analysis (P<0.0001) and 10.2 (2.2) in the revised analysis (P<0.0001). Both analyses yielded comparable results on changes in PANSS Positive and General Psychopathology scales. The revised analysis also revealed a significant treatment effect of RBP-7000 120 mg on PANSS Negative Scale scores vs placebo (P=0.0248) that was not apparent in the original analysis. Conclusions: Similar results were obtained with both analyses, reinforcing the conclusion that RBP-7000 is effective for the treatment of schizophrenia in adults. The revised analysis suggests that RBP-7000 120 mg may be useful in addressing difficult to treat negative symptoms. Funding: Indivior

No. 63

A Combination of Olanzapine and Samidorphan Mitigates Weight Gain Observed With Olanzapine: Results From the Phase 3 ENLIGHTEN-2 Schizophrenia Study

Poster Presenter: Craig Hopkinson
Lead Author: Christoph U. Correll, M.D.
Co-Authors: Rene Kahn, Bernard Silverman, Lauren DiPetrillo, Christine Graham, Ying Jiang, Yangchun Du, Adam Simmons, Peter Weiden, M.D., David McDonnell

SUMMARY:
BACKGROUND: A combination of olanzapine and samidorphan (OLZ/SAM) is in development for the treatment of schizophrenia. SAM is an opioid receptor antagonist intended to mitigate olanzapine-associated weight gain while maintaining the antipsychotic efficacy of olanzapine. The present 24-week (wk), phase 3 study (ENLIGHTEN-2) evaluated weight gain with OLZ/SAM compared with olanzapine alone. METHODS: This was a multicenter, randomized, double-blind study (ClinicalTrials.gov: NCT02694328) in adults with stable schizophrenia suitable for outpatient treatment. Eligible patients (pts) were randomized 1:1 to matching coated bilayer tablets of OLZ/SAM (10/10mg) or olanzapine (10mg) orally once daily. Doses were titrated up to OLZ/SAM 20/10mg or olanzapine 20mg after 1wk (depending on tolerability, dose could be decreased back to OLZ/SAM 10/10 or olanzapine 10mg). After wk 4, doses were fixed for the remainder of the study. Co-primary endpoints were percent change from baseline (BL) in body weight and proportion of pts with >=10% weight gain from BL at wk 24. The key secondary endpoint was the proportion of pts with >=7% weight gain from BL at wk 24. Antipsychotic efficacy was assessed using the Positive and Negative Syndrome Scale (PANSS). Safety and tolerability assessments included adverse events (AEs). RESULTS: Altogether, 561 pts were randomized (OLZ/SAM, n=280; olanzapine, n=281); 550 pts received at least 1 dose of study drug (safety population), 538 of 550 pts had at least 1 post-BL weight assessment (full analysis population), and 352 completed treatment. The most common reason for discontinuation was AEs (10.9%). BL characteristics were generally similar between groups (mean [SD] age, 40.2 [9.90] y; 72.7% male; 71.3% black; mean [SD] BMI, 25.45 [3.158] kg/m2). In the OLZ/SAM and olanzapine groups at BL, mean (SD) weight was 77.00 (13.680) and 77.45 (13.478) kg and PANSS total score was 68.2 (9.51) and 70.2 (9.47) points, respectively. At wk 24, least squares (LS) mean (SE) percent change from BL in body weight was 4.21 (0.681)% vs 6.59 (0.668)% in the OLZ/SAM vs olanzapine groups, respectively (difference: -2.38 [0.765]%; P=0.003). The proportion of pts in the OLZ/SAM and olanzapine groups with >=10% weight gain was 17.8% vs 29.8% (P=0.003), respectively, and with >=7% weight gain was 27.5% vs 42.7% (P=0.001). LS mean (SE) change from BL in PANSS total score was -8.2 (0.73) in the OLZ/SAM group and -9.4 (0.72) in the olanzapine group (P=0.261). The most common AEs reported in >=10% of pts in any treatment group were weight increased, somnolence, dry mouth, and increased appetite. DISCUSSION: In pts treated with OLZ/SAM for 24wks, mean percent weight gain was significantly lower, and significantly fewer pts gained clinically meaningful weight (>=10% and >=7%) vs olanzapine-treated pts. Pts in both treatment groups had similarly improved schizophrenia symptoms. Aside from weight-related AEs, the safety profile of OLZ/SAM was similar to olanzapine.

No. 64

The Impact of Second-Generation Antipsychotic Side Effects on Functioning From a Schizophrenia Patient Perspective: A Global Patient Centered Survey

Poster Presenter: Catherine Weiss

Co-Authors: Stine R. Meehan, William Lenderking, Huda Shalhoub, Jun Chen, Andrea Schulz, Ann Hartry, Mallik Greene, Laëtitia Bouérat Duvold

SUMMARY:
Background: Second-generation antipsychotics (SGAs) used to treat patients with schizophrenia generally have lower risk of motor side effects than first generation antipsychotics, but are associated with other well-known side-effects (SEs). The goal of the study was to understand how specific SEs of SGAs impact daily functioning, emotional well-being, and overall quality of life (QoL) of patients with schizophrenia from their own perspective Methods: This study was a cross-sectional, patient-reported web survey, conducted in the United States (N=180), Canada (N=99), Australia (N=28), and Europe (Italy; Spain; Denmark; Norway: N=128) in 2017-2018. The survey included patient socio-demographics, the Quality of Life Enjoyment and Satisfaction Questionnaire Short Form (Q-LES-Q-SF), and the Glasgow Antipsychotic Side-Effect Scale (GASS). In addition, specific questions about functional and emotional impacts were developed for SEs recognized as being bothersome to patients, such as activating SEs ('Feeling restless/unable to sit still,' 'Shaky hands or arms,' and 'Difficulty sleeping'), sedating SEs ('Feeling sleepy during the day' and 'Feeling drugged/like a zombie'), and metabolic or endocrine SEs ('Weight gain,' 'Problems enjoying sex'). Patients noted on a visual analog scale (VAS) the degree of impact on functioning, 0 indicating 'no impact at all' and 100 indicating the 'largest degree of impact.' Patients with schizophrenia (=18 years old), stable for at least one month, taking an SGA for 1-12 months, and self-reporting at least one SE were included (N=435). Results: The majority of the patients were diagnosed within the last 5 years and nearly half were living with a spouse or partner. Employment rates in different countries ranged from 32.2% to 54.5%. The most prevalent SEs reported on the GASS were 'difficulty sleeping,' 'feeling sleepy during the day' and 'drugged like a zombie.' More than half of the participants stated they have experienced gaining weight. SEs perceived as bothersome by patients were reported to impact patient functioning and emotions. These SEs had at least a moderate to severe impact (defined by a VAS score =50) on all aspects of functioning (physical, psychological, social, and vocational). Activating, sedating, and other SEs investigated showed a low negative correlation with quality of life and satisfaction score indicating worse QoL in participants with higher frequency of SEs. The most common emotions reported by patients with SEs were feeling Frustrated, Ashamed/Embarrassed, and Impatient/Irritated/Angry. Discussion: Findings confirm that stable patients taking SGAs still have many SEs including activating SEs and sedating SEs, sexual SEs, and weight gain. These SEs have considerable negative impact on patient's daily functioning and quality of life satisfaction, including on work, sexual drive and psychosocial effects.

No. 65

Mindfulness-Based Social Cognition Training for Psychosis: A Pilot Study

Poster Presenter: Carmen Bayon
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SUMMARY:
Background: People with schizophrenia tend to perform worse than healthy controls on a variety of social-cognitive tasks, an impairment which is thought to lead to diminished social functioning (Green, Horan & Lee, 2015). Social cognition accounts for an important portion of variance in social functioning (Green et al., 2015) and it is often affected in early stages of psychosis (Healey, Bartholomeusz, & Penn, 2016). Therefore, social cognition and social functioning are core outcomes for any psychiatric or psychological intervention tailor made for psychotic disorders (Warner, 2009). Limited effect of pharmacological strategies have boosted the development of different psychotherapeutic approaches. This research team developed a mindfulness-based social cognition group training (SocialMind) for persons with psychosis. Although there is enough evidence to support the lack of adverse events derived for mindfulness-based interventions specifically designed for psychotic patients (Cramer, Lauche, Haller, Langhorst & Dobos, 2016), many clinicians express their concerns about the beneficial effects of