

Data supplement for Szegedi et al., Randomized, Double-Blind, Placebo-Controlled Trial of Asenapine Maintenance Therapy in Adults With an Acute Manic or Mixed Episode Associated With Bipolar I Disorder. Am J Psychiatry (doi: 10.1176/appi.ajp.2017.16040419)

Supplemental (Online Only) Materials

Table S1. Number of subjects who met predefined limits of change in lipid and endocrine parameters.

A. Open-label period

Parameter	Predefined limit of change	Number of subjects	n	%
Prolactin, ng/mL	>4 x upper limit of normal	484	12	2.5
Fasting total cholesterol, mg/dL	>50% above upper limit of normal	482	15	3.1
Fasting triglycerides, mg/dL	>500 mg/dL	424	7	1.7
Fasting glucose, mg/dL	>20% above upper limit of normal or below lower limit of normal	484	31	6.4
Glycosylated hemoglobin, %	>7.5%	470	10	2.1

B. Double-blind period

Parameter	Predefined limit of change	Placebo			Asenapine		
		Number of subjects	n	%	Number of subjects	n	%
Prolactin, ng/mL	>4 x upper limit of normal	119	3	2.5	124	4	3.2
Fasting total cholesterol, mg/dL	>50% above upper limit of normal	120	2	1.7	124	5	4.0
Fasting triglycerides, mg/dL	>500 mg/dL	107	0	0.0	116	1	0.9
Fasting glucose, mg/dL	>20% above upper limit of normal or below lower limit of normal	119	10	8.4	124	11	8.9
Glycosylated hemoglobin, %	>7.5%	118	2	1.7	123	4	3.3