.

Scott Boyer, founder and chief executive officer of OWP stated, "We are excited to have received IND authorization for the first-ever oral solution of trazodone, providing a unique formulation for patients challenged with MDD. As with our other potential entrants, this alternative dosage form may be preferred by patients who have trouble swallowing tablets or who experience swallowing difficulties. Healthcare providers may also find that in this form, the medication may be easier to administer, and it may simplify dosage titration. This sixth important strategic initiative, following the releases of our oral liquid formulations for lamotrigine, topiramate, quetiapine, duloxetine, atomoxetine, and trazodone aligns well with our goal of expanding our business model 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.rowglobal.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 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 info@owppharma.com .

SOURCE: OWP Pharmaceuticals, Inc.

1. DESYREL® (Trazodone hydrochloride) tablets, for oral use. Full prescribing information. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=704aebf9-2fff-4ef3-8323-9ff0d7f0ffd9 . Accessed July 20, 2023.
2. Symphony Health Data. One year rolling average ending June 2023.
3. Bains N, Abdijadid S. Major Depressive Disorder. [Updated 2023 Apr 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK559078/

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