OWP Pharmaceuticals Announces FDA Filing Acceptance for New Drug Application of SUBVENITE® (lamotrigine) Oral Suspension

NAPERVILLE, ILLINOIS, UNITED STATES, May 20, 2024 /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 U.S. Food and Drug Administration (FDA) acceptance for the New Drug Application (NDA) submission of SUBVENITE® (lamotrigine) oral suspension, which is the first oral liquid of lamotrigine indicated to treat epilepsy and bipolar disorder. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) date of January 3rd, 2025.

Scott Boyer, founder and chief executive officer of OWP stated, “We are incredibly excited to have received FDA acceptance of our NDA, which brings us closer to bringing the first oral liquid of lamotrigine to the US market.”

This milestone marks OWP Pharmaceuticals’ first FDA acceptance of an NDA in a pipeline of six oral liquids being developed through a 505(b)(2) pathway, including lamotrigine, topiramate, quetiapine fumarate, trazodone hydrochloride, atomoxetine hydrochloride and duloxetine hydrochloride.

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.

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