Supernus Announces New Qelbree® Data Showing Improvement in ADHD Symptoms

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- **Topline results from Phase IV study demonstrate Qelbree is safe and well-tolerated, and significantly improved efficacy outcomes when added to a stimulant medication in pediatric patients with ADHD**

- **Final long-term data show Qelbree consistently improved symptoms and executive function in adults with ADHD, with safety and tolerability similar to the short-term pivotal adult Phase III trial**

ROCKVILLE, Md., Sept. 09, 2023 (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, announces the presentation of two posters at Psych Congress 2023 with new data showing improved efficacy in children ages 6 years and older with ADHD when Qelbree is added to a stimulant, as well as in adults with ADHD who undergo long-term treatment with Qelbree.

"While ADHD is recognized as one of the most common psychiatric diagnoses, affecting approximately 16.1 million individuals in the United States, patients are in need of alternative or additional options to stimulants that allow them to manage their symptoms with a safe and tolerable treatment option," says Jonathan Rubin, Chief Medical Officer and Senior Vice President of Research & Development. "The new Qelbree data presented during Psych Congress 2023 reinforce the efficacy and safety of our novel nonstimulant treatment in addition to existing stimulant therapy in children ages 6 and older with ADHD and in a long-term setting in adults with ADHD."

Results from Phase IV Safety Trial of Concomitant Use with Psychostimulants in Children and Adolescents with ADHD

When added to existing psychostimulants, Qelbree demonstrated a favorable safety and tolerability profile as well as a significant improvement in ADHD symptoms in pediatric patients (6-17 years), regardless of timing of dosing.

In an eight-week, Phase IV, open-label study, children (ages 6-11) and adolescents (ages 12-17) took psychostimulants at least five days a week in the morning throughout the duration of the study, and received Qelbree once-daily in the morning through week four and then switched to evening dosing through week eight; children received 100mg per day of Qelbree at week one and were optimized to 100-400mg per day, and adolescents received 200mg per day of Qelbree at week one and were optimized to 200-600mg per day.

Results showed significant symptom improvement from baseline ADHD-RS-5 and CGI-S scores following both morning and evening dosing of Qelbree in combination with the morning psychostimulant. At baseline (N=56), mean (standard deviation) ADHD-RS-5 and CGI-S scores were 37.2 (8.35) and 4.4 (0.56), respectively, and improved at week four (N=54) by -13.5 (9.7) and -0.9 (0.92), respectively, and at week eight (N=48) by -18.2 (9.99) and -1.4 (1.10), respectively. Reported adverse events (AEs) of the combination therapy included headache (17.9%), decreased appetite (12.5%), and upper respiratory tract infection (10.7%), and 3.6% of patients discontinued the combination treatment due to an AE.

"Approximately 10%-30% of individuals living with ADHD experience inadequate response or have difficulty tolerating stimulant medications, which indicates a clear need for alternative or additional treatment options," says Ann Childress, M.D., President of the Center for Psychiatry and Behavioral Medicine in Las Vegas, NV. "These data demonstrate Qelbree's ability to enhance efficacy when co-administered with stimulants, including significant improvement during evening hours when the effects of stimulants often wear off following their morning dose. This study illustrates the versatility of Qelbree to address patient needs, including standalone usage and combination therapy, regardless of dosing time."

Final Results from Long-term, Phase III, Open-label Extension Trial in Adults with ADHD

Conclusive outcomes from a long-term, open-label extension (OLE) trial of the double-blind pivotal Phase III study that led to the U.S. Food and Administration (FDA)-approval of Qelbree in adults with ADHD, found that adult patients (N=159) saw an improvement in ADHD symptoms and executive function with safety and tolerability similar to the initial trial.

Adults received 200mg of Qelbree every day for one week, increased to 400mg, and then optimized over twelve weeks up to 600mg per day (200-600mg per day). Patients in this open-label trial received Qelbree for 265 (254.9) days.

Patients ADHD symptoms improved from 37.9 (6.34) to 19.7 (12.16) on the Adult ADHD Investigator Symptom Rating Scale (AISRS), representing average symptom reduction of -18.2 (11.54). Patients executive function improved from 70.4 (10.94) to 58.3 (16.19) on the BRIEF-A Global Executive Composite scale, representing improvement in executive function of -12.9 (13.48). The treatment related adverse events (TRAEs) seen in this long-term trial were consistent with those seen in the short-term pivotal adult trial. The most commonly occurring TRAEs reported with the use of Qelbree were insomnia (11.3%), nausea (9.4%), headache (5.7%), and fatigue (10.1%). AEs led to discontinuation in 17.6% of patients.

"ADHD is a 24/7 disorder that often persists into adulthood, and it can be difficult to find the right treatment regimen," says Andrew J. Cutler, M.D., Clinical Associate Professor of Psychiatry at SUNY Upstate Medical University, and Chief Medical Officer, Neuroscience Education Institute. "These data are encouraging as they underscore the compelling advantage of long-term medication adherence and benefits with Qelbree for our ADHD patients, including sustained improvement in ADHD symptoms, robust response, reduced severity and improved executive function."

INDICATION

Qelbree® (viloxazine extended-release capsules) is a prescription medicine used to treat ADHD in adults and children 6 years and older.

IMPORTANT SAFETY INFORMATION ABOUT QELBREE

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 or your child have (or if there is a family history of) suicidal thoughts or actions before starting Qelbree. Monitor your or your child's moods, behaviors, thoughts, and feelings during treatment with Qelbree. Report any new or sudden changes in these symptoms right away.

You should not take Qelbree if you or your child:
Take a medicine for depression called a monoamine oxidase inhibitor (MAOI) or have stopped taking an MAOI in the past 14 days. Also, you or your child should avoid alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, and theophylline.

Qelbree can increase blood pressure and heart rate. Your or your child's doctor will monitor these vital signs.

Qelbree may cause manic episodes in patients with bipolar disorder. Tell your doctor if you or your child show any signs of mania.

Do not drive or operate heavy machinery until you know how Qelbree will affect you or your child. Qelbree may cause you or your child to feel sleepy or tired.

The most common side effects of Qelbree in patients 6 to 17 years are sleepiness, not feeling hungry, feeling tired, nausea, vomiting, trouble sleeping, and irritability, and in adults, insomnia, headache, sleepiness, tiredness, nausea, decreased appetite, dry mouth, and constipation. These are not all the possible side effects of Qelbree.

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

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.

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