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Supernus Announces FDA Acceptance of sNDA to Add Migraine to Trokendi XR(R) Label

ROCKVILLE, Md., Oct. 22, 2015 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (NASDAQ:SUPN) announced today that the United States Food and Drug Administration (FDA) has accepted for review the company's supplemental new drug application (sNDA) for Trokendi XR[®]. The application requests FDA approval to expand the indication for Trokendi XR beyond the current indication for the treatment of epilepsy to include treatment for adults for prophylaxis of migraine headache. Under the Prescription Drug User Fee Act (PDUFA) guidelines, the FDA has set a target date in the second quarter of 2016 to complete its review.

"Now that our application is under review, we look forward to working with the FDA to ensure a timely approval of the new indication," said Jack Khattar, president and chief executive officer of Supernus Pharmaceuticals. "If approved for use in migraine, Trokendi XR would represent an important new treatment option for adult patients suffering from this condition."

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system, or CNS, diseases. The Company markets two products for epilepsy, Oxtellar XR[®] (extended-release oxcarbazepine) and Trokendi XR[®] (extended-release topiramate). The Company is also developing several product candidates in psychiatry to address large market opportunities in ADHD, including ADHD patients with impulsive aggression. These product candidates include SPN-810 for impulsive aggression in ADHD and SPN-812 for ADHD.

Forward Looking Statements

This press release contains forward-looking statements regarding the timing of the Company's ability to market Trokendi XR[®] for migraine. 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 obtain final regulatory approval for the migraine indication, 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 described in the Company's Annual Report Form 10-K that was filed with the United States Securities and Exchange Commission on March 12, 2015 under the caption "Risk Factors". 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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