between these groups. Mean dosage was 352.67 mg/28 days (SD = 0.461), and 38.7% needed an adjustment during the first year of treatment (dosage increased in 76.9%). A combination of two or more antipsychotics was prescribed in 64.5% of the patients. Mean psychiatric number of hospitalizations a year declined from 0.483/year pre-initiation to 0.224/year post-initiation ($P < 0.05$), whereas mean visits a year to the emergency psychiatric service declined from 1.419 pre-initiation to 1.032 post-initiation ($P < 0.1$). No significant changes in weight ($p = 0.82$), systolic ($p = 0.56$) or diastolic ($p = 0.29$) blood pressure were observed. No gender differences in dosage were observed ($p = 0.246$). Suffering from dual disorders had no influence on dosage either ($p = 0.68$).

CONCLUSIONS: LAI aripiprazole initiation appears to provide a benefit decreasing hospitalization needs and emergency services consumption and it was well tolerated. This data supports previous evidence indicating superiority of LAI antipsychotics.

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Long-term Efficacy of Brexpiprazole in Patients with Schizophrenia with Clinically Relevant Levels of Negative Symptoms

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ABSTRACT: Background: Effective treatments for patients with high levels of negative symptoms of schizophrenia are lacking. Brexpiprazole is a serotonin–dopamine activity modulator that is a partial agonist at 5-HT1A and dopamine D2 receptors, and an antagonist at 5-HT2A and noradrenaline alpha1B/2C receptors, all with subnanomolar potency. Long-term treatment with brexpiprazole demonstrated broad efficacy across all five Marder factor groupings, including positive, negative, disorganized thoughts, uncontrolled hostility/excitement, and anxiety/depression. This post-hoc analysis of long-term effects of brexpiprazole in patients with clinically relevant levels of negative symptoms of schizophrenia is based on data from two similarly designed short-term, placebo-controlled studies (Vector; NCT01396421 or Beacon; NCT01393613) for the brexpiprazole-treated patients who continued into an open-label extension study (Zenith; NCT01397786).

METHODS: In the short-term studies, patients with acute schizophrenia were randomly assigned to fixed once-daily doses of brexpiprazole 0.25 mg (Vector), 1 mg (Beacon), 2 mg , 4 mg or placebo for 6 weeks. The long-term study was an open-label, 52-week (amended to 26 weeks), safety extension study with flexible-dose (1–4 mg/day) brexpiprazole. The post-hoc analyses were performed on brexpiprazole-treated patients from the short-term studies who continued into the long-term study, and who had clinically relevant negative symptoms, defined as PANSS Factor Score for Negative Symptoms (PANSS-FSNS; N1, N2, N3, N4, G7, G16) of ≥24, and score of ≥4 on at least two of three core negative symptom PANSS items at randomization in the parent study. The outcome of the analysis included change from baseline to up to 58 weeks in PANSS-FSNS, PANSS Total, and PSP. Safety was also assessed.

RESULTS: A total of 187 patients with clinically relevant levels of negative symptoms in the parent study rolled-over into the open-label extension study and were available for analysis. Eighty-three of these patients remained in the studies for 58 weeks. Due to the study amendment, not all patients had the opportunity of complete 52 weeks of open-label treatment. Baseline PANSS Total score was 104.4, while baseline PANSS-FSNS was 27.6 and baseline PSP Total score was 41.3. Mean change (SD) from baseline in PANSS-FSNS was –10.9 (5.0), and –44.2 (17.5) for PANSS Total score at Week 58. Change from baseline (SD) to Week 58 for PSP Total score was 24.8 (12.9) with improvement in all domains (socially useful activities, personal and social relationship, self-care, and disturbing and aggressive behaviors). The TEAEs reported ≥5% were schizophrenia (18.9%), insomnia (8.6%), weight increased (5.9%) and akathisia (5.9%).

CONCLUSION: This post-hoc analysis suggests that brexpiprazole has long-term effectiveness on negative symptoms and functioning in patients with schizophrenia and clinically relevant levels of negative symptoms.
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