



August 19, 2016

Supernus Receives FDA Tentative Approval for Expanded Label of Trokendi XR® to Include Migraine Prophylaxis in Adults

ROCKVILLE, Md., Aug. 19, 2016 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (NASDAQ:SUPN), a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system diseases, today announced that the Food and Drug Administration (FDA) has granted tentative approval to the Company's Supplemental New Drug Application (sNDA) requesting a label expansion for Trokendi XR to include prophylaxis of migraine headache in adults.

The approval of the sNDA is tentative because the FDA has determined that the drug meets all of the required quality, safety, and efficacy standards for approval, but is subject to the pediatric exclusivity which expires March 28, 2017. Final approval may not be made effective until this exclusivity period has expired.

In addition, the Company announced today that the FDA has granted final approval to expand the label for Trokendi XR for monotherapy treatment of partial onset seizures to include adults and pediatric patients 6 years and older, rather than 10 years and older.

"We will continue to work with the FDA to gain final approval upon the expiration of pediatric exclusivity," stated Jack Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. "We are prepared and ready to launch the migraine indication upon receiving full FDA approval."

About Trokendi XR

Trokendi XR is the first approved novel once-daily extended release formulation of topiramate for the treatment of epilepsy. Trokendi XR is an antiepileptic drug indicated for initial monotherapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures; adjunctive therapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures; and adjunctive therapy in patients 6 years of age and older with seizures associated with Lennox-Gastaut syndrome. The product is available in 25mg, 50mg, 100mg and 200mg extended-release capsules.

For current full prescribing and safety information, [click here](#)

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 diseases. The Company has two marketed products for epilepsy, Oxtellar XR® (extended-release oxcarbazepine) and Trokendi XR® (extended-release topiramate). The Company is also developing several product candidates to address large market opportunities in psychiatry, including SPN-810 for the treatment of Impulsive Aggression in ADHD patients and SPN-812 for the treatment of ADHD.

Forward-Looking Statements:

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements do not convey historical information, but relate to predicted or potential future events that are based upon management's current expectations. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. In addition to the factors mentioned in this press release, such risks and uncertainties include, but are not limited to, the Company's ability to sustain and increase its profitability; the Company's ability to raise sufficient capital to fully implement its corporate strategy; the implementation of the Company's corporate strategy; the Company's future financial performance and projected expenditures; the Company's ability to increase the number of prescriptions written for each of its products; the Company's ability to increase its net revenue; the Company's ability to enter into future collaborations with pharmaceutical companies and academic institutions or to obtain funding from government agencies; the Company's product research and development activities, including the timing and progress of the Company's clinical trials, and projected expenditures; the Company's ability to receive, and the timing of any receipt of, regulatory approvals to develop and commercialize the Company's product candidates; the Company's ability to protect its intellectual property and operate its business without infringing upon the intellectual property

rights of others; the Company's expectations regarding federal, state and foreign regulatory requirements; the therapeutic benefits, effectiveness and safety of the Company's product candidates; the accuracy of the Company's estimates of the size and characteristics of the markets that may be addressed by its product candidates; the Company's ability to increase its manufacturing capabilities for its products and product candidates; the Company's projected markets and growth in markets; the Company's product formulations and patient needs and potential funding sources; the Company's staffing needs; and other 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. The Company undertakes no obligation to update the information in this press release to reflect events or circumstances after the date hereof or to reflect the occurrence of anticipated or unanticipated events.

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