Supernus Announces FDA Approval of Qelbree™ (SPN-812) for the Treatment of ADHD

April 2, 2021

Qelbree (viloxazine extended-release capsules) represents the first novel non-stimulant treatment for ADHD in a decade

Supernus plans to make Qelbree available in the U.S. in 2Q 2021

ROCKVILLE, Md., April 02, 2021 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (Nasdaq: SUPN), a biopharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases, today announced that the U.S. Food and Drug Administration (FDA) approved Qelbree (viloxazine extended-release capsules) for the treatment of attention-deficit hyperactivity disorder (ADHD) in pediatric patients 6 to 17 years of age.

“Based on the efficacy demonstrated in the clinical program, we believe Qelbree offers a unique new alternative for the treatment of ADHD,” said Jack A. Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. “Qelbree provides prescribing physicians and patients living with ADHD a therapy that is not a controlled substance with proven efficacy and a tolerable safety profile. We are grateful to the patients, families and their care givers who participated in and supported our research.”

“ADHD is one of the most common mental health issues in the U.S.,” said Andrew J. Cutler, M.D., Clinical Associate Professor of Psychiatry at SUNY Upstate Medical University, and Chief Medical Officer, Neuroscience Education Institute. “The right treatment is key for children and adolescents, as they grow and navigate school and social relationships. This approval offers a novel once a day sprinkleable non-stimulant that can be a great option for children and adolescents with ADHD.”

The approval of Qelbree is supported by data from an extensive development program consisting of four Phase III clinical trials that studied more than 1000 pediatric patients from the age of 6 to 17 years. In December 2020, the Company announced positive results from a Phase III trial in adult patients with ADHD and plans to submit a supplemental New Drug Application to the FDA for Qelbree in adults in the second half of 2021.

IMPORTANT SAFETY INFORMATION

Qelbree may increase suicidal thoughts and actions in some children with ADHD, especially within the first few months of treatment or when the dose is changed. Pay close attention to any new or sudden changes in mood, behavior, thoughts, and feelings. Call your child’s doctor right away if there are any new or sudden changes, or if there is development of suicidal thoughts or actions. Qelbree should not be taken by patients that also take certain anti-depression medicines, especially those called a monoamine oxidase inhibitor or MAOI, or certain asthma medicines.

Please see full Prescribing Information, including Boxed Warning, for Qelbree.

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals 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 epilepsy, migraine, attention-deficit hyperactivity disorder (ADHD), hypomobility in Parkinson’s disease, cervical dystonia and chronic sialorrhea. We are developing a broad range of novel CNS product candidates including new potential treatments for hypomobility in Parkinson’s disease, epilepsy, depression, and rare 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; the Company’s ability to increase its net revenue; the Company’s ability to commercialize its products including Qelbree; 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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