double-blind, phase 3 ENLIGHTEN−2 study comparing weight gain with OLZ/SAM vs olanzapine were eligible for ENLIGHTEN-2-EXT enrollment. Initial OLZ/SAM doses were based on olanzapine dose (10 or 20 mg) received at the conclusion of ENLIGHTEN-2; subsequent olanzapine dose adjustments were allowed. The samidorphan dose (10 mg) remained fixed throughout. Assessments included adverse events (AEs), weight, waist circumference, metabolic laboratory parameters, and Positive and Negative Syndrome Scale (PANSS) scores. Analyses were based on observed results using descriptive statistics. Baseline was relative to the first OLZ/SAM dose in the extension study.

Results. 265 patients received OLZ/SAM; 167 (63.0%) completed the extension study. Common AEs (= 5%) were weight decreased (n=23; 8.7%), extra dose administered (n=21; 7.9%), headache (n=18; 6.8%), and weight increased (n=16; 6.0%). At week 52, mean (SD) change from baseline for weight and waist circumference was −0.03 (6.216) kg and −0.35 (6.115) cm, respectively. Changes in fasting lipid and glycemic parameters were generally small and remained stable over 52 weeks. PANSS total scores remained stable during the extension.

Conclusions. OLZ/SAM was generally well tolerated over 52 weeks. Weight, waist circumference, metabolic laboratory parameters, and schizophrenia symptoms remained stable throughout the study.

Results. 337 patients were analyzed. The upper quartile of baseline total AIMS score was 14. Subgroups were defined as >14 and ≤14 at baseline, respectively (n=64 vs 273); data are presented at Week 145 (n=40 vs 120). Mean treatment duration was 880.5 and 760.8 days. Mean±SE daily doses were 41.1 ± 1.6mg and 38.9 ± 1.0mg. Mean±SE change from baseline in AIMS score was -11.0 ± 0.8 versus -5.1 ± 0.3; percent change from baseline was $-60.1\%\pm3.6\%$ versus $-55.9\%\pm3.0\%$. More patients with AIMS score >14 had ≥50% AIMS reduction (73% vs 65%). Less patients discontinued (38% vs 51%); reasons included withdrawal by subject (16% vs 25%), adverse event (3% vs 11%), and lost to follow-up (6% vs 7%). Withdrawal due to lack of efficacy was uncommon (5% vs 2%).

Conclusions. Patients with baseline total AIMS score >14 had clinically meaningful reductions in AIMS score, suggesting deutetrabenazine has long-term benefit in these patients.

[†]Dr. Bona died on June 1, 2020. Prior to his passing, Dr. Bona was instrumental in designing the post-hoc analyses described in this abstract and interpreted the interim data results for these analyses; however, he was not able to finalize this abstract.

Deutetrabenazine Reduces Severe Tardive Dyskinesia Movements in a 3-year Open-Label Extension Trial

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Abstract

Background. There are no established treatment guidelines for tardive dyskinesia (TD) based on movement severity. The 12-week ARM-TD and AIM-TD studies in TD patients with baseline Abnormal Involuntary Movement Scale (AIMS) total score (items 1–7) ≥6 showed clinically significant improvements in AIMS score with deutetrabenazine versus placebo. Patients who completed these studies were eligible for the open-label extension (OLE) trial. This post-hoc analysis evaluated deutetrabenazine in TD patients with severe movements.

Methods. Subgroups were defined by upper quartile of baseline total AIMS score (local rating). Endpoints were: change and percent change from baseline in AIMS score, and percent of patients achieving ≥50% AIMS reduction from baseline.

Qualitative Clinical Trial Exit Interviews Evaluating Treatment Benefit, Burden, and Satisfaction in Patients with Schizophrenia

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Abstract

Objective. An open-label extension study (NCT02873208) evaluated the long-term tolerability, safety, and efficacy of combination olanzapine/samidorphan (OLZ/SAM) treatment in patients with schizophrenia. This qualitative sub study explored perceptions of benefit, burden, and satisfaction with previous medications and OLZ/SAM.

Methods. Semi-structured interviews (60 minutes; audio-recorded) were conducted. Interviewer sensitivity training, senior interviewer oversight, and a list of common medications to aid recall supported data collection. Interview transcripts were content coded and analyzed (NVivo v11.0).