



June 16, 2016

## **Supernus Provides Update on Trokendi XR® Migraine sNDA and Reiterates Guidance**

ROCKVILLE, Md., June 16, 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 it remains in discussions with the FDA regarding its Supplemental New Drug Application, or sNDA, for migraine. The FDA requested that the Company resubmit the Trokendi XR product label with migraine as an indication in a different format prior to completing its review. No additional new data, studies or analyses for efficacy or safety were requested by the FDA.

The Company will resubmit the revised label before the end of June, and a new PDUFA date will be assigned by the FDA. At this point, the Company believes that such a PDUFA date is likely to be in the third quarter of 2016.

"Supernus is ready to launch the new indication, and a launch later this year or next year should not have any material effect on our business," stated Jack Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. "Upon final approval for prophylaxis of migraine headache in adults, we believe Trokendi XR will represent an important new treatment option for adult patients suffering from this condition."

For full year 2016, the Company reiterates its guidance for net product sales to range from \$200 million to \$210 million, and operating income to range from \$28 million to \$35 million.

### **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 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 is 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 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 patients with ADHD 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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