

A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 13 Clinical chemistry (males)

Sex: Male			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
ALB (g/dL)	-1	Mean	4.37 I ¹	4.19	4.48	4.46	4.23	4.37
		S.D.	0.32	0.41	0.34	0.19	0.49	0.18
		N	4	4	4	4	4	4
	1	Mean	4.29 I ¹	4.07	4.29	4.18	3.93	3.82 d ²
		S.D.	0.35	0.24	0.21	0.11	0.21	0.24
		N	4	4	4	4	4	4
	2	Mean	4.20 I ¹	4.06	4.28	4.14	3.72	3.41 d ²
		S.D.	0.36	0.24	0.32	0.23	0.15	0.72
		N	4	4	4	4	4	4
	3	Mean	4.23 I ¹	4.08	4.32	4.12	3.85	3.65 d ²
		S.D.	0.31	0.25	0.26	0.15	0.13	0.10
		N	4	4	4	4	4	3
	4	Mean	4.25 I ¹	4.12	4.36	4.18	3.84	3.68 d ²
		S.D.	0.32	0.20	0.30	0.10	0.16	0.32
		N	4	4	4	4	4	3

1 [I - Automatic Transformation Selected: Identity (No Transformation)]

2 [d - Test: Dunnett 2 Sided p < 0.05]

A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 13 Clinical chemistry (males)

Sex: Male			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
A/G	-1	Mean	1.15 I ¹	1.14	1.19	1.25	1.19	1.32
		S.D.	0.16	0.12	0.11	0.09	0.22	0.07
		N	4	4	4	4	4	4
	1	Mean	1.18 I ¹	1.15	1.17	1.16	1.09	1.00
		S.D.	0.12	0.10	0.09	0.08	0.13	0.08
		N	4	4	4	4	4	4
	2	Mean	1.17 I ¹	1.16	1.17	1.10	1.05	0.91
		S.D.	0.17	0.12	0.11	0.05	0.13	0.25
		N	4	4	4	4	4	4
	3	Mean	1.16 I ¹	1.18	1.19	1.13	1.08	1.02
		S.D.	0.12	0.12	0.09	0.07	0.11	0.07
		N	4	4	4	4	4	3
	4	Mean	1.17 I ¹	1.20	1.20	1.14	1.08	0.99
		S.D.	0.18	0.12	0.09	0.08	0.10	0.16
		N	4	4	4	4	4	3

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A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 13 Clinical chemistry (males)

Sex: Male			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
T-BA ($\mu\text{mol/L}$)	-1	Mean	0.8 R ¹	1.3	3.6	1.0	6.5	3.0
		S.D.	0.3	0.3	5.5	0.5	7.2	2.1
		N	4	4	4	4	4	4
	1	Mean	1.5 L ²	1.4	1.6	1.0	2.0	11.5 d ³
		S.D.	0.9	0.9	0.9	0.7	1.5	8.7
		N	4	4	4	4	4	4
	2	Mean	1.7 L ²	1.4	2.9	1.5	4.4	38.9 d ³
		S.D.	1.0	0.8	1.9	0.8	4.6	52.4
		N	4	4	4	4	4	4
	3	Mean	7.1 L ²	1.1	6.0	1.4	2.1	18.7
		S.D.	11.4	0.8	7.8	0.7	0.6	14.6
		N	4	4	4	4	4	3
	4	Mean	1.8 L ²	1.5	5.4	1.9	2.7	23.7 dd ⁴
		S.D.	1.0	1.4	5.5	1.1	1.1	21.4
		N	4	4	4	4	4	3

1 [R - Automatic Transformation Selected: Rank]
3 [d - Test: Dunnett 2 Sided p < 0.05]

2 [L - Automatic Transformation Selected: Log]
4 [dd - Test: Dunnett 2 Sided p < 0.01]

A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 13 Clinical chemistry (males)

Sex: Male			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
CRP (mg/dL)	-1	Mean	0.14 I ¹	0.05	0.16	0.13	0.14	0.09
		S.D.	0.10	0.03	0.09	0.12	0.12	0.05
		N	4	4	4	4	4	4
	1	Mean	0.14 I ¹	0.06	0.18	0.15	0.13	0.18
		S.D.	0.15	0.05	0.10	0.11	0.09	0.12
		N	4	4	4	4	4	4
	2	Mean	0.14 L ²	0.06	0.17	0.16	0.20	0.44
		S.D.	0.07	0.03	0.09	0.13	0.16	0.62
		N	4	4	4	4	4	4
	3	Mean	0.21 I ¹	0.05	0.15	0.18	0.16	0.11
		S.D.	0.18	0.03	0.08	0.16	0.14	0.03
		N	4	4	4	4	4	3
	4	Mean	0.17 I ¹	0.06	0.15	0.16	0.17	0.17
		S.D.	0.14	0.04	0.09	0.14	0.16	0.07
		N	4	4	4	4	4	3

1 [I - Automatic Transformation Selected: Identity (No Transformation)]

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A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
AST (U/L)	-1	Mean	28 I ¹	23	23	23	22	22
		S.D.	10	5	3	5	5	7
		N	4	4	4	4	4	4
	1	Mean	28 R ²	26	22	20	21	27
		S.D.	3	10	3	5	1	7
		N	4	4	4	4	4	4
	2	Mean	25 I ¹	26	21	22	20	32
		S.D.	8	7	2	7	3	13
		N	4	4	4	4	4	4
	3	Mean	24 I ¹	28	22	21	21	33 n1 ³
		S.D.	4	9	2	6	3	.
		N	4	4	4	4	4	1
	4	Mean	24 I ¹	26	20	21	21	31 n1 ³
		S.D.	4	6	1	5	3	.
		N	4	4	4	4	4	1

1 [I - Automatic Transformation Selected: Identity (No Transformation)]

2 [R - Automatic Transformation Selected: Rank]

3 [n1 - This group has only one value: Data was not statistically analyzed.]

A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
ALT (U/L)	-1	Mean	48 R ¹	27	30	34	26	26
		S.D.	29	1	6	15	13	2
		N	4	4	4	4	4	4
	1	Mean	49 I ²	33	35	43	31	39
		S.D.	15	8	14	26	12	11
		N	4	4	4	4	4	4
	2	Mean	40 I ²	35	33	36	31	34
		S.D.	5	12	18	18	15	11
		N	4	4	4	4	4	4
	3	Mean	41 I ²	37	38	35	33	26 n1 ³
		S.D.	8	6	25	9	20	.
		N	4	4	4	4	4	1
	4	Mean	42 I ²	42	33	36	36	28 n1 ³
		S.D.	9	7	17	5	20	.
		N	4	4	4	4	4	1

1 [R - Automatic Transformation Selected: Rank]

2 [I - Automatic Transformation Selected: Identity (No Transformation)]

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A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
ALP (U/L)	-1	Mean	1040 I ¹	698	1079	1092	687	1021
		S.D.	173	65	441	367	294	424
		N	4	4	4	4	4	4
	1	Mean	1226 I ¹	916	1152	1376	664	886
		S.D.	177	184	634	389	181	385
		N	4	4	4	4	4	4
	2	Mean	1230 I ¹	963	1094	1337	728	703
		S.D.	211	293	610	350	262	256
		N	4	4	4	4	4	4
	3	Mean	1116 I ¹	910	1023	1210	729	807 n1 ²
		S.D.	193	182	551	381	307	.
		N	4	4	4	4	4	1
	4	Mean	1120 I ¹	870	1045	1254	817	910 n1 ²
		S.D.	183	193	540	395	357	.
		N	4	4	4	4	4	1

1 [I - Automatic Transformation Selected: Identity (No Transformation)]

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A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
LD (U/L)	-1	Mean	222 I ¹	262	296	279	256	240
		S.D.	120	39	23	40	90	32
		N	4	4	4	4	4	4
	1	Mean	206 I ¹	279	304	225	222	274
		S.D.	42	95	64	27	22	46
		N	4	4	4	4	4	4
	2	Mean	173 I ¹	245 d ²	263 dd ³	240	201	269 dd ³
		S.D.	41	40	36	35	24	38
		N	4	4	4	4	4	4
	3	Mean	164 I ¹	244 d ²	241 d ²	213	190	184 n1 ⁴
		S.D.	45	48	32	33	23	.
		N	4	4	4	4	4	1
	4	Mean	159 I ¹	214	224	218	197	226 n1 ⁴
		S.D.	35	30	45	28	38	.
		N	4	4	4	4	4	1

1 [I - Automatic Transformation Selected: Identity (No Transformation)]

3 [dd - Test: Dunnett 2 Sided p < 0.01]

2 [d - Test: Dunnett 2 Sided p < 0.05]

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A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
CK (U/L)	-1	Mean	536 R ¹	86	140	138	102	136
		S.D.	872	26	13	68	32	54
		N	4	4	4	4	4	4
	1	Mean	115 I ²	89	97	93	88	123
		S.D.	26	57	35	15	23	25
		N	4	4	4	4	4	4
	2	Mean	138 I ²	123	102	128	94	124
		S.D.	33	78	43	63	27	31
		N	4	4	4	4	4	4
	3	Mean	134 I ²	124	101	137	107	159 n1 ³
		S.D.	44	83	27	43	24	.
		N	4	4	4	4	4	1
	4	Mean	138 I ²	120	107	134	128	183 n1 ³
		S.D.	29	93	17	25	39	.
		N	4	4	4	4	4	1

1 [R - Automatic Transformation Selected: Rank]

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A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
GGT (U/L)	-1	Mean	50.6 I ¹	40.6	45.0	47.0	38.4	55.3
		S.D.	7.6	2.6	10.8	11.3	4.5	7.2
		N	4	4	4	4	4	4
	1	Mean	47.3 I ¹	37.7	40.5	40.7	37.5	45.3
		S.D.	6.4	4.2	7.9	10.3	11.9	7.6
		N	4	4	4	4	4	4
	2	Mean	44.9 I ¹	37.5	39.4	38.4	34.0	40.9
		S.D.	6.4	5.5	8.6	9.8	9.9	6.6
		N	4	4	4	4	4	4
	3	Mean	43.1 I ¹	37.1	38.2	36.2	31.8	41.1 n ^{1 2}
		S.D.	6.2	4.8	7.6	9.4	8.4	.
		N	4	4	4	4	4	1
	4	Mean	44.4 I ¹	36.9	38.5	37.0	33.2	40.6 n ^{1 2}
		S.D.	1.9	5.0	7.8	8.2	6.7	.
		N	4	4	4	4	4	1

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A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
GLDH (U/L)	-1	Mean	29 L ¹	12	10	12	9	8
		S.D.	32	5	4	5	2	2
		N	4	4	4	4	4	4
	1	Mean	26 I ²	16	17	18	13	12
		S.D.	17	11	12	14	3	4
		N	4	4	4	4	4	4
	2	Mean	22 I ²	18	18	16	14	19
		S.D.	11	19	19	11	8	16
		N	4	4	4	4	4	4
	3	Mean	22 L ¹	16	23	14	11	7 n1 ³
		S.D.	15	9	27	6	4	.
		N	4	4	4	4	4	1
	4	Mean	20 I ²	21	15	18	13	8 n1 ³
		S.D.	13	9	11	10	8	.
		N	4	4	4	4	4	1

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A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
LAP (U/L)	-1	Mean	71 ¹	55	50	61	43	41
		S.D.	37	26	13	22	13	9
		N	4	4	4	4	4	4
	1	Mean	77 ^{L²}	44	45	51	41	44
		S.D.	58	8	10	19	14	10
		N	4	4	4	4	4	4
	2	Mean	73 ^{L²}	45	45	46	40	54
		S.D.	48	7	8	17	14	20
		N	4	4	4	4	4	4
	3	Mean	78 ^{L²}	44	43	45	39	31 ^{n1³}
		S.D.	63	7	7	17	13	.
		N	4	4	4	4	4	1
	4	Mean	68 ^{L²}	44	42	44	39	30 ^{n1³}
		S.D.	40	10	7	16	11	.
		N	4	4	4	4	4	1

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Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
GLU (mg/dL)	-1	Mean	94 ¹	84	91	95	90	86
		S.D.	4	4	11	8	4	7
		N	4	4	4	4	4	4
	1	Mean	81 ¹	82	80	75	83	79
		S.D.	10	7	13	9	8	6
		N	4	4	4	4	4	4
	2	Mean	106 ¹	93	83	81	88	91
		S.D.	13	27	25	12	9	24
		N	4	4	4	4	4	4
	3	Mean	86 ¹	85	86	80	85	71 ^{n1 2}
		S.D.	10	6	19	15	9	.
		N	4	4	4	4	4	1
	4	Mean	101 ¹	90	93	90	90	75 ^{n1 2}
		S.D.	9	27	27	22	17	.
		N	4	4	4	4	4	1

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A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
BIL (mg/dL)	-1	Mean	0.14 I ¹	0.18	0.17	0.20	0.15	0.26
		S.D.	0.03	0.08	0.08	0.07	0.08	0.16
		N	4	4	4	4	4	4
	1	Mean	0.13 L ²	0.19	0.19	0.16	0.23	0.97 dd ³
		S.D.	0.02	0.10	0.12	0.05	0.13	0.27
		N	4	4	4	4	4	4
	2	Mean	0.12 L ²	0.11	0.10	0.10	0.12	0.95 dd ³
		S.D.	0.04	0.02	0.04	0.01	0.07	0.60
		N	4	4	4	4	4	4
	3	Mean	0.11 I ¹	0.14	0.11	0.11	0.15	0.48 n1 ⁴
		S.D.	0.04	0.02	0.05	0.03	0.09	.
		N	4	4	4	4	4	1
	4	Mean	0.10 I ¹	0.10	0.11	0.10	0.12	0.34 n1 ⁴
		S.D.	0.03	0.03	0.06	0.02	0.05	.
		N	4	4	4	4	4	1

1 [I - Automatic Transformation Selected: Identity (No Transformation)]

3 [dd - Test: Dunnett 2 Sided p < 0.01]

2 [L - Automatic Transformation Selected: Log]

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A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
UN (mg/dL)	-1	Mean	19.5 ¹	17.3	16.6	16.9	17.5	16.0
		S.D.	1.9	2.1	2.6	4.5	1.4	1.5
		N	4	4	4	4	4	4
	1	Mean	18.2 ¹	18.7	17.9	16.3	17.9	20.4
		S.D.	1.0	2.0	2.6	4.1	2.6	2.7
		N	4	4	4	4	4	4
	2	Mean	20.1 ¹	19.2	20.3	19.0	18.7	26.5 ^{d2}
		S.D.	2.3	1.2	1.8	4.8	1.4	4.1
		N	4	4	4	4	4	4
	3	Mean	16.4 ¹	15.2	17.0	15.4	15.2	20.7 ⁿ¹³
		S.D.	1.0	1.6	2.3	4.2	0.9	.
		N	4	4	4	4	4	1
	4	Mean	18.7 ¹	17.8	18.3	16.7	16.3	18.3 ⁿ¹³
		S.D.	2.1	1.6	2.3	3.9	1.2	.
		N	4	4	4	4	4	1

1 [I - Automatic Transformation Selected: Identity (No Transformation)]

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Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
CRE (mg/dL)	-1	Mean	0.80 I ¹	0.80	0.77	0.72	0.79	0.72
		S.D.	0.13	0.09	0.10	0.03	0.08	0.05
		N	4	4	4	4	4	4
	1	Mean	0.79 I ¹	0.84	0.82	0.80	0.89	0.94
		S.D.	0.14	0.07	0.08	0.14	0.09	0.10
		N	4	4	4	4	4	4
	2	Mean	0.72 I ¹	0.80	0.75	0.70	0.80	0.87
		S.D.	0.15	0.10	0.06	0.11	0.07	0.13
		N	4	4	4	4	4	4
	3	Mean	0.76 I ¹	0.77	0.75	0.76	0.86	0.81 n ^{1 2}
		S.D.	0.12	0.12	0.08	0.09	0.09	.
		N	4	4	4	4	4	1
	4	Mean	0.74 I ¹	0.75	0.72	0.73	0.88	0.79 n ^{1 2}
		S.D.	0.13	0.08	0.04	0.09	0.10	.
		N	4	4	4	4	4	1

1 [I - Automatic Transformation Selected: Identity (No Transformation)]

2 [n1 - This group has only one value: Data was not statistically analyzed.]

A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
CHO (mg/dL)	-1	Mean	133 I ¹	123	142	131	135	155
		S.D.	25	15	33	10	24	24
		N	4	4	4	4	4	4
	1	Mean	135 I ¹	118	134	117	120	145
		S.D.	20	20	32	15	17	33
		N	4	4	4	4	4	4
	2	Mean	138 I ¹	115	120	111	107	124
		S.D.	25	19	29	17	12	30
		N	4	4	4	4	4	4
	3	Mean	141 I ¹	115	124	123	106	87 n ^{1 2}
		S.D.	23	24	29	18	9	.
		N	4	4	4	4	4	1
	4	Mean	142 I ¹	116	130	123	121	87 n ^{1 2}
		S.D.	30	23	27	18	22	.
		N	4	4	4	4	4	1

1 [I - Automatic Transformation Selected: Identity (No Transformation)]

2 [n1 - This group has only one value: Data was not statistically analyzed.]

A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
TG (mg/dL)	-1	Mean	25 I ¹	36	32	24	39	26
		S.D.	10	17	10	3	11	7
		N	4	4	4	4	4	4
	1	Mean	30 I ¹	25	23	27	31	53
		S.D.	11	12	14	5	10	17
		N	4	4	4	4	4	4
	2	Mean	29 L ²	36	24	44	38	80 d ³
		S.D.	16	10	7	27	5	34
		N	4	4	4	4	4	4
	3	Mean	22 I ¹	24	23	24	30	47 n ^{1 4}
		S.D.	5	9	7	5	7	.
		N	4	4	4	4	4	1
	4	Mean	23 L ²	30	29	44	56	58 n ^{1 4}
		S.D.	4	13	12	35	23	.
		N	4	4	4	4	4	1

1 [I - Automatic Transformation Selected: Identity (No Transformation)]

3 [d - Test: Dunnett 2 Sided p < 0.05]

2 [L - Automatic Transformation Selected: Log]

4 [n1 - This group has only one value: Data was not statistically analyzed.]

A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
PL (mg/dL)	-1	Mean	187 I ¹	153	183	184	162	189
		S.D.	16	25	27	18	15	17
		N	4	4	4	4	4	4
	1	Mean	195 I ¹	154 d ²	179	178	156	173
		S.D.	16	24	26	29	8	7
		N	4	4	4	4	4	4
	2	Mean	206 I ¹	161	178	184	157 d ²	156 d ²
		S.D.	15	30	24	39	10	16
		N	4	4	4	4	4	4
	3	Mean	196 I ¹	152	170	181	147 d ²	146 n ^{1 3}
		S.D.	10	33	24	38	8	.
		N	4	4	4	4	4	1
	4	Mean	202 I ¹	164	183	198	173	141 n ^{1 3}
		S.D.	21	18	20	51	33	.
		N	4	4	4	4	4	1

1 [I - Automatic Transformation Selected: Identity (No Transformation)]

2 [d - Test: Dunnett 2 Sided p < 0.05]

3 [n1 - This group has only one value: Data was not statistically analyzed.]

A 4-Week Oral Dose Toxicity Study of TM5509 in Cynomolgus Monkeys

Table 14 Clinical chemistry (females)

Sex: Female			Control 0.5%CMC-Na	Low TM5509 2 mg/kg/day	Low-Mid TM5509 6 mg/kg/day	Mid TM5509 20 mg/kg/day	Mid-High TM5509 80 mg/kg/day	High TM5509 300 mg/kg/day
Week(s) Relative to Start Date								
IP (mg/dL)	-1	Mean	3.93 ¹	3.70	4.68	5.07	3.37	4.97
		S.D.	0.81	0.68	0.77	0.63	0.34	0.88
		N	4	4	4	4	4	4
	1	Mean	3.89 ¹	3.94	4.10	4.25	3.50	4.13
		S.D.	0.32	0.72	0.61	0.73	0.67	0.50
		N	4	4	4	4	4	4
	2	Mean	3.92 ¹	2.93	2.85	3.68	2.92	3.78
		S.D.	0.29	1.48	0.99	1.00	1.02	0.79
		N	4	4	4	4	4	4
	3	Mean	3.98 ¹	4.09	3.56	4.08	3.24	3.42 ^{n1 2}
		S.D.	0.64	0.68	0.65	0.52	0.48	.
		N	4	4	4	4	4	1
	4	Mean	4.10 ¹	2.88	4.14	3.95	4.16	3.47 ^{n1 2}
		S.D.	0.22	0.94	0.46	0.92	0.45	.
		N	4	4	4	4	4	1

1 [I - Automatic Transformation Selected: Identity (No Transformation)]

2 [n1 - This group has only one value: Data was not statistically analyzed.]