

February 3, 2014

# Supernus Announces Publication of Phase III Study (PROSPER) Results on Oxtellar XR®

ROCKVILLE, Md.--(BUSINESS WIRE)-- Supernus Pharmaceuticals, Inc. (NASDAQ:SUPN), a specialty pharmaceutical company, today announced the publication of the Prospective, Randomized Study of Oxcarbazepine extended release in Subjects with Partial Epilepsy Refractory (PROSPER) data on Oxtellar XR. Results of this Phase III pivotal trial will appear in the upcoming March issue of *Acta Neurologica Scandinavica*, Volume 129, Issue 3, pages 143-153 and is available online at <a href="http://onlinelibrary.wiley.com/doi/10.1111/ane.12207/abstract">http://onlinelibrary.wiley.com/doi/10.1111/ane.12207/abstract</a>.

"We are pleased to see the PROSPER study results published in a renowned peer-reviewed journal in neurology such as *Acta Neurologica Scandinavica*. This represents the first publication for Supernus in such a journal, allowing physicians to have access to the study results. The publication highlights the important role Oxtellar XR can play in improving the lives of patients with epilepsy. These results mirror those seen in numerous patient cases since the launch of our product," said Jack A. Khattar, President and CEO of Supernus.

The PROSPER study evaluated and demonstrated the safety and efficacy of our novel once-daily 1200 mg and 2400 mg doses of Oxtellar XR when added to 1-3 concomitant antiepileptic drugs in adults with refractory partial-onset seizures, with or without secondary generalization. Oxtellar XR also showed the potential to improve tolerability when compared to what is known about the immediate release versions of oxcarbazepine.

This was the Phase III pivotal study that formed the basis of approval by the FDA. It was a randomized, double-blind, parallel-group, placebo controlled study conducted at 88 sites in eight countries throughout North America and Eastern Europe. The primary efficacy endpoint was median percent reduction from baseline in monthly (28-day) seizure frequency for the 16-week double-blind treatment period in the intent-to-treat (ITT) population with analyzable seizure data. Other efficacy analyses included proportion of patients with  $\geq 50\%$  seizure reduction, proportion of patients that are seizure free, and the relationship between clinical response and plasma concentration.

Median percent reduction was significant for once-daily Oxtellar XR compared to placebo at 2400 mg (P = 0.003). In the placebo, 1200mg/day and 2400mg/day treatment groups, respectively, responder rates were 28.1%, 36.1% (P = 0.08), and 40.7% (P = 0.02); 16-week seizure-free rates in a pragmatic ITT analysis were 3.3%, 4.9% (P = 0.59), and 11.4% (P = 0.008). Post hoc analyses demonstrated that both Oxtellar XR dosages were significantly superior to placebo in median percent seizure reduction (placebo: -13.3%; 1200 mg: -34.5%, P = 0.02; 2400 mg: -52.7%, P = 0.006) in the North American study site cluster. A concentration-response analysis also supported a clinically meaningful effect for 1200 mg. Adverse event frequency was consistent with a pharmacokinetic profile of Oxtellar XR producing lower peak plasma concentrations versus oxcarbazepine immediate-release. Once-daily dosing was not associated with any new safety signals.

#### About Oxtellar XR®

Oxtellar XR is the only approved novel once-daily extended release formulation of oxcarbazepine for the treatment of epilepsy. It is an antiepileptic drug indicated for adjunctive therapy in the treatment of partial seizures in adults and in children 6 to 17 years of age. The product is available in 150 mg, 300 mg and 600 mg extended-release tablets.

#### 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 two marketed products for epilepsy, Oxtellar XR® (extended-release oxcarbazepine) and 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 of Oxtellar XR, its safety and efficacy profile. 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, 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 14, 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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