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Supernus Receives Tentative Approval of Trokendi XR(TM) From FDA

ROCKVILLE, Md., June 26, 2012 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (Nasdaq:SUPN), a specialty pharmaceuticals company, received a tentative approval letter from the Food & Drug Administration (the "FDA") for Trokendi XR™, a once-daily extended release formulation of topiramate (formerly known as SPN-538). The letter states that the FDA completed its review of the Trokendi XR NDA and that no additional clinical trials are required. Our initial understanding is that final approval is conditioned on resolving a marketing exclusivity issue raised by the FDA regarding a specific pediatric population.

"We are pleased to announce that the FDA granted us tentative approval for Trokendi XR and that all of the scientific and procedural conditions for approval have been met. We will continue to work closely with the FDA to further understand the outstanding issue and move forward towards final approval," said Jack Khattar, Chief Executive Officer, President and Director of Supernus.

The Company also learned that the FDA denied the Citizen's Petition filed in 2011 by Upsher Smith Laboratories as it relates to its NDA on Trokendi XR.

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 is developing several product candidates in neurology and psychiatry to address large market opportunities in epilepsy and ADHD including ADHD patients with impulsive aggression. These product candidates include Trokendi XR (extended-release topiramate), formerly known as SPN-538 and SPN-804 (extended-release-oxcarbazepine) for epilepsy, 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, its final approval, and the timing of its 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 obtain final approval for its products, commercialize products successfully, whether physicians will prescribe and patients will use Trokendi XR, once available, and competition in the market for Trokendi XR. For a further description of these and other risks facing the company, please see the risk factors described in the company's Registration Statement on Form S-1 that was filed with the United States Securities and Exchange Commission and the amendments thereto, including those factors discussed under the caption "Risk Factors" in those filings. 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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