

Supplementary Table 1. Summary of safety outcomes over 52 weeks for patients with MDD receiving open-label adjunctive brexpiprazole 0.5–3 mg/day

	Safety population (n=2,938)	
Incidence of treatment-emergent suicidality,* % (n/N)		
C-SSRS Suicidal ideation	5.5 (161/2,938)	
C-SSRS Suicidal behavior	0.2 (7/2,938)	
Incidence of categorical increase in prolactin level, by gender,+ % (n/N)		
	Female	Male
>2x ULN	1.2 (23/1,977)	2.7 (25/926)
>3x ULN	0.7 (14/1,977)	2.1 (19/926)
Incidence of categorical shift in lipids and glucose, % (n/N)		
Fasting total cholesterol shift from normal (<200 mg/dL) to high (≥240 mg/dL)	9.5 (107/1,130)	
Fasting HDL cholesterol shift from normal (≥40 mg/dL) to low (<40 mg/dL)	12.7 (300/2,360)	
Fasting LDL cholesterol shift from normal (<100 mg/dL) to high (≥160 mg/dL)	4.3 (31/715)	
Fasting triglycerides shift from normal (<150 mg/dL) to high (200 to <500 mg/dL)	16.8 (307/1,829)	
Fasting triglycerides shift from normal (<150 mg/dL) to very high (≥500 mg/dL)	0.2 (4/1,829)	
Fasting glucose shift from normal/impaired (<126 mg/dL) to high (≥126 mg/dL)	8.2 (212/2,576)	
Incidence of ≥7% weight change, % (n/N)		
≥7% weight increase	25.8 (755/2,931)	
≥7% weight decrease	2.8 (82/2,931)	
Incidence of categorical increase in QT evaluations, % (n/N)		
QT _{CF} >500 msec [‡]	0.0 (1/2,903)	

C-SSRS, Columbia Suicide Severity Rating Scale; HDL, high-density lipoprotein; LDL, low-density lipoprotein; MDD, major depressive disorder; 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 post-baseline visit.

*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/behavior.

†New onset, i.e., a patient who did not meet the criteria at baseline and attained a categorical change during treatment. Patients counted once, in the highest category that applies.

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