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.
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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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Introduction. In RISE, TV46000 once monthly (q1m) or once every 2 months (q2m) significantly extended time to impending schizophrenia relapse. The current study (SHINE, NCT03893825) evaluated the long-term safety, tolerability, and effect of TV46000.
Methods. Patients completing RISE without relapse (rollover) or newly recruited (de novo) were eligible. The de novo and placebo rollover cohorts were randomized 1:1 to q1m or q2m for ≤56 weeks; the TV46000 rollover cohort continued assigned regimen. Exploratory efficacy endpoints included time to impending relapse and patient centered outcomes (PCOs) including Schizophrenia Quality of Life Scale (SQLS).
Results. 334 patients were randomized and received TV46000 q1m (n=172) or q2m (n=162), for 202.3 patient-years [PY] of TV-46000 treatment. Treatment-emergent adverse events (AEs) reported for ≥5% of patients were: overall–injection site pain (event rate/100 PY, n [%]; 23.23, 16 [5%]); de novo (n=109)–injection site pain (56.10, 11 [10%]), injection site nodule (16.03, 6 [6%]), blood creatine phosphokinase increased (16.03, 8 [7%]), urinary tract infection (10.69, 7 [6%]); placebo rollover (n=53)–tremor (18.50, 5 [9%]); TV46000 rollover (n=172)–headache (7.97, n=8 [5%]). Serious AEs reported for ≥2 patients were worsening schizophrenia and hyperglycemia. Kaplan– Meier estimates for remaining relapse-free at week 56 were 0.98 (2% risk; q1m) and 0.88 (12%; q2m). SQLS improved for q1m (least-squares mean change [SE], − 2.16 [0.98]) and q2m (− 0.43 [0.98]); other PCOs (5Level EuroQoL 5Dimensions Questionnaire, Personal and Social Performance Scale, Drug Attitudes Inventory 10-item version) remained stable.
Conclusions. TV-46000 had a favorable long-term benefit–risk profile in patients with schizophrenia.
Funding. Teva Branded Pharmaceutical Products R&D Inc.
Study Registration Number: NCT03893825

Attitudes DriVing Regional Differences in LAI ANtipsychotic Utilization for Schizophrenia Among HCPs, Patients, and CaregivErs (ADVANCE): Social Listening Assessment

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Introduction. The prevalence of schizophrenia is relatively low, yet increasing globally, and the disorder imparts a substantial burden of disease on both individuals and health systems. With regard to schizophrenia treatments, including long-acting injectable antipsychotics (LAIs), social media listening provides a unique source of insight into the experiences and perceptions of healthcare professionals (HCPs), patients, and caregivers who live with and manage this disorder daily.
Objective. To gain insight into HCP and patient/caregiver perceptions of LAIs for the treatment of schizophrenia.
Methods. Publicly available online conversations in global English about LAIs for schizophrenia from May 2, 2022, to May 2, 2023, were analyzed. Posts were collected using customized search strings from social media analysis tools, including Talkwalker and Meltwater. Online forums, such as Reddit, were the main source for patient/caregiver conversations. Conversations among HCPs were examined using publicly available posts from Twitter about schizophrenia/LAIs. Random samples of posts on forums (100) and Twitter (100) were coded for primary topic, author type (patient, caregiver, or HCP), sentiment toward LAIs, and signs of LAI hesitancy. Additional topics in posts, such as barriers and benefits to LAI use, were also examined.
Results. In the analyzed samples, some differences were observed between patients/caregivers (mostly patients) and HCPs (mostly psychiatrists) in lexicon, focus, and perspective. The most common terms for LAIs among patients/caregivers were “injection” or “shot,” while HCPs used the terms “LAIs” or “injectables.” The most frequent primary topic among patients/caregivers was treatment regimen, including impact of symptoms and side effects on quality of life. HCPs focused on drug efficacy, including broader health outcomes such as relapse, hospitalization, adherence, and mortality. Patients/caregivers expressed fewer positive sentiments (11% of posts) and more negative sentiments (35%) than HCPs (34% positive, 14% negative). Both groups noted reduced relapse

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