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Supernus Announces Final FDA Approval and Upcoming Launch of Trokendi XR(TM)

ROCKVILLE, Md., Aug. 19, 2013 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (Nasdaq:SUPN), a specialty pharmaceutical company, received final approval from the Food & Drug Administration (the "FDA") for Trokendi XR, a novel once-daily extended release formulation of topiramate for the treatment of epilepsy. The company expects to launch the product and for it to be available in pharmacies over the next few weeks.

The approval letter states that the FDA has completed its review of the application and that Trokendi XR is approved effective August 16, 2013 for use as recommended in the agreed-upon labeling. The FDA granted a waiver for certain pediatric study requirements and a deferral for submission of post-marketing pediatric pharmacokinetic assessments that are due in 2019 followed by clinical assessments in 2025.

"We are very excited about the approval of Trokendi XR and its upcoming launch. This is excellent news for Supernus, its shareholders, and patients with epilepsy. We remain committed to the epilepsy community and very much look forward to now having two products, Trokendi XR and Oxtellar XR, available to patients," said Jack Khattar, Chief Executive Officer, President and Director of Supernus.

About Trokendi XR™

Trokendi XR is a novel once- daily extended release formulation of topiramate. Trokendi XR is an antiepileptic drug (AED) indicated for initial monotherapy in patients 10 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 will be available in 25mg, 50mg, 100mg and 200mg extended-release capsules.

For 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, or CNS, diseases. The Company has one marketed product for epilepsy, Oxtellar XR™ (extended release oxcarbazepine), and one approved product for epilepsy, 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 potential for Trokendi XR to treat epilepsy, and the timing of the product's availability to physicians. Actual results may differ materially from those in these forward-looking statements as a result of various factors, including, but not limited to, risks regarding the company's ability to commercialize the product successfully, whether physicians will prescribe and patients will use the product, once available, and competition in the market. 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 15, 2013 and under the caption "Risk Factors" and the updates to these risk factors in the Company's quarterly report form 10-Q that was filed with the Commission on August 15, 2013. 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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