Supernus Announces Qelbree™ sNDA for Adult Indication Accepted for Review by FDA

September 2, 2021

ROCKVILLE, Md., Sept. 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) has acknowledged it has received the supplemental new drug application (sNDA) for Qelbree (viloxazine extended-release capsules) for the treatment of attention-deficit hyperactivity disorder (ADHD) in adult patients. The sNDA is now considered filed, with a user fee goal date (PDUFA date) of April 29, 2022.

In December 2020, Supernus announced positive topline results from a Phase III study of Qelbree in adults for the treatment of attention deficit hyperactivity disorder (ADHD). The results showed that at a daily dose of up to 600mg, the trial met the primary endpoint with robust statistical significance (p=0.0040) compared to placebo in improving the symptoms of ADHD from baseline to end of study as measured by ADHD Investigator Symptom Rating Scale. In addition to meeting the primary efficacy endpoint, the Phase III study met the key secondary efficacy endpoint with statistical significance (p=0.0023) in the change from baseline of the Clinical Global Impression – Severity of Illness Scale at week 6. The active dose was well tolerated.

Qelbree was approved in the U.S. in April 2021 for the treatment of ADHD in pediatric patients 6 to 17 years of age.

Jack Khattar, President and CEO of Supernus, said, “We look forward to making Qelbree available to adult patients, if approved by the FDA. Approximately 10 million adults in the U.S. have ADHD, and every adult who has ADHD had it as a child. Adults with ADHD often cope with difficulties at school, at work, and in their personal and family lives.”

Mr. Khattar continued, “We are currently focused on Qelbree’s launch in the pediatric market and on providing physicians, parents and patients with a new ADHD treatment that is not a controlled substance with proven efficacy and a tolerable safety profile.”

IMPORTANT SAFETY INFORMATION

Qelbree (viloxazine extended-release capsules) 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, 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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