Supernus Announces Label Update for Non-Stimulant ADHD Treatment, Qelbree®, Including New Pharmacodynamic Data and Information for Breastfeeding Women

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- **Updated label includes new data in Section 12.2, detailing serotonin 5-HT2C partial agonist activity and norepinephrine transporter inhibition, highlighting Qelbree's multimodal pharmacodynamics**
- **Qelbree is the first ADHD treatment to meet its post marketing requirement and receive labeling approval following the 2019 FDA guidance on Clinical Lactation Studies[1]**

ROCKVILLE, Md., Jan. 27, 2025 (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 that the U.S. Food and Drug Administration (FDA) has approved an update for the label for Qelbree (viloxazine extended-release capsules) to include new pharmacodynamic data in Section 12.2. The updated label describes viloxazine's partial agonist activity at the serotonin 5-HT2C receptor and inhibition of the norepinephrine transporter, reinforcing its multimodal pharmacodynamic profile. The mechanism of action of Qelbree, though unclear, is thought to be through inhibiting the reuptake of norepinephrine. Additionally, the updated label now includes new lactation data for breastfeeding women with attention-deficit/hyperactivity disorder (ADHD), showing that the transfer of Qelbree into breastmilk is low. Qelbree is approved for use in patients ages 6 years and older with ADHD.

"This label update and new data deepens our understanding of Qelbree, providing valuable insights to help support treatment decision-making for people living with ADHD," says Dr. Stephen M. Stahl, M.D., PhD, DSc (Hon.) Distinguished Health Sciences Clinical Professor of Psychiatry and Neuroscience, University of California Riverside and Adjunct Professor of Psychiatry, University of California San Diego. "The updated pharmacodynamic data, which highlights viloxazine's effects on the serotonin 5-HT2C receptor and inhibition of the norepinephrine transporter, adds depth to our understanding of Qelbree's multimodal pharmacodynamics."

The update to include lactation data in the label (Section 8.2) follows the 2019 FDA guidance suggesting lactation studies be conducted to inform breastfeeding with drug use recommendations and is based on a study involving 15 healthy lactating women.[1] The study evaluated the secretion of viloxazine and its metabolite (5-HVLX-gluc) into breast milk following a multi-dose (600 mg daily for three days) regimen of viloxazine. Results showed that the estimated daily infant dose (using a nominal infant body weight of 6 kg) of viloxazine and 5-HVLX-gluc was 0.085 mg/kg and 0.00595 mg/kg, respectively, and the relative infant dose was approximately 1% and 0.07%, respectively, of the weight-normalized maternal daily dose (8.58 mg/kg) of viloxazine. These data support that the transfer of viloxazine into breastmilk is low. The study did not specifically evaluate the effects of viloxazine on breastfed infants or milk production, nor is there additional data regarding these effects. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Qelbree and any potential adverse effects on the breastfed child from Qelbree or from the underlying maternal condition.

"By expanding Qelbree's label to include new data on the pharmacodynamics and use in breastfeeding mothers, Supernus continues to empower healthcare providers and patients to make informed treatment decisions," says Jack A. Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. "We are committed to building the body of evidence surrounding Qelbree's use within the ADHD space and providing an effective treatment option for those living with ADHD."

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

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 or your child 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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

[1]U.S. Food and Drug Administration. (2019). Clinical Lactation Studies: Considerations for Study Design. Guidance for Industry. Retrieved from https://www.fda.gov/media/124749/download.

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 attention-deficit hyperactivity disorder (ADHD), dyskinesia in Parkinson's Disease (PD) patients receiving levodopa-based therapy, hypomobility in PD, epilepsy, migraine, cervical dystonia, and chronic sialorrhea. 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 reporting on preliminary and exploratory open label clinical study on SPN-820, 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 net revenue; 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 ability to conduct and progress 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 including SPN-820 and SPN-830; 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 including SPN-820; 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 including SPN-820; 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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