Supernus Announces Paragraph IV ANDA Filing for Oxtellar XR®

May 15, 2020

ROCKVILLE, Md., May 15, 2020 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (Nasdaq: SUPN), a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases, today announced that on May 14, 2020 the Company received a Paragraph IV Notice Letter from Apotex Inc. and Apotex Corp advising Supernus of the submission by Apotex of an Abbreviated New Drug Application to the U.S. Food and Drug Administration (FDA) seeking approval for oxcarbazepine extended-release tablets. Supernus is currently reviewing the details of this Notice Letter and intends to vigorously enforce its intellectual property rights (IPR) relating to Oxtellar XR.

Supernus has previously defended the Oxtellar XR IPR against two earlier generic filers; namely, Actavis and Twi Pharmaceuticals and related entities. In both cases, Supernus prevailed before the district court as well as on appeal. Oxtellar XR is currently protected by nine patents listed in the FDA's Approved Drugs Product List (Orange Book) that expire no earlier than 2027.

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals, Inc. is a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. The Company currently markets Trokendi XR® (extended-release topiramate) for the prophylaxis of migraine and the treatment of epilepsy, and Oxtellar XR® (extended-release oxcarbazepine) for the treatment of epilepsy. The Company is also developing several product candidates to address large market opportunities in the CNS market, including SPN-812 for the treatment of ADHD, SPN-820 (NV-5138) for treatment-resistant depression, and SPN-817 for the treatment of epilepsy.

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 filings with the Securities and Exchange Commission 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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