Supplementary material

A long-term, open-label study to evaluate the safety and tolerability of brexpiprazole as maintenance treatment in adults with schizophrenia

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Supplementary Table S1. Summary of safety outcomes over 52 weeks for patients with schizophrenia receiving open-label brexpiprazole 1–4 mg/day

	Safety population (n=1,031)	
Incidence of treatment-emergent suicidality,[a] % (n/N)		
C-SSRS Suicidal ideation	3.6 (37/1,031)	
C-SSRS Suicidal behavior	0.2 (2/1,031)	
Incidence of categorical increase in prolactin level, by gender,[b] % (n/N)		
	Female	**Male**
>2x ULN	4.5 (17/374)	4.1 (24/592)
>3x ULN	3.7 (14/374)	2.0 (12/592)
Incidence of treatment-emergent potentially clinically significant change in lipids and glucose, % (n/N)		
Fasting total cholesterol shift from normal (<200 mg/dL) to high (≥240 mg/dL)	6.1 (35/571)	
Fasting HDL cholesterol shift from normal (≥40 mg/dL) to low (<40 mg/dL)	20.6 (150/727)	
Fasting LDL cholesterol shift from normal (<100 mg/dL) to high (≥160 mg/dL)	2.9 (10/350)	
Fasting triglycerides shift from normal (<150 mg/dL) to high (200 to <500 mg/dL)	14.8 (93/629)	
Fasting glucose shift from normal/impaired (<126 mg/dL) to high (≥126 mg/dL)	10.7 (93/867)	
Incidence of ≥7% weight change, % (n/N)		
≥7% weight increase	18.6 (189/1,016)	
≥7% weight decrease	9.2 (93/1,016)	
Incidence of categorical increase in QT evaluations, % (n/N)		
QT_{cF} >500 msec[c]	0.1 (1/978)	

Abbreviations: C-SSRS, Columbia Suicide Severity Rating Scale; HDL, high-density lipoprotein; LDL, low-density lipoprotein; n/N, number of patients with potentially clinically relevant shift/total number of patients in category; QT_{cF}, QT interval corrected by Fridericia's formula; ULN, upper limit of the normal range.

Incidences are at any time post-baseline during the open-label treatment phase.

[a]Emergence of suicidal ideation/behavior was defined as a report of any type of suicidal ideation/behavior during treatment when there was no baseline suicidal ideation (past 6 months)/behavior (past 2 years).

[b]Patients counted once, in the highest category that applies.

[c]New onset, i.e., a patient with a value of >500 msec during treatment but not at baseline.

Supplementary Table S2. Summary of formal extrapyramidal symptom rating scale scores over 52 weeks for patients with schizophrenia receiving open-label brexpiprazole 1–4 mg/day

	Safety population	
	Mean (SD) at baseline (n=1,024)	**Mean (SD) change from baseline to last visit (n=1,012)**
SAS Total score	0.40 (1.20)[a]	0.00 (1.20)[b]
BARS Global score	0.09 (0.41)	0.01 (0.48)
AIMS Movement rating score[c]	0.22 (0.93)	0.05 (0.97)

Abbreviations: AIMS, Abnormal Involuntary Movement Scale; BARS, Barnes Akathisia Rating Scale; SAS, Simpson–Angus Scale; SD, standard deviation.

[a]n=1,020.

[b]n=1,010.

[c]AIMS Movement rating score was defined as the sum of items 1–7 (facial and oral, extremity, and trunk movements).

Supplementary Table S3. Summary of resource utilization over 52 weeks for patients with schizophrenia receiving open-label brexpiprazole 1–4 mg/day

	Safety population (n=1,031)	
Hospitalized for exacerbation of symptoms, n (%)	108 (10.5)	
Annual use (average use per 365.25 person days)	**Baseline (n=1,024)**	**Week 52 (n=409)**
Primary care doctor	1.2	1.1
Psychiatrist	2.6	0.7
Counsellor, psychologist, or other mental health professional	2.3	1.5
Other physician	0.2	0.2
Emergency room or urgent care facility for emotions, nerves, or mental health	0.2	0.0
Emergency room or urgent care facility for other reason	0.0	0.0