

**Table S1. Change From Baseline on Efficacy Measures: Observed Case and Last-Observation-Carried-Forward Analyses**

Characteristic	Lurasidone 40 mg		Lurasidone 120 mg		Olanzapine 15 mg		Placebo	
	LS mean	SE	LS mean	SE	LS mean	SE	LS mean	SE
<b>PANSS Total score, change</b>								
<b>Day 4</b>	<b>N=118</b> -5.1	0.7	<b>N=118</b> -5.4	0.7	<b>N=121</b> -6.1	0.7	<b>N=114</b> -4.8	0.7
	P=0.778		P=0.537		P=0.158			
<b>Week 1</b>	<b>N=113</b> -10.4	0.9	<b>N=113</b> -8.7	0.9	<b>N=119</b> -11.0	0.9	<b>N=112</b> -7.2	0.9
	P=0.016		P=0.237		P=0.004			
<b>Week 2</b>	<b>N=109</b> -15.4	1.2	<b>N=103</b> -13.8	1.2	<b>N=116</b> -16.3	1.2	<b>N=106</b> -11.6	1.2
	P=0.026		P=0.205		P=0.006			
<b>Week 3</b>	<b>N=107</b> -18.5	1.4	<b>N=86</b> -20.9	1.6	<b>N=111</b> -21.7	1.4	<b>N=94</b> -15.6	1.5
	P=0.159		P=0.016		P=0.003			
<b>Week 4</b>	<b>N=93</b> -22.8	1.5	<b>N=79</b> -25.1	1.6	<b>N=102</b> -25.8	1.4	<b>N=85</b> -18.9	1.6
	P=0.068		P=0.006		P=0.001			
<b>Week 5</b>	<b>N=87</b> -26.8	1.6	<b>N=72</b> -28.6	1.8	<b>N=96</b> -29.1	1.6	<b>N=78</b> -22.5	1.7
	P=0.069		P=0.015		P=0.004			
<b>Week 6</b>	<b>N=79</b> -30.5	1.7	<b>N=68</b> -27.3	1.9	<b>N=87</b> -30.8	1.6	<b>N=73</b> -23.6	1.8
	P=0.006		P=0.161		P=0.003			
<b>LOCF-endpoint</b>	-23.1	1.7	-20.0	1.7	-26.7	1.7	-15.2	1.7
	P=0.001		P=0.049		P<0.001			

(Continued)

Table S1, Continued

Characteristic	Lurasidone 40 mg		Lurasidone 120 mg		Olanzapine 15 mg		Placebo	
	LS mean	SE	LS mean	SE	LS mean	SE	LS mean	SE
<b>PANSS Positive subscale score, change</b>								
<b>Day 4</b>	<b>N=118</b>		<b>N=118</b>		<b>N=121</b>		<b>N=114</b>	
	-1.6	0.3	-2.2	0.3	-2.1	0.3	-1.7	0.3
	P=0.867		P=0.209		P=0.264			
<b>Week 1</b>	<b>N=113</b>		<b>N=113</b>		<b>N=119</b>		<b>N=112</b>	
	-3.3	0.4	-3.4	0.4	-3.5	0.3	-2.5	0.4
	P=0.119		P=0.070		P=0.038			
<b>Week 2</b>	<b>N=109</b>		<b>N=103</b>		<b>N=116</b>		<b>N=106</b>	
	-5.0	0.4	-5.2	0.5	-5.0	0.4	-3.9	0.4
	P=0.060		P=0.031		P=0.064			
<b>Week 3</b>	<b>N=107</b>		<b>N=86</b>		<b>N=111</b>		<b>N=94</b>	
	-5.9	0.5	-7.4	0.5	-7.3	0.5	-5.2	0.5
	P=0.355		P=0.004		P=0.003			
<b>Week 4</b>	<b>N=93</b>		<b>N=79</b>		<b>N=102</b>		<b>N=85</b>	
	-7.1	0.5	-8.6	0.6	-8.8	0.5	-5.7	0.5
	P=0.073		P<0.001		P<0.001			
<b>Week 5</b>	<b>N=87</b>		<b>N=72</b>		<b>N=96</b>		<b>N=78</b>	
	-8.3	0.6	-9.4	0.6	-9.8	0.5	-6.9	0.6
	P=0.069		P=0.002		P<0.001			
<b>Week 6</b>	<b>N=79</b>		<b>N=68</b>		<b>N=87</b>		<b>N=73</b>	
	-9.5	0.6	-9.1	0.6	-10.3	0.6	-7.3	0.6
	P=0.010		P=0.041		P<0.001			
<b>LOCF-endpoint</b>								
	-7.1	0.6	-6.6	0.6	-8.8	0.6	-4.8	0.6
	P=0.007		P=0.038		P<0.001			

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Table S1, Continued

Characteristic	Lurasidone 40 mg		Lurasidone 120 mg		Olanzapine 15 mg		Placebo	
	LS mean	SE	LS mean	SE	LS mean	SE	LS mean	SE
<b>PANSS Negative subscale score, change</b>								
<b>Day 4</b>	<b>N=118</b>		<b>N=118</b>		<b>N=121</b>		<b>N=114</b>	
	-1.1	0.2	-0.7	0.2	-0.9	0.2	-0.8	0.2
	P=0.397		P=0.635		P=0.741			
<b>Week 1</b>	<b>N=113</b>		<b>N=113</b>		<b>N=119</b>		<b>N=112</b>	
	-2.3	0.3	-1.3	0.3	-2.1	0.3	-1.2	0.3
	P=0.011		P=0.946		P=0.035			
<b>Week 2</b>	<b>N=109</b>		<b>N=103</b>		<b>N=116</b>		<b>N=106</b>	
	-3.1	0.3	-2.3	0.3	-3.1	0.3	-2.3	0.3
	P=0.087		P=0.994		P=0.070			
<b>Week 3</b>	<b>N=107</b>		<b>N=86</b>		<b>N=111</b>		<b>N=94</b>	
	-4.2	0.4	-3.8	0.4	-4.5	0.4	-2.9	0.4
	P=0.029		P=0.155		P=0.030			
<b>Week 4</b>	<b>N=93</b>		<b>N=79</b>		<b>N=102</b>		<b>N=85</b>	
	-5.4	0.4	-5.2	0.5	-5.0	0.4	-4.0	0.5
	P=0.026		P=0.067		P=0.103			
<b>Week 5</b>	<b>N=87</b>		<b>N=72</b>		<b>N=96</b>		<b>N=78</b>	
	-6.0	0.5	-6.1	0.5	-5.8	0.5	-4.9	0.5
	P=0.122		P=0.119		P=0.212			
<b>Week 6</b>	<b>N=79</b>		<b>N=68</b>		<b>N=87</b>		<b>N=73</b>	
	-6.6	0.5	-5.8	0.5	-6.4	0.5	-4.9	0.5
	P=0.021		P=0.284		P=0.040			
<b>LOCF-endpoint</b>	<b>N=79</b>		<b>N=68</b>		<b>N=87</b>		<b>N=73</b>	
	-5.1	0.4	-4.1	0.4	-5.4	0.4	-3.3	0.4
	P=0.004		P=0.229		P<0.001			

(Continued)

Table S1, Continued

Characteristic	Lurasidone 40 mg		Lurasidone 120 mg		Olanzapine 15 mg		Placebo	
	LS mean	SE	LS mean	SE	LS mean	SE	LS mean	SE
<b>PANSS General Psychopathology subscale score, change</b>								
<b>Day 4</b>	-2.3	0.4	-2.4	0.4	-3.1	0.4	-2.3	0.4
	N=118		N=118		N=121		N=114	
	P=0.948		P=0.804		P=0.159			
<b>Week 1</b>	-4.8	0.5	-3.9	0.5	-5.4	0.5	-3.5	0.5
	N=113		N=113		N=119		N=112	
	P=0.066		P=0.552		P=0.009			
<b>Week 2</b>	-7.3	0.6	-6.2	0.6	-8.2	0.6	-5.5	0.6
	N=109		N=103		N=116		N=106	
	P=0.045		P=0.429		P=0.002			
<b>Week 3</b>	-8.4	0.7	-9.6	0.8	-10.2	0.7	-7.5	0.8
	N=107		N=86		N=111		N=94	
	P=0.378		P=0.050		P=0.008			
<b>Week 4</b>	-10.4	0.8	-11.3	0.8	-12.0	0.7	-9.1	0.8
	N=93		N=79		N=102		N=85	
	P=0.260		P=0.061		P=0.008			
<b>Week 5</b>	-12.5	0.8	-12.9	0.9	-13.6	0.8	-10.7	0.9
	N=87		N=72		N=96		N=78	
	P=0.129		P=0.072		P=0.013			
<b>Week 6</b>	-14.5	0.8	-12.4	0.9	-14.1	0.8	-11.4	0.9
	N=79		N=68		N=87		N=73	
	P=0.012		P=0.432		P=0.020			
<b>LOCF-endpoint</b>	-10.9	0.8	-9.2	0.9	-12.4	0.8	-7.1	0.9
	P=0.002		P=0.083		P<0.001			

(Continued)

Table S1, Continued

Characteristic	Lurasidone 40 mg		Lurasidone 120 mg		Olanzapine 15 mg		Placebo	
	LS mean	SE	LS mean	SE	LS mean	SE	LS mean	SE
<b>CGI-severity score, change</b>								
<b>Day 4</b>	<b>N=118</b> -0.2 P=0.610	0.0	<b>N=118</b> -0.2 P=0.985	0.0	<b>N=121</b> -0.2 P=0.388	0.0	<b>N=114</b> -0.2 P=0.388	0.0
<b>Week 1</b>	<b>N=113</b> -0.4 P=0.286	0.1	<b>N=113</b> -0.5 P=0.037	0.1	<b>N=119</b> -0.4 P=0.079	0.1	<b>N=112</b> -0.3 P=0.079	0.1
<b>Week 2</b>	<b>N=109</b> -0.7 P=0.053	0.1	<b>N=103</b> -0.8 P=0.046	0.1	<b>N=116</b> -0.8 P=0.021	0.1	<b>N=106</b> -0.6 P=0.021	0.1
<b>Week 3</b>	<b>N=107</b> -0.9 P=0.430	0.1	<b>N=87</b> -1.1 P=0.016	0.1	<b>N=111</b> -1.1 P=0.016	0.1	<b>N=94</b> -0.8 P=0.016	0.1
<b>Week 4</b>	<b>N=93</b> -1.2 P=0.191	0.1	<b>N=79</b> -1.3 P=0.023	0.1	<b>N=102</b> -1.4 P=0.009	0.1	<b>N=86</b> -1.0 P=0.009	0.1
<b>Week 5</b>	<b>N=87</b> -1.4 P=0.084	0.1	<b>N=72</b> -1.5 P=0.013	0.1	<b>N=96</b> -1.5 P=0.048	0.1	<b>N=78</b> -1.2 P=0.048	0.1
<b>Week 6</b>	<b>N=79</b> -1.6 P=0.013	0.1	<b>N=68</b> -1.5 P=0.243	0.1	<b>N=87</b> -1.6 P=0.010	0.1	<b>N=73</b> -1.3 P=0.010	0.1
<b>LOCF-endpoint</b>	-1.2 P=0.012	0.1	-1.1 P=0.075	0.1	-1.4 P<0.001	0.1	-0.9 P<0.001	0.1

PANSS: Positive and Negative Syndrome Scale; CGI: Clinical Global Impressions scale. P-values, comparing drug to placebo, are based on an ANCOVA with treatment and pooled center as fixed factors and baseline value as a covariate..

**Table S2. Patients Treated With Antiparkinsonism Medications During the Double-blind Phase, N (%)**

	<b>Lurasidone 40 mg (n=119)</b>	<b>Lurasidone 120 mg (n=118)</b>	<b>Olanzapine 15 mg (n=122)</b>	<b>Placebo (n=116)</b>
<b>Anticholinergic drugs</b>	24 (20%)	48 (41%)	22 (18%)	10 (9%)
<b>Benzatropine</b>	14 (12%)	27 (23%)	12 (10%)	4 (3%)
<b>Biperiden</b>	4 (3%)	11 (9%)	2 (2%)	1 (<1%)
<b>Profenamine</b>	0 (0%)	0 (0%)	1 (<1%)	0 (0%)
<b>Trihexyphenidyl</b>	6 (5%)	11 (9%)	7 (6%)	5 (4%)
<b>Diphenhydramine*</b>	7 (6%)	2 (2%)	2 (2%)	0 (0%)
<b>Beta-blocking agents**</b>	7 (6%)	11 (9%)	4 (3%)	5 (4%)

\* May also have been used for uses other than antiparkinsonism.

\*\* Atenolol, metoprolol, propranolol.

**Table S3. Shift From Baseline on the Barnes Akathisia Scale: Proportion (N, %) of Subjects with 1, 2, 3, 4 and 5-point Improvement or Worsening During Study Treatment**

Study drug	n	Treatment-Emergent Improvement					No Change	Treatment-Emergent Worsening				
		-5	-4	-3	-2	-1		+1	+2	+3	+4	+5
Placebo	115	0 (0.0%)	0 (0.0%)	2 (1.7%)	4 (3.5%)	9 (7.8%)	95 (82.6%)	11 (9.6%)	5 (4.3%)	1 (0.9%)	0 (0.0%)	0 (0.0%)
Lurasidone 40 mg	119	2 (1.7%)	3 (2.5%)	5 (4.2%)	9 (7.6%)	11 (9.2%)	95 (79.8%)	13 (10.9%)	7 (5.9%)	5 (4.2%)	4 (3.4%)	2 (1.7%)
Lurasidone 120 mg	118	0 (0.0%)	1 (0.8%)	1 (0.8%)	6 (5.1%)	8 (6.8%)	82 (69.5%)	28 (23.7%)	20 (16.9%)	9 (7.6%)	7 (5.9%)	5 (4.2%)
Olanzapine 15 mg	122	0 (0.0%)	1 (0.8%)	4 (3.3%)	7 (5.7%)	17 (13.9%)	94 (77.0%)	11 (9.0%)	7 (5.7%)	5 (4.1%)	1 (0.8%)	1 (0.8%)

**Table S4. Shift From Baseline on the Simpson-Angus Scale: Proportion (N, %) of Subjects with 0.1, 0.2, 0.3, 0.4 and 0.5-point Improvement or Worsening During Study Treatment**

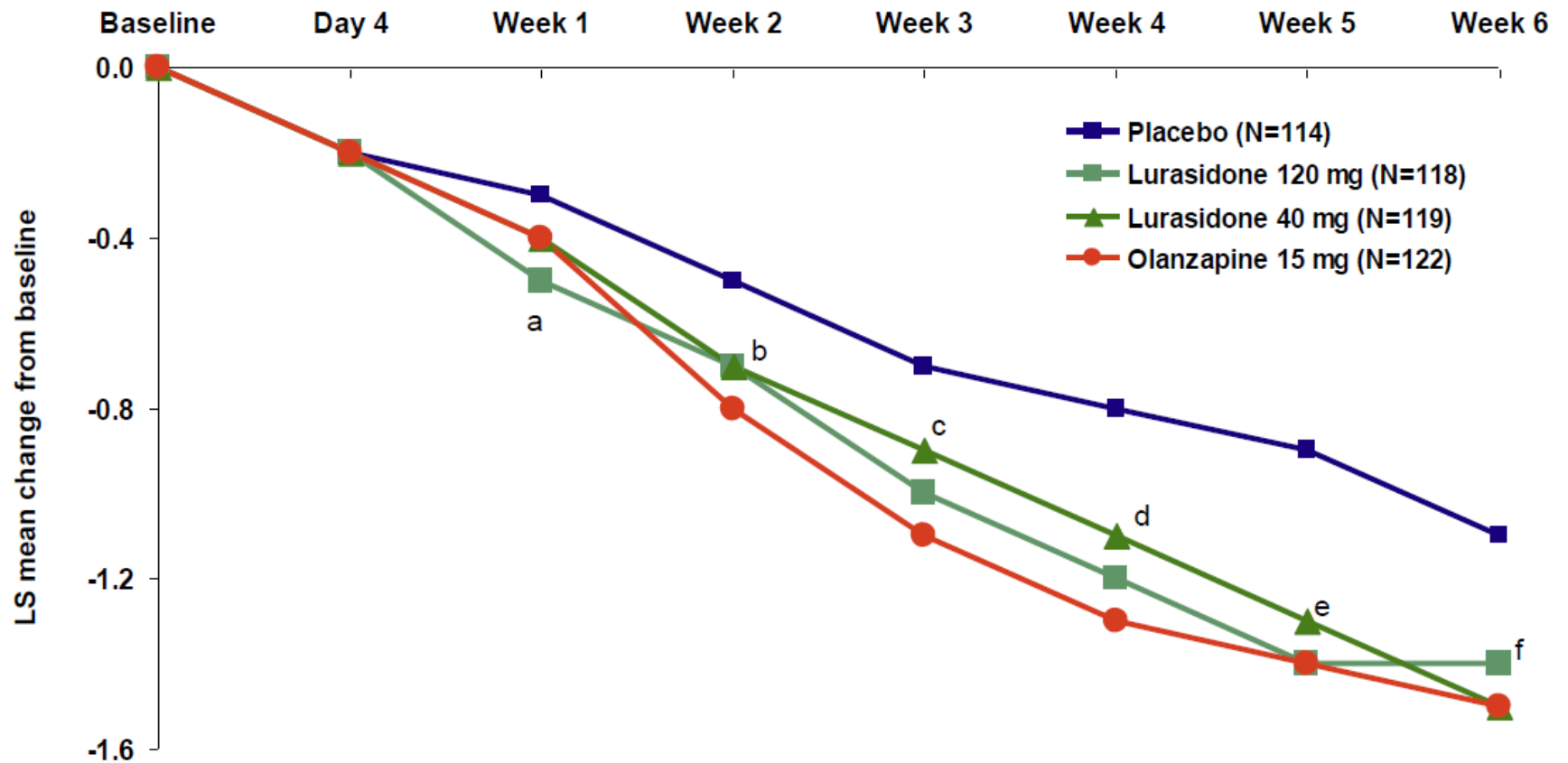
Study drug	n	Treatment-emergent Improvement					No Change	Treatment-emergent Worsening				
		-0.5	-0.4	-0.3	-0.2	-0.1		+0.1	+0.2	+0.3	+0.4	+0.5
Placebo	115	1 (0.9%)	2 (1.7%)	4 (3.5%)	12 (10.4%)	20 (17.4%)	82 (71.3%)	13 (11.3%)	4 (3.5%)	1 (0.9%)	0 (0.0%)	0 (0.0%)
Lurasidone 40 mg	119	3 (2.5%)	4 (3.4%)	8 (6.7%)	9 (7.6%)	20 (16.8%)	82 (68.9%)	17 (14.3%)	10 (8.4%)	7 (5.9%)	4 (3.4%)	2 (1.7%)
Lurasidone 120 mg	118	1 (0.8%)	2 (1.7%)	3 (2.5%)	5 (4.2%)	13 (11.0%)	69 (58.5%)	36 (30.5%)	23 (19.5%)	18 (15.3%)	14 (11.9%)	12 (10.2%)
Olanzapine 15 mg	122	3 (2.5%)	5 (4.1%)	7 (5.7%)	15 (12.3%)	21 (17.2%)	80 (65.6%)	21 (17.2%)	12 (9.8%)	8 (6.6%)	4 (3.3%)	2 (1.6%)

**Table S5. Shift From Baseline on the Abnormal Involuntary Movement Scale: Proportion (N, %) of Subjects with  $\geq 1$ ,  $\geq 2$ ,  $\geq 3$ ,  $\geq 4$  and  $\geq 5$ -point Improvement or Worsening During Study Treatment**

Study drug	n	Treatment-emergent Improvement					No Change	Treatment-emergent Worsening				
		-5	-4	-3	-2	-1		+1	+2	+3	+4	+5
Placebo	115	0 (0.0%)	1 (0.9%)	2 (1.7%)	2 (1.7%)	9 (7.8%)	96 (83.5%)	10 (8.7%)	4 (3.5%)	2 (1.7%)	1 (0.9%)	1 (0.9%)
Lurasidone 40 mg	119	2 (1.7%)	2 (1.7%)	2 (1.7%)	6 (5.0%)	8 (6.7%)	102 (85.7%)	9 (7.6%)	4 (3.4%)	2 (1.7%)	2 (1.7%)	0 (0.0%)
Lurasidone 120 mg	118	2 (1.7%)	2 (1.7%)	2 (1.7%)	5 (4.2%)	9 (7.6%)	91 (77.1%)	18 (15.3%)	9 (7.6%)	4 (3.4%)	2 (1.7%)	1 (0.8%)
Olanzapine 15 mg	122	4 (3.3%)	5 (4.1%)	8 (6.6%)	9 (7.4%)	11 (9.0%)	101 (82.8%)	10 (8.2%)	6 (4.9%)	4 (3.3%)	3 (2.5%)	2 (1.6%)



Figure S1. Change From Baseline in CGI-Severity Score - mixed model repeated measurements analysis



P-values are based on a repeated measures linear regression model of the change from Baseline score, with fixed effects for pooled center, visit as a categorical variable, Baseline score, treatment and treatment by visit interaction, assuming an unstructured covariance matrix; p-values are unadjusted. Only significant p-values are noted.

<sup>a</sup> Week 1 comparison to placebo: p=0.038 for lurasidone 120 mg

<sup>b</sup> Week 2 comparisons to placebo: p=0.012 vs. lurasidone 40 mg; p=0.015 for lurasidone 120 mg; p=0.006 for olanzapine

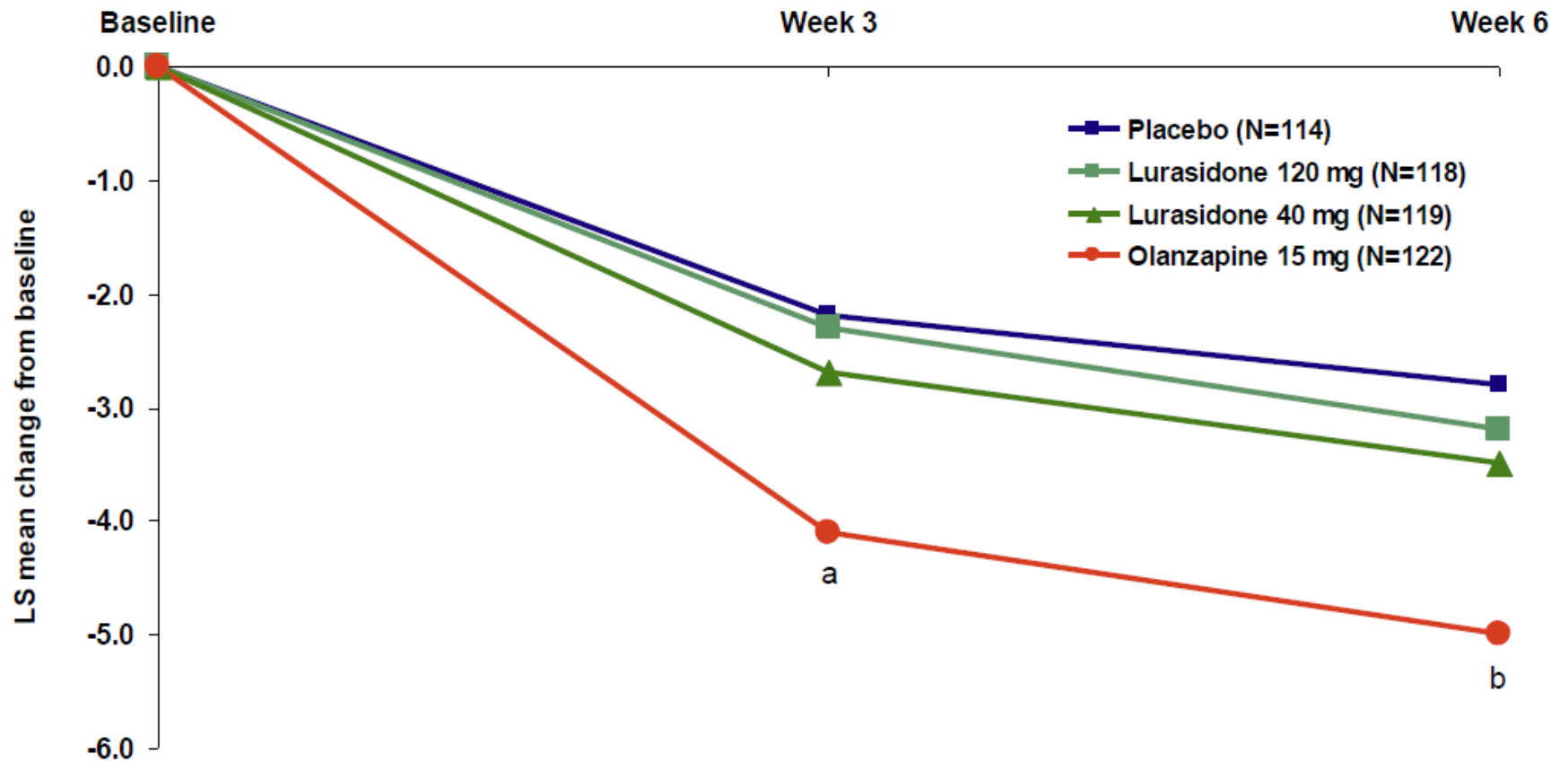
<sup>c</sup> Week 3 comparisons to placebo: p=0.022 vs. lurasidone 40 mg; p=0.008 for lurasidone 120 mg; p<0.001 for olanzapine

<sup>d</sup> Week 4 comparisons to placebo: p=0.014 vs. lurasidone 40 mg; p=0.003 for lurasidone 120 mg; p<0.001 for olanzapine

<sup>e</sup> Week 5 comparisons to placebo: p=0.004 vs. lurasidone 40 mg; p<0.001 for lurasidone 120 mg; p<0.001 for olanzapine

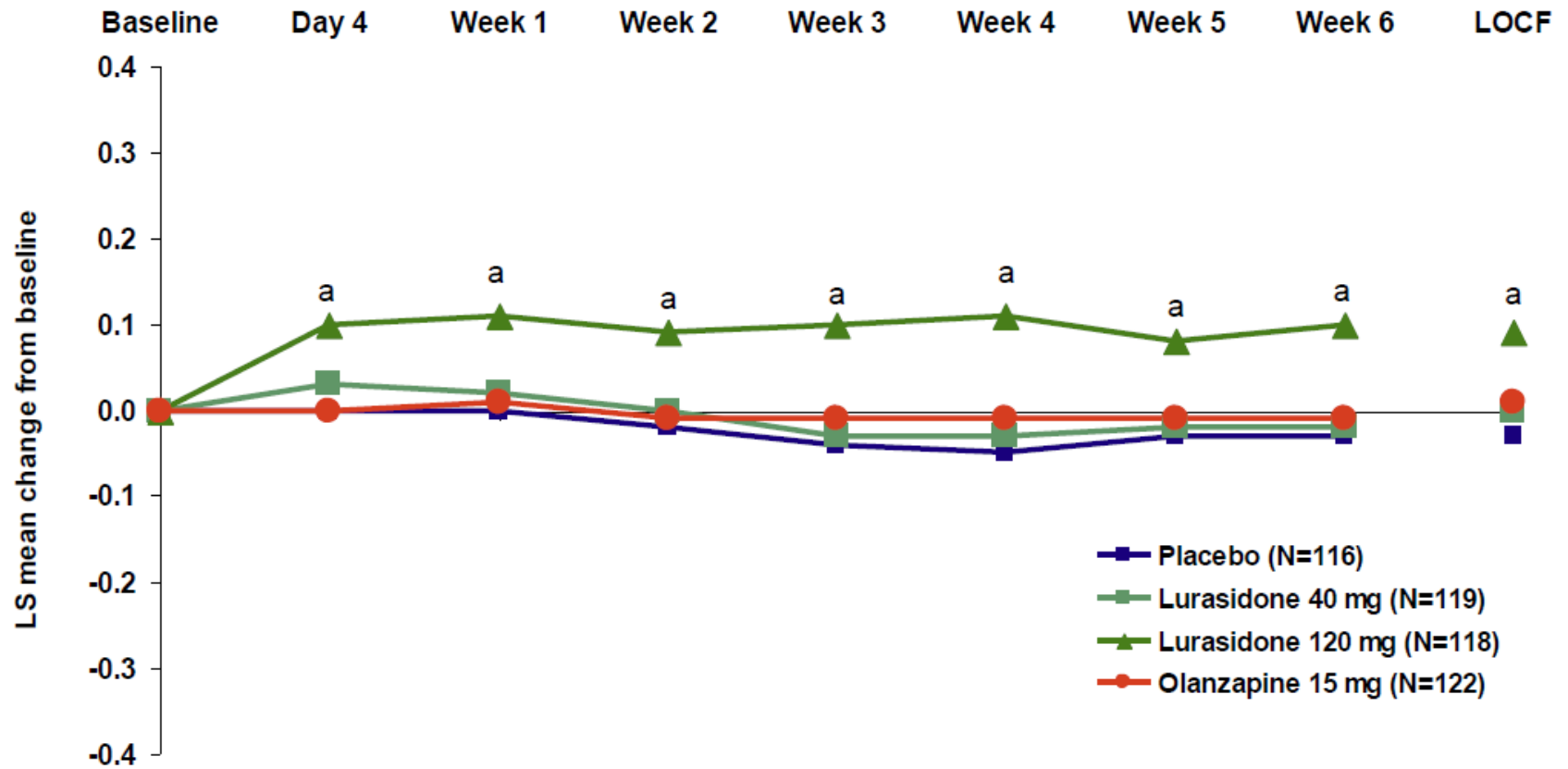
<sup>f</sup> Week 6 comparisons to placebo: p=0.006 vs. lurasidone 40 mg; p=0.040 for lurasidone 120 mg; p<0.001 for olanzapine

Figure S2. Change From Baseline in MADRS Total Score - mixed model repeated measurements analysis



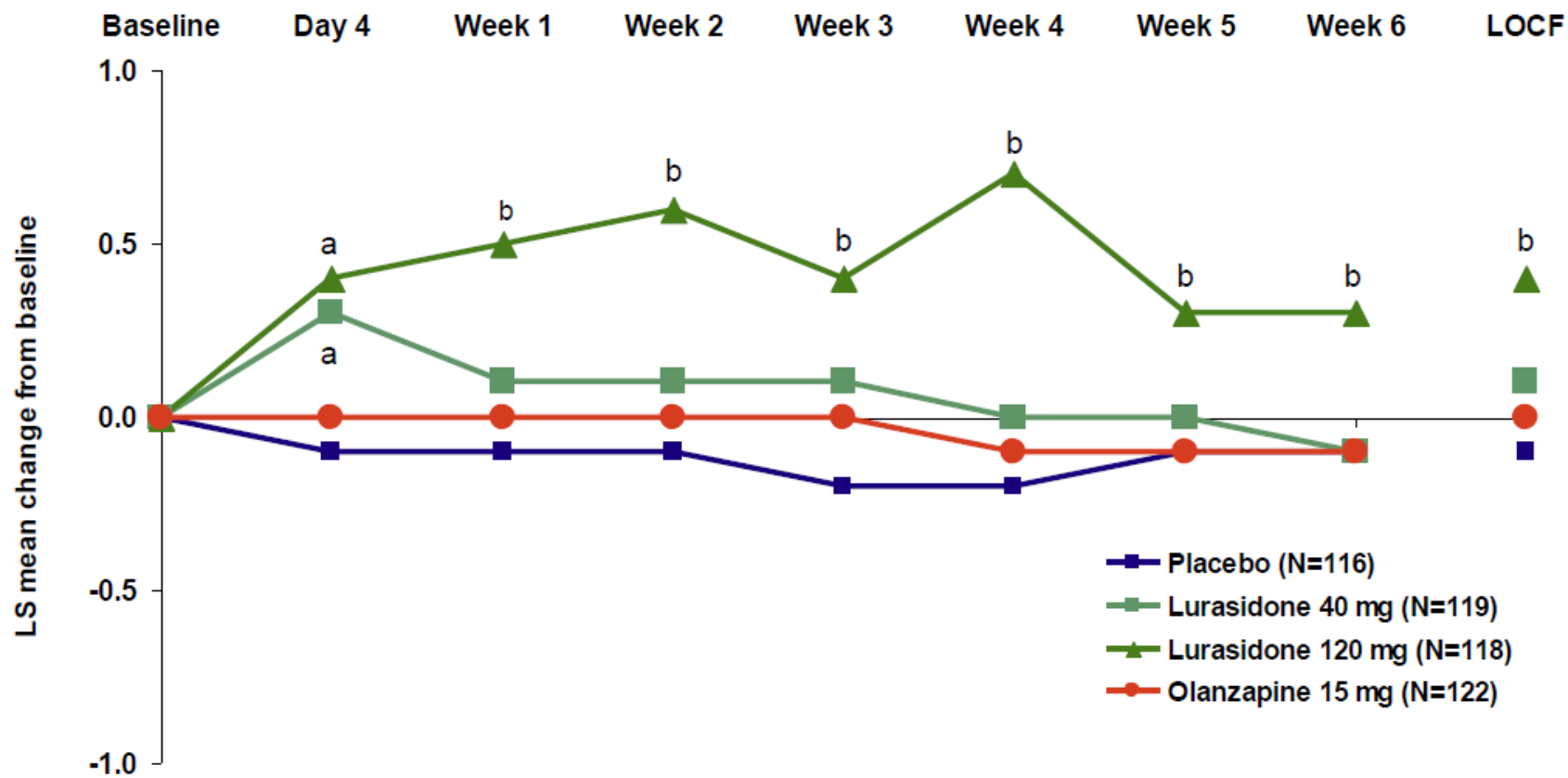
P-values are based on a repeated measures linear regression model of the change from Baseline score, with fixed effects for pooled center, visit as a categorical variable, baseline score, treatment and treatment by visit interaction, assuming an unstructured covariance matrix. Only significant p-values are noted.  
<sup>a</sup> Week 3 comparison to placebo: p=0.004 for olanzapine  
<sup>b</sup> Week 6 comparisons to placebo: p=0.003 for olanzapine

Figure S3. LS Mean Change From Baseline in Simpson-Angus Scale Score



Comparison of active drugs to placebo are based on an ANCOVA with treatment and pooled center as fixed factors and Baseline value as a covariate  
<sup>a</sup> Lurasidone 120 mg vs. placebo:  $p < 0.001$

Figure S4. LS Mean Change From Baseline in Barnes Akathisia Rating Scale Score



Comparison of active drugs to placebo are based on an ANCOVA with treatment and pooled center as fixed factors and Baseline value as a covariate

<sup>a</sup> Lurasidone 40 mg or 120 mg vs. placebo:  $p < 0.01$

<sup>b</sup> Lurasidone 120 mg vs. placebo:  $p < 0.001$

Figure S5. Mean Change in Weight at LOCF-endpoint, kg

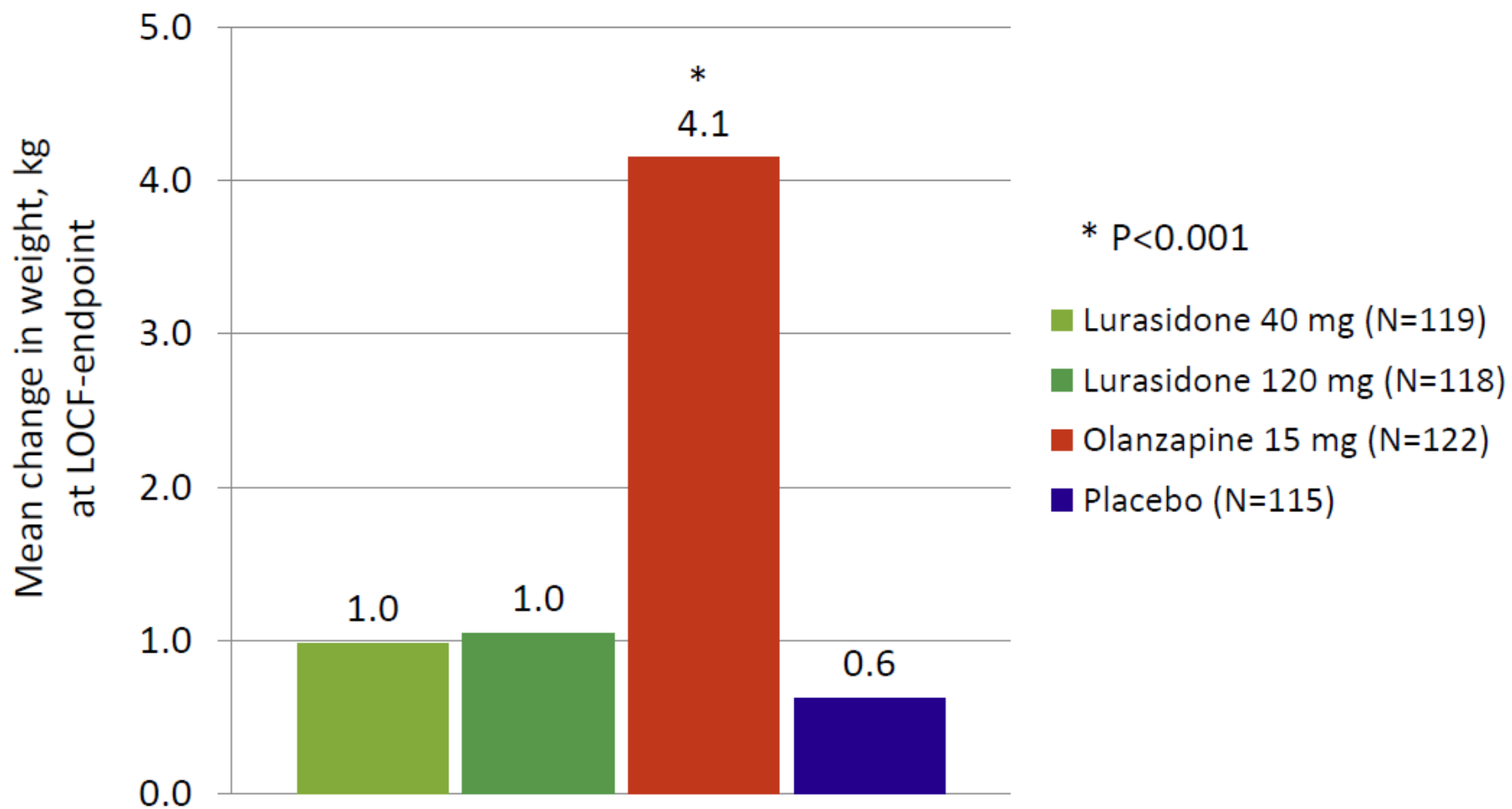


Figure S6. Mean Change in Total Cholesterol, HDL Cholesterol, LDL Cholesterol and Triglycerides at LOCF-endpoint, mg/dL

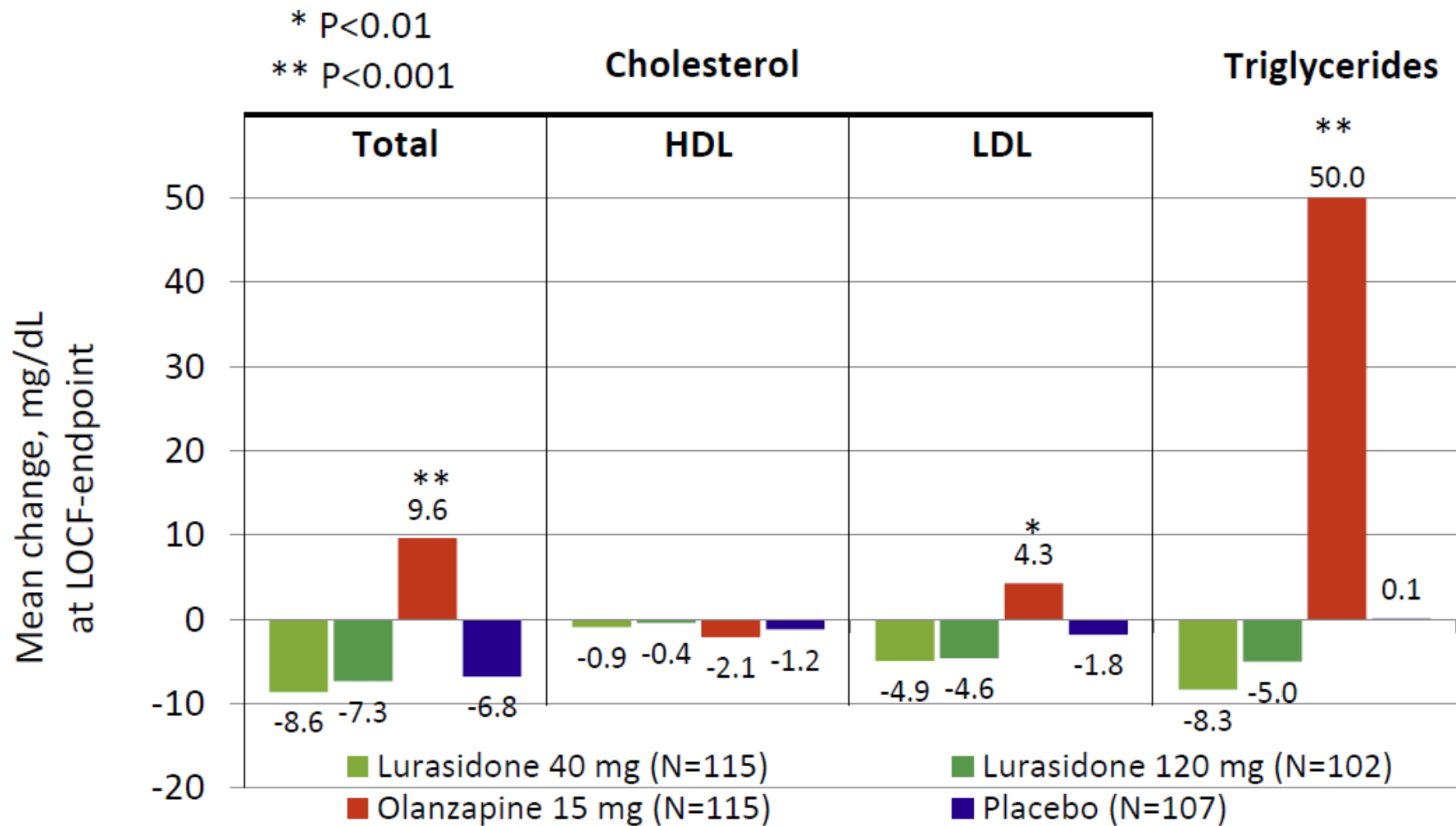


Figure S7. Mean Change in Glucose (mg/dL) and HbA1c (%) at LOCF-endpoint

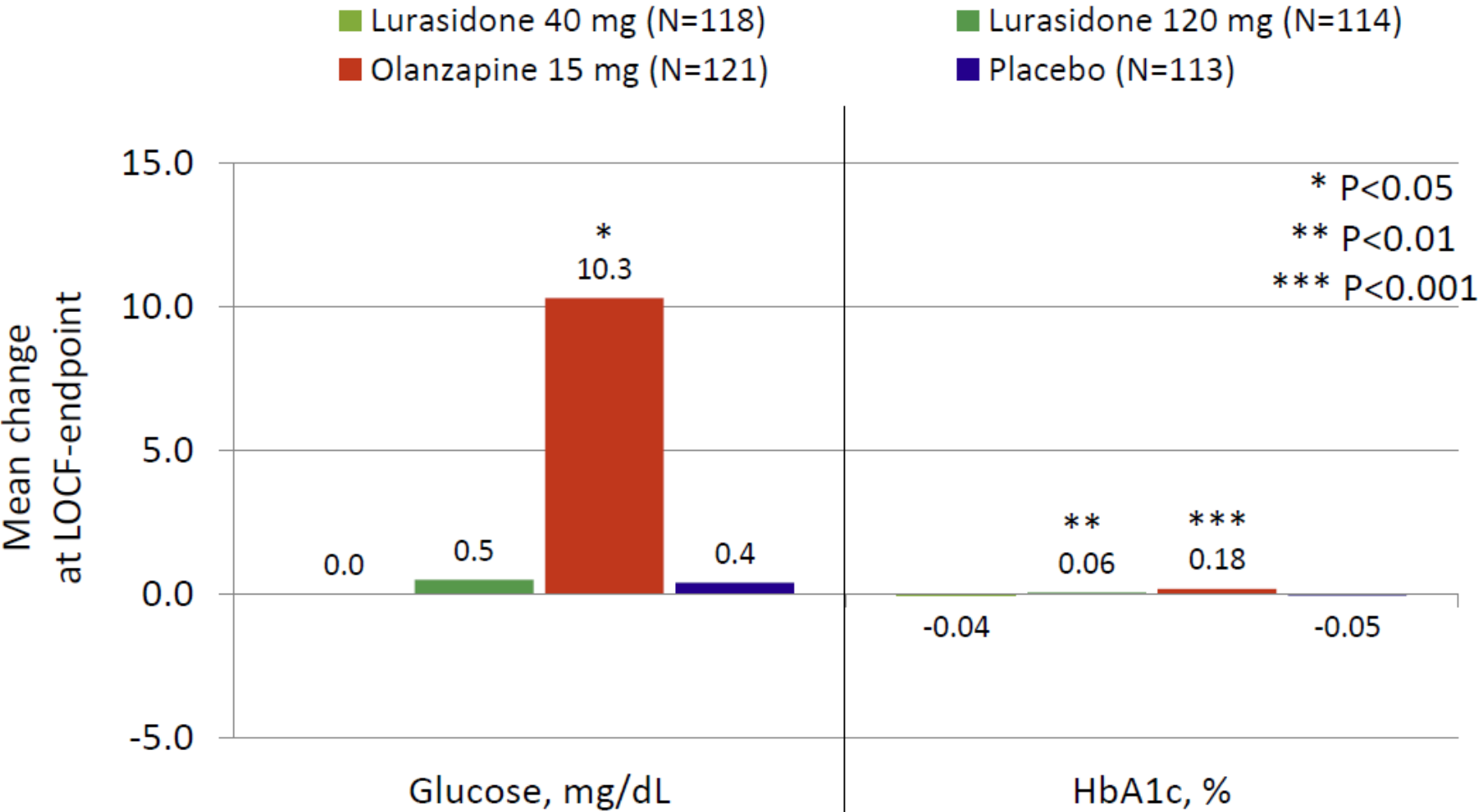


Figure S8. Mean Change in Insulin(mU/L) and HOMA-IR (U) at LOCF-endpoint

