supplements without experiencing symptoms of overdose. This may include burning sensation of the mouth or stomach, flatulence, nausea/vomiting, diarrhea, thrombocytopenia, and anaphylaxis [Bayan 2014]. The efficacy of garlic for treatment of true parasitosis is unknown, but can be found in common practice especially those who practice naturopathic medicine. In this case, it is unlikely to have a positive effect, especially when delusional in nature. The use of homeopathic medication in those with true parasitosis and delusional parasitosis should be queried.

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5
Clinical Evaluation of the Abuse Potential of Buprenorphine/Samidorphan Combination

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ABSTRACT: Introduction: Buprenorphine (BUP)/samidorphan (SAM) combination is an opioid system modulator being investigated as an adjunctive treatment for major depressive disorder (MDD). BUP/SAM is a fixed-dose combination of BUP, a partial μ-opioid receptor agonist and κ-opioid receptor antagonist, and SAM, a μ-opioid receptor antagonist added to address the abuse and dependence potential of BUP.[1,2]

STUDY OBJECTIVE: We assessed the effects of SAM on the abuse potential of BUP in the BUP/SAM combination in two ways: (1) a human abuse potential (HAP) study in volunteers; and (2) an evaluation of the clinical experience across studies of patients with MDD.

METHODS: Study 212 (ClinicalTrials.gov ID: NCT02413281) was a HAP study in nondependent, recreational, adult opioid users. Following a qualification period, participants were randomized to 6 treatments in a blinded, crossover design: placebo (PBO), BUP/SAM at the target therapeutic dose (BUP/SAM 2 mg/2 mg), at 8 mg/8 mg and 16 mg/16 mg , and BUP alone (8 mg and 16 mg). The primary endpoint was maximum effect (Emax) for "At The Moment" Drug Liking Visual Analog Scale (VAS).
The clinical program for BUP/SAM included 4 PBO-controlled studies of patients with MDD (n = 961). Pooled safety data were evaluated for adverse events (AEs) that may be associated with abuse, dependence, or withdrawal, as well as for objective signs of withdrawal with the Clinical Opioid Withdrawal Scale (COWS).

RESULTS: In Study 212 (n = 38), Emax Drug Liking VAS scores for the BUP/SAM 2 mg/2 mg dose were similar to those for PBO (median within-subject difference [90% CI]: 2.5 [0.0–9.0]). Emax Drug Liking VAS scores for all BUP/SAM dose groups, including supratherapeutic doses, were significantly lower than those observed for either of the BUP doses. The supratherapeutic doses of BUP/SAM (8 mg/8 mg and 16 mg/16 mg) had higher Emax Drug Liking VAS scores than PBO, but the differences were small.
In the MDD controlled studies, the incidence of euphoria-related AEs was low for BUP/SAM 2 mg/2 mg and PBO (1.6% vs 0.2%, respectively) and there was no evidence of abuse or dependence behavior. Euphoria-related events typically occurred with treatment initiation and resolved with continued treatment. There was minimal evidence of withdrawal by reported AEs or COWS assessment.

CONCLUSIONS: These findings indicate that SAM mitigates the abuse potential of BUP in the BUP/SAM combination.

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6
Presence and Impact of Possible Tardive Dyskinesia in Patients Prescribed Antipsychotics: Results from the RE-KINECT Study

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ABSTRACT: Objective: Tardive dyskinesia (TD) is a hyperkinetic movement disorder associated with antipsychotic treatment. RE KINECT (NCT03062033), a real-world study of outpatients prescribed antipsychotics, was designed to identify the presence of possible TD and characterize the impact of involuntary movements on functioning and quality of life. Data from RE-KINECT were used to compare the impact of possible TD in patients with schizophrenia/schizoaffective disorder [SZD] versus mood/other psychiatric disorders [Mood].

METHODS: Adults with ≥3 months of lifetime exposure to antipsychotics and ≥1 psychiatric disorder were recruited. The presence of possible TD was based on clinicians' observation of involuntary movements in 4 body regions (head, trunk, upper extremities, and lower extremities). Baseline outcomes included demographics, medication history, location/severity of abnormal movements, impact of abnormal movements on daily activities, the Sheehan Disability Scale (SDS), and the EuroQoL 5-Dimensional questionnaire (EQ-5D-5L).

RESULTS: Of 204 patients with clinician-confirmed possible TD, 111 (54.4%) had a SZD diagnosis and 93 (45.6%) had a mood/other psychiatric diagnosis. Significant differences found between groups (Mood vs SZD) included: mean age (56.9 vs 52.7 years; $P = 0.0263$); male sex (33.3% vs 62.2%; $P < 0.0001$); African-American race (7.5% vs 26.1%; $P = 0.0005$); mean lifetime exposure to antipsychotics (9.5 vs 19.5 years; $P < 0.0001$); and percentage of patients currently taking ≥2 psychiatric medications (93.5% vs 79.3%; $P = 0.0093$). Based on clinician observation, there were no significant differences between diagnosis groups in the number of body regions impacted by abnormal movements, maximum severity score across all 4 regions, or patient awareness of possible TD. Over 30% of patients in both groups reported that involuntary movements had "some" or "a lot" of impact on their ability to continue usual activities, be productive, and socialize. No significant differences between the diagnosis groups (Mood vs SZD) were found for mean SDS total score (12.8 vs 10.8), SDS domain scores (work/school [4.1 vs 4.2], social life [4.3 vs 3.7], family life [4.1 vs 3.5]), EQ-5D-5L utility score (0.68 vs 0.74), or EQ-5D-5L health state VAS (64.8 vs 68.5).

CONCLUSIONS: In this cohort of outpatients with possible TD, those with Mood disorders were more likely to be older, female, and white than patients with SZD. The ability to function and quality of life were equally impaired in both groups. Further studies on the impact of TD are needed.
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Phase 3 Randomized, Double-blind, Placebo-Controlled Studies Evaluating Efficacy and Safety of Extended-Release Viloxazine for Pediatric ADHD

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ABSTRACT: Study Objectives: Although stimulants are commonly used for attention-deficit/hyperactivity disorder (ADHD), 10–30% of patients have an inadequate response, adverse events, or comorbidities preventing use. Thus, there is a need for safe, effective nonstimulant options. Extended-release viloxazine (SPN-812), a nonstimulant, is currently in development for the treatment of ADHD in children and adolescents. SPN-812 is a structurally distinct, bicyclic norepinephrine reuptake inhibitor with selective serotonergic activity. Results of the Phase 2 program demonstrated efficacy (improved mean ADHD Rating Scale-IV total score) and safety of SPN-812 in children (6–12 years), as well as an onset of action within 1–2 weeks.

METHOD: Four ongoing Phase 3 randomized, double-blind, placebo-controlled, outpatient, US studies are investigating the efficacy and safety of once-daily SPN-812 for ADHD in children (ages 6–11; 100–400 mg) and adolescents (ages 12–17; 200–600 mg). Two studies are enrolling children and two are enrolling adolescents. Eligible subjects are required to have minimum baseline scores of ≥28 for ADHD-RS-5 and ≥4 for Clinical Global Impression-Severity scale (CGI-S). These studies will randomize ~1200 subjects, with ~800 subjects receiving SPN-812 over a 1–3-week titration and 5-week

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