April 5, 2017

Supernus Receives Final FDA Approval for Trokendi XR® for Migraine Prophylaxis in Adults and Adolescents

Trokendi XR is the Leading Extended-Release Topiramate Product and Brand of Topiramate

ROCKVILLE, Md., April 05, 2017 (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 final approval to the Company's Supplemental New Drug Applications (sNDAs) requesting a label expansion for Trokendi XR to include prophylaxis of migraine headache in adults and adolescents 12 years and older. Supernus was granted tentative approval of one of the two sNDAs in August 2016, with final approval subject to the pediatric exclusivity of the innovator's drug in the adolescent population, which expired March 28, 2017.

Based on IMS prescription data, Topiramate is the most prescribed drug for the treatment of migraine prophylaxis with more than 9 million prescriptions annually. This represents approximately 50% of all IMS prescriptions written for migraine prophylaxis.

"This approval and our imminent launch in migraine represent an opportunity for Supernus to further strengthen its leadership position in this market with Trokendi XR," stated Jack Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. "Trokendi XR, with its novel formulation, provides full 24 hour coverage for patients with smooth pharmacokinetics compared to the immediate-release topiramate products, making it an important new treatment option for adult and adolescent patients suffering from migraine headache. This is an important advancement for patients and another step towards realizing the full potential of Trokendi XR."

About Trokendi XR

Trokendi XR is a novel once-daily extended release formulation of topiramate for the treatment of epilepsy, and migraine prophylaxis. Trokendi XR is indicated for the prophylaxis of migraine headache in adults and adolescents 12 years of age and older, 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 contains forward-looking statements regarding the Company's ability to market Trokendi XR® in the migraine market. Actual results may differ materially from those in these forward-looking statements as a result of various factors, including, but not limited to, the ability of the Company to increase the number of prescriptions written for each of its products and the Company's ability to increase its net revenue. For a further description of these and other risks facing the Company, please see the risk factors described in the Company's 2016 Annual Report Form 10-K that was filed with the United States Securities and Exchange Commission on March 16, 2017 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.

Contact:

Jack A. Khattar, President and CEO

Gregory S. Patrick, Vice President and CFO

Supernus Pharmaceuticals, Inc.

301-838-2591

Or

Investor Contact:

Peter Vozzo

Westwicke Partners

Office: (443) 213-0505

Mobile: (443) 377-4767

Email: peter.vozzo@westwicke.com

Primary Logo

Source: Supernus Pharmaceuticals, Inc.

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