assessments included the ADHD Rating Scale, 4th (Phase 2) or 5th (Phase 3) Edition (ADHD-RS-IV/5), and the Clinical Global Impression-Improvement (CGI-I) scale. Efficacy was assessed relative to DB baseline at study visits ˜ 3 months apart. Two response measures, 50% improvement in ADHD-RS-IV/5 Total score and CGI-I score of 1-2, were also evaluated.

**Results.** 1100 individuals (646 children; 454 adolescents; 66.5% male/33.5% female) received treatment. Median (range) exposure to viloxazine ER was 260 (1 to 1896) days. AEs were reported by 57.3% participants, most commonly (≥5%) nasopharyngitis (9.7%), somnolence (9.5%), headache (8.9%) decreased appetite (6.0%), and fatigue (5.7%). AEs were mostly mild or moderate in severity (3.9% reported any severe AE); AEs led to viloxazine ER discontinuation for 8.2%. The mean (SD) changes from DB baseline in ADHD-RS IV/5 Total score were -17.0 (14.18) (viloxazine ER) and -11.2 (13.19) (placebo) at the last DB study visit, 24.3 (11.96) at OLE Month 3, and 22.4 (13.62) at participants' last OLE study visit. ADHD-RS-IV/5 and CGI-I responder rates each exceeded 65% at all OLE visits following Dose-Optimization.

**Conclusions.** The safety and efficacy of viloxazine ER were maintained with long-term use in children and adolescents with ADHD. No new safety concerns emerged, and efficacy results suggested potential for continued improvement over that seen during DB treatment.

**Funding.** Supernus Pharmaceuticals, Inc.

# Diagnosis and Treatment of Tardive Dyskinesia: Online Medical Education Improves Psychiatrists Knowledge, Competence, and Confidence

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**Objectives.** This study examined whether online continuing medical education (CME) could improve the knowledge, competence, confidence of psychiatrists regarding the diagnosis and management of tardive dyskinesia (TD).

**Methods.** Psychiatrists participated in a 30-minute online video-based lecture presented by an expert faculty. Educational effect was assessed using a repeated-pair design with pre-/post-assessment. 3 multiple choice questions assessed knowledge, and 1 question rated on a Likert-type scale assessed confidence. A paired samples t-test was conducted for significance testing on overall average number of correct responses and for confidence rating, and a McNemar's test was conducted at the question level (5% significance level, $P$ <.05). Data were collected from 4/14/2022 to 7/8/2022.

**Results.** Psychiatrists (n=579) showed significant improvements in overall knowledge and competence (P<.001) as well as confidence.

- There was a 9% relative improvement in knowledge among psychiatrists regarding the factors that differentiate TD from other motor symptoms associated with antipsychotic use
- There was a 18% relative improvement in competence among psychiatrists regarding the selection of appropriate pharmacotherapy for TD
- 38% of psychiatrists had measurable increases in confidence to diagnose and treat TD

**Conclusions.** This study demonstrated the success of online, video-based lecture CME on improving knowledge, competence, and confidence related to the diagnosis and management of TD. These findings suggest the benefits of education that addresses clinicians' individual needs across the continuum of their professional development.

**Funding.** Medscape Education, Neurocrine Biosciences

# Impact of a Virtual Patient Simulation on Clinical Decision Making for Pediatric Patients with ADHD

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**Objectives.** Attention-deficit/hyperactivity disorder (ADHD) is a common childhood disorder that can persist into adulthood in up to two-thirds of patients. ADHD is a heterogeneous disease, with a wide spectrum of symptoms and severity. Thus, ADHD presents diagnostic and treatment challenges for clinicians. This study utilized an online, virtual patient simulation (VPS)-based continuing medical education intervention to improve the ability of psychiatrists to diagnose, assess, and treat pediatric patients with ADHD.

**Methods.** A cohort of US-practicing psychiatrists who participated in the simulation-based education was evaluated. The simulation consisted of 2 patient cases that allowed learners to order lab tests, make diagnoses, and prescribe treatments in a manner matching the scope and depth of actual practice. Tailored clinical guidance (CG), based on current evidence and expert recommendation, was provided following each decision, followed by the opportunity for the learner to modify their decisions. Decisions were collected post-CG and compared with each user's baseline (pre-CG) decisions using a McNemar's test to determine P values (5% significance level, $P < 0.05$). Data were collected from February 2022 through May 2022.

**Results.** The assessment sample consisted of psychiatrists (n=420 for case 1, n=358 for case 2) who made clinical decisions within the simulation and proceeded to the concluding debrief section. As a result of clinical guidance provided through simulation,

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significant improvements ($P<0.001$) were observed in several areas of clinical care:

- Assessing symptoms of ADHD using evidence-based tools/scales (70% relative improvement case 1; 100% relative improvement case 2)
- Diagnosing ADHD and comorbidities across ages (162% relative improvement case 1; 370% relative improvement case 2))
- Ordering evidence-based treatments for ADHD based on individual patient presentation (71% relative improvement case 1; 53% relative improvement case 2)

**Conclusion.** VPS that immerses and engages specialists in an authentic, patient-based, practical learning environment can significantly improve evidence-based clinical decision making for the assessment and appropriate management of patients with ADHD to improve patient outcomes.

**Funding.** Medscape Education, Supernus

# Zuranolone Safety and Tolerability in Adults with Postpartum Depression: Analyses from SKYLARK, a 50 mg Placebo-Controlled Study

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**Background.** Zuranolone is an investigational positive allosteric modulator of synaptic and extrasynaptic $GABA_A$ receptors and a neuroactive steroid in clinical development as a once-daily, oral, 14-day treatment course for adults with major depressive disorder or postpartum depression (PPD). The randomized, double-blind, placebo-controlled SKYLARK Study (NCT04442503) demonstrated that zuranolone 50 mg significantly improved depressive symptoms (as assessed by 17-item Hamilton Rating Scale for Depression total score) at Day 15 (primary endpoint; $p<0.001$) and was generally well tolerated in adults with PPD.

**Methods.** In the SKYLARK Study, patients were randomized 1:1 to receive zuranolone 50 mg or placebo for 14 days. Safety and tolerability were assessed by the incidence and severity of treatment-emergent adverse events (TEAEs), rates of dose reduction and treatment discontinuation, as well as weight gain and sexual dysfunction.

**Results.** The SKYLARK Study assessed safety data from 98 patients treated with zuranolone 50 mg and 98 patients treated with placebo. TEAEs were reported in 66.3% of zuranolone-treated patients and 53.1% of placebo-treated patients. In patients that experienced TEAEs, most reported mild (zuranolone, 50.8%; placebo, 75%) or moderate (zuranolone, 44.6%; placebo, 23.1%) events. The most common (≥5%) TEAEs were somnolence (26.5%), dizziness (13.3%), sedation (11.2%), headache (9.2%), diarrhea (6.1%), nausea (5.1%), urinary tract infection (5.1%), and COVID-19 (5.1%) with zuranolone, and headache (13.3%), dizziness (10.2%), nausea (6.1%), and somnolence (5.1%) with placebo. Dose reduction due to TEAEs was 16.3% in patients receiving zuranolone vs 1.0% in patients receiving placebo; the most common TEAEs (>1 patient) leading to zuranolone dose reduction were somnolence (7.1%), dizziness (6.1%), and sedation (3.1%). Treatment discontinuation due to TEAEs was 4.1% in patients receiving zuranolone vs 2.0% in patients receiving placebo; TEAEs leading to zuranolone discontinuation in >1 patient included somnolence (2.0%). Serious TEAEs were reported in 2.0% of zuranolone-treated and 0% of placebo-treated patients; these included upper abdominal pain (1.0%, [1/98]), peripheral edema (1.0%, [1/98]), perinatal depression (1.0%, [1/98]), and hypertension (1.0%, [1/98]). Per investigators, serious TEAEs were not related to zuranolone. No signals for weight gain or sexual dysfunction were identified.

**Conclusions.** In adults with PPD, zuranolone 50 mg was generally well tolerated. Most TEAEs were mild or moderate in severity. Dose reduction due to TEAEs mainly resulted from somnolence, dizziness, and sedation, while treatment discontinuation due to TEAEs was low. No signals for weight gain or sexual dysfunction were identified.

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# Long-term Safety, Tolerability, and Effectiveness of TV-46000, a Long-Acting Subcutaneous Antipsychotic (LASCA), in Patients With Schizophrenia (SHINE)

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