# Supernus Celebrates Five-Year Anniversary of Qelbree® FDA Approval, Continuing to Deliver on Real-World Experience in ADHD

July 14, 2026

- Qelbree remains the first novel, non-stimulant ADHD medication approved in over a decade and is the only ADHD treatment with serotonin (5-$HT_{2C}$) pharmacodynamics approved in its FDA product labeling.
- Qelbree has provided convenient 24-hour medication exposure for patients with ADHD ages 6 years and older, with approximately 3 million prescriptions filled since launch.
- As a non-controlled treatment option, Qelbree has no evidence of abuse potential and is supported by years of clinical and real-world data.

ROCKVILLE, Md., July 14, 2026 (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, celebrates the five-year anniversary of the U.S. Food and Drug Administration (FDA) approval of Qelbree (viloxazine extended-release capsules) for attention-deficit/hyperactivity disorder (ADHD). Since its initial approval for pediatric (6 to 17 years) ADHD in April 2021, and subsequent approval for adults in April 2022, Qelbree has served as a valuable option for the nearly 16 million adults and 7 million children and teens living with ADHD in the U.S.,[1,2] showcasing Supernus' 25+ year legacy in ADHD research.

Five years after its market introduction, Qelbree offers a once-a-day, non-stimulant option that has been widely adopted in ADHD treatment plans, with approximately 3 million total prescriptions filled since launch and over 1 million prescriptions filled in 2025 alone. Qelbree has given healthcare providers an alternative, backed by clinical and real-world data, for those seeking non-stimulant approaches for help managing ADHD symptoms.

First approved by the FDA for ADHD in pediatric patients 6 to 17 years old, Qelbree was the first novel, non-stimulant approach in ADHD in over a decade. With no evidence of abuse potential, 24-hour exposure, and versatile administration options – including the ability to be sprinkled and to be taken at any time of day – Qelbree offers added flexibility for patients.

Recognizing the evolving understanding of ADHD, with 90% of children continuing to have symptoms into adulthood,[3] Supernus secured an expanded indication from the FDA in April 2022 for the treatment of ADHD in adults aged 18 years and older, marking the first non-stimulant treatment option for adults in two decades.

The FDA approved labeling updates for Qelbree in January 2025 to include additional pharmacodynamic data. Today, Qelbree stands out as the first and only non-stimulant ADHD treatment with a multimodal pharmacodynamic profile, meaning it influences important chemical messengers in the brain in different ways. Qelbree takes a differentiated approach by helping to increase norepinephrine and also acting as a partial agonist at the serotonin (5-$HT_{2C}$) receptor.

This January 2025 labeling update also included lactation data for breastfeeding women, making Qelbree the first ADHD treatment to meet this post marketing requirement and receive labeling approval following the 2019 FDA guidance on Clinical Lactation Studies.

"ADHD care is ever-changing, but one thing remains constant: the need for flexible treatment options that enable healthcare providers and patients to make truly tailored decisions. For the past five years, Qelbree has delivered on this need, standing as a trusted choice for many," said Jack A. Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. "ADHD can present differently throughout a person's life – from childhood through adulthood. Our focus has been on delivering a versatile treatment option with demonstrated safety and efficacy that can be used in real-world clinical practice."

"This five-year milestone is a testament to the data, but also to the dedication of the whole Supernus team, whose continued hard work has helped make it possible," he concluded.

Supernus continues to expand its support for the ADHD community through initiatives designed to empower and provide resources for those living with and impacted by ADHD. Recent campaigns like *You, Me & Qelbree* and *Ms. Represented* aim to share real-life experiences of patients, educate on the different ways symptoms can present (especially in men versus women), and highlight the important role that support systems such as friends and loved ones play in management. For more information, visit www.qelbree.com.

**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.**

Qelbree (viloxazine extended-release capsules) is available in 100 mg, 150 mg and 200 mg capsules.

**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, postpartum depression (PPD), epilepsy, migraine, cervical dystonia, and chronic sialorrhea. We are developing a broad range of novel product candidates for 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, and the products of its subsidiaries; the Company's ability to increase its net revenue from its products, and the products of its subsidiaries; 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 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 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; 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; changes to laws and regulations applicable to our industry, the impact of macroeconomic factors, such as economic downturns or uncertainty, international conflict, trade disputes and tariffs; 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.


1. Centers for Disease Control and Prevention (CDC). ADHD in Adults: An Overview. October 8, 2024. https://www.cdc.gov/adhd/articles/adhd-across-the-lifetime.html
2. CDC. Data and Statistics on ADHD. November 19, 2024. https://www.cdc.gov/adhd/data/index.html
3. Sibley, M. et al. American Journal of Psychiatry. February 2022. https://psychiatryonline.org/journal/ajp


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