Supernus Announces FDA Approval of Qelbree® for the Treatment of ADHD in Adults

April 30, 2022

- ***First novel, nonstimulant option for adults with ADHD in 20 years***
- ***ADHD affects an estimated 10 million adults in the U.S.***

ROCKVILLE, Md., April 29, 2022 (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, announced today that the U.S. Food and Drug Administration (FDA) approved an expanded indication for Qelbree (viloxazine extended-release capsules) for the treatment of attention deficit hyperactivity disorder (ADHD) in adult patients aged 18 and older. The FDA has now approved Qelbree for the treatment of ADHD in children (starting at age 6), adolescents and adults.

Approximately 16 million children, adolescents, and adults have ADHD in the U.S. While many children with ADHD outgrow it, up to 90% of those diagnosed with ADHD in childhood continue to have ADHD as adults.

"Until today, nonstimulant ADHD options for adults have been very limited," said Greg Mattingly, M.D, founding partner of St. Charles Psychiatric Associates in St. Louis, Mo. "This approval is positive news and offers a new novel option for the millions of American adults who are trying to find the right treatment to manage their ADHD symptoms."

Qelbree is a novel nonstimulant taken once-daily for full-day exposure. Efficacy and symptom improvement was observed early in treatment. It has a proven safety and tolerability profile, with no evidence of abuse potential in clinical studies. The approval is based on positive results from a randomized, double blind, placebo-controlled Phase III study of Qelbree in adults with ADHD and represents the first approval of a novel nonstimulant treatment for adults in 20 years.

"As a leader in the field of CNS, we are fully committed to better understanding how to treat complex diseases such as ADHD," said Jack Khattar, President and CEO of Supernus Pharmaceuticals. "Today's approval marks a major advancement in the treatment of ADHD and is an important milestone just one year after the approval of Qelbree to treat pediatric patients. We are proud to bring a new novel nonstimulant option for adults into the market after two decades."

At a daily flexible-dose between 200mg to 600mg, the Phase III trial met the primary endpoint showing the reduction in the change from baseline of the Adult ADHD Investigator Symptom Rating Scale (AISRS) total score at end of study was statistically significantly greater in adults treated with Qelbree versus placebo (p=0.0040). Significant improvement in AISRS subscale scores of inattention and hyperactivity/impulsivity symptoms were also observed in the study[1]. Moreover, the 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 (CGI-S) Scale at week 6. The active dose was well tolerated. Please see additional Important Safety Information included below.

IMPORTANT SAFETY INFORMATION

Qelbree may increase suicidal thoughts and actions, in children and adults with ADHD, especially within the first few months of treatment or when the dose is changed. Tell your doctor if you have (or if there is a family history of) suicidal thoughts or actions before starting Qelbree. Monitor your moods, behaviors, thoughts, and feelings during treatment with Qelbree. Report any new or sudden changes in these symptoms right away. 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 (PD), cervical dystonia, chronic sialorrhea, dyskinesia in PD patients receiving levodopa-based therapy, and drug-induced extrapyramidal reactions in adult patients. We are developing a broad range of novel CNS product candidates including new potential treatments for hypomobility in PD, epilepsy, depression, and other 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.

CONTACTS:

Jack A. Khattar, President and CEO
Timothy C. Dec, Senior Vice President and CFO
Supernus Pharmaceuticals, Inc.
Tel: (301) 838-2591

or

INVESTOR CONTACT:
Peter Vozzo
ICR Westwicke
Office: (443) 213-0505
Mobile: (443) 377-4767
Email: peter.vozzo@westwicke.com

[1] Qelbree was studied in 4 clinical trials. In one study of children 6 to 11 years of age, ADHD symptom score reductions were statistically significant for 100 mg and 200 mg doses, beginning at week 1. In the study of adolescents 12 to 17 years of age, ADHD symptom score reductions were statistically significant for 400mg, beginning at week 2. In the flexible-dose study of adults 18 to 65 years of age, ADHD symptom score reductions were statistically significant in the Qelbree patients, beginning at week 2.

Source: Supernus Pharmaceuticals, Inc.