Supernus Sues Apotex for Infringement of Oxtellar XR® Patents

June 26, 2020

ROCKVILLE, Md., June 26, 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, announced that earlier today it sued generic drug maker Apotex Inc. and Apotex Corp. (collectively, Apotex) for infringement of nine patents covering its antiepileptic drug Oxtellar XR®. Supernus's United States Patent Nos. 7,722,898, 7,910,131, 8,617,600, 8,821,930, 9,119,791, 9,351,975, 9,370,525, 9,855,278, and 10,220,042 cover once-a-day oxcarbazepine formulations and methods of treating seizures using those formulations. These nine patents do not expire until April 13, 2027.

The Complaint – filed in the U.S. District Court for the District of New Jersey – alleges that Apotex infringed Supernus's Oxtellar XR patents by submitting to the U.S. Food and Drug Administration (FDA) an Abbreviated New Drug Application (ANDA) seeking to market a generic version of Oxtellar XR prior to the expiration of Supernus's patents. Filing its Complaint within 45 days of receiving Apotex's Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving Apotex's ANDA for 30 months.

Supernus has previously defended the Oxtellar XR intellectual property rights separately 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 Drug Products with Therapeutic Equivalence Evaluations (Orange Book) that expire on April 13, 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 markets Trokendi XR® (extended-release topiramate) for the prophylaxis of migraine and the treatment of epilepsy, Oxtellar XR® (extended-release oxcarbazepine) for the treatment of epilepsy, Apokyn® (apomorphine hydrochloride injection) for the acute treatment of hypomobility in advanced Parkinson's disease (PD), Myobloc® (rimabotulinumtoxinB) for the treatment of cervical dystonia and treatment of chronic sialorrhea in adults, and Xadago® (safinamide) as an adjunctive treatment to levodopa/carbidopa in PD patients with hypomobility. 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, apomorphine infusion pump for hypomobility in PD, SPN-820 (NV-5138) for treatment-resistant depression, and SPN-817 for the treatment of epilepsy.

APOKYN Pen and apomorphine infusion pump product candidate are under a license from Britannia Pharmaceuticals Limited

XADAGO is under a license from Zambon S.p.A

All trademarks are the property of their respective owners

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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