

Table, Supplemental Digital Content 3. Safety Parameters (Safety Populations)

Safety Parameter, Mean Change From Baseline (SD) ^a	Open-Label	Double-Blind		
	Vilazodone 40 mg/d n=1204	Placebo n=192	Vilazodone 20 mg/d n=185	Vilazodone 40 mg/d n=186
Chemistry				
Alanine aminotransferase, U/L	1.3 (15.7)	0.6 (10.3)	1.0 (13.0)	2.0 (11.5)
Alkaline phosphatase, U/L	-0.3 (12.0)	1.4 (12.3)	0.8 (10.7)	-0.7 (11.9)
Aspartate aminotransferase, U/L	0.7 (8.6)	1.1 (8.7)	0.9 (7.6)	1.3 (7.2)
Total bilirubin, mg/dL	0.0 (0.2)	0.0 (0.2)	0.0 (0.2)	0.0 (0.2)
Blood urea nitrogen, mg/dL	0.5 (3.5)	0.8 (3.7)	-0.1 (3.5)	0.8 (3.7)
Creatine kinase, U/L	5.3 (111.5)	29.0 (224.7)	5.9 (116.5)	20.1 (132.2)
Creatinine, mg/dL	0.1 (0.1)	0.0 (0.1)	0.0 (0.2)	0.1 (0.1)
Metabolic				
Total cholesterol, mg/dL	2.7 (27.8)	0.5 (31.4)	0.5 (27.3)	1.9 (32.0)
Glucose, mg/dL	3.6 (18.7)	4.0 (14.7)	4.5 (17.9)	6.5 (21.5)
Triglycerides, mg/dL	6.8 (84.0)	10.0 (88.2)	4.2 (69.8)	-3.6 (74.2)
Vital signs, supine				
Systolic blood pressure, mm Hg	0.3 (10.5)	-2.0 (10.8)	0.6 (10.2)	-0.7 (10.5)
Diastolic blood pressure, mm Hg	0.3 (7.6)	0.4 (7.8)	1.0 (7.4)	0.6 (9.2)
Pulse rate, bpm	0.4 (8.9)	-0.6 (9.6)	0.2 (9.2)	-0.1 (9.8)
Electrocardiogram				
Heart rate, bpm	3.3 (10.7)	3.0 (10.9)	3.1 (8.5)	2.9 (10.2)
PR interval, msec	-0.6 (12.5)	1.4 (15.5)	0.2 (13.3)	-1.2 (13.6)
QRS interval, msec	-0.2 (6.9)	-0.6 (7.2)	0.1 (7.4)	0.4 (7.4)
RR interval, msec	-43.4 (135.4)	-40.8 (138.4)	-43.7 (118.9)	-35.1 (131.1)
QTcB, msec	0.5 (19.0)	1.6 (20.1)	2.9 (19.4)	0.2 (19.5)
QTcF, msec	-2.6 (16.0)	-1.6 (15.9)	-0.4 (16.4)	-2.4 (15.9)
PCS Laboratory Values				
Patients with any PCS laboratory parameter ^b	336/1141 (29.4)	73/187 (39.0)	63/173 (36.4)	66/183 (36.1)
Triglycerides >1.2×ULN	147/908 (16.2)	37/145 (25.5)	31/139 (22.3)	29/142 (20.4)
Creatine kinase > 1.5×ULN	85/1079 (7.9)	22/173 (12.7)	13/165 (7.9)	20/175 (11.4)
Glucose >1.2×ULN	53/1119 (4.7)	13/183 (7.1)	12/169 (7.1)	14/182 (7.7)
Hemoglobin <0.9×LLN	18/1128 (1.6)	4/183 (2.2)	9/172 (5.2)	4/179 (2.2)

^a Baseline was defined as the last available assessment prior to first dose of open-label vilazodone treatment.

^b Individual PCS laboratory values reported in ≥3% of patients in any treatment group.

LLN, lower limit of normal; N1, number of patients in which value was available; PCS, potentially clinically significant; QTcB, QT interval corrected for heart rate using the Bazett formula; QTcF, QT interval corrected for heart rate using the Fridericia formula; SD, standard deviation; ULN, upper limit of normal.