Supernus Announces FDA Approval of sNDA to Expand Oxtellar XR® Label to Include Monotherapy

December 14, 2018

ROCKVILLE, Md., Dec. 14, 2018 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (NASADQ: SUPN) announced today that the United States Food and Drug Administration (FDA) has approved the Company's supplemental new drug application (sNDA) for Oxtellar XR ®. The application requested FDA approval to expand the indication for Oxtellar XR® beyond the current indication of adjunctive therapy in the treatment of partial-onset seizures in adults and in children 6 to 17 years of age.

"We are pleased with the timely approval of the expanded indication for Oxtellar XR. We look forward to launching Oxtellar XR in the first quarter 2019 as a new monotherapy treatment option for partial-onset seizures. We believe that expanding the indication to include monotherapy represents an additional growth opportunity for Oxtellar XR," said Jack Khattar, president and chief executive officer of Supernus Pharmaceuticals.

About Oxtellar XR®

Oxtellar XR is the first approved novel, oral once-daily extended release formulation of oxcarbazepine for the treatment of partial-onset seizures in patients 6 years of age and older. The product is available in 150mg, 300mg, and 600mg extended-release tablets.

For full prescribing and safety information https://oxtellarxr.com/assets/OxtellarXRPrescribingInformation.pdf

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals, Inc. is a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. The Company currently markets Trokendi XR® (extended-release topiramate) for the prophylaxis of migraine and the treatment of epilepsy, and Oxtellar XR® (extended-release oxcarbazepine) for the treatment of partial seizures. The Company is also developing several product candidates to address large opportunities in the CNS market, including SPN-810 for the treatment of Impulsive Aggression in ADHD patients, SPN-812 for the treatment of ADHD, and SPN-604 for the treatment of bipolar disorder.

Forward Looking Statements

This press release contains forward-looking statements regarding the timing of the Company's ability to market Oxtellar XR ® for monotherapy treatment in epilepsy. Actual results may differ materially from those in these forward-looking statements as a result of various factors, including, but not limited to, the Company's ability to commercialize its products successfully, whether physicians will prescribe and patients will use its products, once available, and competition in their respective markets. For a further description of these and other risks facing the Company, please see the risk factors set forth from time to time in the Company's SEC filings made pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended. Forward-looking statements speak only as of the date of this press release, and the Company undertakes no obligation to update or revise these statements, except as may be required by law.

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