

Table 14.2.10.3
Summary of Pharmacodynamic Parameters - Insulin Resistance
Safety Population

Parameter: Glucose, Fasting (mg/dL)

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	12	12	12	10	46
	Mean	87.5	88.9	89.3	92.3	89.4
	SD	9.44	18.71	7.91	8.19	11.79
	Median	88.5	84.5	87.0	95.0	88.0
	Minimum	70	77	81	74	70
	Maximum	106	146	101	104	146
	Interquartile Range	81.0, 91.0	79.0, 89.0	82.5, 97.0	88.0, 97.0	82.0, 95.0
Week 2	n	12	12	12	12	48
	Mean	85.3	83.1	89.5	89.2	86.8
	SD	9.29	6.69	5.20	11.12	8.56
	Median	87.0	83.0	90.0	89.5	87.5
	Minimum	68	74	77	70	68
	Maximum	97	97	97	116	116
	Interquartile Range	79.0, 92.5	77.5, 86.5	87.5, 93.0	85.0, 92.5	82.0, 91.5

(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	12	12	12	10	46
	Mean	-2.2	-5.8	0.2	-1.3	-2.3
	SD	10.46	18.92	8.79	9.41	12.49
	Median	-6.5	-1.5	2.5	-2.0	-2.0
	Minimum	-15	-63	-12	-14	-63
	Maximum	20	9	12	21	21
	Interquartile Range	-9.0, 4.5	-6.5, 3.5	-8.5, 7.0	-7.0, 3.0	-8.0, 5.0
	P-Value	0.4880	0.3085	0.9488	0.6723	0.2131
Week 2 Percent change from Baseline (1)	n	12	12	12	10	46
	Mean	-1.8	-4.2	0.8	-1.2	-1.6
	SD	13.07	13.98	9.76	9.80	11.64
	Median	-7.3	-1.8	2.9	-2.2	-2.2
	Minimum	-16	-43	-12	-13	-43
	Maximum	29	10	15	22	29
	Interquartile Range	-10.0, 5.3	-7.6, 4.3	-9.1, 8.2	-7.7, 3.5	-8.4, 5.6

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