

Table 14.2.10.3
Summary of Pharmacodynamic Parameters - Insulin Resistance
Safety Population

Parameter: Insulin (µIU/mL)

Visit	Statistic	Treatments				Total (N=48)
		Dose Group 1 0.25 mg/kg/day (N=12)	Dose Group 2 0.75 mg/kg/day (N=12)	Dose Group 3 2.0 mg/kg/day (N=12)	Dose Group 4 6.0 mg/kg/day (N=12)	
Baseline	n	11	8	12	12	43
	Mean	5.54	3.09	3.40	3.96	4.04
	SD	3.651	2.033	1.548	2.027	2.539
	Median	4.50	2.35	3.35	3.65	3.50
	Minimum	1.7	1.2	1.1	1.7	1.1
	Maximum	14.6	6.4	5.6	9.7	14.6
	Interquartile Range	3.20, 6.00	1.55, 4.65	2.00, 4.80	2.75, 4.45	2.30, 5.20
Week 2	n	11	11	12	12	46
	Mean	5.29	3.22	3.87	6.73	4.80
	SD	2.671	1.924	2.118	4.599	3.252
	Median	5.10	2.70	2.90	6.05	4.35
	Minimum	1.4	0.9	1.4	2.7	0.9
	Maximum	11.7	7.1	7.7	18.4	18.4
	Interquartile Range	3.50, 6.60	1.70, 4.60	2.25, 5.85	3.40, 7.05	2.70, 6.30

(1) Percentage change is calculated as $100 \times (\text{change from baseline} / \text{baseline})$.

Baseline for insulin and glucose is defined as the response obtained prior to the dose administration on Day 1. Baseline for HbA1C is defined as the last response during Screening prior to Study Day -1 (note that HbA1c is only collected once). P-values are from paired t-tests testing statistical significance of the change from baseline.

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Week 2 Change from Baseline	n	10	8	12	12	42
	Mean	-0.65	0.34	0.47	2.78	0.84
	SD	2.913	1.289	2.777	4.651	3.427
	Median	-0.45	0.00	0.55	2.10	0.30
	Minimum	-8.0	-1.1	-3.8	-2.9	-8.0
	Maximum	2.5	2.9	5.5	14.6	14.6
	Interquartile Range	-1.00, 1.00	-0.60, 1.05	-1.55, 1.75	-0.10, 2.80	-0.60, 2.20
	P-Value	0.4982	0.4832	0.5722	0.0631	0.1217
Week 2 Percent change from Baseline (1)	n	10	8	12	12	42
	Mean	-5.54	26.07	42.85	83.55	39.76
	SD	32.622	76.483	107.337	117.064	95.400
	Median	-10.71	0.00	15.65	54.93	8.75
	Minimum	-54.8	-25.0	-73.1	-29.9	-73.1
	Maximum	48.9	207.1	250.0	384.2	384.2
	Interquartile Range	-25.00, 27.17	-17.68, 30.91	-37.00, 70.43	-3.57, 104.12	-18.18, 56.52

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