



Supernus Announces Orphan Drug Exclusivity for ONAPGO™ (apomorphine HCl)

October 21, 2026

Orphan-drug exclusivity provides seven years of market exclusivity for ONAPGO

Additionally, the Company submitted an sNDA to the FDA for a second supplier for ONAPGO, with potential approval by mid-year 2027

ROCKVILLE, Md., Oct. 21, 2026 (GLOBE NEWSWIRE) -- Supernus, Inc. (Nasdaq: SUPN), a biopharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases, announced today that the U.S. Food and Drug Administration (FDA) has recognized seven years of orphan-drug exclusive approval for ONAPGO (apomorphine HCl) for the treatment of motor fluctuations in adults with advanced Parkinson's disease. ONAPGO is the first and only subcutaneous apomorphine infusion device for the treatment of motor fluctuations in adults with advanced Parkinson's disease.

The seven-year market exclusivity for ONAPGO began on February 3, 2025, the date of FDA approval. The FDA's Orphan Drug Designation program is designed to advance the development of drugs that treat a condition affecting 200,000 or fewer U.S. patients annually.

In addition, the Company submitted a supplemental New Drug Application (sNDA) to the FDA for a second supplier for ONAPGO and continues to expect potential FDA approval of the second supplier by mid-year 2027.

"Securing orphan-drug exclusivity marks an important milestone for individuals and families navigating Parkinson's disease. This designation validates the urgent need for targeted therapies and helps safeguard continued innovation in a long-underserved community," said Jack Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. "In addition to resolving the supply issue from earlier this year, submitting our sNDA further reinforces our ongoing commitment to providing novel treatments for patients with Parkinson's disease, backed by our unwavering focus on ensuring an uninterrupted drug supply for every patient in need."

More information about ONAPGO, including Full Prescribing Information and Medication Guide, is available here: www.onapgo.com.

About Supernus, Inc.

Supernus, Inc. is a biopharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases.

Our diverse neuroscience portfolio includes approved treatments for attention-deficit hyperactivity disorder (ADHD), dyskinesia in Parkinson's disease (PD) patients receiving levodopa-based therapy, hypomobility in PD, postpartum depression (PPD), epilepsy, migraine, cervical dystonia, and chronic sialorrhea. We are developing a broad range of novel product candidates for CNS disorders.

For more information, please visit www.supernus.com.

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 and the products of its subsidiaries; the Company's ability to increase its net revenue from its products and the products of its subsidiaries; the Company's ability to commercialize its products and the products of its subsidiaries; 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 or manufacture ONAPGO at the second supplier; the Company's ability to protect its intellectual property and the intellectual property of its subsidiaries 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, including ONAPGO, 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; changes to laws and regulations applicable to our industry, the impact of macroeconomic factors, such as economic downturns or uncertainty, international conflict, trade disputes and tariffs; 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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