

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Basophils (10 ⁹ /L)				
Baseline				
N	15			15
Mean (SD)	0.023 (0.0202)			0.023 (0.0202)
Median	0.020			0.020
Min, Max	0.000, 0.060			0.000, 0.060
Week 1				
N	15			15
Mean (SD)	0.033 (0.0302)			0.033 (0.0302)
Median	0.020			0.020
Min, Max	0.000, 0.110			0.000, 0.110
Change from Baseline to Week 1				
N	15			15
Mean (SD)	0.011 (0.0284)			0.011 (0.0284)
Median	0.010			0.010
Min, Max	-0.040, 0.090			-0.040, 0.090
Week 2				
N	15			15
Mean (SD)	0.023 (0.0153)			0.023 (0.0153)
Median	0.020			0.020
Min, Max	0.000, 0.050			0.000, 0.050

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Change from Baseline to Week 2				
N	15			15
Mean (SD)	0.000 (0.0136)			0.000 (0.0136)
Median	0.000			0.000
Min, Max	-0.020, 0.020			-0.020, 0.020
Week 4				
N	2	13		15
Mean (SD)	0.020 (0.0000)	0.032 (0.0374)		0.030 (0.0348)
Median	0.020	0.020		0.020
Min, Max	0.020, 0.020	0.000, 0.150		0.000, 0.150
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	0.020 (0.0000)	0.005 (0.0461)		0.007 (0.0430)
Median	0.020	0.000		0.000
Min, Max	0.020, 0.020	-0.030, 0.150		-0.030, 0.150
Week 6				
N	3	5	7	15
Mean (SD)	0.023 (0.0252)	0.016 (0.0089)	0.023 (0.0221)	0.021 (0.0183)
Median	0.020	0.020	0.020	0.020
Min, Max	0.000, 0.050	0.000, 0.020	0.000, 0.060	0.000, 0.060
Change from Baseline to Week 6				

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Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	0.013 (0.0404)	-0.012 (0.0164)	-0.001 (0.0273)	-0.002 (0.0268)
Median	0.020	-0.020	0.010	0.010
Min, Max	-0.030, 0.050	-0.030, 0.010	-0.060, 0.020	-0.060, 0.050
Week 8				
N	3	2	10	15
Mean (SD)	0.020 (0.0100)	0.030 (0.0283)	0.027 (0.0189)	0.026 (0.0176)
Median	0.020	0.030	0.020	0.020
Min, Max	0.010, 0.030	0.010, 0.050	0.010, 0.060	0.010, 0.060
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	0.010 (0.0265)	0.015 (0.0212)	-0.001 (0.0242)	0.003 (0.0235)
Median	0.020	0.015	0.005	0.010
Min, Max	-0.020, 0.030	0.000, 0.030	-0.040, 0.030	-0.040, 0.030
Week 12				
N	3	2	8	13
Mean (SD)	0.017 (0.0058)	0.015 (0.0071)	0.031 (0.0264)	0.025 (0.0218)
Median	0.020	0.015	0.025	0.020
Min, Max	0.010, 0.020	0.010, 0.020	0.000, 0.080	0.000, 0.080
Change from Baseline to Week 12				
N	3	2	8	13

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Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	0.007 (0.0153)	0.000 (0.0141)	0.001 (0.0387)	0.002 (0.0306)
Median	0.010	0.000	-0.010	0.000
Min, Max	-0.010, 0.020	-0.010, 0.010	-0.030, 0.080	-0.030, 0.080
Week 16				
N	3	3	7	13
Mean (SD)	0.017 (0.0153)	0.010 (0.0100)	0.039 (0.0248)	0.027 (0.0232)
Median	0.020	0.010	0.040	0.020
Min, Max	0.000, 0.030	0.000, 0.020	0.010, 0.080	0.000, 0.080
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	0.007 (0.0321)	-0.007 (0.0115)	0.007 (0.0364)	0.004 (0.0299)
Median	0.020	0.000	0.000	0.000
Min, Max	-0.030, 0.030	-0.020, 0.000	-0.040, 0.080	-0.040, 0.080
Week 20				
N	4	3	6	13
Mean (SD)	0.020 (0.0216)	0.010 (0.0000)	0.038 (0.0248)	0.026 (0.0229)
Median	0.015	0.010	0.035	0.020
Min, Max	0.000, 0.050	0.010, 0.010	0.010, 0.080	0.000, 0.080
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	0.010 (0.0216)	-0.007 (0.0058)	0.003 (0.0151)	0.003 (0.0160)

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Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	0.005	-0.010	0.000	0.000
Min, Max	-0.010, 0.040	-0.010, 0.000	-0.010, 0.030	-0.010, 0.040
Week 24				
N	4	3	6	13
Mean (SD)	0.020 (0.0216)	0.030 (0.0265)	0.037 (0.0273)	0.030 (0.0245)
Median	0.015	0.020	0.035	0.020
Min, Max	0.000, 0.050	0.010, 0.060	0.000, 0.070	0.000, 0.070
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	0.010 (0.0283)	0.013 (0.0231)	0.002 (0.0440)	0.007 (0.0335)
Median	0.000	0.000	0.000	0.000
Min, Max	-0.010, 0.050	0.000, 0.040	-0.060, 0.060	-0.060, 0.060
Week 28				
N	5	3	7	15
Mean (SD)	0.014 (0.0089)	0.027 (0.0306)	0.021 (0.0204)	0.020 (0.0189)
Median	0.010	0.020	0.030	0.010
Min, Max	0.010, 0.030	0.000, 0.060	0.000, 0.040	0.000, 0.060
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	0.006 (0.0055)	0.010 (0.0300)	-0.014 (0.0346)	-0.003 (0.0279)
Median	0.010	0.010	-0.020	0.000

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Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	0.000, 0.010	-0.020, 0.040	-0.060, 0.040	-0.060, 0.040
Week 32				
N	4	3	7	14
Mean (SD)	0.018 (0.0050)	0.027 (0.0153)	0.019 (0.0168)	0.020 (0.0136)
Median	0.020	0.030	0.010	0.020
Min, Max	0.010, 0.020	0.010, 0.040	0.000, 0.050	0.000, 0.050
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	0.010 (0.0141)	0.010 (0.0200)	-0.017 (0.0198)	-0.004 (0.0221)
Median	0.015	0.010	-0.020	-0.005
Min, Max	-0.010, 0.020	-0.010, 0.030	-0.050, 0.010	-0.050, 0.030
Week 36				
N	3	3	7	13
Mean (SD)	0.013 (0.0058)	0.010 (0.0000)	0.023 (0.0125)	0.018 (0.0109)
Median	0.010	0.010	0.020	0.020
Min, Max	0.010, 0.020	0.010, 0.010	0.000, 0.040	0.000, 0.040
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	0.003 (0.0115)	-0.007 (0.0058)	-0.013 (0.0275)	-0.008 (0.0213)
Median	0.010	-0.010	-0.020	-0.010
Min, Max	-0.010, 0.010	-0.010, 0.000	-0.040, 0.040	-0.040, 0.040

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Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	0.014 (0.0114)	0.010 (0.0000)	0.026 (0.0190)	0.019 (0.0155)
Median	0.010	0.010	0.030	0.010
Min, Max	0.000, 0.030	0.010, 0.010	0.000, 0.060	0.000, 0.060
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	0.006 (0.0055)	-0.007 (0.0058)	-0.010 (0.0306)	-0.004 (0.0216)
Median	0.010	-0.010	0.000	0.000
Min, Max	0.000, 0.010	-0.010, 0.000	-0.060, 0.030	-0.060, 0.030
Week 44				
N	5	3	7	15
Mean (SD)	0.018 (0.0084)	0.010 (0.0000)	0.021 (0.0090)	0.018 (0.0086)
Median	0.020	0.010	0.020	0.020
Min, Max	0.010, 0.030	0.010, 0.010	0.010, 0.040	0.010, 0.040
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	0.010 (0.0158)	-0.007 (0.0058)	-0.014 (0.0190)	-0.005 (0.0188)
Median	0.010	-0.010	-0.010	-0.010
Min, Max	-0.010, 0.030	-0.010, 0.000	-0.040, 0.020	-0.040, 0.030
Week 48				

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Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	0.018 (0.0084)	0.007 (0.0058)	0.033 (0.0160)	0.023 (0.0158)
Median	0.020	0.010	0.030	0.020
Min, Max	0.010, 0.030	0.000, 0.010	0.020, 0.060	0.000, 0.060
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	0.010 (0.0071)	-0.010 (0.0000)	-0.003 (0.0243)	0.000 (0.0181)
Median	0.010	-0.010	0.010	0.010
Min, Max	0.000, 0.020	-0.010, -0.010	-0.040, 0.020	-0.040, 0.020
Early Term				
N	1		1	2
Mean (SD)	0.050 ()		0.010 ()	0.030 (0.0283)
Median	0.050		0.010	0.030
Min, Max	0.050, 0.050		0.010, 0.010	0.010, 0.050
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	0.050 ()		-0.030 ()	0.010 (0.0566)
Median	0.050		-0.030	0.010
Min, Max	0.050, 0.050		-0.030, -0.030	-0.030, 0.050

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Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Eosinophils (10 ⁹ /L)				
Baseline				
N	15			15
Mean (SD)	0.182 (0.1348)			0.182 (0.1348)
Median	0.130			0.130
Min, Max	0.020, 0.550			0.020, 0.550
Week 1				
N	15			15
Mean (SD)	0.157 (0.1206)			0.157 (0.1206)
Median	0.130			0.130
Min, Max	0.020, 0.460			0.020, 0.460
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.025 (0.0664)			-0.025 (0.0664)
Median	-0.010			-0.010
Min, Max	-0.190, 0.080			-0.190, 0.080
Week 2				
N	15			15
Mean (SD)	0.159 (0.1551)			0.159 (0.1551)
Median	0.090			0.090
Min, Max	0.020, 0.580			0.020, 0.580

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Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.023 (0.0651)			-0.023 (0.0651)
Median	0.000			0.000
Min, Max	-0.200, 0.060			-0.200, 0.060
Week 4				
N	2	13		15
Mean (SD)	0.030 (0.0141)	0.143 (0.1063)		0.128 (0.1062)
Median	0.030	0.090		0.080
Min, Max	0.020, 0.040	0.010, 0.340		0.010, 0.340
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-0.170 (0.1131)	-0.036 (0.0835)		-0.054 (0.0955)
Median	-0.170	-0.050		-0.050
Min, Max	-0.250, -0.090	-0.210, 0.160		-0.250, 0.160
Week 6				
N	3	5	7	15
Mean (SD)	0.047 (0.0643)	0.154 (0.1036)	0.103 (0.0974)	0.109 (0.0964)
Median	0.020	0.210	0.060	0.080
Min, Max	0.000, 0.120	0.010, 0.250	0.000, 0.260	0.000, 0.260
Change from Baseline to Week 6				

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Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-0.127 (0.1401)	-0.046 (0.1868)	-0.070 (0.1108)	-0.073 (0.1375)
Median	-0.120	-0.020	-0.050	-0.040
Min, Max	-0.270, 0.010	-0.340, 0.180	-0.280, 0.060	-0.340, 0.180
Week 8				
N	3	2	10	15
Mean (SD)	0.090 (0.0624)	0.065 (0.0495)	0.098 (0.0784)	0.092 (0.0694)
Median	0.110	0.065	0.060	0.070
Min, Max	0.020, 0.140	0.030, 0.100	0.010, 0.230	0.010, 0.230
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-0.083 (0.1060)	-0.005 (0.0212)	-0.109 (0.1516)	-0.090 (0.1331)
Median	-0.100	-0.005	-0.065	-0.060
Min, Max	-0.180, 0.030	-0.020, 0.010	-0.510, 0.000	-0.510, 0.030
Week 12				
N	3	2	8	13
Mean (SD)	0.100 (0.0700)	0.055 (0.0495)	0.129 (0.0903)	0.111 (0.0809)
Median	0.070	0.055	0.120	0.090
Min, Max	0.050, 0.180	0.020, 0.090	0.020, 0.270	0.020, 0.270
Change from Baseline to Week 12				
N	3	2	8	13

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Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-0.057 (0.1607)	-0.015 (0.0212)	-0.054 (0.0921)	-0.048 (0.0975)
Median	0.010	-0.015	-0.035	-0.020
Min, Max	-0.240, 0.060	-0.030, 0.000	-0.180, 0.110	-0.240, 0.110
Week 16				
N	3	3	7	13
Mean (SD)	0.087 (0.0896)	0.110 (0.1229)	0.149 (0.0903)	0.125 (0.0932)
Median	0.040	0.060	0.160	0.110
Min, Max	0.030, 0.190	0.020, 0.250	0.040, 0.260	0.020, 0.260
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-0.070 (0.1952)	0.040 (0.1249)	-0.050 (0.0716)	-0.034 (0.1156)
Median	-0.080	0.000	-0.060	-0.060
Min, Max	-0.260, 0.130	-0.060, 0.180	-0.150, 0.080	-0.260, 0.180
Week 20				
N	4	3	6	13
Mean (SD)	0.103 (0.0427)	0.050 (0.0361)	0.153 (0.1093)	0.114 (0.0866)
Median	0.105	0.060	0.130	0.090
Min, Max	0.050, 0.150	0.010, 0.080	0.010, 0.310	0.010, 0.310
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-0.063 (0.0967)	-0.020 (0.0361)	-0.047 (0.0734)	-0.045 (0.0711)

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Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-0.085	-0.010	-0.030	-0.030
Min, Max	-0.140, 0.060	-0.060, 0.010	-0.170, 0.030	-0.170, 0.060
Week 24				
N	4	3	6	13
Mean (SD)	0.090 (0.0440)	0.053 (0.0503)	0.178 (0.1269)	0.122 (0.1035)
Median	0.090	0.060	0.150	0.100
Min, Max	0.040, 0.140	0.000, 0.100	0.060, 0.400	0.000, 0.400
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-0.075 (0.0870)	-0.017 (0.0058)	-0.022 (0.0886)	-0.037 (0.0766)
Median	-0.080	-0.020	-0.020	-0.020
Min, Max	-0.150, 0.010	-0.020, -0.010	-0.150, 0.120	-0.150, 0.120
Week 28				
N	5	3	7	15
Mean (SD)	0.126 (0.0956)	0.080 (0.0964)	0.193 (0.1400)	0.148 (0.1204)
Median	0.080	0.040	0.150	0.130
Min, Max	0.060, 0.290	0.010, 0.190	0.040, 0.460	0.010, 0.460
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-0.028 (0.0614)	0.010 (0.0529)	-0.057 (0.0962)	-0.034 (0.0784)
Median	0.000	-0.010	-0.030	-0.010

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Min, Max	-0.130, 0.020	-0.030, 0.070	-0.240, 0.060	-0.240, 0.070
Week 32				
N	4	3	7	14
Mean (SD)	0.185 (0.1034)	0.067 (0.0231)	0.196 (0.1465)	0.165 (0.1238)
Median	0.135	0.080	0.150	0.130
Min, Max	0.130, 0.340	0.040, 0.080	0.030, 0.440	0.030, 0.440
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	0.040 (0.0258)	-0.003 (0.0321)	-0.054 (0.0559)	-0.016 (0.0596)
Median	0.040	0.010	-0.060	0.000
Min, Max	0.010, 0.070	-0.040, 0.020	-0.130, 0.030	-0.130, 0.070
Week 36				
N	3	3	7	13
Mean (SD)	0.200 (0.1562)	0.043 (0.0306)	0.213 (0.1419)	0.171 (0.1400)
Median	0.120	0.050	0.160	0.120
Min, Max	0.100, 0.380	0.010, 0.070	0.050, 0.440	0.010, 0.440
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	0.043 (0.0451)	-0.027 (0.0379)	-0.037 (0.1839)	-0.016 (0.1366)
Median	0.040	-0.010	-0.020	0.000
Min, Max	0.000, 0.090	-0.070, 0.000	-0.420, 0.130	-0.420, 0.130

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Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	0.178 (0.0792)	0.057 (0.0351)	0.214 (0.1288)	0.171 (0.1133)
Median	0.150	0.060	0.210	0.150
Min, Max	0.100, 0.310	0.020, 0.090	0.080, 0.380	0.020, 0.380
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	0.024 (0.0404)	-0.013 (0.0153)	-0.036 (0.0796)	-0.011 (0.0629)
Median	0.030	-0.010	-0.030	0.000
Min, Max	-0.040, 0.070	-0.030, 0.000	-0.190, 0.070	-0.190, 0.070
Week 44				
N	5	3	7	15
Mean (SD)	0.128 (0.0482)	0.090 (0.0700)	0.230 (0.1156)	0.168 (0.1043)
Median	0.100	0.120	0.260	0.160
Min, Max	0.080, 0.180	0.010, 0.140	0.050, 0.420	0.010, 0.420
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	-0.026 (0.0723)	0.020 (0.0436)	-0.020 (0.0627)	-0.014 (0.0614)
Median	-0.010	0.000	-0.020	-0.010
Min, Max	-0.110, 0.060	-0.010, 0.070	-0.130, 0.040	-0.130, 0.070
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	0.168 (0.0936)	0.093 (0.0603)	0.247 (0.1389)	0.190 (0.1229)
Median	0.140	0.100	0.240	0.150
Min, Max	0.080, 0.310	0.030, 0.150	0.060, 0.450	0.030, 0.450
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	0.014 (0.0650)	0.023 (0.0513)	-0.003 (0.0655)	0.008 (0.0595)
Median	0.020	0.010	-0.020	0.020
Min, Max	-0.090, 0.090	-0.020, 0.080	-0.100, 0.090	-0.100, 0.090
Early Term				
N	1		1	2
Mean (SD)	0.150 ()		0.110 ()	0.130 (0.0283)
Median	0.150		0.110	0.130
Min, Max	0.150, 0.150		0.110, 0.110	0.110, 0.150
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	0.040 ()		-0.440 ()	-0.200 (0.3394)
Median	0.040		-0.440	-0.200
Min, Max	0.040, 0.040		-0.440, -0.440	-0.440, 0.040

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Ery. Mean Corpuscular HGB Concentration (g/L)				
Baseline				
N	15			15
Mean (SD)	345.600 (9.5603)			345.600 (9.5603)
Median	344.000			344.000
Min, Max	325.000, 359.000			325.000, 359.000
Week 1				
N	15			15
Mean (SD)	346.867 (10.3845)			346.867 (10.3845)
Median	349.000			349.000
Min, Max	323.000, 361.000			323.000, 361.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	1.267 (7.7779)			1.267 (7.7779)
Median	4.000			4.000
Min, Max	-15.000, 15.000			-15.000, 15.000
Week 2				
N	15			15
Mean (SD)	346.467 (8.2883)			346.467 (8.2883)
Median	349.000			349.000
Min, Max	331.000, 360.000			331.000, 360.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	0.867 (7.4149)			0.867 (7.4149)
Median	0.000			0.000
Min, Max	-12.000, 20.000			-12.000, 20.000
Week 4				
N	2	13		15
Mean (SD)	341.000 (8.4853)	347.077 (12.1687)		346.267 (11.6892)
Median	341.000	347.000		347.000
Min, Max	335.000, 347.000	321.000, 369.000		321.000, 369.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	11.000 (15.5563)	-0.923 (11.1987)		0.667 (11.9323)
Median	11.000	0.000		0.000
Min, Max	0.000, 22.000	-32.000, 14.000		-32.000, 22.000
Week 6				
N	3	5	7	15
Mean (SD)	345.000 (18.2483)	344.400 (19.1651)	348.429 (6.9488)	346.400 (13.3084)
Median	354.000	352.000	348.000	348.000
Min, Max	324.000, 357.000	311.000, 357.000	341.000, 363.000	311.000, 363.000
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	6.667 (20.4042)	-6.400 (14.4672)	3.429 (5.3497)	0.800 (12.6841)
Median	2.000	-2.000	3.000	2.000
Min, Max	-11.000, 29.000	-32.000, 3.000	-6.000, 10.000	-32.000, 29.000
Week 8				
N	3	2	10	15
Mean (SD)	316.667 (32.3316)	344.000 (16.9706)	349.800 (7.6999)	342.400 (19.7332)
Median	298.000	344.000	349.500	348.000
Min, Max	298.000, 354.000	332.000, 356.000	341.000, 364.000	298.000, 364.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-21.667 (18.5831)	-5.000 (8.4853)	2.700 (7.3944)	-3.200 (13.7124)
Median	-27.000	-5.000	3.000	1.000
Min, Max	-37.000, -1.000	-11.000, 1.000	-12.000, 12.000	-37.000, 12.000
Week 12				
N	3	2	8	13
Mean (SD)	338.000 (7.0000)	337.000 (9.8995)	342.000 (10.2817)	340.308 (9.1140)
Median	335.000	337.000	347.000	344.000
Min, Max	333.000, 346.000	330.000, 344.000	326.000, 354.000	326.000, 354.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-3.667 (11.9304)	-12.000 (1.4142)	-5.875 (5.8417)	-6.308 (7.1459)
Median	-9.000	-12.000	-6.500	-7.000
Min, Max	-12.000, 10.000	-13.000, -11.000	-15.000, 3.000	-15.000, 10.000
Week 16				
N	3	3	7	13
Mean (SD)	338.333 (6.6583)	349.333 (10.0167)	339.000 (11.3871)	341.231 (10.5052)
Median	340.000	350.000	340.000	340.000
Min, Max	331.000, 344.000	339.000, 359.000	326.000, 354.000	326.000, 359.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-3.333 (8.6217)	-1.333 (5.5076)	-8.000 (9.2376)	-5.385 (8.3220)
Median	-5.000	-4.000	-5.000	-5.000
Min, Max	-11.000, 6.000	-5.000, 5.000	-28.000, -1.000	-28.000, 6.000
Week 20				
N	4	3	6	13
Mean (SD)	329.250 (10.5948)	327.333 (17.2434)	336.000 (11.2606)	331.923 (12.1000)
Median	325.000	324.000	336.500	326.000
Min, Max	322.000, 345.000	312.000, 346.000	322.000, 353.000	312.000, 353.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-13.000 (16.4722)	-23.333 (16.9214)	-11.500 (6.0910)	-14.692 (12.4792)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-10.000	-19.000	-9.500	-11.000
Min, Max	-33.000, 1.000	-42.000, -9.000	-22.000, -6.000	-42.000, 1.000
Week 24				
N	4	3	6	13
Mean (SD)	327.500 (6.4031)	341.000 (8.5440)	328.667 (6.3770)	331.154 (8.4345)
Median	330.000	340.000	327.500	330.000
Min, Max	318.000, 332.000	333.000, 350.000	321.000, 340.000	318.000, 350.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-14.750 (7.5884)	-9.667 (4.5092)	-18.833 (10.0681)	-15.462 (8.6180)
Median	-13.500	-10.000	-19.500	-14.000
Min, Max	-25.000, -7.000	-14.000, -5.000	-33.000, -4.000	-33.000, -4.000
Week 28				
N	5	3	7	15
Mean (SD)	333.200 (12.4378)	335.000 (7.9373)	329.286 (9.2144)	331.733 (9.7795)
Median	326.000	332.000	330.000	330.000
Min, Max	323.000, 350.000	329.000, 344.000	314.000, 344.000	314.000, 350.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-7.600 (10.3102)	-15.667 (8.9629)	-17.571 (7.5907)	-13.867 (9.3874)
Median	-12.000	-11.000	-16.000	-12.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-20.000, 5.000	-26.000, -10.000	-28.000, -9.000	-28.000, 5.000
Week 32				
N	4	3	7	14
Mean (SD)	335.750 (9.5000)	327.333 (7.0946)	332.000 (10.6771)	332.071 (9.5149)
Median	336.000	326.000	333.000	332.000
Min, Max	325.000, 346.000	321.000, 335.000	315.000, 350.000	315.000, 350.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	-4.250 (9.3229)	-23.333 (4.1633)	-14.857 (4.2984)	-13.643 (8.9924)
Median	-4.500	-22.000	-17.000	-15.500
Min, Max	-14.000, 6.000	-28.000, -20.000	-19.000, -9.000	-28.000, 6.000
Week 36				
N	3	3	7	13
Mean (SD)	344.333 (8.1445)	337.000 (9.0000)	335.429 (12.8174)	337.846 (10.9913)
Median	348.000	337.000	336.000	337.000
Min, Max	335.000, 350.000	328.000, 346.000	314.000, 353.000	314.000, 353.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	2.667 (7.5056)	-13.667 (11.5902)	-11.429 (7.5687)	-8.692 (10.1603)
Median	3.000	-8.000	-8.000	-6.000
Min, Max	-5.000, 10.000	-27.000, -6.000	-24.000, -4.000	-27.000, 10.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	338.800 (14.9064)	341.667 (11.0604)	341.000 (14.6629)	340.400 (13.2115)
Median	346.000	343.000	341.000	343.000
Min, Max	319.000, 353.000	330.000, 352.000	317.000, 358.000	317.000, 358.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	-2.000 (8.0312)	-9.000 (6.0828)	-5.857 (6.2564)	-5.200 (6.8889)
Median	-6.000	-12.000	-3.000	-6.000
Min, Max	-9.000, 9.000	-13.000, -2.000	-16.000, 0.000	-16.000, 9.000
Week 44				
N	5	3	7	15
Mean (SD)	337.400 (16.0873)	337.333 (4.0415)	341.429 (16.4404)	339.267 (14.0177)
Median	341.000	338.000	342.000	341.000
Min, Max	314.000, 358.000	333.000, 341.000	312.000, 358.000	312.000, 358.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	-3.400 (14.1527)	-13.333 (3.0551)	-5.429 (8.1006)	-6.333 (10.0333)
Median	-2.000	-14.000	-2.000	-7.000
Min, Max	-21.000, 13.000	-16.000, -10.000	-21.000, 2.000	-21.000, 13.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	339.200 (11.7558)	335.000 (13.0000)	339.857 (13.5453)	338.667 (12.0811)
Median	341.000	342.000	338.000	341.000
Min, Max	323.000, 351.000	320.000, 343.000	321.000, 358.000	320.000, 358.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	-1.600 (8.0808)	-15.667 (6.4291)	-7.000 (6.3770)	-6.933 (8.2762)
Median	-2.000	-13.000	-7.000	-7.000
Min, Max	-14.000, 7.000	-23.000, -11.000	-16.000, 4.000	-23.000, 7.000
Early Term				
N	1		1	2
Mean (SD)	321.000 ()		345.000 ()	333.000 (16.9706)
Median	321.000		345.000	333.000
Min, Max	321.000, 321.000		345.000, 345.000	321.000, 345.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-14.000 ()		2.000 ()	-6.000 (11.3137)
Median	-14.000		2.000	-6.000
Min, Max	-14.000, -14.000		2.000, 2.000	-14.000, 2.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Ery. Mean Corpuscular Hemoglobin (pg)				
Baseline				
N	15			15
Mean (SD)	30.460 (2.0416)			30.460 (2.0416)
Median	30.800			30.800
Min, Max	25.700, 34.200			25.700, 34.200
Week 1				
N	15			15
Mean (SD)	30.433 (1.9551)			30.433 (1.9551)
Median	30.800			30.800
Min, Max	25.900, 34.400			25.900, 34.400
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.027 (0.4682)			-0.027 (0.4682)
Median	-0.100			-0.100
Min, Max	-0.800, 0.800			-0.800, 0.800
Week 2				
N	15			15
Mean (SD)	30.187 (1.8951)			30.187 (1.8951)
Median	30.500			30.500
Min, Max	25.200, 32.700			25.200, 32.700

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.273 (0.5788)			-0.273 (0.5788)
Median	-0.300			-0.300
Min, Max	-1.500, 0.600			-1.500, 0.600
Week 4				
N	2	13		15
Mean (SD)	28.650 (0.6364)	30.569 (2.0122)		30.313 (1.9888)
Median	28.650	30.800		30.300
Min, Max	28.200, 29.100	25.900, 34.600		25.900, 34.600
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	0.000 (0.4243)	-0.169 (0.5633)		-0.147 (0.5370)
Median	0.000	-0.100		-0.100
Min, Max	-0.300, 0.300	-1.200, 0.500		-1.200, 0.500
Week 6				
N	3	5	7	15
Mean (SD)	30.667 (2.7062)	30.200 (1.0392)	30.171 (2.0230)	30.280 (1.7745)
Median	29.800	30.200	30.900	30.200
Min, Max	28.500, 33.700	29.200, 31.600	25.800, 31.900	25.800, 33.700
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	0.167 (0.7638)	-0.580 (0.4207)	-0.043 (0.4237)	-0.180 (0.5506)
Median	0.000	-0.600	-0.100	-0.200
Min, Max	-0.500, 1.000	-1.200, -0.100	-0.700, 0.600	-1.200, 1.000
Week 8				
N	3	2	10	15
Mean (SD)	31.000 (3.4220)	29.500 (0.4243)	30.320 (1.6798)	30.347 (1.9220)
Median	29.600	29.500	30.950	30.600
Min, Max	28.500, 34.900	29.200, 29.800	26.300, 31.900	26.300, 34.900
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	0.500 (0.4359)	-0.550 (0.6364)	-0.210 (0.5646)	-0.113 (0.6128)
Median	0.700	-0.550	-0.300	-0.100
Min, Max	0.000, 0.800	-1.000, -0.100	-1.000, 0.600	-1.000, 0.800
Week 12				
N	3	2	8	13
Mean (SD)	32.267 (2.4542)	29.900 (0.7071)	30.388 (1.7594)	30.746 (1.9064)
Median	32.100	29.900	31.000	31.000
Min, Max	29.900, 34.800	29.400, 30.400	26.200, 31.700	26.200, 34.800
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	0.867 (0.2517)	-0.150 (0.3536)	-0.188 (0.7453)	0.062 (0.7456)
Median	0.900	-0.150	-0.050	0.300
Min, Max	0.600, 1.100	-0.400, 0.100	-1.100, 0.600	-1.100, 1.100
Week 16				
N	3	3	7	13
Mean (SD)	32.000 (1.6703)	30.900 (1.1000)	30.257 (1.7135)	30.808 (1.6337)
Median	31.700	30.900	30.500	30.700
Min, Max	30.500, 33.800	29.800, 32.000	26.600, 31.800	26.600, 33.800
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	0.600 (1.0536)	0.367 (0.2309)	-0.186 (1.0668)	0.123 (0.9435)
Median	0.500	0.500	0.400	0.500
Min, Max	-0.400, 1.700	0.100, 0.500	-1.600, 0.900	-1.600, 1.700
Week 20				
N	4	3	6	13
Mean (SD)	31.100 (0.4967)	30.833 (1.2583)	29.650 (1.9233)	30.369 (1.5354)
Median	31.050	31.000	30.050	30.600
Min, Max	30.600, 31.700	29.500, 32.000	26.100, 31.700	26.100, 32.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-0.175 (1.8839)	0.300 (0.1732)	-0.717 (0.7808)	-0.315 (1.1524)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-0.100	0.200	-1.000	0.100
Min, Max	-2.500, 2.000	0.200, 0.500	-1.500, 0.400	-2.500, 2.000
Week 24				
N	4	3	6	13
Mean (SD)	30.500 (1.1045)	30.967 (1.4978)	29.367 (1.9190)	30.085 (1.6502)
Median	30.450	31.400	30.050	30.300
Min, Max	29.500, 31.600	29.300, 32.200	25.800, 31.000	25.800, 32.200
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-0.775 (1.7840)	0.433 (0.8386)	-1.000 (0.9571)	-0.600 (1.2852)
Median	-0.450	0.000	-1.400	-0.100
Min, Max	-2.900, 0.700	-0.100, 1.400	-1.800, 0.300	-2.900, 1.400
Week 28				
N	5	3	7	15
Mean (SD)	30.480 (1.7683)	30.100 (1.4933)	29.000 (2.1726)	29.713 (1.9316)
Median	31.300	30.700	29.800	30.100
Min, Max	27.800, 32.100	28.400, 31.200	24.400, 30.700	24.400, 32.100
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-0.240 (1.1992)	-0.433 (0.4163)	-1.243 (0.7743)	-0.747 (0.9635)
Median	0.100	-0.300	-1.400	-0.900

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-2.100, 0.800	-0.900, -0.100	-2.100, 0.300	-2.100, 0.800
Week 32				
N	4	3	7	14
Mean (SD)	30.225 (2.0271)	29.733 (1.1719)	29.157 (2.5198)	29.586 (2.0784)
Median	30.500	30.200	30.100	30.150
Min, Max	27.600, 32.300	28.400, 30.600	23.700, 31.000	23.700, 32.300
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	-0.450 (1.2396)	-0.800 (0.1732)	-1.086 (1.0479)	-0.843 (0.9725)
Median	-0.450	-0.900	-1.500	-0.900
Min, Max	-1.900, 1.000	-0.900, -0.600	-2.000, 0.700	-2.000, 1.000
Week 36				
N	3	3	7	13
Mean (SD)	31.100 (1.4526)	30.033 (1.1015)	29.214 (3.0504)	29.838 (2.4168)
Median	31.200	30.100	30.300	30.300
Min, Max	29.600, 32.500	28.900, 31.100	22.500, 31.400	22.500, 32.500
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	-0.300 (1.2767)	-0.500 (0.1732)	-1.029 (1.1672)	-0.738 (1.0340)
Median	0.000	-0.400	-1.200	-0.400
Min, Max	-1.700, 0.800	-0.700, -0.400	-3.200, 0.300	-3.200, 0.800

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	30.380 (1.8700)	29.600 (1.1000)	29.343 (3.3009)	29.740 (2.4640)
Median	31.100	29.600	30.300	30.300
Min, Max	27.700, 32.400	28.500, 30.700	22.200, 32.300	22.200, 32.400
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	-0.340 (0.9762)	-0.933 (0.2309)	-0.900 (1.3241)	-0.720 (1.0530)
Median	-0.100	-0.800	-0.500	-0.600
Min, Max	-1.800, 0.500	-1.200, -0.800	-3.500, 0.200	-3.500, 0.500
Week 44				
N	5	3	7	15
Mean (SD)	30.400 (1.6971)	29.600 (1.1790)	29.371 (3.5659)	29.760 (2.5881)
Median	30.500	29.300	30.300	30.300
Min, Max	27.800, 31.900	28.600, 30.900	21.600, 32.400	21.600, 32.400
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	-0.320 (1.3349)	-0.933 (0.4933)	-0.871 (1.6183)	-0.700 (1.3207)
Median	-0.400	-0.700	-0.400	-0.600
Min, Max	-2.300, 1.100	-1.500, -0.600	-4.100, 0.600	-4.100, 1.100
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	30.600 (1.2981)	29.800 (1.2000)	29.457 (3.3620)	29.907 (2.4096)
Median	31.100	29.800	30.200	30.200
Min, Max	28.800, 31.800	28.600, 31.000	22.100, 32.000	22.100, 32.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	-0.120 (1.3312)	-0.733 (0.2517)	-0.786 (1.5657)	-0.553 (1.2911)
Median	0.300	-0.700	-0.100	-0.100
Min, Max	-2.400, 0.900	-1.000, -0.500	-3.600, 0.600	-3.600, 0.900
Early Term				
N	1		1	2
Mean (SD)	28.100 ()		28.800 ()	28.450 (0.4950)
Median	28.100		28.800	28.450
Min, Max	28.100, 28.100		28.800, 28.800	28.100, 28.800
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-0.400 ()		-0.700 ()	-0.550 (0.2121)
Median	-0.400		-0.700	-0.550
Min, Max	-0.400, -0.400		-0.700, -0.700	-0.700, -0.400

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Ery. Mean Corpuscular Volume (fL)				
Baseline				
N	15			15
Mean (SD)	88.047 (4.5070)			88.047 (4.5070)
Median	88.500			88.500
Min, Max	77.200, 96.500			77.200, 96.500
Week 1				
N	15			15
Mean (SD)	87.727 (4.4907)			87.727 (4.4907)
Median	88.300			88.300
Min, Max	75.800, 95.500			75.800, 95.500
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.320 (1.2599)			-0.320 (1.2599)
Median	-0.600			-0.600
Min, Max	-1.600, 2.800			-1.600, 2.800
Week 2				
N	15			15
Mean (SD)	87.060 (4.3695)			87.060 (4.3695)
Median	87.000			87.000
Min, Max	75.700, 93.500			75.700, 93.500

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.987 (1.1370)			-0.987 (1.1370)
Median	-0.900			-0.900
Min, Max	-3.400, 0.600			-3.400, 0.600
Week 4				
N	2	13		15
Mean (SD)	84.000 (0.2828)	88.100 (4.2381)		87.553 (4.1812)
Median	84.000	88.600		87.600
Min, Max	83.800, 84.200	76.400, 93.800		76.400, 93.800
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-2.750 (2.7577)	-0.146 (2.6024)		-0.493 (2.6810)
Median	-2.750	-0.600		-0.700
Min, Max	-4.700, -0.800	-2.700, 7.700		-4.700, 7.700
Week 6				
N	3	5	7	15
Mean (SD)	88.700 (5.0744)	87.800 (3.7202)	86.586 (5.6322)	87.413 (4.6881)
Median	87.700	87.500	88.700	87.900
Min, Max	84.200, 94.200	84.400, 93.700	75.500, 91.800	75.500, 94.200

Change from Baseline to Week 6

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-1.300 (3.6056)	0.160 (4.2146)	-0.914 (0.8630)	-0.633 (2.7588)
Median	-2.300	-1.300	-0.900	-1.300
Min, Max	-4.300, 2.700	-2.800, 7.600	-1.900, 0.400	-4.300, 7.600
Week 8				
N	3	2	10	15
Mean (SD)	97.867 (1.9088)	85.950 (3.0406)	86.600 (3.6588)	88.767 (5.6585)
Median	98.600	85.950	87.800	88.100
Min, Max	95.700, 99.300	83.800, 88.100	77.200, 90.500	77.200, 99.300
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	7.867 (4.9943)	-0.050 (3.8891)	-1.270 (1.5290)	0.720 (4.4726)
Median	10.700	-0.050	-1.250	-0.900
Min, Max	2.100, 10.800	-2.800, 2.700	-3.700, 1.500	-3.700, 10.800
Week 12				
N	3	2	8	13
Mean (SD)	95.333 (5.8106)	88.850 (0.4950)	88.863 (4.1884)	90.354 (4.8928)
Median	96.300	88.850	90.050	89.500
Min, Max	89.100, 100.600	88.500, 89.200	80.500, 93.000	80.500, 100.600
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	3.567 (2.7392)	2.850 (1.3435)	1.075 (2.0804)	1.923 (2.2855)
Median	4.100	2.850	0.550	1.200
Min, Max	0.600, 6.000	1.900, 3.800	-1.500, 4.900	-1.500, 6.000
Week 16				
N	3	3	7	13
Mean (SD)	94.667 (3.2716)	88.367 (0.6429)	89.271 (4.1664)	90.308 (4.1050)
Median	93.300	88.100	90.300	90.300
Min, Max	92.300, 98.400	87.900, 89.100	81.700, 93.600	81.700, 98.400
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	2.900 (0.9539)	1.433 (1.1015)	1.629 (2.5124)	1.877 (1.9639)
Median	3.000	1.500	2.200	2.200
Min, Max	1.900, 3.800	0.300, 2.500	-2.100, 4.500	-2.100, 4.500
Week 20				
N	4	3	6	13
Mean (SD)	94.625 (3.1973)	94.433 (7.0209)	88.200 (4.3561)	91.615 (5.4327)
Median	94.450	91.100	89.750	91.100
Min, Max	90.900, 98.700	89.700, 102.500	80.100, 91.700	80.100, 102.500
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	3.375 (2.1884)	7.500 (5.5245)	0.900 (2.4125)	3.185 (3.9983)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	3.050	5.700	1.500	2.900
Min, Max	1.200, 6.200	3.100, 13.700	-2.000, 3.200	-2.000, 13.700
Week 24				
N	4	3	6	13
Mean (SD)	93.175 (2.5889)	90.833 (2.3692)	89.400 (5.9977)	90.892 (4.5223)
Median	93.900	92.100	91.100	92.300
Min, Max	89.700, 95.200	88.100, 92.300	78.400, 95.100	78.400, 95.200
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	1.925 (3.4345)	3.900 (1.4422)	2.100 (1.8740)	2.462 (2.3319)
Median	1.800	3.500	2.150	3.000
Min, Max	-1.400, 5.500	2.700, 5.500	-0.800, 4.100	-1.400, 5.500
Week 28				
N	5	3	7	15
Mean (SD)	91.560 (4.2951)	89.800 (4.0262)	88.071 (5.1561)	89.580 (4.6399)
Median	90.800	90.700	88.300	89.600
Min, Max	86.200, 97.600	85.400, 93.300	77.700, 93.600	77.700, 97.600
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	1.560 (4.0581)	2.867 (3.4530)	0.943 (2.2854)	1.533 (3.0335)
Median	1.200	1.900	0.500	1.200

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-2.900, 7.900	0.000, 6.700	-2.200, 4.600	-2.900, 7.900
Week 32				
N	4	3	7	14
Mean (SD)	90.000 (4.0033)	90.800 (2.6907)	87.743 (5.8776)	89.043 (4.7604)
Median	90.100	90.000	88.400	90.000
Min, Max	85.000, 94.800	88.600, 93.800	75.200, 93.100	75.200, 94.800
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	-0.075 (1.3074)	3.867 (0.9866)	0.614 (3.1861)	1.114 (2.7473)
Median	-0.050	3.400	0.200	0.250
Min, Max	-1.700, 1.500	3.200, 5.000	-3.300, 5.600	-3.300, 5.600
Week 36				
N	3	3	7	13
Mean (SD)	90.267 (2.2745)	89.133 (2.9263)	86.929 (7.4703)	88.208 (5.6939)
Median	89.600	89.900	88.800	89.600
Min, Max	88.400, 92.800	85.900, 91.600	71.600, 93.500	71.600, 93.500
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	-1.500 (1.9287)	2.200 (2.4434)	-0.200 (2.9676)	0.054 (2.7948)
Median	-0.700	1.100	0.300	0.300
Min, Max	-3.700, -0.100	0.500, 5.000	-5.600, 2.900	-5.600, 5.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	89.760 (3.4041)	86.667 (0.5508)	85.914 (7.5050)	87.347 (5.5406)
Median	89.100	86.400	88.500	88.500
Min, Max	84.900, 93.900	86.300, 87.300	70.100, 92.200	70.100, 93.900
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	-0.240 (2.2345)	-0.267 (1.2014)	-1.214 (2.9157)	-0.700 (2.3504)
Median	-0.700	-0.200	-1.100	-0.700
Min, Max	-2.600, 3.400	-1.500, 0.900	-7.100, 2.100	-7.100, 3.400
Week 44				
N	5	3	7	15
Mean (SD)	90.100 (2.0384)	87.833 (3.1770)	85.800 (7.6894)	87.640 (5.6419)
Median	89.200	86.100	88.300	89.100
Min, Max	88.500, 93.600	85.900, 91.500	69.200, 90.500	69.200, 93.600
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	0.100 (2.4930)	0.900 (1.7088)	-1.329 (3.5752)	-0.407 (2.9246)
Median	-0.500	0.700	-0.800	-0.500
Min, Max	-2.900, 3.500	-0.700, 2.700	-8.000, 2.300	-8.000, 3.500
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	90.080 (2.5840)	89.000 (1.7059)	86.514 (8.1227)	88.200 (5.7810)
Median	89.900	89.500	88.800	89.100
Min, Max	86.500, 93.200	87.100, 90.400	68.900, 94.400	68.900, 94.400
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	0.080 (2.5361)	2.067 (1.8448)	-0.614 (4.9506)	0.153 (3.7294)
Median	0.200	1.600	-0.300	0.500
Min, Max	-3.300, 3.300	0.500, 4.100	-8.300, 6.300	-8.300, 6.300
Early Term				
N	1		1	2
Mean (SD)	87.700 ()		83.500 ()	85.600 (2.9698)
Median	87.700		83.500	85.600
Min, Max	87.700, 87.700		83.500, 83.500	83.500, 87.700
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	2.700 ()		-2.600 ()	0.050 (3.7477)
Median	2.700		-2.600	0.050
Min, Max	2.700, 2.700		-2.600, -2.600	-2.600, 2.700

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Erythrocytes (10 ¹² /L)				
Baseline				
N	15			15
Mean (SD)	4.948 (0.5407)			4.948 (0.5407)
Median	5.120			5.120
Min, Max	3.710, 5.720			3.710, 5.720
Week 1				
N	15			15
Mean (SD)	5.008 (0.5099)			5.008 (0.5099)
Median	5.160			5.160
Min, Max	3.810, 5.560			3.810, 5.560
Change from Baseline to Week 1				
N	15			15
Mean (SD)	0.060 (0.1225)			0.060 (0.1225)
Median	0.070			0.070
Min, Max	-0.160, 0.250			-0.160, 0.250
Week 2				
N	15			15
Mean (SD)	4.945 (0.5398)			4.945 (0.5398)
Median	5.070			5.070
Min, Max	3.670, 5.750			3.670, 5.750

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.003 (0.1612)			-0.003 (0.1612)
Median	-0.010			-0.010
Min, Max	-0.220, 0.390			-0.220, 0.390
Week 4				
N	2	13		15
Mean (SD)	4.150 (0.4101)	4.927 (0.6129)		4.823 (0.6393)
Median	4.150	5.010		4.970
Min, Max	3.860, 4.440	3.210, 5.630		3.210, 5.630
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-0.215 (0.2899)	-0.111 (0.1914)		-0.125 (0.1969)
Median	-0.215	-0.120		-0.120
Min, Max	-0.420, -0.010	-0.500, 0.270		-0.500, 0.270
Week 6				
N	3	5	7	15
Mean (SD)	3.750 (0.5941)	5.084 (0.2314)	5.024 (0.5272)	4.789 (0.6891)
Median	3.830	5.100	4.930	4.930
Min, Max	3.120, 4.300	4.730, 5.380	4.290, 5.750	3.120, 5.750
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-0.397 (0.2248)	-0.090 (0.2727)	-0.106 (0.2464)	-0.159 (0.2640)
Median	-0.450	-0.190	-0.040	-0.190
Min, Max	-0.590, -0.150	-0.410, 0.200	-0.490, 0.270	-0.590, 0.270
Week 8				
N	3	2	10	15
Mean (SD)	3.727 (0.7939)	4.505 (0.1768)	4.835 (0.3898)	4.569 (0.6270)
Median	4.180	4.505	4.850	4.720
Min, Max	2.810, 4.190	4.380, 4.630	4.020, 5.390	2.810, 5.390
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-0.420 (0.4233)	-0.410 (0.1838)	-0.360 (0.2767)	-0.379 (0.2793)
Median	-0.260	-0.410	-0.340	-0.330
Min, Max	-0.900, -0.100	-0.540, -0.280	-0.840, 0.060	-0.900, 0.060
Week 12				
N	3	2	8	13
Mean (SD)	3.950 (0.5116)	4.610 (0.0141)	4.749 (0.3901)	4.543 (0.4993)
Median	4.220	4.610	4.870	4.600
Min, Max	3.360, 4.270	4.600, 4.620	4.100, 5.110	3.360, 5.110
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-0.460 (0.3005)	-0.305 (0.0071)	-0.421 (0.2940)	-0.412 (0.2608)
Median	-0.350	-0.305	-0.380	-0.310
Min, Max	-0.800, -0.230	-0.310, -0.300	-0.870, -0.070	-0.870, -0.070
Week 16				
N	3	3	7	13
Mean (SD)	4.230 (0.5756)	4.750 (0.0954)	4.821 (0.3709)	4.668 (0.4346)
Median	4.260	4.700	4.970	4.760
Min, Max	3.640, 4.790	4.690, 4.860	4.250, 5.190	3.640, 5.190
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-0.180 (0.1054)	-0.307 (0.3092)	-0.324 (0.3793)	-0.287 (0.3058)
Median	-0.190	-0.220	-0.290	-0.220
Min, Max	-0.280, -0.070	-0.650, -0.050	-0.900, 0.090	-0.900, 0.090
Week 20				
N	4	3	6	13
Mean (SD)	4.245 (0.4342)	4.630 (0.2425)	4.988 (0.3101)	4.677 (0.4563)
Median	4.185	4.670	5.035	4.830
Min, Max	3.780, 4.830	4.370, 4.850	4.440, 5.400	3.780, 5.400
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-0.350 (0.4401)	-0.427 (0.1644)	-0.157 (0.3216)	-0.278 (0.3326)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-0.250	-0.490	-0.150	-0.240
Min, Max	-0.970, 0.070	-0.550, -0.240	-0.660, 0.220	-0.970, 0.220
Week 24				
N	4	3	6	13
Mean (SD)	4.273 (0.5300)	4.777 (0.1350)	5.108 (0.3415)	4.775 (0.5114)
Median	4.100	4.780	5.160	4.910
Min, Max	3.860, 5.030	4.640, 4.910	4.520, 5.550	3.860, 5.550
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-0.323 (0.5967)	-0.280 (0.1500)	-0.037 (0.3246)	-0.181 (0.3953)
Median	-0.125	-0.280	0.005	-0.130
Min, Max	-1.190, 0.150	-0.430, -0.130	-0.460, 0.370	-1.190, 0.370
Week 28				
N	5	3	7	15
Mean (SD)	4.390 (0.4733)	4.750 (0.1908)	5.214 (0.3432)	4.847 (0.5136)
Median	4.330	4.650	5.320	4.970
Min, Max	3.890, 5.170	4.630, 4.970	4.520, 5.620	3.890, 5.620
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-0.142 (0.4595)	-0.307 (0.0551)	0.016 (0.1827)	-0.101 (0.3025)
Median	0.070	-0.280	0.030	-0.100

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-0.940, 0.180	-0.370, -0.270	-0.240, 0.220	-0.940, 0.220
Week 32				
N	4	3	7	14
Mean (SD)	4.478 (0.4555)	4.763 (0.2401)	5.033 (0.4759)	4.816 (0.4717)
Median	4.585	4.640	5.300	4.905
Min, Max	3.840, 4.900	4.610, 5.040	4.030, 5.350	3.840, 5.350
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	0.100 (0.2312)	-0.293 (0.0115)	-0.166 (0.1881)	-0.117 (0.2272)
Median	0.090	-0.300	-0.220	-0.195
Min, Max	-0.170, 0.390	-0.300, -0.280	-0.400, 0.170	-0.400, 0.390
Week 36				
N	3	3	7	13
Mean (SD)	4.553 (0.7071)	5.013 (0.1464)	5.180 (0.5336)	4.997 (0.5460)
Median	4.490	4.990	5.290	5.070
Min, Max	3.880, 5.290	4.880, 5.170	4.160, 5.700	3.880, 5.700
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	0.143 (0.0929)	-0.043 (0.1250)	-0.019 (0.1425)	0.013 (0.1408)
Median	0.170	-0.040	-0.020	0.040
Min, Max	0.040, 0.220	-0.170, 0.080	-0.210, 0.160	-0.210, 0.220

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	4.564 (0.5385)	5.093 (0.2318)	5.201 (0.5713)	4.967 (0.5651)
Median	4.650	5.060	5.110	5.040
Min, Max	3.760, 5.240	4.880, 5.340	4.220, 5.850	3.760, 5.850
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	0.032 (0.2880)	0.037 (0.1002)	0.003 (0.2385)	0.019 (0.2231)
Median	0.050	0.000	-0.070	0.000
Min, Max	-0.410, 0.370	-0.040, 0.150	-0.250, 0.490	-0.410, 0.490
Week 44				
N	5	3	7	15
Mean (SD)	4.580 (0.4708)	4.960 (0.1311)	5.204 (0.4123)	4.947 (0.4689)
Median	4.620	4.980	5.340	4.980
Min, Max	3.920, 5.230	4.820, 5.080	4.420, 5.610	3.920, 5.610
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	0.048 (0.3532)	-0.097 (0.1650)	0.006 (0.2378)	-0.001 (0.2581)
Median	0.160	-0.100	0.100	0.070
Min, Max	-0.530, 0.400	-0.260, 0.070	-0.380, 0.250	-0.530, 0.400
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	4.558 (0.4998)	4.940 (0.1300)	5.094 (0.3474)	4.885 (0.4316)
Median	4.520	4.870	5.180	4.940
Min, Max	3.840, 5.110	4.860, 5.090	4.510, 5.560	3.840, 5.560
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	0.026 (0.1744)	-0.117 (0.1159)	-0.104 (0.2528)	-0.063 (0.2057)
Median	0.040	-0.060	-0.140	-0.060
Min, Max	-0.210, 0.240	-0.250, -0.040	-0.430, 0.210	-0.430, 0.240
Early Term				
N	1		1	2
Mean (SD)	4.050 ()		4.550 ()	4.300 (0.3536)
Median	4.050		4.550	4.300
Min, Max	4.050, 4.050		4.550, 4.550	4.050, 4.550
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-0.230 ()		-0.970 ()	-0.600 (0.5233)
Median	-0.230		-0.970	-0.600
Min, Max	-0.230, -0.230		-0.970, -0.970	-0.970, -0.230

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Hematocrit (%)				
Baseline				
N	15			15
Mean (SD)	43.440 (4.0893)			43.440 (4.0893)
Median	45.100			45.100
Min, Max	35.800, 47.900			35.800, 47.900
Week 1				
N	15			15
Mean (SD)	43.813 (3.8877)			43.813 (3.8877)
Median	44.600			44.600
Min, Max	36.400, 48.000			36.400, 48.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	0.373 (1.0074)			0.373 (1.0074)
Median	0.500			0.500
Min, Max	-1.700, 2.100			-1.700, 2.100
Week 2				
N	15			15
Mean (SD)	42.933 (4.0635)			42.933 (4.0635)
Median	43.500			43.500
Min, Max	34.300, 48.100			34.300, 48.100

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.507 (1.2470)			-0.507 (1.2470)
Median	-0.500			-0.500
Min, Max	-2.400, 2.100			-2.400, 2.100
Week 4				
N	2	13		15
Mean (SD)	34.850 (3.3234)	43.269 (4.7745)		42.147 (5.3948)
Median	34.850	43.900		43.500
Min, Max	32.500, 37.200	30.100, 50.200		30.100, 50.200
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-3.050 (1.2021)	-1.023 (2.0113)		-1.293 (2.0197)
Median	-3.050	-0.700		-0.900
Min, Max	-3.900, -2.200	-5.700, 2.300		-5.700, 2.300
Week 6				
N	3	5	7	15
Mean (SD)	33.067 (3.4312)	44.660 (3.3035)	43.300 (2.8937)	41.707 (5.3637)
Median	33.600	44.600	42.500	42.500
Min, Max	29.400, 36.200	39.900, 47.900	39.400, 47.600	29.400, 47.900
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-4.133 (1.9732)	-0.680 (1.6453)	-1.457 (1.8752)	-1.733 (2.1226)
Median	-3.200	0.300	-0.900	-1.800
Min, Max	-6.400, -2.800	-2.800, 0.800	-4.400, 1.100	-6.400, 1.100
Week 8				
N	3	2	10	15
Mean (SD)	36.433 (7.6055)	38.700 (0.1414)	41.690 (2.5839)	40.240 (4.1836)
Median	40.000	38.700	41.850	41.600
Min, Max	27.700, 41.600	38.600, 38.800	36.400, 45.900	27.700, 45.900
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-0.767 (6.3893)	-3.550 (0.2121)	-3.860 (1.7564)	-3.200 (3.0685)
Median	2.200	-3.550	-3.850	-3.700
Min, Max	-8.100, 3.600	-3.700, -3.400	-6.300, -0.800	-8.100, 3.600
Week 12				
N	3	2	8	13
Mean (SD)	37.500 (3.6510)	40.950 (0.3536)	42.113 (2.8901)	40.869 (3.3127)
Median	37.600	40.950	41.700	41.000
Min, Max	33.800, 41.100	40.700, 41.200	37.800, 46.600	33.800, 46.600
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-2.833 (1.6197)	-1.300 (0.7071)	-3.163 (2.3868)	-2.800 (2.0652)
Median	-2.000	-1.300	-3.150	-2.000
Min, Max	-4.700, -1.800	-1.800, -0.800	-7.600, -0.600	-7.600, -0.600
Week 16				
N	3	3	7	13
Mean (SD)	39.933 (4.4837)	41.967 (0.7638)	42.986 (3.2137)	42.046 (3.2007)
Median	39.300	41.800	42.600	41.800
Min, Max	35.800, 44.700	41.300, 42.800	39.200, 47.900	35.800, 47.900
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-0.400 (0.6083)	-2.000 (3.1575)	-1.986 (3.0575)	-1.623 (2.6237)
Median	-0.100	-0.700	-0.700	-0.700
Min, Max	-1.100, 0.000	-5.600, 0.300	-7.000, 1.300	-7.000, 1.300
Week 20				
N	4	3	6	13
Mean (SD)	40.125 (3.7223)	43.800 (5.2163)	43.967 (3.1104)	42.746 (3.9170)
Median	38.850	41.900	44.550	41.900
Min, Max	37.300, 45.500	39.800, 49.700	40.200, 48.400	37.300, 49.700
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-1.675 (4.4139)	-0.167 (2.2811)	-0.800 (1.8580)	-0.923 (2.7414)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	0.000	-0.600	-0.500	-0.300
Min, Max	-8.200, 1.500	-2.200, 2.300	-4.100, 1.100	-8.200, 2.300
Week 24				
N	4	3	6	13
Mean (SD)	39.700 (3.7559)	43.400 (2.2605)	45.700 (4.7053)	43.323 (4.5613)
Median	38.500	44.000	46.300	44.000
Min, Max	36.700, 45.100	40.900, 45.300	39.200, 52.800	36.700, 52.800
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-2.100 (4.3174)	-0.567 (1.8583)	0.933 (2.7689)	-0.346 (3.2072)
Median	-0.400	-1.100	1.150	-0.100
Min, Max	-8.500, 0.900	-2.100, 1.500	-2.200, 5.500	-8.500, 5.500
Week 28				
N	5	3	7	15
Mean (SD)	40.120 (3.8900)	42.667 (2.7392)	45.886 (3.5225)	43.320 (4.2134)
Median	39.300	43.200	46.800	43.200
Min, Max	36.400, 46.300	39.700, 45.100	39.800, 49.600	36.400, 49.600
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-0.600 (2.5515)	-1.300 (1.7321)	0.729 (1.2244)	-0.120 (1.9162)
Median	0.500	-2.300	0.900	0.500

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-5.100, 1.100	-2.300, 0.700	-1.600, 2.000	-5.100, 2.000
Week 32				
N	4	3	7	14
Mean (SD)	40.200 (3.2031)	43.300 (3.4699)	44.043 (4.0078)	42.786 (3.8214)
Median	40.100	41.500	44.200	42.850
Min, Max	36.400, 44.200	41.100, 47.300	37.500, 48.600	36.400, 48.600
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	0.850 (2.0108)	-0.667 (0.4933)	-1.114 (1.3146)	-0.457 (1.5926)
Median	0.850	-0.900	-1.200	-0.900
Min, Max	-1.600, 3.300	-1.000, -0.100	-2.800, 1.100	-2.800, 3.300
Week 36				
N	3	3	7	13
Mean (SD)	41.033 (5.8158)	44.700 (2.4576)	44.829 (4.1189)	43.923 (4.2242)
Median	39.700	45.700	47.000	45.700
Min, Max	36.000, 47.400	41.900, 46.500	38.900, 49.200	36.000, 49.200
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	0.700 (0.7810)	0.733 (2.1733)	-0.329 (1.1968)	0.154 (1.3782)
Median	0.300	-0.100	-0.300	0.000
Min, Max	0.200, 1.600	-0.900, 3.200	-1.900, 1.700	-1.900, 3.200

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	40.880 (4.1439)	44.133 (2.2811)	44.414 (3.6512)	43.180 (3.7695)
Median	40.700	43.700	44.600	43.400
Min, Max	35.300, 46.700	42.100, 46.600	38.900, 49.300	35.300, 49.300
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	0.160 (2.6567)	0.167 (1.0017)	-0.743 (1.2856)	-0.260 (1.7569)
Median	0.900	0.100	-1.200	-0.400
Min, Max	-4.000, 3.100	-0.800, 1.200	-2.000, 1.800	-4.000, 3.100
Week 44				
N	5	3	7	15
Mean (SD)	41.200 (3.5588)	43.600 (2.5942)	44.500 (3.8267)	43.220 (3.6281)
Median	41.200	42.800	44.800	42.800
Min, Max	36.700, 46.600	41.500, 46.500	38.800, 48.300	36.700, 48.300
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	0.480 (3.5633)	-0.367 (0.6110)	-0.657 (1.6400)	-0.220 (2.2603)
Median	0.800	-0.500	-0.300	0.300
Min, Max	-5.000, 5.000	-0.900, 0.300	-3.100, 1.000	-5.000, 5.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	41.000 (3.9718)	43.967 (1.8448)	43.914 (3.4465)	42.953 (3.4826)
Median	40.200	43.500	45.900	43.500
Min, Max	35.800, 45.500	42.400, 46.000	38.300, 47.000	35.800, 47.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	0.280 (1.6483)	0.000 (1.4526)	-1.243 (1.8091)	-0.487 (1.7398)
Median	0.000	-0.100	-1.300	-0.300
Min, Max	-1.800, 2.700	-1.400, 1.500	-3.300, 1.900	-3.300, 2.700
Early Term				
N	1		1	2
Mean (SD)	35.500 ()		38.000 ()	36.750 (1.7678)
Median	35.500		38.000	36.750
Min, Max	35.500, 35.500		38.000, 38.000	35.500, 38.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-0.900 ()		-9.500 ()	-5.200 (6.0811)
Median	-0.900		-9.500	-5.200
Min, Max	-0.900, -0.900		-9.500, -9.500	-9.500, -0.900

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Hemoglobin (g/L)				
Baseline				
N	15			15
Mean (SD)	150.333 (16.4085)			150.333 (16.4085)
Median	155.000			155.000
Min, Max	122.000, 170.000			122.000, 170.000
Week 1				
N	15			15
Mean (SD)	152.133 (15.8063)			152.133 (15.8063)
Median	156.000			156.000
Min, Max	123.000, 173.000			123.000, 173.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	1.800 (3.9857)			1.800 (3.9857)
Median	2.000			2.000
Min, Max	-6.000, 8.000			-6.000, 8.000
Week 2				
N	15			15
Mean (SD)	148.867 (15.4959)			148.867 (15.4959)
Median	155.000			155.000
Min, Max	119.000, 167.000			119.000, 167.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-1.467 (4.6425)			-1.467 (4.6425)
Median	-3.000			-3.000
Min, Max	-9.000, 7.000			-9.000, 7.000
Week 4				
N	2	13		15
Mean (SD)	119.000 (14.1421)	149.769 (14.5496)		145.667 (17.6905)
Median	119.000	153.000		152.000
Min, Max	109.000, 129.000	111.000, 167.000		109.000, 167.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-6.000 (9.8995)	-4.462 (6.2532)		-4.667 (6.3882)
Median	-6.000	-3.000		-3.000
Min, Max	-13.000, 1.000	-16.000, 8.000		-16.000, 8.000
Week 6				
N	3	5	7	15
Mean (SD)	114.000 (12.2882)	153.600 (11.6748)	151.000 (12.4900)	144.467 (19.4270)
Median	109.000	154.000	148.000	148.000
Min, Max	105.000, 128.000	138.000, 170.000	137.000, 173.000	105.000, 173.000

Change from Baseline to Week 6

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-11.667 (11.0604)	-5.600 (7.1624)	-3.571 (7.6563)	-5.867 (8.1929)
Median	-13.000	-6.000	-5.000	-5.000
Min, Max	-22.000, 0.000	-14.000, 3.000	-15.000, 7.000	-22.000, 7.000
Week 8				
N	3	2	10	15
Mean (SD)	113.667 (13.7961)	133.000 (7.0711)	146.300 (10.9550)	138.000 (16.9579)
Median	119.000	133.000	147.000	142.000
Min, Max	98.000, 124.000	128.000, 138.000	125.000, 167.000	98.000, 167.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-12.000 (14.7309)	-14.500 (2.1213)	-12.000 (8.8694)	-12.333 (9.0921)
Median	-4.000	-14.500	-12.000	-12.000
Min, Max	-29.000, -3.000	-16.000, -13.000	-27.000, 4.000	-29.000, 4.000
Week 12				
N	3	2	8	13
Mean (SD)	126.667 (10.0167)	138.000 (2.8284)	144.125 (12.5293)	139.154 (12.8313)
Median	126.000	138.000	143.000	137.000
Min, Max	117.000, 137.000	136.000, 140.000	127.000, 162.000	117.000, 162.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-11.000 (9.5394)	-9.500 (2.1213)	-13.625 (7.8365)	-12.385 (7.3659)
Median	-10.000	-9.500	-11.500	-11.000
Min, Max	-21.000, -2.000	-11.000, -8.000	-29.000, -5.000	-29.000, -2.000
Week 16				
N	3	3	7	13
Mean (SD)	135.000 (15.1327)	146.667 (5.7735)	145.714 (12.1479)	143.462 (11.8716)
Median	130.000	150.000	146.000	146.000
Min, Max	123.000, 152.000	140.000, 150.000	134.000, 165.000	123.000, 165.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-2.667 (4.1633)	-7.667 (9.0738)	-10.571 (8.3238)	-8.077 (7.8895)
Median	-4.000	-4.000	-9.000	-5.000
Min, Max	-6.000, 2.000	-18.000, -1.000	-25.000, -3.000	-25.000, 2.000
Week 20				
N	4	3	6	13
Mean (SD)	132.000 (11.6905)	143.000 (13.1149)	148.000 (14.1845)	141.923 (14.0799)
Median	130.000	145.000	148.000	145.000
Min, Max	120.000, 148.000	129.000, 155.000	131.000, 171.000	120.000, 171.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-11.000 (12.2474)	-11.333 (4.7258)	-7.833 (7.0545)	-9.615 (8.0575)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-8.500	-13.000	-8.000	-9.000
Min, Max	-28.000, 1.000	-15.000, -6.000	-19.000, 1.000	-28.000, 1.000
Week 24				
N	4	3	6	13
Mean (SD)	130.000 (12.8062)	148.000 (10.3923)	150.167 (15.4456)	143.462 (15.6983)
Median	125.000	154.000	153.000	149.000
Min, Max	121.000, 149.000	136.000, 154.000	129.000, 172.000	121.000, 172.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-13.000 (14.2127)	-6.333 (8.6217)	-5.667 (5.2409)	-8.077 (9.2778)
Median	-7.500	-8.000	-7.000	-8.000
Min, Max	-34.000, -3.000	-14.000, 3.000	-12.000, 2.000	-34.000, 3.000
Week 28				
N	5	3	7	15
Mean (SD)	133.800 (16.3615)	143.000 (11.5326)	151.286 (14.2328)	143.800 (15.6899)
Median	128.000	142.000	160.000	142.000
Min, Max	121.000, 162.000	132.000, 155.000	125.000, 161.000	121.000, 162.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-5.000 (11.9583)	-11.333 (2.0817)	-5.571 (4.8599)	-6.533 (7.6051)
Median	-1.000	-12.000	-4.000	-4.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-26.000, 4.000	-13.000, -9.000	-13.000, 0.000	-26.000, 4.000
Week 32				
N	4	3	7	14
Mean (SD)	135.000 (12.6754)	141.667 (11.2398)	146.429 (15.9463)	142.143 (14.1250)
Median	131.500	139.000	148.000	141.500
Min, Max	124.000, 153.000	132.000, 154.000	125.000, 165.000	124.000, 165.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	1.250 (6.1305)	-12.667 (1.1547)	-10.429 (4.8255)	-7.571 (7.3455)
Median	1.500	-12.000	-12.000	-11.500
Min, Max	-5.000, 7.000	-14.000, -12.000	-17.000, -3.000	-17.000, 7.000
Week 36				
N	3	3	7	13
Mean (SD)	141.333 (20.7926)	150.667 (10.0167)	150.714 (18.1816)	148.538 (16.4601)
Median	133.000	150.000	155.000	150.000
Min, Max	126.000, 165.000	141.000, 161.000	124.000, 167.000	124.000, 167.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	3.667 (4.1633)	-3.667 (3.0551)	-6.143 (5.9000)	-3.308 (6.2234)
Median	5.000	-3.000	-6.000	-3.000
Min, Max	-1.000, 7.000	-7.000, -1.000	-14.000, 4.000	-14.000, 7.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	138.600 (16.9204)	151.000 (12.5300)	151.714 (16.9383)	147.200 (16.3366)
Median	130.000	150.000	157.000	149.000
Min, Max	122.000, 163.000	139.000, 164.000	128.000, 168.000	122.000, 168.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	-0.200 (7.1204)	-3.333 (2.0817)	-5.143 (4.5981)	-3.133 (5.4099)
Median	2.000	-4.000	-7.000	-5.000
Min, Max	-10.000, 7.000	-5.000, -1.000	-10.000, 3.000	-10.000, 7.000
Week 44				
N	5	3	7	15
Mean (SD)	139.200 (16.5892)	147.000 (9.5394)	152.286 (18.5537)	146.867 (16.5782)
Median	133.000	146.000	159.000	146.000
Min, Max	125.000, 167.000	138.000, 157.000	121.000, 171.000	121.000, 171.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	0.400 (11.1490)	-7.333 (3.2146)	-4.571 (7.0204)	-3.467 (8.2016)
Median	5.000	-6.000	-4.000	-4.000
Min, Max	-18.000, 9.000	-11.000, -5.000	-17.000, 4.000	-18.000, 9.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	139.400 (16.8760)	147.333 (9.7125)	149.429 (14.4321)	145.667 (14.3461)
Median	130.000	145.000	155.000	154.000
Min, Max	122.000, 159.000	139.000, 158.000	123.000, 163.000	122.000, 163.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	0.600 (5.0299)	-7.000 (2.6458)	-7.429 (4.8599)	-4.667 (5.7652)
Median	1.000	-6.000	-7.000	-5.000
Min, Max	-5.000, 8.000	-10.000, -5.000	-15.000, -1.000	-15.000, 8.000
Early Term				
N	1		1	2
Mean (SD)	114.000 ()		131.000 ()	122.500 (12.0208)
Median	114.000		131.000	122.500
Min, Max	114.000, 114.000		131.000, 131.000	114.000, 131.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-8.000 ()		-32.000 ()	-20.000 (16.9706)
Median	-8.000		-32.000	-20.000
Min, Max	-8.000, -8.000		-32.000, -32.000	-32.000, -8.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Leukocytes (10 ⁹ /L)				
Baseline				
N	15			15
Mean (SD)	5.935 (1.5539)			5.935 (1.5539)
Median	5.470			5.470
Min, Max	3.820, 10.330			3.820, 10.330
Week 1				
N	15			15
Mean (SD)	6.605 (1.7097)			6.605 (1.7097)
Median	6.450			6.450
Min, Max	4.040, 10.510			4.040, 10.510
Change from Baseline to Week 1				
N	15			15
Mean (SD)	0.670 (0.8643)			0.670 (0.8643)
Median	0.770			0.770
Min, Max	-0.720, 1.860			-0.720, 1.860
Week 2				
N	15			15
Mean (SD)	6.371 (1.7856)			6.371 (1.7856)
Median	5.990			5.990
Min, Max	3.760, 10.040			3.760, 10.040

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	0.435 (1.0355)			0.435 (1.0355)
Median	0.440			0.440
Min, Max	-1.050, 2.610			-1.050, 2.610
Week 4				
N	2	13		15
Mean (SD)	6.260 (2.1779)	5.988 (1.5356)		6.025 (1.5392)
Median	6.260	5.950		5.950
Min, Max	4.720, 7.800	3.450, 8.780		3.450, 8.780
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	0.665 (2.4395)	0.001 (0.8809)		0.089 (1.0700)
Median	0.665	-0.070		-0.070
Min, Max	-1.060, 2.390	-1.550, 1.270		-1.550, 2.390
Week 6				
N	3	5	7	15
Mean (SD)	3.593 (1.4674)	5.584 (1.4851)	7.781 (1.9560)	6.211 (2.3279)
Median	3.690	5.010	7.580	5.870
Min, Max	2.080, 5.010	3.790, 7.550	5.700, 11.210	2.080, 11.210
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-1.410 (0.8920)	-0.356 (0.4099)	1.450 (1.0158)	0.276 (1.4300)
Median	-1.740	-0.380	1.570	0.080
Min, Max	-2.090, -0.400	-0.970, 0.080	0.270, 3.030	-2.090, 3.030
Week 8				
N	3	2	10	15
Mean (SD)	4.257 (1.5716)	4.755 (0.5728)	6.857 (1.7984)	6.057 (1.9620)
Median	4.520	4.755	6.365	5.680
Min, Max	2.570, 5.680	4.350, 5.160	4.510, 9.620	2.570, 9.620
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-0.747 (0.8805)	-1.115 (0.9970)	0.629 (1.4449)	0.121 (1.4449)
Median	-1.250	-1.115	0.290	-0.410
Min, Max	-1.260, 0.270	-1.820, -0.410	-0.960, 3.130	-1.820, 3.130
Week 12				
N	3	2	8	13
Mean (SD)	4.160 (0.5977)	4.805 (2.8921)	5.698 (2.9679)	5.205 (2.5212)
Median	3.830	4.805	5.380	4.850
Min, Max	3.800, 4.850	2.760, 6.850	2.180, 11.370	2.180, 11.370
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-1.043 (1.0845)	-1.065 (1.3223)	-0.386 (1.5771)	-0.642 (1.3807)
Median	-0.930	-1.065	0.190	-0.130
Min, Max	-2.180, -0.020	-2.000, -0.130	-2.850, 1.270	-2.850, 1.270
Week 16				
N	3	3	7	13
Mean (SD)	5.093 (1.4097)	4.943 (1.4406)	6.424 (1.8018)	5.775 (1.6839)
Median	4.790	4.990	6.670	4.990
Min, Max	3.860, 6.630	3.480, 6.360	4.220, 8.640	3.480, 8.640
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-0.110 (0.8154)	-0.793 (0.4272)	0.253 (1.8376)	-0.072 (1.4219)
Median	0.040	-0.620	-0.620	-0.620
Min, Max	-0.990, 0.620	-1.280, -0.480	-1.690, 3.320	-1.690, 3.320
Week 20				
N	4	3	6	13
Mean (SD)	4.988 (1.1521)	4.883 (1.3937)	6.440 (1.5107)	5.634 (1.4871)
Median	5.075	5.260	6.175	5.850
Min, Max	3.500, 6.300	3.340, 6.050	4.540, 9.110	3.340, 9.110
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-0.250 (0.4637)	-0.853 (1.2503)	0.130 (1.1326)	-0.214 (1.0053)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-0.230	-1.420	-0.125	-0.320
Min, Max	-0.830, 0.290	-1.720, 0.580	-1.220, 1.760	-1.720, 1.760
Week 24				
N	4	3	6	13
Mean (SD)	4.678 (0.9184)	5.143 (1.2608)	6.223 (1.1628)	5.498 (1.2483)
Median	4.335	5.700	6.285	5.700
Min, Max	4.020, 6.020	3.700, 6.030	4.560, 7.760	3.700, 7.760
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-0.560 (0.7727)	-0.593 (0.7151)	-0.087 (1.3420)	-0.349 (1.0243)
Median	-0.585	-0.950	0.295	0.010
Min, Max	-1.270, 0.200	-1.060, 0.230	-2.570, 1.110	-2.570, 1.110
Week 28				
N	5	3	7	15
Mean (SD)	4.902 (0.7111)	4.717 (1.3336)	6.496 (1.9263)	5.609 (1.6526)
Median	4.830	4.150	6.070	4.990
Min, Max	3.820, 5.580	3.760, 6.240	4.300, 9.460	3.760, 9.460
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-0.370 (0.4533)	-1.020 (0.2905)	0.001 (0.8907)	-0.327 (0.7538)
Median	-0.500	-1.000	0.040	-0.500

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-0.950, 0.170	-1.320, -0.740	-1.300, 1.100	-1.320, 1.100
Week 32				
N	4	3	7	14
Mean (SD)	4.783 (1.0517)	5.163 (0.9592)	5.494 (1.4940)	5.220 (1.2357)
Median	4.975	4.850	5.490	5.215
Min, Max	3.460, 5.720	4.400, 6.240	2.850, 7.300	2.850, 7.300
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	-0.473 (0.6284)	-0.573 (0.1943)	-1.000 (1.3723)	-0.758 (1.0152)
Median	-0.325	-0.620	-0.730	-0.490
Min, Max	-1.360, 0.120	-0.740, -0.360	-3.030, 0.600	-3.030, 0.600
Week 36				
N	3	3	7	13
Mean (SD)	4.637 (1.2994)	4.850 (1.4131)	5.993 (1.3808)	5.416 (1.4119)
Median	4.760	5.600	5.240	5.240
Min, Max	3.280, 5.870	3.220, 5.730	4.610, 8.300	3.220, 8.300
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	-0.567 (0.4406)	-0.887 (0.9963)	-0.501 (0.7921)	-0.605 (0.7334)
Median	-0.540	-1.380	-0.360	-0.420
Min, Max	-1.020, -0.140	-1.540, 0.260	-2.030, 0.200	-2.030, 0.260

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	5.562 (1.7571)	4.987 (0.7685)	6.201 (1.5308)	5.745 (1.4867)
Median	5.070	5.400	6.450	5.400
Min, Max	3.460, 8.260	4.100, 5.460	4.260, 8.290	3.460, 8.290
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	0.290 (1.1892)	-0.750 (0.7889)	-0.293 (1.1337)	-0.190 (1.0948)
Median	-0.280	-0.660	-0.600	-0.360
Min, Max	-0.710, 2.250	-1.580, -0.010	-2.040, 1.420	-2.040, 2.250
Week 44				
N	5	3	7	15
Mean (SD)	5.384 (0.8503)	5.957 (1.6435)	6.167 (1.2634)	5.864 (1.1860)
Median	4.880	6.850	5.710	5.710
Min, Max	4.760, 6.720	4.060, 6.960	4.480, 8.000	4.060, 8.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	0.112 (0.7955)	0.220 (1.0606)	-0.327 (1.3622)	-0.071 (1.0953)
Median	0.340	-0.020	-0.150	-0.020
Min, Max	-0.900, 0.940	-0.700, 1.380	-3.090, 1.030	-3.090, 1.380
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	5.990 (0.8873)	5.287 (1.7638)	6.040 (1.7106)	5.873 (1.4198)
Median	5.940	5.420	5.870	5.870
Min, Max	4.970, 7.170	3.460, 6.980	3.830, 7.980	3.460, 7.980
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	0.718 (1.6376)	-0.450 (0.7365)	-0.454 (1.2987)	-0.063 (1.3759)
Median	-0.070	-0.050	-0.320	-0.070
Min, Max	-0.810, 3.350	-1.300, 0.000	-2.420, 1.010	-2.420, 3.350
Early Term				
N	1		1	2
Mean (SD)	5.140 ()		7.270 ()	6.205 (1.5061)
Median	5.140		7.270	6.205
Min, Max	5.140, 5.140		7.270, 7.270	5.140, 7.270
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-0.270 ()		-0.330 ()	-0.300 (0.0424)
Median	-0.270		-0.330	-0.300
Min, Max	-0.270, -0.270		-0.330, -0.330	-0.330, -0.270

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Lymphocytes (10 ⁹ /L)				
Baseline				
N	15			15
Mean (SD)	2.219 (0.4731)			2.219 (0.4731)
Median	2.240			2.240
Min, Max	1.210, 3.170			1.210, 3.170
Week 1				
N	15			15
Mean (SD)	2.213 (0.6691)			2.213 (0.6691)
Median	1.980			1.980
Min, Max	1.460, 3.570			1.460, 3.570
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.006 (0.5047)			-0.006 (0.5047)
Median	0.090			0.090
Min, Max	-1.120, 0.820			-1.120, 0.820
Week 2				
N	15			15
Mean (SD)	2.160 (0.5464)			2.160 (0.5464)
Median	2.060			2.060
Min, Max	1.220, 3.440			1.220, 3.440

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.059 (0.3952)			-0.059 (0.3952)
Median	-0.020			-0.020
Min, Max	-0.750, 0.640			-0.750, 0.640
Week 4				
N	2	13		15
Mean (SD)	1.935 (0.0778)	2.042 (0.4769)		2.028 (0.4437)
Median	1.935	2.180		2.160
Min, Max	1.880, 1.990	1.000, 2.700		1.000, 2.700
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-0.570 (0.3536)	-0.133 (0.5404)		-0.191 (0.5319)
Median	-0.570	0.070		0.020
Min, Max	-0.820, -0.320	-1.240, 0.530		-1.240, 0.530
Week 6				
N	3	5	7	15
Mean (SD)	1.610 (0.2254)	1.892 (0.6916)	2.601 (0.7938)	2.167 (0.7758)
Median	1.490	2.030	2.410	2.030
Min, Max	1.470, 1.870	1.100, 2.780	1.560, 3.620	1.100, 3.620
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-0.653 (0.7167)	-0.378 (0.6017)	0.437 (0.5618)	-0.053 (0.7397)
Median	-0.710	-0.220	0.350	0.020
Min, Max	-1.340, 0.090	-1.200, 0.310	-0.330, 1.230	-1.340, 1.230
Week 8				
N	3	2	10	15
Mean (SD)	1.730 (0.1253)	1.935 (0.4031)	2.028 (0.4531)	1.956 (0.4006)
Median	1.720	1.935	2.095	1.940
Min, Max	1.610, 1.860	1.650, 2.220	1.310, 2.860	1.310, 2.860
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-0.533 (0.4477)	-0.495 (0.1202)	-0.136 (0.4470)	-0.263 (0.4393)
Median	-0.590	-0.495	-0.020	-0.060
Min, Max	-0.950, -0.060	-0.580, -0.410	-0.940, 0.470	-0.950, 0.470
Week 12				
N	3	2	8	13
Mean (SD)	1.390 (0.4187)	1.850 (1.0182)	1.698 (0.4622)	1.650 (0.5151)
Median	1.580	1.850	1.705	1.680
Min, Max	0.910, 1.680	1.130, 2.570	0.880, 2.390	0.880, 2.570
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-0.637 (0.5052)	-0.580 (0.4950)	-0.464 (0.2507)	-0.522 (0.3252)
Median	-0.520	-0.580	-0.475	-0.520
Min, Max	-1.190, -0.200	-0.930, -0.230	-0.790, -0.080	-1.190, -0.080
Week 16				
N	3	3	7	13
Mean (SD)	1.573 (0.1474)	2.127 (0.8563)	1.680 (0.4093)	1.758 (0.5056)
Median	1.520	2.430	1.520	1.520
Min, Max	1.460, 1.740	1.160, 2.790	1.180, 2.430	1.160, 2.790
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-0.453 (0.3585)	-0.140 (0.8974)	-0.513 (0.6016)	-0.413 (0.6012)
Median	-0.640	-0.370	-0.620	-0.620
Min, Max	-0.680, -0.040	-0.900, 0.850	-1.490, 0.250	-1.490, 0.850
Week 20				
N	4	3	6	13
Mean (SD)	1.563 (0.1434)	1.750 (0.5902)	1.682 (0.5385)	1.661 (0.4352)
Median	1.570	1.840	1.610	1.580
Min, Max	1.380, 1.730	1.120, 2.290	1.110, 2.590	1.110, 2.590
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-0.408 (0.2399)	-0.517 (0.4200)	-0.577 (0.3399)	-0.511 (0.3125)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-0.355	-0.510	-0.520	-0.470
Min, Max	-0.720, -0.200	-0.940, -0.100	-0.980, -0.100	-0.980, -0.100
Week 24				
N	4	3	6	13
Mean (SD)	1.510 (0.3521)	1.757 (0.6787)	2.162 (0.4859)	1.868 (0.5432)
Median	1.460	1.600	2.325	1.740
Min, Max	1.190, 1.930	1.170, 2.500	1.430, 2.750	1.170, 2.750
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-0.460 (0.4426)	-0.510 (0.3297)	-0.097 (0.8003)	-0.304 (0.6117)
Median	-0.540	-0.340	-0.350	-0.530
Min, Max	-0.910, 0.150	-0.890, -0.300	-0.810, 1.190	-0.910, 1.190
Week 28				
N	5	3	7	15
Mean (SD)	1.580 (0.4832)	1.947 (0.4801)	2.174 (0.5018)	1.931 (0.5303)
Median	1.620	1.700	2.080	1.930
Min, Max	0.990, 2.150	1.640, 2.500	1.480, 2.840	0.990, 2.840
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-0.558 (0.3733)	-0.320 (0.0917)	-0.083 (0.3196)	-0.289 (0.3635)
Median	-0.590	-0.300	-0.160	-0.270

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-1.110, -0.160	-0.420, -0.240	-0.560, 0.300	-1.110, 0.300
Week 32				
N	4	3	7	14
Mean (SD)	1.653 (0.3500)	2.153 (0.5046)	1.847 (0.6100)	1.857 (0.5219)
Median	1.725	2.350	2.040	1.980
Min, Max	1.180, 1.980	1.580, 2.530	0.800, 2.410	0.800, 2.530
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	-0.570 (0.3625)	-0.113 (0.6093)	-0.410 (0.5300)	-0.392 (0.4949)
Median	-0.595	-0.450	-0.200	-0.385
Min, Max	-0.920, -0.170	-0.480, 0.590	-1.440, 0.010	-1.440, 0.590
Week 36				
N	3	3	7	13
Mean (SD)	1.560 (0.4543)	1.937 (0.6374)	2.070 (0.5139)	1.922 (0.5289)
Median	1.360	2.000	2.310	2.000
Min, Max	1.240, 2.080	1.270, 2.540	1.360, 2.700	1.240, 2.700
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	-0.467 (0.3722)	-0.330 (0.8054)	-0.187 (0.5009)	-0.285 (0.5206)
Median	-0.420	-0.790	0.070	-0.420
Min, Max	-0.860, -0.120	-0.800, 0.600	-0.850, 0.450	-0.860, 0.600

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	1.818 (0.4385)	2.047 (0.2969)	1.856 (0.3342)	1.881 (0.3507)
Median	1.640	2.120	1.820	1.820
Min, Max	1.320, 2.390	1.720, 2.300	1.450, 2.330	1.320, 2.390
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	-0.320 (0.3308)	-0.220 (0.5303)	-0.401 (0.6371)	-0.338 (0.5005)
Median	-0.460	-0.340	-0.240	-0.340
Min, Max	-0.660, 0.190	-0.680, 0.360	-1.720, 0.260	-1.720, 0.360
Week 44				
N	5	3	7	15
Mean (SD)	1.888 (0.4414)	1.990 (0.6359)	2.006 (0.5758)	1.963 (0.5086)
Median	2.060	1.890	2.030	2.030
Min, Max	1.290, 2.280	1.410, 2.670	1.270, 3.000	1.270, 3.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	-0.250 (0.5514)	-0.277 (0.3258)	-0.251 (0.5133)	-0.256 (0.4638)
Median	-0.240	-0.130	-0.210	-0.210
Min, Max	-0.810, 0.500	-0.650, -0.050	-0.870, 0.610	-0.870, 0.610
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	2.094 (0.4554)	2.280 (0.8266)	2.006 (0.4701)	2.090 (0.5127)
Median	2.320	2.400	2.240	2.260
Min, Max	1.520, 2.510	1.400, 3.040	1.300, 2.440	1.300, 3.040
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	-0.044 (0.5076)	0.013 (0.5934)	-0.251 (0.4207)	-0.129 (0.4628)
Median	-0.110	0.240	-0.010	-0.010
Min, Max	-0.580, 0.730	-0.660, 0.460	-0.850, 0.140	-0.850, 0.730
Early Term				
N	1		1	2
Mean (SD)	1.900 ()		2.310 ()	2.105 (0.2899)
Median	1.900		2.310	2.105
Min, Max	1.900, 1.900		2.310, 2.310	1.900, 2.310
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-0.910 ()		0.060 ()	-0.425 (0.6859)
Median	-0.910		0.060	-0.425
Min, Max	-0.910, -0.910		0.060, 0.060	-0.910, 0.060

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Monocytes (10 ⁹ /L)				
Baseline				
N	15			15
Mean (SD)	0.540 (0.1604)			0.540 (0.1604)
Median	0.550			0.550
Min, Max	0.220, 0.840			0.220, 0.840
Week 1				
N	15			15
Mean (SD)	0.540 (0.1311)			0.540 (0.1311)
Median	0.510			0.510
Min, Max	0.350, 0.750			0.350, 0.750
Change from Baseline to Week 1				
N	15			15
Mean (SD)	0.000 (0.1174)			0.000 (0.1174)
Median	0.000			0.000
Min, Max	-0.310, 0.190			-0.310, 0.190
Week 2				
N	15			15
Mean (SD)	0.482 (0.1850)			0.482 (0.1850)
Median	0.470			0.470
Min, Max	0.210, 0.890			0.210, 0.890

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.058 (0.1400)			-0.058 (0.1400)
Median	-0.030			-0.030
Min, Max	-0.430, 0.110			-0.430, 0.110
Week 4				
N	2	13		15
Mean (SD)	0.465 (0.1626)	0.462 (0.1537)		0.463 (0.1488)
Median	0.465	0.490		0.490
Min, Max	0.350, 0.580	0.100, 0.670		0.100, 0.670
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	0.065 (0.0919)	-0.099 (0.1249)		-0.077 (0.1316)
Median	0.065	-0.080		-0.060
Min, Max	0.000, 0.130	-0.380, 0.050		-0.380, 0.130
Week 6				
N	3	5	7	15
Mean (SD)	0.240 (0.1732)	0.438 (0.1728)	0.624 (0.1765)	0.485 (0.2225)
Median	0.340	0.390	0.580	0.500
Min, Max	0.040, 0.340	0.250, 0.720	0.500, 1.010	0.040, 1.010
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-0.187 (0.2838)	-0.146 (0.1588)	0.067 (0.1245)	-0.055 (0.1987)
Median	-0.240	-0.160	0.100	0.000
Min, Max	-0.440, 0.120	-0.370, 0.050	-0.160, 0.200	-0.440, 0.200
Week 8				
N	3	2	10	15
Mean (SD)	0.407 (0.0651)	0.460 (0.1414)	0.551 (0.1810)	0.510 (0.1641)
Median	0.410	0.460	0.645	0.480
Min, Max	0.340, 0.470	0.360, 0.560	0.270, 0.720	0.270, 0.720
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-0.020 (0.2152)	-0.135 (0.2051)	-0.012 (0.2003)	-0.030 (0.1930)
Median	-0.010	-0.135	-0.035	-0.020
Min, Max	-0.240, 0.190	-0.280, 0.010	-0.320, 0.380	-0.320, 0.380
Week 12				
N	3	2	8	13
Mean (SD)	0.383 (0.0874)	0.420 (0.1273)	0.419 (0.1599)	0.411 (0.1333)
Median	0.360	0.420	0.425	0.420
Min, Max	0.310, 0.480	0.330, 0.510	0.150, 0.670	0.150, 0.670
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-0.190 (0.1389)	-0.175 (0.0636)	-0.106 (0.1983)	-0.136 (0.1675)
Median	-0.120	-0.175	-0.070	-0.120
Min, Max	-0.350, -0.100	-0.220, -0.130	-0.470, 0.110	-0.470, 0.110
Week 16				
N	3	3	7	13
Mean (SD)	0.387 (0.1012)	0.380 (0.0700)	0.511 (0.1853)	0.452 (0.1553)
Median	0.440	0.410	0.520	0.440
Min, Max	0.270, 0.450	0.300, 0.430	0.240, 0.780	0.240, 0.780
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-0.187 (0.0493)	-0.223 (0.0907)	0.000 (0.1993)	-0.095 (0.1820)
Median	-0.210	-0.210	0.020	-0.150
Min, Max	-0.220, -0.130	-0.320, -0.140	-0.190, 0.360	-0.320, 0.360
Week 20				
N	4	3	6	13
Mean (SD)	0.470 (0.1010)	0.390 (0.1758)	0.498 (0.1992)	0.465 (0.1619)
Median	0.465	0.320	0.465	0.420
Min, Max	0.360, 0.590	0.260, 0.590	0.270, 0.730	0.260, 0.730
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-0.093 (0.0704)	-0.213 (0.2230)	-0.010 (0.1410)	-0.082 (0.1573)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-0.115	-0.300	-0.025	-0.110
Min, Max	-0.150, 0.010	-0.380, 0.040	-0.170, 0.170	-0.380, 0.170
Week 24				
N	4	3	6	13
Mean (SD)	0.515 (0.0624)	0.457 (0.0551)	0.473 (0.1009)	0.482 (0.0793)
Median	0.515	0.460	0.505	0.500
Min, Max	0.440, 0.590	0.400, 0.510	0.350, 0.590	0.350, 0.590
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-0.048 (0.0591)	-0.147 (0.0814)	-0.035 (0.1647)	-0.065 (0.1245)
Median	-0.035	-0.110	-0.030	-0.070
Min, Max	-0.130, 0.010	-0.240, -0.090	-0.320, 0.150	-0.320, 0.150
Week 28				
N	5	3	7	15
Mean (SD)	0.490 (0.0900)	0.503 (0.0850)	0.540 (0.2137)	0.516 (0.1532)
Median	0.460	0.500	0.550	0.500
Min, Max	0.400, 0.600	0.420, 0.590	0.170, 0.820	0.170, 0.820
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-0.004 (0.1172)	-0.100 (0.1249)	-0.006 (0.1846)	-0.024 (0.1494)
Median	-0.060	-0.140	0.020	-0.020

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-0.080, 0.200	-0.200, 0.040	-0.270, 0.210	-0.270, 0.210
Week 32				
N	4	3	7	14
Mean (SD)	0.493 (0.1204)	0.400 (0.1153)	0.503 (0.2167)	0.478 (0.1699)
Median	0.465	0.360	0.500	0.465
Min, Max	0.380, 0.660	0.310, 0.530	0.180, 0.860	0.180, 0.860
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	0.008 (0.1486)	-0.203 (0.1595)	-0.043 (0.1380)	-0.063 (0.1552)
Median	-0.045	-0.280	0.000	-0.025
Min, Max	-0.100, 0.220	-0.310, -0.020	-0.260, 0.090	-0.310, 0.220
Week 36				
N	3	3	7	13
Mean (SD)	0.483 (0.0961)	0.477 (0.0896)	0.481 (0.0960)	0.481 (0.0866)
Median	0.500	0.430	0.420	0.430
Min, Max	0.380, 0.570	0.420, 0.580	0.390, 0.610	0.380, 0.610
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	-0.090 (0.0755)	-0.127 (0.0651)	-0.064 (0.1302)	-0.085 (0.1041)
Median	-0.100	-0.130	0.000	-0.090
Min, Max	-0.160, -0.010	-0.190, -0.060	-0.240, 0.070	-0.240, 0.070

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	0.504 (0.1006)	0.580 (0.1931)	0.633 (0.2012)	0.579 (0.1704)
Median	0.480	0.540	0.610	0.540
Min, Max	0.380, 0.630	0.410, 0.790	0.360, 0.950	0.360, 0.950
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	0.010 (0.1453)	-0.023 (0.2346)	0.087 (0.2234)	0.039 (0.1939)
Median	-0.030	-0.100	0.010	-0.030
Min, Max	-0.100, 0.260	-0.210, 0.240	-0.080, 0.560	-0.210, 0.560
Week 44				
N	5	3	7	15
Mean (SD)	0.506 (0.0764)	0.620 (0.0985)	0.561 (0.1920)	0.555 (0.1437)
Median	0.520	0.590	0.590	0.550
Min, Max	0.390, 0.590	0.540, 0.730	0.240, 0.750	0.240, 0.750
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	0.012 (0.1846)	0.017 (0.0874)	0.016 (0.1388)	0.015 (0.1381)
Median	-0.060	0.040	-0.040	-0.040
Min, Max	-0.140, 0.330	-0.080, 0.090	-0.150, 0.170	-0.150, 0.330
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	0.560 (0.1458)	0.497 (0.1106)	0.539 (0.2705)	0.537 (0.1993)
Median	0.520	0.510	0.460	0.510
Min, Max	0.430, 0.810	0.380, 0.600	0.230, 0.930	0.230, 0.930
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	0.066 (0.1958)	-0.107 (0.1550)	-0.007 (0.2077)	-0.003 (0.1920)
Median	-0.030	-0.110	-0.070	-0.040
Min, Max	-0.140, 0.330	-0.260, 0.050	-0.200, 0.370	-0.260, 0.370
Early Term				
N	1		1	2
Mean (SD)	0.360 ()		0.580 ()	0.470 (0.1556)
Median	0.360		0.580	0.470
Min, Max	0.360, 0.360		0.580, 0.580	0.360, 0.580
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	0.140 ()		-0.190 ()	-0.025 (0.2333)
Median	0.140		-0.190	-0.025
Min, Max	0.140, 0.140		-0.190, -0.190	-0.190, 0.140

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Neutrophils Band Form (10 ⁹ /L)				
Baseline				
N	15			15
Mean (SD)	0.134 (0.2432)			0.134 (0.2432)
Median	0.000			0.000
Min, Max	0.000, 0.680			0.000, 0.680
Week 1				
N	15			15
Mean (SD)	0.057 (0.1391)			0.057 (0.1391)
Median	0.000			0.000
Min, Max	0.000, 0.460			0.000, 0.460
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.077 (0.2533)			-0.077 (0.2533)
Median	0.000			0.000
Min, Max	-0.610, 0.460			-0.610, 0.460
Week 2				
N	15			15
Mean (SD)	0.061 (0.2115)			0.061 (0.2115)
Median	0.000			0.000
Min, Max	0.000, 0.820			0.000, 0.820

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.073 (0.3377)			-0.073 (0.3377)
Median	0.000			0.000
Min, Max	-0.680, 0.820			-0.680, 0.820
Week 4				
N	2	13		15
Mean (SD)	0.000 (0.0000)	0.087 (0.2123)		0.075 (0.1989)
Median	0.000	0.000		0.000
Min, Max	0.000, 0.000	0.000, 0.580		0.000, 0.580
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-0.135 (0.1909)	-0.047 (0.2899)		-0.059 (0.2749)
Median	-0.135	0.000		0.000
Min, Max	-0.270, 0.000	-0.680, 0.550		-0.680, 0.550
Week 6				
N	3	5	7	15
Mean (SD)	0.057 (0.0981)	0.110 (0.2460)	0.190 (0.2256)	0.137 (0.2086)
Median	0.000	0.000	0.080	0.000
Min, Max	0.000, 0.170	0.000, 0.550	0.000, 0.560	0.000, 0.560
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-0.033 (0.2219)	-0.026 (0.4363)	0.039 (0.2711)	0.003 (0.3068)
Median	0.000	0.000	0.000	0.000
Min, Max	-0.270, 0.170	-0.680, 0.550	-0.460, 0.350	-0.680, 0.550
Week 8				
N	3	2	10	15
Mean (SD)	0.117 (0.2021)	0.025 (0.0354)	0.005 (0.0158)	0.030 (0.0902)
Median	0.000	0.025	0.000	0.000
Min, Max	0.000, 0.350	0.000, 0.050	0.000, 0.050	0.000, 0.350
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	0.027 (0.3109)	0.025 (0.0354)	-0.169 (0.2870)	-0.104 (0.2755)
Median	0.000	0.025	0.000	0.000
Min, Max	-0.270, 0.350	0.000, 0.050	-0.680, 0.050	-0.680, 0.350
Week 12				
N	3	2	8	13
Mean (SD)	0.000 (0.0000)	0.000 (0.0000)	0.156 (0.4419)	0.096 (0.3467)
Median	0.000	0.000	0.000	0.000
Min, Max	0.000, 0.000	0.000, 0.000	0.000, 1.250	0.000, 1.250
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-0.180 (0.3118)	0.000 (0.0000)	0.006 (0.3770)	-0.038 (0.3251)
Median	0.000	0.000	0.000	0.000
Min, Max	-0.540, 0.000	0.000, 0.000	-0.680, 0.730	-0.680, 0.730
Week 16				
N	3	3	7	13
Mean (SD)	0.527 (0.9122)	0.117 (0.2021)	0.000 (0.0000)	0.148 (0.4409)
Median	0.000	0.000	0.000	0.000
Min, Max	0.000, 1.580	0.000, 0.350	0.000, 0.000	0.000, 1.580
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	0.347 (1.1017)	0.117 (0.2021)	-0.171 (0.2964)	0.015 (0.5508)
Median	0.000	0.000	0.000	0.000
Min, Max	-0.540, 1.580	0.000, 0.350	-0.680, 0.000	-0.680, 1.580
Week 20				
N	4	2	5	11
Mean (SD)	0.243 (0.3548)	0.000 (0.0000)	0.012 (0.0268)	0.094 (0.2280)
Median	0.100	0.000	0.000	0.000
Min, Max	0.000, 0.770	0.000, 0.000	0.000, 0.060	0.000, 0.770
Change from Baseline to Week 20				
N	4	2	5	11
Mean (SD)	0.108 (0.5349)	0.000 (0.0000)	-0.228 (0.3142)	-0.065 (0.3890)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	0.100	0.000	0.000	0.000
Min, Max	-0.540, 0.770	0.000, 0.000	-0.620, 0.000	-0.620, 0.770
Week 24				
N	4	3	6	13
Mean (SD)	0.065 (0.0755)	0.020 (0.0346)	0.088 (0.1327)	0.065 (0.0987)
Median	0.060	0.000	0.035	0.000
Min, Max	0.000, 0.140	0.000, 0.060	0.000, 0.340	0.000, 0.340
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-0.070 (0.3194)	0.020 (0.0346)	-0.112 (0.3982)	-0.068 (0.3077)
Median	0.060	0.000	0.035	0.000
Min, Max	-0.540, 0.140	0.000, 0.060	-0.680, 0.340	-0.680, 0.340
Week 28				
N	5	3	7	15
Mean (SD)	0.000 (0.0000)	0.207 (0.1888)	0.123 (0.1868)	0.099 (0.1622)
Median	0.000	0.250	0.000	0.000
Min, Max	0.000, 0.000	0.000, 0.370	0.000, 0.500	0.000, 0.500
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-0.162 (0.2415)	0.207 (0.1888)	-0.049 (0.1600)	-0.035 (0.2260)
Median	0.000	0.250	0.000	0.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-0.540, 0.000	0.000, 0.370	-0.330, 0.170	-0.540, 0.370
Week 32				
N	4	1	7	12
Mean (SD)	0.173 (0.2451)	1.410 ()	0.110 (0.2106)	0.239 (0.4212)
Median	0.085	1.410	0.000	0.000
Min, Max	0.000, 0.520	1.410, 1.410	0.000, 0.550	0.000, 1.410
Change from Baseline to Week 32				
N	4	1	7	12
Mean (SD)	-0.030 (0.3986)	1.410 ()	-0.061 (0.1158)	0.072 (0.4780)
Median	-0.135	1.410	0.000	0.000
Min, Max	-0.370, 0.520	1.410, 1.410	-0.300, 0.000	-0.370, 1.410
Week 36				
N	3	3	6	12
Mean (SD)	0.960 (0.6223)	0.243 (0.2122)	0.070 (0.1197)	0.336 (0.4819)
Median	1.070	0.340	0.000	0.210
Min, Max	0.290, 1.520	0.000, 0.390	0.000, 0.290	0.000, 1.520
Change from Baseline to Week 36				
N	3	3	6	12
Mean (SD)	0.780 (0.9199)	0.243 (0.2122)	-0.043 (0.1776)	0.234 (0.5474)
Median	1.070	0.340	0.000	0.000
Min, Max	-0.250, 1.520	0.000, 0.390	-0.390, 0.130	-0.390, 1.520

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	0.048 (0.1073)	0.040 (0.0693)	0.207 (0.4581)	0.121 (0.3177)
Median	0.000	0.000	0.000	0.000
Min, Max	0.000, 0.240	0.000, 0.120	0.000, 1.240	0.000, 1.240
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	-0.114 (0.2385)	0.040 (0.0693)	0.036 (0.3781)	-0.013 (0.2892)
Median	0.000	0.000	0.000	0.000
Min, Max	-0.540, 0.000	0.000, 0.120	-0.580, 0.720	-0.580, 0.720
Week 44				
N	5	3	7	15
Mean (SD)	0.010 (0.0224)	0.117 (0.2021)	0.000 (0.0000)	0.027 (0.0904)
Median	0.000	0.000	0.000	0.000
Min, Max	0.000, 0.050	0.000, 0.350	0.000, 0.000	0.000, 0.350
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	-0.152 (0.2507)	0.117 (0.2021)	-0.171 (0.2964)	-0.107 (0.2738)
Median	0.000	0.000	0.000	0.000
Min, Max	-0.540, 0.050	0.000, 0.350	-0.680, 0.000	-0.680, 0.350
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	0.706 (0.9111)	0.130 (0.0794)	0.087 (0.1567)	0.302 (0.5799)
Median	0.540	0.100	0.000	0.070
Min, Max	0.000, 2.220	0.070, 0.220	0.000, 0.390	0.000, 2.220
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	0.544 (0.8166)	0.130 (0.0794)	-0.084 (0.3837)	0.168 (0.5807)
Median	0.230	0.100	0.000	0.070
Min, Max	0.000, 1.950	0.070, 0.220	-0.680, 0.390	-0.680, 1.950
Early Term				
N	1		1	2
Mean (SD)	0.000 ()		0.000 ()	0.000 (0.0000)
Median	0.000		0.000	0.000
Min, Max	0.000, 0.000		0.000, 0.000	0.000, 0.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-0.270 ()		0.000 ()	-0.135 (0.1909)
Median	-0.270		0.000	-0.135
Min, Max	-0.270, -0.270		0.000, 0.000	-0.270, 0.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Neutrophils, Segmented (10 ⁹ /L)				
Baseline				
N	15			15
Mean (SD)	2.837 (1.1092)			2.837 (1.1092)
Median	2.720			2.720
Min, Max	1.270, 5.650			1.270, 5.650
Week 1				
N	15			15
Mean (SD)	3.605 (1.2600)			3.605 (1.2600)
Median	3.560			3.560
Min, Max	1.380, 5.890			1.380, 5.890
Change from Baseline to Week 1				
N	15			15
Mean (SD)	0.768 (0.8296)			0.768 (0.8296)
Median	0.740			0.740
Min, Max	-0.300, 2.790			-0.300, 2.790
Week 2				
N	15			15
Mean (SD)	3.481 (1.3878)			3.481 (1.3878)
Median	3.110			3.110
Min, Max	1.620, 6.260			1.620, 6.260

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	0.644 (1.1379)			0.644 (1.1379)
Median	0.530			0.530
Min, Max	-1.060, 3.620			-1.060, 3.620
Week 4				
N	2	13		15
Mean (SD)	3.830 (2.2345)	3.221 (1.2615)		3.302 (1.3291)
Median	3.830	3.490		3.490
Min, Max	2.250, 5.410	0.450, 5.870		0.450, 5.870
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	1.470 (2.7436)	0.310 (0.6570)		0.465 (1.0365)
Median	1.470	0.220		0.220
Min, Max	-0.470, 3.410	-0.960, 1.710		-0.960, 3.410
Week 6				
N	3	5	7	15
Mean (SD)	1.617 (1.5252)	2.974 (1.1355)	4.240 (1.4272)	3.293 (1.6311)
Median	1.820	3.250	4.710	3.250
Min, Max	0.000, 3.030	1.700, 4.570	2.340, 6.280	0.000, 6.280
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-0.427 (1.2870)	0.252 (1.1401)	0.980 (1.0638)	0.456 (1.1883)
Median	-0.900	-0.050	0.950	0.570
Min, Max	-1.410, 1.030	-1.120, 1.980	-0.470, 2.510	-1.410, 2.510
Week 8				
N	3	2	10	15
Mean (SD)	1.897 (1.6894)	2.235 (0.1909)	4.133 (1.4997)	3.433 (1.7079)
Median	2.450	2.235	3.920	2.870
Min, Max	0.000, 3.240	2.100, 2.370	2.560, 6.650	0.000, 6.650
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-0.147 (1.3293)	-0.525 (0.7142)	1.042 (1.3539)	0.595 (1.3809)
Median	-0.270	-0.525	0.545	0.480
Min, Max	-1.410, 1.240	-1.030, -0.020	-0.410, 3.520	-1.410, 3.520
Week 12				
N	3	2	8	13
Mean (SD)	2.270 (0.5311)	2.470 (1.7112)	3.124 (1.7642)	2.826 (1.5047)
Median	2.520	2.470	3.065	2.630
Min, Max	1.660, 2.630	1.260, 3.680	0.840, 5.910	0.840, 5.910
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	0.013 (0.2055)	-0.290 (0.8061)	0.090 (1.3562)	0.014 (1.0739)
Median	-0.090	-0.290	0.650	0.260
Min, Max	-0.120, 0.250	-0.860, 0.280	-2.380, 1.260	-2.380, 1.260
Week 16				
N	3	3	7	13
Mean (SD)	2.503 (2.1524)	2.200 (1.0956)	4.047 (1.4565)	3.265 (1.6788)
Median	2.770	1.880	3.940	3.150
Min, Max	0.230, 4.510	1.300, 3.420	2.050, 6.260	0.230, 6.260
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	0.247 (1.5345)	-0.580 (0.8244)	0.983 (1.0069)	0.452 (1.2058)
Median	0.050	-0.240	0.610	0.320
Min, Max	-1.180, 1.870	-1.520, 0.020	0.090, 2.820	-1.520, 2.820
Week 20				
N	4	2	5	11
Mean (SD)	2.583 (1.4923)	2.705 (1.5486)	4.194 (1.3211)	3.337 (1.5102)
Median	2.675	2.705	4.030	3.400
Min, Max	0.700, 4.280	1.610, 3.800	2.520, 5.680	0.700, 5.680
Change from Baseline to Week 20				
N	4	2	5	11
Mean (SD)	0.188 (1.0407)	0.235 (1.0536)	0.992 (1.0481)	0.562 (1.0224)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-0.090	0.235	0.500	0.210
Min, Max	-0.710, 1.640	-0.510, 0.980	0.030, 2.130	-0.710, 2.130
Week 24				
N	4	3	6	13
Mean (SD)	2.480 (1.1915)	2.830 (0.6976)	3.287 (0.8936)	2.933 (0.9499)
Median	2.095	3.010	2.880	2.680
Min, Max	1.520, 4.210	2.060, 3.420	2.570, 4.750	1.520, 4.750
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	0.085 (1.0599)	0.050 (0.5041)	0.180 (0.9545)	0.121 (0.8404)
Median	-0.225	-0.060	0.100	0.050
Min, Max	-0.780, 1.570	-0.390, 0.600	-0.900, 1.810	-0.900, 1.810
Week 28				
N	5	3	7	15
Mean (SD)	2.690 (0.8490)	1.957 (0.6897)	3.449 (1.5495)	2.897 (1.2883)
Median	2.870	1.620	3.980	2.750
Min, Max	1.690, 3.830	1.500, 2.750	1.400, 5.680	1.400, 5.680
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	0.374 (0.7205)	-0.823 (0.3265)	0.214 (0.3814)	0.060 (0.6635)
Median	0.280	-0.650	0.130	0.130

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-0.690, 1.190	-1.200, -0.620	-0.390, 0.760	-1.200, 1.190
Week 32				
N	4	1	7	12
Mean (SD)	2.263 (1.2389)	0.790 ()	2.817 (0.8618)	2.463 (1.0829)
Median	2.340	0.790	3.090	2.570
Min, Max	0.800, 3.570	0.790, 0.790	1.710, 4.020	0.790, 4.020
Change from Baseline to Week 32				
N	4	1	7	12
Mean (SD)	0.070 (1.0165)	-1.330 ()	-0.417 (0.7652)	-0.331 (0.8690)
Median	0.160	-1.330	-0.400	-0.505
Min, Max	-0.990, 0.950	-1.330, -1.330	-1.630, 0.710	-1.630, 0.950
Week 36				
N	3	3	6	12
Mean (SD)	1.420 (2.0104)	2.137 (0.5537)	2.795 (0.6964)	2.287 (1.1675)
Median	0.330	2.340	2.880	2.450
Min, Max	0.190, 3.740	1.510, 2.560	2.020, 3.850	0.190, 3.850
Change from Baseline to Week 36				
N	3	3	6	12
Mean (SD)	-0.837 (1.8272)	-0.643 (0.1823)	-0.037 (0.5882)	-0.388 (0.9541)
Median	-1.080	-0.610	0.010	-0.475
Min, Max	-2.530, 1.100	-0.840, -0.480	-0.900, 0.750	-2.530, 1.100

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	3.002 (1.7790)	2.253 (0.7047)	3.257 (1.4659)	2.971 (1.4310)
Median	2.920	2.640	3.990	2.680
Min, Max	1.310, 5.880	1.440, 2.680	1.470, 4.690	1.310, 5.880
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	0.686 (1.5796)	-0.527 (0.3372)	0.023 (0.9006)	0.134 (1.1337)
Median	0.310	-0.680	-0.010	-0.100
Min, Max	-0.940, 3.240	-0.760, -0.140	-1.160, 1.110	-1.160, 3.240
Week 44				
N	5	3	7	15
Mean (SD)	2.834 (1.1965)	3.133 (1.1110)	3.347 (0.6357)	3.133 (0.9019)
Median	2.750	3.080	3.420	3.010
Min, Max	1.800, 4.750	2.050, 4.270	2.520, 4.070	1.800, 4.750
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	0.518 (1.1209)	0.353 (0.9579)	0.113 (1.0412)	0.296 (0.9949)
Median	0.390	-0.070	0.220	0.220
Min, Max	-0.860, 2.110	-0.320, 1.450	-1.630, 1.400	-1.630, 2.110
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	2.442 (1.7142)	2.283 (1.0385)	3.130 (1.2320)	2.731 (1.3403)
Median	3.030	2.130	2.620	2.620
Min, Max	0.110, 4.220	1.330, 3.390	1.950, 4.790	0.110, 4.790
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	0.126 (1.7793)	-0.497 (0.4244)	-0.104 (0.9233)	-0.106 (1.1608)
Median	0.390	-0.690	-0.500	-0.500
Min, Max	-1.890, 2.200	-0.790, -0.010	-0.980, 1.350	-1.890, 2.200
Early Term				
N	1		1	2
Mean (SD)	2.680 ()		4.260 ()	3.470 (1.1172)
Median	2.680		4.260	3.470
Min, Max	2.680, 2.680		4.260, 4.260	2.680, 4.260
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	0.680 ()		0.260 ()	0.470 (0.2970)
Median	0.680		0.260	0.470
Min, Max	0.680, 0.680		0.260, 0.260	0.260, 0.680

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Platelets (10 ⁹ /L)				
Baseline				
N	15			15
Mean (SD)	169.067 (63.7668)			169.067 (63.7668)
Median	158.000			158.000
Min, Max	85.000, 310.000			85.000, 310.000
Week 1				
N	13			13
Mean (SD)	178.308 (56.1611)			178.308 (56.1611)
Median	181.000			181.000
Min, Max	100.000, 307.000			100.000, 307.000
Change from Baseline to Week 1				
N	13			13
Mean (SD)	1.462 (25.2442)			1.462 (25.2442)
Median	0.000			0.000
Min, Max	-43.000, 36.000			-43.000, 36.000
Week 2				
N	15			15
Mean (SD)	177.933 (62.4356)			177.933 (62.4356)
Median	170.000			170.000
Min, Max	105.000, 334.000			105.000, 334.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	8.867 (31.5139)			8.867 (31.5139)
Median	5.000			5.000
Min, Max	-55.000, 64.000			-55.000, 64.000
Week 4				
N	2	13		15
Mean (SD)	199.500 (30.4056)	163.385 (58.7772)		168.200 (56.4690)
Median	199.500	151.000		158.000
Min, Max	178.000, 221.000	91.000, 300.000		91.000, 300.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-44.000 (2.8284)	5.769 (20.2861)		-0.867 (25.6901)
Median	-44.000	1.000		-4.000
Min, Max	-46.000, -42.000	-20.000, 47.000		-46.000, 47.000
Week 6				
N	3	5	7	15
Mean (SD)	222.667 (63.2877)	141.200 (24.1806)	193.000 (58.0661)	181.667 (56.5113)
Median	208.000	151.000	178.000	167.000
Min, Max	168.000, 292.000	112.000, 166.000	117.000, 294.000	112.000, 294.000
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	13.667 (25.6970)	7.400 (34.1511)	15.857 (27.0335)	12.600 (27.4949)
Median	28.000	2.000	2.000	2.000
Min, Max	-16.000, 29.000	-39.000, 47.000	-16.000, 56.000	-39.000, 56.000
Week 8				
N	3	2	8	13
Mean (SD)	227.333 (53.2009)	121.500 (0.7071)	182.250 (64.0976)	183.308 (63.1696)
Median	255.000	121.500	195.500	181.000
Min, Max	166.000, 261.000	121.000, 122.000	103.000, 279.000	103.000, 279.000
Change from Baseline to Week 8				
N	3	2	8	13
Mean (SD)	18.333 (17.7858)	-12.500 (33.2340)	18.000 (44.9984)	13.385 (38.1828)
Median	26.000	-12.500	9.000	11.000
Min, Max	-2.000, 31.000	-36.000, 11.000	-31.000, 119.000	-36.000, 119.000
Week 12				
N	3	1	6	10
Mean (SD)	150.333 (40.5010)	191.000 ()	247.000 (102.9660)	212.400 (91.5838)
Median	168.000	191.000	232.000	185.000
Min, Max	104.000, 179.000	191.000, 191.000	135.000, 416.000	104.000, 416.000
Change from Baseline to Week 12				
N	3	1	6	10

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-11.667 (50.1431)	33.000 ()	60.667 (78.4236)	36.200 (71.6904)
Median	-36.000	33.000	44.500	36.000
Min, Max	-45.000, 46.000	33.000, 33.000	-4.000, 213.000	-45.000, 213.000
Week 16				
N	3	3	6	12
Mean (SD)	148.667 (70.2163)	139.667 (18.5831)	196.000 (72.0472)	170.083 (63.7373)
Median	118.000	145.000	190.500	150.000
Min, Max	99.000, 229.000	119.000, 155.000	120.000, 320.000	99.000, 320.000
Change from Baseline to Week 16				
N	3	3	6	12
Mean (SD)	-13.333 (15.8850)	22.000 (33.4515)	9.667 (7.1461)	7.000 (21.2261)
Median	-22.000	9.000	9.500	9.000
Min, Max	-23.000, 5.000	-3.000, 60.000	-3.000, 17.000	-23.000, 60.000
Week 20				
N	4	3	6	13
Mean (SD)	141.000 (39.8079)	133.000 (32.0780)	186.333 (64.8218)	160.077 (54.4770)
Median	135.500	126.000	182.000	146.000
Min, Max	107.000, 186.000	105.000, 168.000	120.000, 276.000	105.000, 276.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-24.500 (12.3962)	15.333 (23.4592)	10.833 (27.9672)	1.000 (27.7939)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-23.500	10.000	14.500	-5.000
Min, Max	-38.000, -13.000	-5.000, 41.000	-34.000, 42.000	-38.000, 42.000
Week 24				
N	4	2	5	11
Mean (SD)	143.500 (36.4189)	129.500 (24.7487)	205.200 (62.9897)	169.000 (57.2154)
Median	144.000	129.500	228.000	153.000
Min, Max	110.000, 176.000	112.000, 147.000	127.000, 278.000	110.000, 278.000
Change from Baseline to Week 24				
N	4	2	5	11
Mean (SD)	-22.000 (21.1029)	-4.500 (9.1924)	20.000 (31.8983)	0.273 (30.7672)
Median	-19.000	-4.500	25.000	-2.000
Min, Max	-48.000, -2.000	-11.000, 2.000	-32.000, 49.000	-48.000, 49.000
Week 28				
N	5	3	7	15
Mean (SD)	177.800 (49.7715)	140.667 (51.7333)	188.143 (70.8200)	175.200 (59.8441)
Median	183.000	117.000	205.000	183.000
Min, Max	128.000, 252.000	105.000, 200.000	113.000, 312.000	105.000, 312.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-7.200 (22.7969)	23.000 (17.6918)	8.429 (9.4138)	6.133 (18.9279)
Median	-11.000	20.000	6.000	7.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-41.000, 14.000	7.000, 42.000	-4.000, 22.000	-41.000, 42.000
Week 32				
N	4	3	7	14
Mean (SD)	177.500 (53.4447)	129.333 (46.5439)	174.714 (63.8219)	165.786 (57.1330)
Median	168.500	127.000	202.000	157.500
Min, Max	130.000, 243.000	84.000, 177.000	92.000, 259.000	84.000, 259.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	-9.750 (15.4137)	11.667 (11.0151)	-5.000 (27.2336)	-2.786 (21.9446)
Median	-11.000	17.000	-1.000	-1.000
Min, Max	-25.000, 8.000	-1.000, 19.000	-51.000, 36.000	-51.000, 36.000
Week 36				
N	3	3	7	13
Mean (SD)	141.000 (33.8674)	142.667 (33.2916)	173.429 (65.1175)	158.846 (52.5846)
Median	130.000	126.000	186.000	130.000
Min, Max	114.000, 179.000	121.000, 181.000	99.000, 279.000	99.000, 279.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	-21.000 (26.8514)	25.000 (10.1489)	-6.286 (19.1808)	-2.462 (24.5819)
Median	-26.000	23.000	1.000	8.000
Min, Max	-45.000, 8.000	16.000, 36.000	-31.000, 13.000	-45.000, 36.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	178.800 (65.6635)	137.333 (42.0634)	175.857 (60.9465)	169.133 (57.8728)
Median	178.000	140.000	192.000	178.000
Min, Max	120.000, 284.000	94.000, 178.000	106.000, 261.000	94.000, 284.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	-6.200 (23.4457)	19.667 (10.5040)	-3.857 (28.0026)	0.067 (24.7573)
Median	2.000	20.000	-5.000	2.000
Min, Max	-39.000, 21.000	9.000, 30.000	-49.000, 37.000	-49.000, 37.000
Week 44				
N	5	3	7	15
Mean (SD)	181.800 (62.1868)	136.667 (18.0093)	177.571 (67.4064)	170.800 (58.4321)
Median	159.000	136.000	167.000	155.000
Min, Max	138.000, 288.000	119.000, 155.000	94.000, 294.000	94.000, 294.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	-3.200 (26.0711)	19.000 (19.4679)	-2.143 (27.8653)	1.733 (25.7140)
Median	0.000	26.000	3.000	3.000
Min, Max	-40.000, 25.000	-3.000, 34.000	-36.000, 39.000	-40.000, 39.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.1
Laboratory Summary - Hematology
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	177.400 (50.7425)	141.333 (43.0968)	178.571 (86.5041)	170.733 (66.6317)
Median	174.000	138.000	194.000	174.000
Min, Max	113.000, 248.000	100.000, 186.000	77.000, 334.000	77.000, 334.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	-7.600 (28.4482)	23.667 (7.5056)	-1.143 (24.3750)	1.667 (25.1443)
Median	-9.000	28.000	3.000	8.000
Min, Max	-50.000, 24.000	15.000, 28.000	-34.000, 27.000	-50.000, 28.000
Early Term				
N	1		1	2
Mean (SD)	244.000 ()		167.000 ()	205.500 (54.4472)
Median	244.000		167.000	205.500
Min, Max	244.000, 244.000		167.000, 167.000	167.000, 244.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-19.000 ()		-38.000 ()	-28.500 (13.4350)
Median	-19.000		-38.000	-28.500
Min, Max	-19.000, -19.000		-38.000, -38.000	-38.000, -19.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Alanine Aminotransferase (IU/L)				
Baseline				
N	15			15
Mean (SD)	111.400 (82.8491)			111.400 (82.8491)
Median	82.000			82.000
Min, Max	53.000, 362.000			53.000, 362.000
Week 1				
N	15			15
Mean (SD)	108.133 (82.4178)			108.133 (82.4178)
Median	84.000			84.000
Min, Max	41.000, 367.000			41.000, 367.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-3.267 (39.0777)			-3.267 (39.0777)
Median	-8.000			-8.000
Min, Max	-86.000, 87.000			-86.000, 87.000
Week 2				
N	15			15
Mean (SD)	118.267 (81.3427)			118.267 (81.3427)
Median	85.000			85.000
Min, Max	45.000, 343.000			45.000, 343.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	6.867 (54.1768)			6.867 (54.1768)
Median	-1.000			-1.000
Min, Max	-98.000, 130.000			-98.000, 130.000
Week 4				
N	2	13		15
Mean (SD)	135.500 (103.9447)	127.000 (76.8125)		128.133 (76.4067)
Median	135.500	107.000		107.000
Min, Max	62.000, 209.000	45.000, 270.000		45.000, 270.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	82.000 (103.2376)	6.692 (84.9857)		16.733 (87.4883)
Median	82.000	-2.000		9.000
Min, Max	9.000, 155.000	-122.000, 180.000		-122.000, 180.000
Week 6				
N	3	5	7	15
Mean (SD)	258.667 (222.1921)	181.400 (99.2260)	87.000 (46.6905)	152.800 (125.1349)
Median	248.000	223.000	64.000	120.000
Min, Max	42.000, 486.000	48.000, 294.000	46.000, 157.000	42.000, 486.000

Change from Baseline to Week 6

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	184.667 (225.9742)	25.400 (159.1204)	-8.571 (50.7965)	41.400 (146.1955)
Median	133.000	29.000	-16.000	-5.000
Min, Max	-11.000, 432.000	-132.000, 235.000	-91.000, 60.000	-132.000, 432.000
Week 8				
N	3	2	10	15
Mean (SD)	86.000 (43.5890)	102.000 (46.6690)	101.100 (70.2922)	98.200 (60.3599)
Median	106.000	102.000	75.500	80.000
Min, Max	36.000, 116.000	69.000, 135.000	48.000, 274.000	36.000, 274.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	12.000 (43.4856)	22.000 (16.9706)	-27.800 (66.0468)	-13.200 (59.6684)
Median	-9.000	22.000	-12.500	-11.000
Min, Max	-17.000, 62.000	10.000, 34.000	-131.000, 71.000	-131.000, 71.000
Week 12				
N	3	2	8	13
Mean (SD)	100.333 (108.9097)	50.000 (2.8284)	77.375 (38.4594)	78.462 (55.6396)
Median	63.000	50.000	73.000	63.000
Min, Max	15.000, 223.000	48.000, 52.000	42.000, 156.000	15.000, 223.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	21.333 (136.4197)	-30.000 (32.5269)	-64.875 (76.6466)	-39.615 (89.3659)
Median	-5.000	-30.000	-31.000	-24.000
Min, Max	-100.000, 169.000	-53.000, -7.000	-206.000, 14.000	-206.000, 169.000
Week 16				
N	3	3	7	13
Mean (SD)	142.667 (199.6155)	101.333 (85.5005)	74.857 (60.8507)	96.615 (102.5805)
Median	35.000	55.000	61.000	55.000
Min, Max	20.000, 373.000	49.000, 200.000	29.000, 206.000	20.000, 373.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	63.667 (223.2876)	-10.333 (109.5004)	-62.714 (64.7707)	-21.462 (123.4542)
Median	-33.000	-10.000	-47.000	-34.000
Min, Max	-95.000, 319.000	-120.000, 99.000	-156.000, 16.000	-156.000, 319.000
Week 20				
N	4	3	6	13
Mean (SD)	49.250 (27.1585)	42.333 (6.6583)	89.000 (94.1382)	66.000 (66.1992)
Median	46.500	44.000	56.500	47.000
Min, Max	19.000, 85.000	35.000, 48.000	35.000, 279.000	19.000, 279.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-37.500 (54.5436)	-69.333 (55.3384)	-53.167 (53.1956)	-52.077 (50.7846)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-42.500	-53.000	-36.000	-47.000
Min, Max	-96.000, 31.000	-131.000, -24.000	-145.000, 0.000	-145.000, 31.000
Week 24				
N	4	3	6	13
Mean (SD)	265.500 (459.1510)	67.333 (21.5019)	93.500 (113.4350)	140.385 (256.5046)
Median	44.000	67.000	47.500	48.000
Min, Max	20.000, 954.000	46.000, 89.000	32.000, 323.000	20.000, 954.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	178.750 (481.8432)	-44.333 (55.1392)	-48.667 (44.0076)	22.308 (266.7281)
Median	-45.000	-13.000	-35.000	-31.000
Min, Max	-95.000, 900.000	-108.000, -12.000	-136.000, -20.000	-136.000, 900.000
Week 28				
N	5	3	7	15
Mean (SD)	103.800 (40.4191)	238.333 (313.4619)	159.143 (211.2032)	156.533 (189.8717)
Median	111.000	70.000	57.000	111.000
Min, Max	34.000, 135.000	45.000, 600.000	47.000, 629.000	34.000, 629.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	23.800 (37.4393)	126.667 (260.5270)	25.429 (114.5613)	45.133 (132.2978)
Median	18.000	11.000	-19.000	-4.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-19.000, 67.000	-56.000, 425.000	-71.000, 267.000	-71.000, 425.000
Week 32				
N	4	3	7	14
Mean (SD)	88.000 (31.6544)	121.333 (44.7921)	376.286 (352.8506)	239.286 (279.9328)
Median	101.000	105.000	193.000	107.000
Min, Max	41.000, 109.000	87.000, 172.000	55.000, 938.000	41.000, 938.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	15.500 (34.8951)	9.667 (72.2657)	242.571 (266.4644)	127.786 (219.2007)
Median	14.500	28.000	110.000	44.000
Min, Max	-17.000, 50.000	-70.000, 71.000	-8.000, 590.000	-70.000, 590.000
Week 36				
N	3	3	7	13
Mean (SD)	264.333 (161.4074)	88.000 (29.8161)	180.571 (148.6101)	178.538 (139.3722)
Median	354.000	80.000	137.000	121.000
Min, Max	78.000, 361.000	63.000, 121.000	49.000, 423.000	49.000, 423.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	185.333 (142.3037)	-23.667 (76.5005)	46.857 (78.7854)	62.538 (114.9997)
Median	239.000	20.000	14.000	21.000
Min, Max	24.000, 293.000	-112.000, 21.000	-14.000, 212.000	-112.000, 293.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	105.600 (51.5829)	111.667 (41.0528)	87.000 (37.4477)	98.133 (41.5105)
Median	87.000	101.000	75.000	77.000
Min, Max	49.000, 173.000	77.000, 157.000	41.000, 156.000	41.000, 173.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	25.600 (24.5927)	0.000 (85.1587)	-46.714 (88.8814)	-13.267 (75.7038)
Median	21.000	42.000	-9.000	8.000
Min, Max	-5.000, 63.000	-98.000, 56.000	-206.000, 33.000	-206.000, 63.000
Week 44				
N	5	3	7	15
Mean (SD)	233.000 (268.6410)	107.000 (26.1534)	80.143 (26.1752)	136.467 (161.5894)
Median	146.000	119.000	66.000	91.000
Min, Max	50.000, 706.000	77.000, 125.000	55.000, 120.000	50.000, 706.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	153.000 (280.4969)	-4.667 (82.8090)	-53.571 (106.1851)	25.067 (193.4379)
Median	31.000	24.000	-6.000	9.000
Min, Max	-4.000, 653.000	-98.000, 60.000	-254.000, 37.000	-254.000, 653.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	99.400 (37.1389)	128.000 (8.7178)	81.857 (37.5785)	96.933 (36.5073)
Median	99.000	132.000	65.000	97.000
Min, Max	56.000, 157.000	118.000, 134.000	49.000, 160.000	49.000, 160.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	19.400 (48.5778)	16.333 (59.0028)	-51.857 (114.9296)	-14.467 (90.2464)
Median	2.000	17.000	-6.000	-4.000
Min, Max	-16.000, 104.000	-43.000, 75.000	-265.000, 78.000	-265.000, 104.000
Early Term				
N	1		1	2
Mean (SD)	31.000 ()		120.000 ()	75.500 (62.9325)
Median	31.000		120.000	75.500
Min, Max	31.000, 31.000		120.000, 120.000	31.000, 120.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-22.000 ()		37.000 ()	7.500 (41.7193)
Median	-22.000		37.000	7.500
Min, Max	-22.000, -22.000		37.000, 37.000	-22.000, 37.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Albumin (g/L)				
Baseline				
N	15			15
Mean (SD)	44.133 (2.6690)			44.133 (2.6690)
Median	45.000			45.000
Min, Max	37.000, 47.000			37.000, 47.000
Week 1				
N	15			15
Mean (SD)	44.333 (2.5261)			44.333 (2.5261)
Median	45.000			45.000
Min, Max	40.000, 48.000			40.000, 48.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	0.200 (1.7809)			0.200 (1.7809)
Median	0.000			0.000
Min, Max	-4.000, 3.000			-4.000, 3.000
Week 2				
N	15			15
Mean (SD)	44.000 (2.7775)			44.000 (2.7775)
Median	44.000			44.000
Min, Max	39.000, 49.000			39.000, 49.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.133 (2.4162)			-0.133 (2.4162)
Median	0.000			0.000
Min, Max	-5.000, 3.000			-5.000, 3.000
Week 4				
N	2	13		15
Mean (SD)	44.000 (0.0000)	43.077 (2.4311)		43.200 (2.2741)
Median	44.000	43.000		44.000
Min, Max	44.000, 44.000	39.000, 46.000		39.000, 46.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-0.500 (2.1213)	-1.000 (2.7386)		-0.933 (2.6040)
Median	-0.500	0.000		0.000
Min, Max	-2.000, 1.000	-6.000, 3.000		-6.000, 3.000
Week 6				
N	3	5	7	15
Mean (SD)	43.333 (2.5166)	42.400 (4.0373)	44.714 (3.4983)	43.667 (3.4572)
Median	43.000	43.000	44.000	44.000
Min, Max	41.000, 46.000	36.000, 47.000	39.000, 49.000	36.000, 49.000
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-0.333 (4.5092)	-1.400 (2.0736)	0.143 (2.4785)	-0.467 (2.6957)
Median	0.000	-2.000	-1.000	-1.000
Min, Max	-5.000, 4.000	-3.000, 2.000	-2.000, 4.000	-5.000, 4.000
Week 8				
N	3	2	10	15
Mean (SD)	42.000 (1.0000)	39.500 (6.3640)	43.400 (1.7127)	42.600 (2.6132)
Median	42.000	39.500	43.500	43.000
Min, Max	41.000, 43.000	35.000, 44.000	41.000, 46.000	35.000, 46.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-1.667 (1.1547)	-2.000 (0.0000)	-1.400 (2.3664)	-1.533 (1.9591)
Median	-1.000	-2.000	-1.000	-1.000
Min, Max	-3.000, -1.000	-2.000, -2.000	-4.000, 3.000	-4.000, 3.000
Week 12				
N	3	2	8	13
Mean (SD)	44.000 (1.7321)	40.500 (3.5355)	43.750 (2.1213)	43.308 (2.3939)
Median	43.000	40.500	43.500	43.000
Min, Max	43.000, 46.000	38.000, 43.000	41.000, 47.000	38.000, 47.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	1.667 (2.0817)	-1.000 (2.8284)	-1.375 (1.9955)	-0.615 (2.3288)
Median	1.000	-1.000	-0.500	0.000
Min, Max	0.000, 4.000	-3.000, 1.000	-4.000, 1.000	-4.000, 4.000
Week 16				
N	3	3	7	13
Mean (SD)	43.667 (0.5774)	42.667 (2.5166)	43.714 (2.7516)	43.462 (2.2589)
Median	44.000	43.000	44.000	44.000
Min, Max	43.000, 44.000	40.000, 45.000	38.000, 46.000	38.000, 46.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	1.333 (0.5774)	-0.333 (3.0551)	-1.286 (1.7995)	-0.462 (2.1062)
Median	1.000	-1.000	-1.000	0.000
Min, Max	1.000, 2.000	-3.000, 3.000	-4.000, 1.000	-4.000, 3.000
Week 20				
N	4	3	6	13
Mean (SD)	42.250 (2.6300)	41.333 (3.7859)	45.000 (1.0954)	43.308 (2.7198)
Median	42.000	43.000	45.000	44.000
Min, Max	40.000, 45.000	37.000, 44.000	43.000, 46.000	37.000, 46.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	0.250 (2.7538)	-1.667 (1.5275)	-0.667 (1.2111)	-0.615 (1.8502)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	0.500	-2.000	-0.500	-1.000
Min, Max	-3.000, 3.000	-3.000, 0.000	-2.000, 1.000	-3.000, 3.000
Week 24				
N	4	3	6	13
Mean (SD)	41.000 (2.4495)	43.333 (4.5092)	45.333 (1.9664)	43.538 (3.2046)
Median	41.500	43.000	46.000	43.000
Min, Max	38.000, 43.000	39.000, 48.000	43.000, 47.000	38.000, 48.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-1.000 (2.3094)	0.333 (2.8868)	-0.333 (2.2509)	-0.385 (2.2560)
Median	-1.000	2.000	0.500	1.000
Min, Max	-3.000, 1.000	-3.000, 2.000	-4.000, 2.000	-4.000, 2.000
Week 28				
N	5	3	7	15
Mean (SD)	43.000 (3.7417)	40.333 (2.3094)	44.429 (2.5071)	43.133 (3.1593)
Median	45.000	39.000	45.000	43.000
Min, Max	38.000, 46.000	39.000, 43.000	41.000, 48.000	38.000, 48.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	0.200 (3.5637)	-2.667 (4.5092)	-1.143 (1.8645)	-1.000 (3.0237)
Median	0.000	-3.000	0.000	0.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-5.000, 4.000	-7.000, 2.000	-4.000, 1.000	-7.000, 4.000
Week 32				
N	4	3	7	14
Mean (SD)	42.250 (2.0616)	40.333 (2.5166)	43.571 (1.7182)	42.500 (2.2447)
Median	42.500	40.000	43.000	43.000
Min, Max	40.000, 44.000	38.000, 43.000	42.000, 47.000	38.000, 47.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	-1.000 (2.1602)	-2.667 (5.5076)	-2.000 (1.9149)	-1.857 (2.7972)
Median	-1.500	-3.000	-2.000	-2.000
Min, Max	-3.000, 2.000	-8.000, 3.000	-5.000, 1.000	-8.000, 3.000
Week 36				
N	3	3	7	13
Mean (SD)	43.333 (2.0817)	41.667 (1.5275)	43.000 (1.9149)	42.769 (1.8328)
Median	44.000	42.000	43.000	43.000
Min, Max	41.000, 45.000	40.000, 43.000	40.000, 45.000	40.000, 45.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	1.000 (2.6458)	-1.333 (3.7859)	-2.571 (1.7182)	-1.462 (2.6962)
Median	2.000	-3.000	-2.000	-2.000
Min, Max	-2.000, 3.000	-4.000, 3.000	-5.000, -1.000	-5.000, 3.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	43.000 (1.8708)	42.000 (2.6458)	44.286 (1.9760)	43.400 (2.1314)
Median	43.000	43.000	44.000	44.000
Min, Max	40.000, 45.000	39.000, 44.000	41.000, 47.000	39.000, 47.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	0.200 (2.2804)	-1.000 (2.6458)	-1.286 (1.6036)	-0.733 (2.0166)
Median	1.000	-2.000	-1.000	-1.000
Min, Max	-3.000, 3.000	-3.000, 2.000	-4.000, 1.000	-4.000, 3.000
Week 44				
N	5	3	7	15
Mean (SD)	44.600 (2.6077)	41.667 (1.5275)	44.857 (1.8645)	44.133 (2.3258)
Median	43.000	42.000	46.000	44.000
Min, Max	43.000, 49.000	40.000, 43.000	41.000, 46.000	40.000, 49.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	1.800 (3.7014)	-1.333 (3.7859)	-0.714 (1.6036)	0.000 (2.9761)
Median	2.000	-3.000	0.000	0.000
Min, Max	-3.000, 7.000	-4.000, 3.000	-4.000, 1.000	-4.000, 7.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	43.400 (2.5100)	43.333 (1.1547)	44.857 (1.7728)	44.067 (1.9809)
Median	44.000	44.000	45.000	44.000
Min, Max	41.000, 47.000	42.000, 44.000	42.000, 47.000	41.000, 47.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	0.600 (3.2094)	0.333 (4.0415)	-0.714 (1.8898)	-0.067 (2.6851)
Median	-1.000	-2.000	-1.000	-1.000
Min, Max	-2.000, 5.000	-2.000, 5.000	-3.000, 2.000	-3.000, 5.000
Early Term				
N	1		1	2
Mean (SD)	42.000 ()		37.000 ()	39.500 (3.5355)
Median	42.000		37.000	39.500
Min, Max	42.000, 42.000		37.000, 37.000	37.000, 42.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-4.000 ()		-8.000 ()	-6.000 (2.8284)
Median	-4.000		-8.000	-6.000
Min, Max	-4.000, -4.000		-8.000, -8.000	-8.000, -4.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Alkaline Phosphatase (IU/L)				
Baseline				
N	15			15
Mean (SD)	80.467 (24.8420)			80.467 (24.8420)
Median	70.000			70.000
Min, Max	53.000, 143.000			53.000, 143.000
Week 1				
N	15			15
Mean (SD)	79.867 (25.3543)			79.867 (25.3543)
Median	68.000			68.000
Min, Max	52.000, 135.000			52.000, 135.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.600 (7.6886)			-0.600 (7.6886)
Median	-2.000			-2.000
Min, Max	-13.000, 16.000			-13.000, 16.000
Week 2				
N	15			15
Mean (SD)	83.867 (30.0044)			83.867 (30.0044)
Median	70.000			70.000
Min, Max	53.000, 161.000			53.000, 161.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	3.400 (12.7492)			3.400 (12.7492)
Median	0.000			0.000
Min, Max	-12.000, 42.000			-12.000, 42.000
Week 4				
N	2	13		15
Mean (SD)	64.500 (7.7782)	90.615 (34.6664)		87.133 (33.4490)
Median	64.500	80.000		78.000
Min, Max	59.000, 70.000	59.000, 165.000		59.000, 165.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-0.500 (2.1213)	7.769 (15.6905)		6.667 (14.8260)
Median	-0.500	7.000		6.000
Min, Max	-2.000, 1.000	-16.000, 46.000		-16.000, 46.000
Week 6				
N	3	5	7	15
Mean (SD)	72.000 (12.2882)	86.000 (35.3341)	98.286 (30.4561)	88.933 (29.7333)
Median	77.000	70.000	97.000	81.000
Min, Max	58.000, 81.000	59.000, 146.000	61.000, 154.000	58.000, 154.000
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-3.333 (11.5036)	10.000 (10.5830)	12.429 (11.9144)	8.467 (12.2583)
Median	-3.000	5.000	11.000	8.000
Min, Max	-15.000, 8.000	0.000, 27.000	-7.000, 29.000	-15.000, 29.000
Week 8				
N	3	2	10	15
Mean (SD)	70.667 (6.6583)	110.000 (50.9117)	93.900 (32.6001)	91.400 (31.9482)
Median	69.000	110.000	86.000	80.000
Min, Max	65.000, 78.000	74.000, 146.000	58.000, 169.000	58.000, 169.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-4.667 (19.5021)	15.500 (16.2635)	14.700 (14.2677)	10.933 (16.4120)
Median	4.000	15.500	20.500	17.000
Min, Max	-27.000, 9.000	4.000, 27.000	-10.000, 26.000	-27.000, 27.000
Week 12				
N	3	2	8	13
Mean (SD)	85.667 (13.6504)	127.000 (66.4680)	112.625 (52.1507)	108.615 (46.7378)
Median	88.000	127.000	102.500	98.000
Min, Max	71.000, 98.000	80.000, 174.000	63.000, 235.000	63.000, 235.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	4.000 (10.3923)	32.500 (31.8198)	31.375 (28.2283)	25.231 (26.7181)
Median	10.000	32.500	27.000	21.000
Min, Max	-8.000, 10.000	10.000, 55.000	-5.000, 92.000	-8.000, 92.000
Week 16				
N	3	3	7	13
Mean (SD)	94.333 (7.5056)	120.000 (33.1512)	113.143 (52.6575)	110.385 (40.8769)
Median	94.000	105.000	99.000	99.000
Min, Max	87.000, 102.000	97.000, 158.000	68.000, 223.000	68.000, 223.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	12.667 (11.5470)	29.000 (9.1652)	32.286 (26.4368)	27.000 (21.3151)
Median	6.000	27.000	36.000	26.000
Min, Max	6.000, 26.000	21.000, 39.000	0.000, 80.000	0.000, 80.000
Week 20				
N	4	3	6	13
Mean (SD)	134.250 (75.3276)	139.333 (45.5009)	97.667 (28.1543)	118.538 (50.0210)
Median	99.500	139.000	95.500	97.000
Min, Max	91.000, 247.000	94.000, 185.000	62.000, 147.000	62.000, 247.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	37.250 (45.7484)	48.333 (21.7792)	27.167 (23.4300)	35.154 (30.1298)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	19.000	55.000	32.000	30.000
Min, Max	7.000, 104.000	24.000, 66.000	-6.000, 61.000	-6.000, 104.000
Week 24				
N	4	3	6	13
Mean (SD)	151.750 (67.0591)	143.333 (16.9214)	100.333 (33.3746)	126.077 (47.5560)
Median	128.000	139.000	104.500	112.000
Min, Max	103.000, 248.000	129.000, 162.000	51.000, 150.000	51.000, 248.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	54.750 (48.0304)	52.333 (29.5691)	29.833 (27.1398)	42.692 (34.4054)
Median	53.500	59.000	32.500	38.000
Min, Max	7.000, 105.000	20.000, 78.000	-17.000, 64.000	-17.000, 105.000
Week 28				
N	5	3	7	15
Mean (SD)	134.600 (61.8409)	173.000 (70.6612)	95.286 (27.7051)	123.933 (55.6936)
Median	117.000	141.000	91.000	117.000
Min, Max	83.000, 242.000	124.000, 254.000	56.000, 134.000	56.000, 254.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	43.200 (35.0386)	82.000 (77.8717)	27.143 (20.2438)	43.467 (42.9433)
Median	25.000	54.000	31.000	31.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	14.000, 99.000	22.000, 170.000	-12.000, 48.000	-12.000, 170.000
Week 32				
N	4	3	7	14
Mean (SD)	103.000 (21.3229)	141.333 (17.0392)	89.571 (28.7336)	104.500 (31.0552)
Median	107.000	132.000	90.000	111.000
Min, Max	74.000, 124.000	131.000, 161.000	47.000, 122.000	47.000, 161.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	24.500 (20.0416)	50.333 (34.0343)	21.429 (23.9990)	28.500 (26.0495)
Median	21.000	62.000	21.000	24.500
Min, Max	5.000, 51.000	12.000, 77.000	-21.000, 55.000	-21.000, 77.000
Week 36				
N	3	3	7	13
Mean (SD)	158.667 (49.9633)	123.667 (19.4251)	83.286 (25.6691)	110.000 (43.1683)
Median	186.000	119.000	86.000	107.000
Min, Max	101.000, 189.000	107.000, 145.000	57.000, 121.000	57.000, 189.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	77.000 (32.5115)	32.667 (30.7300)	15.143 (15.4427)	33.462 (33.5053)
Median	90.000	37.000	19.000	27.000
Min, Max	40.000, 101.000	0.000, 61.000	-11.000, 35.000	-11.000, 101.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	124.600 (58.6626)	121.000 (20.8806)	76.571 (22.4266)	101.467 (42.9399)
Median	106.000	131.000	69.000	97.000
Min, Max	73.000, 216.000	97.000, 135.000	55.000, 111.000	55.000, 216.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	33.200 (28.1016)	30.000 (19.6723)	8.429 (11.4289)	21.000 (22.0551)
Median	20.000	27.000	9.000	15.000
Min, Max	4.000, 73.000	12.000, 51.000	-12.000, 25.000	-12.000, 73.000
Week 44				
N	5	3	7	15
Mean (SD)	135.000 (49.7845)	107.333 (18.7172)	74.429 (16.8410)	101.200 (40.6715)
Median	138.000	115.000	66.000	91.000
Min, Max	81.000, 201.000	86.000, 121.000	56.000, 103.000	56.000, 201.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	43.600 (29.6867)	16.333 (20.5020)	6.286 (6.4734)	20.733 (25.0013)
Median	58.000	16.000	6.000	10.000
Min, Max	4.000, 69.000	-4.000, 37.000	-3.000, 17.000	-4.000, 69.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	116.400 (46.8327)	105.000 (20.8806)	69.571 (21.2042)	92.267 (37.1742)
Median	104.000	115.000	58.000	86.000
Min, Max	72.000, 191.000	81.000, 119.000	47.000, 104.000	47.000, 191.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	25.000 (15.2807)	14.000 (19.6723)	1.429 (9.9642)	11.800 (16.7809)
Median	17.000	11.000	1.000	11.000
Min, Max	11.000, 48.000	-4.000, 35.000	-12.000, 18.000	-12.000, 48.000
Early Term				
N	1		1	2
Mean (SD)	77.000 ()		57.000 ()	67.000 (14.1421)
Median	77.000		57.000	67.000
Min, Max	77.000, 77.000		57.000, 57.000	57.000, 77.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	8.000 ()		3.000 ()	5.500 (3.5355)
Median	8.000		3.000	5.500
Min, Max	8.000, 8.000		3.000, 3.000	3.000, 8.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Amylase (IU/L)				
Baseline				
N	15			15
Mean (SD)	80.667 (22.8994)			80.667 (22.8994)
Median	85.000			85.000
Min, Max	44.000, 121.000			44.000, 121.000
Week 1				
N	15			15
Mean (SD)	75.933 (28.2071)			75.933 (28.2071)
Median	74.000			74.000
Min, Max	41.000, 149.000			41.000, 149.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-4.733 (14.9211)			-4.733 (14.9211)
Median	-7.000			-7.000
Min, Max	-25.000, 40.000			-25.000, 40.000
Week 2				
N	15			15
Mean (SD)	79.533 (28.0812)			79.533 (28.0812)
Median	83.000			83.000
Min, Max	42.000, 135.000			42.000, 135.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-1.133 (11.4759)			-1.133 (11.4759)
Median	-5.000			-5.000
Min, Max	-14.000, 26.000			-14.000, 26.000
Week 4				
N	2	13		15
Mean (SD)	64.500 (41.7193)	86.923 (25.7114)		83.933 (27.4447)
Median	64.500	88.000		88.000
Min, Max	35.000, 94.000	50.000, 124.000		35.000, 124.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-5.000 (19.7990)	4.538 (13.2011)		3.267 (13.7346)
Median	-5.000	3.000		3.000
Min, Max	-19.000, 9.000	-21.000, 28.000		-21.000, 28.000
Week 6				
N	3	5	7	15
Mean (SD)	59.000 (26.6271)	91.000 (26.9351)	93.714 (42.7228)	85.867 (35.8566)
Median	56.000	83.000	86.000	83.000
Min, Max	34.000, 87.000	57.000, 119.000	41.000, 174.000	34.000, 174.000

Change from Baseline to Week 6

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-8.667 (11.0151)	-2.400 (10.0150)	16.571 (33.0497)	5.200 (25.3101)
Median	-8.000	-2.000	11.000	-1.000
Min, Max	-20.000, 2.000	-16.000, 9.000	-15.000, 86.000	-20.000, 86.000
Week 8				
N	3	2	10	15
Mean (SD)	72.667 (23.7136)	101.000 (26.8701)	82.800 (27.8759)	83.200 (26.4688)
Median	66.000	101.000	84.500	83.000
Min, Max	53.000, 99.000	82.000, 120.000	44.000, 122.000	44.000, 122.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	5.000 (7.9373)	-0.500 (16.2635)	2.400 (12.0481)	2.533 (11.1283)
Median	2.000	-0.500	1.500	2.000
Min, Max	-1.000, 14.000	-12.000, 11.000	-18.000, 28.000	-18.000, 28.000
Week 12				
N	3	2	8	13
Mean (SD)	67.667 (27.5015)	126.500 (36.0624)	82.625 (24.5120)	85.923 (30.8206)
Median	68.000	126.500	87.000	88.000
Min, Max	40.000, 95.000	101.000, 152.000	49.000, 121.000	40.000, 152.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-6.667 (9.4516)	25.000 (25.4558)	1.750 (9.3312)	3.385 (14.9863)
Median	-10.000	25.000	1.000	2.000
Min, Max	-14.000, 4.000	7.000, 43.000	-15.000, 17.000	-15.000, 43.000
Week 16				
N	3	3	7	13
Mean (SD)	67.000 (31.4325)	108.333 (9.5044)	73.857 (17.9669)	80.231 (24.6176)
Median	73.000	108.000	80.000	87.000
Min, Max	33.000, 95.000	99.000, 118.000	53.000, 95.000	33.000, 118.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-7.333 (15.1767)	0.333 (11.7189)	-1.286 (12.5129)	-2.308 (12.1750)
Median	-10.000	5.000	0.000	0.000
Min, Max	-21.000, 9.000	-13.000, 9.000	-23.000, 14.000	-23.000, 14.000
Week 20				
N	4	3	6	13
Mean (SD)	82.250 (22.8965)	100.667 (12.6623)	71.167 (23.1812)	81.385 (22.9584)
Median	85.000	103.000	73.000	89.000
Min, Max	54.000, 105.000	87.000, 112.000	46.000, 94.000	46.000, 112.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	4.750 (5.5000)	-7.333 (1.5275)	-2.000 (16.4317)	-1.154 (11.9153)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	4.500	-7.000	3.000	0.000
Min, Max	0.000, 10.000	-9.000, -6.000	-34.000, 13.000	-34.000, 13.000
Week 24				
N	4	3	6	13
Mean (SD)	78.750 (26.1964)	121.000 (55.4346)	76.167 (27.0364)	87.308 (36.8587)
Median	85.000	113.000	70.000	79.000
Min, Max	43.000, 102.000	70.000, 180.000	50.000, 114.000	43.000, 180.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	1.250 (10.2754)	13.000 (42.2256)	3.000 (18.6333)	4.769 (22.1553)
Median	2.000	4.000	2.000	4.000
Min, Max	-11.000, 12.000	-24.000, 59.000	-21.000, 33.000	-24.000, 59.000
Week 28				
N	5	3	7	15
Mean (SD)	89.000 (23.6643)	95.667 (17.9258)	76.143 (24.4570)	84.333 (23.0455)
Median	100.000	105.000	79.000	89.000
Min, Max	54.000, 112.000	75.000, 107.000	49.000, 106.000	49.000, 112.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	10.000 (11.1580)	-12.333 (9.0738)	6.000 (10.0333)	3.667 (12.7429)
Median	12.000	-16.000	5.000	1.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-2.000, 25.000	-19.000, -2.000	-4.000, 25.000	-19.000, 25.000
Week 32				
N	4	3	7	14
Mean (SD)	76.500 (21.7025)	105.000 (16.6433)	69.286 (21.0215)	79.000 (23.7487)
Median	76.500	112.000	66.000	82.000
Min, Max	51.000, 102.000	86.000, 117.000	46.000, 102.000	46.000, 117.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	-0.500 (3.7859)	-3.000 (9.5394)	-0.857 (11.3788)	-1.214 (8.8333)
Median	-2.000	-8.000	-1.000	-2.000
Min, Max	-3.000, 5.000	-9.000, 8.000	-16.000, 21.000	-16.000, 21.000
Week 36				
N	3	3	7	13
Mean (SD)	69.000 (17.3205)	112.000 (17.3205)	72.714 (17.4806)	80.923 (23.8553)
Median	79.000	122.000	69.000	79.000
Min, Max	49.000, 79.000	92.000, 122.000	52.000, 99.000	49.000, 122.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	-5.333 (20.5020)	4.000 (7.9373)	2.571 (9.7101)	1.077 (11.8916)
Median	-5.000	1.000	3.000	1.000
Min, Max	-26.000, 15.000	-2.000, 13.000	-13.000, 14.000	-26.000, 15.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	91.000 (30.2242)	119.333 (17.0098)	75.000 (22.6789)	89.200 (28.6237)
Median	94.000	120.000	67.000	93.000
Min, Max	50.000, 125.000	102.000, 136.000	52.000, 109.000	50.000, 136.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	12.000 (15.5403)	11.333 (3.5119)	4.857 (10.2702)	8.533 (11.3444)
Median	9.000	11.000	4.000	8.000
Min, Max	-4.000, 38.000	8.000, 15.000	-15.000, 18.000	-15.000, 38.000
Week 44				
N	5	3	7	15
Mean (SD)	88.800 (27.3167)	133.000 (41.7253)	66.429 (14.7970)	87.200 (34.9555)
Median	88.000	128.000	68.000	81.000
Min, Max	51.000, 125.000	94.000, 177.000	45.000, 84.000	45.000, 177.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	9.800 (17.4843)	25.000 (28.4781)	-3.714 (7.2276)	6.533 (18.8409)
Median	3.000	19.000	0.000	1.000
Min, Max	-4.000, 38.000	0.000, 56.000	-14.000, 4.000	-14.000, 56.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	91.400 (26.4159)	118.000 (18.0278)	72.000 (22.5610)	87.667 (28.0858)
Median	86.000	123.000	71.000	85.000
Min, Max	70.000, 134.000	98.000, 133.000	44.000, 109.000	44.000, 134.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	12.400 (21.1967)	10.000 (5.2915)	1.857 (13.4837)	7.000 (15.3576)
Median	6.000	12.000	-3.000	4.000
Min, Max	-8.000, 47.000	4.000, 14.000	-11.000, 28.000	-11.000, 47.000
Early Term				
N	1		1	2
Mean (SD)	90.000 ()		66.000 ()	78.000 (16.9706)
Median	90.000		66.000	78.000
Min, Max	90.000, 90.000		66.000, 66.000	66.000, 90.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	5.000 ()		14.000 ()	9.500 (6.3640)
Median	5.000		14.000	9.500
Min, Max	5.000, 5.000		14.000, 14.000	5.000, 14.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Aspartate Aminotransferase (IU/L)				
Baseline				
N	15			15
Mean (SD)	56.200 (30.9866)			56.200 (30.9866)
Median	43.000			43.000
Min, Max	32.000, 135.000			32.000, 135.000
Week 1				
N	15			15
Mean (SD)	55.000 (27.9694)			55.000 (27.9694)
Median	49.000			49.000
Min, Max	33.000, 133.000			33.000, 133.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-1.200 (20.4737)			-1.200 (20.4737)
Median	-1.000			-1.000
Min, Max	-45.000, 51.000			-45.000, 51.000
Week 2				
N	15			15
Mean (SD)	53.733 (25.6472)			53.733 (25.6472)
Median	43.000			43.000
Min, Max	28.000, 115.000			28.000, 115.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-2.467 (20.3535)			-2.467 (20.3535)
Median	0.000			0.000
Min, Max	-43.000, 38.000			-43.000, 38.000
Week 4				
N	2	13		15
Mean (SD)	78.500 (55.8614)	54.923 (25.6465)		58.067 (29.2489)
Median	78.500	50.000		50.000
Min, Max	39.000, 118.000	28.000, 103.000		28.000, 118.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	41.500 (51.6188)	-4.231 (30.5100)		1.867 (35.3146)
Median	41.500	-1.000		1.000
Min, Max	5.000, 78.000	-52.000, 50.000		-52.000, 78.000
Week 6				
N	3	5	7	15
Mean (SD)	106.667 (77.0541)	73.000 (32.3883)	40.000 (11.3284)	64.333 (43.7014)
Median	110.000	72.000	38.000	42.000
Min, Max	28.000, 182.000	41.000, 114.000	28.000, 58.000	28.000, 182.000

Change from Baseline to Week 6

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	56.667 (76.5593)	2.200 (45.5982)	-8.429 (21.0385)	8.133 (47.7028)
Median	34.000	7.000	-2.000	0.000
Min, Max	-6.000, 142.000	-47.000, 61.000	-52.000, 12.000	-52.000, 142.000
Week 8				
N	3	2	10	15
Mean (SD)	35.667 (7.5719)	41.000 (2.8284)	46.700 (21.0241)	43.733 (17.7260)
Median	39.000	41.000	43.000	41.000
Min, Max	27.000, 41.000	39.000, 43.000	30.000, 100.000	27.000, 100.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-14.333 (20.0333)	-7.000 (9.8995)	-13.000 (26.9568)	-12.467 (23.1667)
Median	-7.000	-7.000	-5.500	-6.000
Min, Max	-37.000, 1.000	-14.000, 0.000	-63.000, 16.000	-63.000, 16.000
Week 12				
N	3	2	8	13
Mean (SD)	49.667 (46.4579)	30.500 (13.4350)	43.625 (18.0471)	43.000 (24.5391)
Median	28.000	30.500	42.500	40.000
Min, Max	18.000, 103.000	21.000, 40.000	20.000, 81.000	18.000, 103.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	0.333 (60.6163)	-17.500 (6.3640)	-22.625 (24.8994)	-16.538 (32.7633)
Median	-4.000	-17.500	-14.500	-13.000
Min, Max	-58.000, 63.000	-22.000, -13.000	-60.000, 2.000	-60.000, 63.000
Week 16				
N	3	3	7	13
Mean (SD)	83.000 (104.7903)	56.333 (29.3655)	43.286 (27.5845)	55.462 (51.2894)
Median	23.000	43.000	37.000	37.000
Min, Max	22.000, 204.000	36.000, 90.000	21.000, 103.000	21.000, 204.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	33.667 (114.9014)	-5.000 (49.6890)	-19.857 (21.6905)	-4.077 (57.8683)
Median	-10.000	-10.000	-10.000	-10.000
Min, Max	-53.000, 164.000	-52.000, 47.000	-63.000, 2.000	-63.000, 164.000
Week 20				
N	4	3	6	13
Mean (SD)	36.500 (21.7025)	31.333 (4.7258)	50.833 (42.1351)	41.923 (30.6389)
Median	26.500	33.000	37.500	32.000
Min, Max	24.000, 69.000	26.000, 35.000	23.000, 135.000	23.000, 135.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-12.000 (33.4963)	-30.000 (21.6564)	-15.167 (22.6223)	-17.615 (24.9751)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-12.500	-18.000	-6.000	-16.000
Min, Max	-52.000, 29.000	-55.000, -17.000	-60.000, 0.000	-60.000, 29.000
Week 24				
N	4	3	6	13
Mean (SD)	188.000 (325.3357)	42.667 (3.0551)	58.000 (59.5113)	94.462 (179.4155)
Median	26.000	42.000	38.000	40.000
Min, Max	24.000, 676.000	40.000, 46.000	20.000, 177.000	20.000, 676.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	139.500 (331.5464)	-18.667 (20.5994)	-8.000 (30.8610)	34.923 (182.2990)
Median	-13.000	-11.000	-6.500	-8.000
Min, Max	-52.000, 636.000	-42.000, -3.000	-54.000, 42.000	-54.000, 636.000
Week 28				
N	5	3	7	15
Mean (SD)	68.000 (26.4858)	174.667 (223.8444)	85.286 (102.4381)	97.400 (116.2631)
Median	66.000	67.000	40.000	66.000
Min, Max	28.000, 99.000	25.000, 432.000	28.000, 311.000	25.000, 432.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	22.400 (25.1853)	113.333 (200.4029)	23.714 (68.9727)	41.200 (96.7029)
Median	18.000	14.000	-7.000	7.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-6.000, 59.000	-18.000, 344.000	-13.000, 176.000	-18.000, 344.000
Week 32				
N	4	3	7	14
Mean (SD)	62.750 (25.7730)	69.333 (8.6217)	176.143 (151.1373)	120.857 (118.3417)
Median	64.500	71.000	94.000	72.500
Min, Max	31.000, 91.000	60.000, 77.000	28.000, 402.000	28.000, 402.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	17.250 (25.5131)	8.000 (31.2410)	114.571 (117.9645)	63.929 (97.4486)
Median	10.500	24.000	59.000	23.500
Min, Max	-3.000, 51.000	-28.000, 28.000	-4.000, 267.000	-28.000, 267.000
Week 36				
N	3	3	7	13
Mean (SD)	186.000 (102.2350)	61.333 (11.9304)	85.857 (67.5905)	103.308 (79.8597)
Median	242.000	65.000	57.000	65.000
Min, Max	68.000, 248.000	48.000, 71.000	29.000, 214.000	29.000, 248.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	136.667 (97.3721)	0.000 (34.6987)	24.286 (38.7587)	44.615 (73.4104)
Median	166.000	18.000	8.000	18.000
Min, Max	28.000, 216.000	-40.000, 22.000	-3.000, 109.000	-40.000, 216.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	60.800 (20.8734)	68.333 (16.8622)	49.286 (16.1422)	56.933 (18.4176)
Median	51.000	76.000	53.000	53.000
Min, Max	42.000, 94.000	49.000, 80.000	25.000, 73.000	25.000, 94.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	15.200 (4.9699)	7.000 (39.9500)	-12.286 (32.4331)	0.733 (29.2195)
Median	15.000	27.000	-1.000	10.000
Min, Max	10.000, 22.000	-39.000, 33.000	-62.000, 27.000	-62.000, 33.000
Week 44				
N	5	3	7	15
Mean (SD)	125.000 (123.6548)	72.333 (25.4231)	47.429 (11.5016)	78.267 (76.0314)
Median	67.000	67.000	45.000	53.000
Min, Max	52.000, 342.000	50.000, 100.000	30.000, 63.000	30.000, 342.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	79.400 (128.0558)	11.000 (43.9659)	-14.143 (35.2724)	22.067 (85.7342)
Median	21.000	24.000	-2.000	12.000
Min, Max	12.000, 308.000	-38.000, 47.000	-72.000, 25.000	-72.000, 308.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	61.000 (25.8554)	81.000 (19.9750)	44.714 (13.2503)	57.400 (22.9714)
Median	48.000	76.000	45.000	48.000
Min, Max	37.000, 89.000	64.000, 103.000	28.000, 63.000	28.000, 103.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	15.400 (23.7339)	19.667 (31.0215)	-16.857 (36.6262)	1.200 (34.3723)
Median	10.000	21.000	-4.000	6.000
Min, Max	-9.000, 55.000	-12.000, 50.000	-76.000, 24.000	-76.000, 55.000
Early Term				
N	1		1	2
Mean (SD)	25.000 ()		37.000 ()	31.000 (8.4853)
Median	25.000		37.000	31.000
Min, Max	25.000, 25.000		37.000, 37.000	25.000, 37.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-9.000 ()		2.000 ()	-3.500 (7.7782)
Median	-9.000		2.000	-3.500
Min, Max	-9.000, -9.000		2.000, 2.000	-9.000, 2.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Bicarbonate (mmol/L)				
Baseline				
N	15			15
Mean (SD)	24.067 (2.0166)			24.067 (2.0166)
Median	24.000			24.000
Min, Max	20.000, 28.000			20.000, 28.000
Week 1				
N	15			15
Mean (SD)	24.133 (2.5875)			24.133 (2.5875)
Median	24.000			24.000
Min, Max	18.000, 28.000			18.000, 28.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	0.067 (2.4631)			0.067 (2.4631)
Median	0.000			0.000
Min, Max	-4.000, 5.000			-4.000, 5.000
Week 2				
N	15			15
Mean (SD)	24.933 (2.4631)			24.933 (2.4631)
Median	25.000			25.000
Min, Max	22.000, 31.000			22.000, 31.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	0.867 (2.4746)			0.867 (2.4746)
Median	2.000			2.000
Min, Max	-4.000, 4.000			-4.000, 4.000
Week 4				
N	2	13		15
Mean (SD)	24.000 (4.2426)	25.000 (2.2361)		24.867 (2.3865)
Median	24.000	26.000		26.000
Min, Max	21.000, 27.000	21.000, 28.000		21.000, 28.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-1.000 (0.0000)	1.077 (2.3260)		0.800 (2.2741)
Median	-1.000	2.000		2.000
Min, Max	-1.000, -1.000	-4.000, 4.000		-4.000, 4.000
Week 6				
N	3	5	7	15
Mean (SD)	25.667 (3.2146)	24.600 (3.1305)	22.857 (2.5448)	24.000 (2.9032)
Median	27.000	24.000	23.000	24.000
Min, Max	22.000, 28.000	20.000, 28.000	19.000, 26.000	19.000, 28.000
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	1.000 (2.6458)	0.600 (1.9494)	-1.000 (2.3094)	-0.067 (2.2824)
Median	0.000	0.000	-1.000	0.000
Min, Max	-1.000, 4.000	-2.000, 3.000	-4.000, 2.000	-4.000, 4.000
Week 8				
N	3	2	10	15
Mean (SD)	25.000 (2.0000)	25.500 (0.7071)	22.300 (2.0028)	23.267 (2.2824)
Median	25.000	25.500	22.500	23.000
Min, Max	23.000, 27.000	25.000, 26.000	18.000, 25.000	18.000, 27.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	0.333 (1.1547)	0.500 (0.7071)	-1.400 (1.1738)	-0.800 (1.3732)
Median	1.000	0.500	-1.500	-1.000
Min, Max	-1.000, 1.000	0.000, 1.000	-3.000, 0.000	-3.000, 1.000
Week 12				
N	3	2	8	13
Mean (SD)	25.667 (2.0817)	25.000 (1.4142)	24.000 (3.0706)	24.538 (2.6336)
Median	25.000	25.000	24.000	25.000
Min, Max	24.000, 28.000	24.000, 26.000	20.000, 29.000	20.000, 29.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-0.333 (0.5774)	0.000 (0.0000)	0.875 (2.4749)	0.462 (1.9839)
Median	0.000	0.000	1.000	0.000
Min, Max	-1.000, 0.000	0.000, 0.000	-2.000, 5.000	-2.000, 5.000
Week 16				
N	3	3	7	13
Mean (SD)	25.667 (0.5774)	23.667 (3.5119)	22.000 (1.2910)	23.231 (2.3149)
Median	26.000	24.000	22.000	23.000
Min, Max	25.000, 26.000	20.000, 27.000	20.000, 24.000	20.000, 27.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-0.333 (2.5166)	-1.000 (3.6056)	-1.000 (2.3094)	-0.846 (2.4443)
Median	0.000	-2.000	-1.000	-1.000
Min, Max	-3.000, 2.000	-4.000, 3.000	-5.000, 2.000	-5.000, 3.000
Week 20				
N	4	3	6	13
Mean (SD)	25.250 (2.9861)	22.000 (3.4641)	22.167 (4.2622)	23.077 (3.7519)
Median	25.000	20.000	22.500	24.000
Min, Max	22.000, 29.000	20.000, 26.000	17.000, 28.000	17.000, 29.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-0.500 (1.7321)	-2.667 (2.3094)	-0.500 (3.9370)	-1.000 (3.0000)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-0.500	-4.000	-0.500	-1.000
Min, Max	-2.000, 1.000	-4.000, 0.000	-7.000, 4.000	-7.000, 4.000
Week 24				
N	4	3	6	13
Mean (SD)	25.750 (2.3629)	21.000 (1.0000)	20.500 (2.0736)	22.231 (3.0592)
Median	25.000	21.000	20.500	22.000
Min, Max	24.000, 29.000	20.000, 22.000	18.000, 23.000	18.000, 29.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	0.000 (1.4142)	-3.667 (2.0817)	-2.167 (1.9408)	-1.846 (2.1926)
Median	0.500	-3.000	-1.500	-2.000
Min, Max	-2.000, 1.000	-6.000, -2.000	-5.000, 0.000	-6.000, 1.000
Week 28				
N	5	3	7	15
Mean (SD)	25.800 (3.6332)	21.667 (1.5275)	22.429 (2.5728)	23.400 (3.1803)
Median	24.000	22.000	23.000	23.000
Min, Max	23.000, 32.000	20.000, 23.000	19.000, 25.000	19.000, 32.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	0.800 (2.5884)	-3.000 (1.0000)	-0.714 (2.8702)	-0.667 (2.7430)
Median	1.000	-3.000	-1.000	-1.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-3.000, 4.000	-4.000, -2.000	-5.000, 3.000	-5.000, 4.000
Week 32				
N	4	3	7	14
Mean (SD)	24.250 (2.8723)	21.667 (1.5275)	22.571 (2.4398)	22.857 (2.4450)
Median	25.500	22.000	23.000	23.000
Min, Max	20.000, 26.000	20.000, 23.000	19.000, 26.000	19.000, 26.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	-0.750 (1.5000)	-3.000 (2.6458)	-0.571 (1.8127)	-1.143 (2.0327)
Median	-1.000	-2.000	0.000	-1.000
Min, Max	-2.000, 1.000	-6.000, -1.000	-4.000, 2.000	-6.000, 2.000
Week 36				
N	3	3	7	13
Mean (SD)	26.000 (3.4641)	23.667 (1.5275)	23.714 (2.2887)	24.231 (2.4547)
Median	24.000	24.000	24.000	24.000
Min, Max	24.000, 30.000	22.000, 25.000	21.000, 27.000	21.000, 30.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	0.000 (2.0000)	-1.000 (1.0000)	0.571 (2.8785)	0.077 (2.3260)
Median	0.000	-1.000	2.000	0.000
Min, Max	-2.000, 2.000	-2.000, 0.000	-3.000, 4.000	-3.000, 4.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	23.000 (3.0822)	23.667 (3.2146)	22.571 (2.6992)	22.933 (2.7377)
Median	23.000	25.000	23.000	23.000
Min, Max	19.000, 26.000	20.000, 26.000	20.000, 26.000	19.000, 26.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	-2.000 (1.2247)	-1.000 (2.6458)	-0.571 (2.4398)	-1.133 (2.0999)
Median	-2.000	0.000	0.000	0.000
Min, Max	-3.000, 0.000	-4.000, 1.000	-4.000, 2.000	-4.000, 2.000
Week 44				
N	5	3	7	15
Mean (SD)	22.800 (2.8636)	20.333 (1.1547)	22.571 (2.2254)	22.200 (2.3664)
Median	23.000	21.000	23.000	21.000
Min, Max	19.000, 26.000	19.000, 21.000	20.000, 25.000	19.000, 26.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	-2.200 (1.9235)	-4.333 (1.1547)	-0.571 (2.3705)	-1.867 (2.4162)
Median	-2.000	-5.000	0.000	-2.000
Min, Max	-5.000, 0.000	-5.000, -3.000	-4.000, 3.000	-5.000, 3.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	25.000 (1.5811)	24.000 (1.0000)	21.857 (2.3401)	23.333 (2.3197)
Median	25.000	24.000	22.000	24.000
Min, Max	23.000, 27.000	23.000, 25.000	18.000, 24.000	18.000, 27.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	0.000 (2.0000)	-0.667 (1.5275)	-1.286 (2.8702)	-0.733 (2.3135)
Median	1.000	-1.000	-2.000	-1.000
Min, Max	-3.000, 2.000	-2.000, 1.000	-6.000, 2.000	-6.000, 2.000
Early Term				
N	1		1	2
Mean (SD)	21.000 ()		26.000 ()	23.500 (3.5355)
Median	21.000		26.000	23.500
Min, Max	21.000, 21.000		26.000, 26.000	21.000, 26.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-1.000 ()		0.000 ()	-0.500 (0.7071)
Median	-1.000		0.000	-0.500
Min, Max	-1.000, -1.000		0.000, 0.000	-1.000, 0.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Bilirubin (umol/L)				
Baseline				
N	15			15
Mean (SD)	9.133 (3.7582)			9.133 (3.7582)
Median	7.000			7.000
Min, Max	5.000, 15.000			5.000, 15.000
Week 1				
N	15			15
Mean (SD)	9.067 (2.8402)			9.067 (2.8402)
Median	9.000			9.000
Min, Max	5.000, 13.000			5.000, 13.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.067 (2.4044)			-0.067 (2.4044)
Median	0.000			0.000
Min, Max	-4.000, 6.000			-4.000, 6.000
Week 2				
N	15			15
Mean (SD)	7.267 (2.1202)			7.267 (2.1202)
Median	7.000			7.000
Min, Max	2.000, 10.000			2.000, 10.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-1.867 (2.7740)			-1.867 (2.7740)
Median	-1.000			-1.000
Min, Max	-7.000, 1.000			-7.000, 1.000
Week 4				
N	2	13		15
Mean (SD)	7.500 (3.5355)	7.385 (3.6180)		7.400 (3.4806)
Median	7.500	6.000		6.000
Min, Max	5.000, 10.000	3.000, 17.000		3.000, 17.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	1.500 (2.1213)	-2.231 (3.5859)		-1.733 (3.6148)
Median	1.500	-2.000		-1.000
Min, Max	0.000, 3.000	-9.000, 3.000		-9.000, 3.000
Week 6				
N	3	5	7	15
Mean (SD)	6.667 (2.3094)	8.200 (6.7602)	6.857 (1.3452)	7.267 (3.8816)
Median	8.000	6.000	7.000	7.000
Min, Max	4.000, 8.000	3.000, 20.000	5.000, 8.000	3.000, 20.000
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	0.333 (1.1547)	-2.600 (4.9800)	-2.286 (3.9036)	-1.867 (3.8889)
Median	1.000	-3.000	-1.000	-1.000
Min, Max	-1.000, 1.000	-7.000, 5.000	-8.000, 2.000	-8.000, 5.000
Week 8				
N	3	2	10	15
Mean (SD)	5.000 (1.0000)	5.500 (0.7071)	7.400 (1.9551)	6.667 (1.9518)
Median	5.000	5.500	7.500	6.000
Min, Max	4.000, 6.000	5.000, 6.000	4.000, 10.000	4.000, 10.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-1.333 (0.5774)	-1.000 (1.4142)	-3.100 (3.3149)	-2.467 (2.8502)
Median	-1.000	-1.000	-3.000	-2.000
Min, Max	-2.000, -1.000	-2.000, 0.000	-8.000, 1.000	-8.000, 1.000
Week 12				
N	3	2	8	13
Mean (SD)	8.667 (3.5119)	4.500 (0.7071)	8.000 (3.3381)	7.615 (3.2542)
Median	9.000	4.500	8.500	8.000
Min, Max	5.000, 12.000	4.000, 5.000	2.000, 12.000	2.000, 12.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	1.333 (3.0551)	-2.000 (0.0000)	-2.625 (3.3354)	-1.615 (3.3050)
Median	2.000	-2.000	-2.500	-2.000
Min, Max	-2.000, 4.000	-2.000, -2.000	-7.000, 3.000	-7.000, 4.000
Week 16				
N	3	3	7	13
Mean (SD)	7.333 (3.7859)	6.000 (3.0000)	6.714 (3.8173)	6.692 (3.3760)
Median	9.000	6.000	5.000	6.000
Min, Max	3.000, 10.000	3.000, 9.000	2.000, 14.000	2.000, 14.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	0.000 (3.6056)	-3.000 (2.0000)	-3.429 (2.9358)	-2.538 (3.0445)
Median	1.000	-3.000	-3.000	-3.000
Min, Max	-4.000, 3.000	-5.000, -1.000	-8.000, -1.000	-8.000, 3.000
Week 20				
N	4	3	6	13
Mean (SD)	6.250 (2.2174)	5.667 (1.5275)	7.000 (1.7889)	6.462 (1.8081)
Median	7.000	6.000	7.500	7.000
Min, Max	3.000, 8.000	4.000, 7.000	4.000, 9.000	3.000, 9.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-2.000 (2.3094)	-3.333 (3.2146)	-3.000 (3.7947)	-2.769 (3.0592)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-2.000	-2.000	-3.500	-2.000
Min, Max	-4.000, 0.000	-7.000, -1.000	-7.000, 2.000	-7.000, 2.000
Week 24				
N	4	3	6	13
Mean (SD)	8.500 (3.1091)	6.333 (0.5774)	7.167 (3.0605)	7.385 (2.6627)
Median	8.500	6.000	6.500	7.000
Min, Max	5.000, 12.000	6.000, 7.000	3.000, 12.000	3.000, 12.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	0.250 (4.0311)	-2.667 (3.7859)	-2.833 (3.1885)	-1.846 (3.5788)
Median	0.000	-1.000	-2.500	-2.000
Min, Max	-4.000, 5.000	-7.000, 0.000	-7.000, 1.000	-7.000, 5.000
Week 28				
N	5	3	7	15
Mean (SD)	9.200 (4.4944)	11.333 (7.5056)	7.286 (3.7289)	8.733 (4.7278)
Median	7.000	7.000	6.000	7.000
Min, Max	6.000, 17.000	7.000, 20.000	2.000, 12.000	2.000, 20.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	1.600 (4.7223)	2.333 (3.2146)	-3.000 (2.7689)	-0.400 (4.1884)
Median	1.000	1.000	-3.000	0.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-4.000, 9.000	0.000, 6.000	-8.000, 0.000	-8.000, 9.000
Week 32				
N	4	3	7	14
Mean (SD)	8.000 (2.7080)	8.000 (1.7321)	8.857 (4.0178)	8.429 (3.1308)
Median	7.000	9.000	8.000	7.500
Min, Max	6.000, 12.000	6.000, 9.000	4.000, 15.000	4.000, 15.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	1.250 (1.8930)	-1.000 (3.6056)	-1.429 (1.8127)	-0.571 (2.4088)
Median	0.500	0.000	-1.000	0.000
Min, Max	0.000, 4.000	-5.000, 2.000	-5.000, 0.000	-5.000, 4.000
Week 36				
N	3	3	7	13
Mean (SD)	8.667 (1.1547)	8.000 (1.0000)	9.143 (5.8146)	8.769 (4.1864)
Median	8.000	8.000	8.000	8.000
Min, Max	8.000, 10.000	7.000, 9.000	3.000, 20.000	3.000, 20.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	1.333 (1.5275)	-1.000 (3.6056)	-1.143 (3.1848)	-0.538 (2.9613)
Median	1.000	0.000	-2.000	0.000
Min, Max	0.000, 3.000	-5.000, 2.000	-4.000, 5.000	-5.000, 5.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	7.800 (3.1937)	5.667 (2.0817)	9.286 (4.1519)	8.067 (3.5950)
Median	7.000	5.000	10.000	8.000
Min, Max	4.000, 12.000	4.000, 8.000	2.000, 14.000	2.000, 14.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	0.200 (3.4205)	-3.333 (2.5166)	-1.000 (4.0000)	-1.067 (3.5750)
Median	-1.000	-3.000	-2.000	-1.000
Min, Max	-4.000, 5.000	-6.000, -1.000	-6.000, 7.000	-6.000, 7.000
Week 44				
N	5	3	7	15
Mean (SD)	10.800 (4.6043)	6.333 (0.5774)	9.857 (5.1130)	9.467 (4.4860)
Median	11.000	6.000	8.000	8.000
Min, Max	5.000, 17.000	6.000, 7.000	4.000, 19.000	4.000, 19.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	3.200 (4.9699)	-2.667 (3.7859)	-0.429 (2.7603)	0.333 (4.1861)
Median	1.000	-1.000	-1.000	0.000
Min, Max	-2.000, 9.000	-7.000, 0.000	-4.000, 4.000	-7.000, 9.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	7.400 (2.3022)	7.333 (3.0551)	10.143 (6.9144)	8.667 (5.0380)
Median	7.000	8.000	8.000	8.000
Min, Max	5.000, 11.000	4.000, 10.000	5.000, 25.000	4.000, 25.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	-0.200 (3.2711)	-1.667 (2.5166)	-0.143 (5.3363)	-0.467 (4.0685)
Median	1.000	-2.000	-1.000	-1.000
Min, Max	-5.000, 3.000	-4.000, 1.000	-6.000, 10.000	-6.000, 10.000
Early Term				
N	1		1	2
Mean (SD)	6.000 ()		7.000 ()	6.500 (0.7071)
Median	6.000		7.000	6.500
Min, Max	6.000, 6.000		7.000, 7.000	6.000, 7.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	1.000 ()		-5.000 ()	-2.000 (4.2426)
Median	1.000		-5.000	-2.000
Min, Max	1.000, 1.000		-5.000, -5.000	-5.000, 1.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Blood Urea Nitrogen (mg/dL)				
Baseline				
N	15			15
Mean (SD)	13.141 (4.0775)			13.141 (4.0775)
Median	12.880			12.880
Min, Max	5.600, 21.280			5.600, 21.280
Week 1				
N	15			15
Mean (SD)	13.981 (4.1402)			13.981 (4.1402)
Median	12.600			12.600
Min, Max	8.120, 21.560			8.120, 21.560
Change from Baseline to Week 1				
N	15			15
Mean (SD)	0.840 (3.3733)			0.840 (3.3733)
Median	1.400			1.400
Min, Max	-4.480, 6.720			-4.480, 6.720
Week 2				
N	15			15
Mean (SD)	13.720 (3.1430)			13.720 (3.1430)
Median	13.440			13.440
Min, Max	8.400, 20.440			8.400, 20.440

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	0.579 (3.1420)			0.579 (3.1420)
Median	0.280			0.280
Min, Max	-4.480, 7.560			-4.480, 7.560
Week 4				
N	2	13		15
Mean (SD)	13.580 (2.9698)	14.065 (4.8741)		14.000 (4.5850)
Median	13.580	12.320		12.320
Min, Max	11.480, 15.680	9.240, 26.040		9.240, 26.040
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	1.960 (5.5437)	0.689 (2.9269)		0.859 (3.1206)
Median	1.960	1.120		1.120
Min, Max	-1.960, 5.880	-3.080, 7.280		-3.080, 7.280
Week 6				
N	3	5	7	15
Mean (SD)	11.573 (2.5252)	13.104 (3.2857)	13.400 (4.2539)	12.936 (3.5023)
Median	11.760	12.880	12.320	12.320
Min, Max	8.960, 14.000	9.240, 17.920	8.120, 19.600	8.120, 19.600
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	0.093 (3.5233)	-1.232 (1.3803)	0.400 (4.9322)	-0.205 (3.6499)
Median	0.560	-0.840	0.840	-0.560
Min, Max	-3.640, 3.360	-3.360, 0.280	-6.720, 8.400	-6.720, 8.400
Week 8				
N	3	2	10	15
Mean (SD)	11.480 (2.1869)	10.780 (6.5337)	14.616 (3.8950)	13.477 (4.0380)
Median	10.360	10.780	14.280	14.000
Min, Max	10.080, 14.000	6.160, 15.400	8.680, 20.720	6.160, 20.720
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	0.000 (4.3105)	-4.900 (1.3859)	1.484 (4.8534)	0.336 (4.7767)
Median	-1.120	-4.900	0.420	-0.560
Min, Max	-3.640, 4.760	-5.880, -3.920	-3.920, 13.720	-5.880, 13.720
Week 12				
N	3	2	8	13
Mean (SD)	12.040 (1.0096)	14.700 (6.5337)	13.300 (5.2469)	13.225 (4.5281)
Median	11.760	14.700	11.900	11.760
Min, Max	11.200, 13.160	10.080, 19.320	7.840, 23.800	7.840, 23.800
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-1.400 (2.7002)	-0.980 (1.3859)	0.070 (5.2676)	-0.431 (4.2443)
Median	-0.280	-0.980	-1.260	-0.840
Min, Max	-4.480, 0.560	-1.960, 0.000	-6.160, 9.520	-6.160, 9.520
Week 16				
N	3	3	7	13
Mean (SD)	14.093 (5.8756)	11.573 (4.6207)	12.720 (4.0860)	12.772 (4.2962)
Median	12.040	12.880	11.200	12.040
Min, Max	9.520, 20.720	6.440, 15.400	8.680, 19.040	6.440, 20.720
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	0.653 (7.6902)	-3.173 (2.9676)	-0.560 (5.7063)	-0.883 (5.4376)
Median	-1.680	-3.640	-2.240	-2.240
Min, Max	-5.600, 9.240	-5.880, 0.000	-4.480, 12.040	-5.880, 12.040
Week 20				
N	4	3	6	13
Mean (SD)	16.730 (9.7005)	14.280 (4.2000)	13.627 (3.6878)	14.732 (5.8416)
Median	12.880	14.280	13.160	13.440
Min, Max	10.080, 31.080	10.080, 18.480	8.960, 20.160	8.960, 31.080
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	4.900 (13.2412)	-0.467 (2.1385)	-0.700 (2.1158)	1.077 (7.3148)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	0.700	0.000	-0.280	0.000
Min, Max	-5.880, 24.080	-2.800, 1.400	-3.640, 1.400	-5.880, 24.080
Week 24				
N	4	3	6	13
Mean (SD)	14.980 (3.9433)	12.040 (3.8899)	14.280 (6.4217)	13.978 (4.9911)
Median	13.720	10.080	14.000	13.440
Min, Max	11.760, 20.720	9.520, 16.520	7.280, 22.680	7.280, 22.680
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	3.150 (8.0517)	-2.707 (2.1016)	-0.047 (6.0195)	0.323 (6.0884)
Median	2.380	-2.800	-0.840	-0.560
Min, Max	-5.880, 13.720	-4.760, -0.560	-6.440, 9.240	-6.440, 13.720
Week 28				
N	5	3	7	15
Mean (SD)	11.424 (2.5921)	12.227 (4.2403)	15.560 (6.8849)	13.515 (5.3676)
Median	10.080	10.360	13.160	12.600
Min, Max	9.240, 15.680	9.240, 17.080	10.360, 30.800	9.240, 30.800
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	0.840 (5.4690)	-2.520 (2.4410)	1.280 (4.9586)	0.373 (4.7135)
Median	-1.120	-3.640	0.280	-0.560

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-5.600, 8.680	-4.200, 0.280	-2.520, 12.040	-5.600, 12.040
Week 32				
N	4	3	7	14
Mean (SD)	12.530 (2.6004)	13.720 (5.6210)	12.160 (1.9049)	12.600 (2.9140)
Median	13.020	11.200	10.920	11.900
Min, Max	8.960, 15.120	9.800, 20.160	10.360, 15.120	8.960, 20.160
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	1.050 (4.1048)	-1.027 (2.1016)	-2.120 (1.7021)	-0.980 (2.8059)
Median	2.800	-1.120	-1.960	-1.400
Min, Max	-5.040, 3.640	-3.080, 1.120	-4.480, 0.560	-5.040, 3.640
Week 36				
N	3	3	7	13
Mean (SD)	11.480 (2.1869)	13.067 (2.8047)	13.040 (2.0503)	12.686 (2.1640)
Median	10.360	12.040	12.600	12.320
Min, Max	10.080, 14.000	10.920, 16.240	10.640, 15.960	10.080, 16.240
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	-1.960 (1.4549)	-1.680 (3.5084)	-1.240 (3.2164)	-1.508 (2.7708)
Median	-1.120	-1.960	-1.120	-1.120
Min, Max	-3.640, -1.120	-5.040, 1.960	-6.160, 3.360	-6.160, 3.360

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	13.776 (6.0973)	12.973 (2.5096)	11.360 (1.4355)	12.488 (3.6992)
Median	13.160	14.280	11.480	11.760
Min, Max	8.680, 24.080	10.080, 14.560	9.240, 13.720	8.680, 24.080
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	3.192 (8.3217)	-1.773 (4.6037)	-2.920 (2.4879)	-0.653 (5.7953)
Median	1.960	0.000	-3.360	-1.680
Min, Max	-4.480, 17.080	-7.000, 1.680	-7.560, 0.280	-7.560, 17.080
Week 44				
N	5	3	7	15
Mean (SD)	14.168 (4.0797)	13.067 (6.6516)	11.160 (2.7168)	12.544 (4.0246)
Median	16.520	9.800	11.480	11.480
Min, Max	7.840, 17.640	8.680, 20.720	7.560, 16.240	7.560, 20.720
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	3.584 (4.5253)	-1.680 (2.1869)	-3.120 (3.0776)	-0.597 (4.5023)
Median	2.240	-0.560	-3.360	-1.120
Min, Max	-1.120, 10.640	-4.200, -0.280	-7.280, 2.240	-7.280, 10.640
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	13.440 (3.7826)	14.373 (5.8756)	12.480 (1.8981)	13.179 (3.3374)
Median	15.680	12.320	11.760	12.320
Min, Max	8.400, 16.520	9.800, 21.000	9.520, 15.400	8.400, 21.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	2.856 (4.6068)	-0.373 (2.6612)	-1.800 (1.5239)	0.037 (3.5542)
Median	2.800	-0.280	-1.680	-0.840
Min, Max	-1.960, 9.520	-3.080, 2.240	-3.360, 0.560	-3.360, 9.520
Early Term				
N	1		1	2
Mean (SD)	12.040 ()		16.520 ()	14.280 (3.1678)
Median	12.040		16.520	14.280
Min, Max	12.040, 12.040		16.520, 16.520	12.040, 16.520
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	6.440 ()		2.520 ()	4.480 (2.7719)
Median	6.440		2.520	4.480
Min, Max	6.440, 6.440		2.520, 2.520	2.520, 6.440

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Calcium (mmol/L)				
Baseline				
N	15			15
Mean (SD)	2.356 (0.0739)			2.356 (0.0739)
Median	2.370			2.370
Min, Max	2.190, 2.440			2.190, 2.440
Week 1				
N	15			15
Mean (SD)	2.349 (0.0613)			2.349 (0.0613)
Median	2.350			2.350
Min, Max	2.260, 2.460			2.260, 2.460
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.007 (0.0620)			-0.007 (0.0620)
Median	-0.010			-0.010
Min, Max	-0.130, 0.100			-0.130, 0.100
Week 2				
N	15			15
Mean (SD)	2.354 (0.0988)			2.354 (0.0988)
Median	2.340			2.340
Min, Max	2.220, 2.540			2.220, 2.540

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.002 (0.0985)			-0.002 (0.0985)
Median	0.010			0.010
Min, Max	-0.170, 0.170			-0.170, 0.170
Week 4				
N	2	13		15
Mean (SD)	2.360 (0.0141)	2.346 (0.0658)		2.348 (0.0612)
Median	2.360	2.350		2.350
Min, Max	2.350, 2.370	2.220, 2.470		2.220, 2.470
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-0.020 (0.0707)	-0.006 (0.0496)		-0.008 (0.0499)
Median	-0.020	-0.010		-0.010
Min, Max	-0.070, 0.030	-0.090, 0.100		-0.090, 0.100
Week 6				
N	3	5	7	15
Mean (SD)	2.390 (0.0436)	2.350 (0.0570)	2.319 (0.0869)	2.343 (0.0723)
Median	2.410	2.350	2.320	2.350
Min, Max	2.340, 2.420	2.280, 2.420	2.170, 2.440	2.170, 2.440
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	0.023 (0.0896)	-0.026 (0.0527)	-0.019 (0.0367)	-0.013 (0.0536)
Median	0.070	-0.020	-0.020	-0.020
Min, Max	-0.080, 0.080	-0.080, 0.030	-0.070, 0.030	-0.080, 0.080
Week 8				
N	3	2	10	15
Mean (SD)	2.397 (0.0757)	2.245 (0.0778)	2.313 (0.0796)	2.321 (0.0861)
Median	2.430	2.245	2.320	2.320
Min, Max	2.310, 2.450	2.190, 2.300	2.160, 2.420	2.160, 2.450
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	0.030 (0.0721)	-0.100 (0.0566)	-0.042 (0.0895)	-0.035 (0.0876)
Median	0.010	-0.100	-0.040	-0.030
Min, Max	-0.030, 0.110	-0.140, -0.060	-0.230, 0.070	-0.230, 0.110
Week 12				
N	3	2	8	13
Mean (SD)	2.393 (0.0651)	2.305 (0.1344)	2.340 (0.0795)	2.347 (0.0822)
Median	2.390	2.305	2.350	2.380
Min, Max	2.330, 2.460	2.210, 2.400	2.200, 2.440	2.200, 2.460
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	0.083 (0.1137)	-0.040 (0.0000)	-0.024 (0.0614)	-0.002 (0.0820)
Median	0.050	-0.040	-0.010	-0.010
Min, Max	-0.010, 0.210	-0.040, -0.040	-0.130, 0.040	-0.130, 0.210
Week 16				
N	3	3	7	13
Mean (SD)	2.450 (0.0520)	2.400 (0.0300)	2.306 (0.0920)	2.361 (0.0947)
Median	2.480	2.400	2.310	2.380
Min, Max	2.390, 2.480	2.370, 2.430	2.150, 2.420	2.150, 2.480
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	0.140 (0.0000)	0.027 (0.0814)	-0.049 (0.0527)	0.012 (0.0937)
Median	0.140	-0.010	-0.060	-0.020
Min, Max	0.140, 0.140	-0.030, 0.120	-0.110, 0.050	-0.110, 0.140
Week 20				
N	4	3	6	13
Mean (SD)	2.313 (0.0763)	2.253 (0.0961)	2.370 (0.0576)	2.325 (0.0820)
Median	2.325	2.270	2.370	2.340
Min, Max	2.220, 2.380	2.150, 2.340	2.300, 2.440	2.150, 2.440
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	0.033 (0.0050)	-0.120 (0.0346)	-0.012 (0.0360)	-0.023 (0.0647)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	0.030	-0.100	-0.010	0.010
Min, Max	0.030, 0.040	-0.160, -0.100	-0.050, 0.030	-0.160, 0.040
Week 24				
N	4	3	6	13
Mean (SD)	2.285 (0.1097)	2.310 (0.0872)	2.323 (0.0781)	2.308 (0.0843)
Median	2.315	2.350	2.325	2.340
Min, Max	2.130, 2.380	2.210, 2.370	2.220, 2.430	2.130, 2.430
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	0.005 (0.0473)	-0.063 (0.0208)	-0.058 (0.0688)	-0.040 (0.0599)
Median	0.020	-0.070	-0.060	-0.050
Min, Max	-0.060, 0.040	-0.080, -0.040	-0.150, 0.060	-0.150, 0.060
Week 28				
N	5	3	7	15
Mean (SD)	2.340 (0.0894)	2.267 (0.0462)	2.359 (0.0807)	2.334 (0.0817)
Median	2.360	2.240	2.370	2.360
Min, Max	2.190, 2.430	2.240, 2.320	2.200, 2.440	2.190, 2.440
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	0.032 (0.0665)	-0.107 (0.0907)	-0.024 (0.0730)	-0.022 (0.0855)
Median	0.010	-0.120	-0.020	-0.010

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-0.050, 0.110	-0.190, -0.010	-0.170, 0.070	-0.190, 0.110
Week 32				
N	4	3	7	14
Mean (SD)	2.358 (0.0591)	2.297 (0.1193)	2.336 (0.0541)	2.334 (0.0696)
Median	2.365	2.260	2.340	2.345
Min, Max	2.280, 2.420	2.200, 2.430	2.260, 2.420	2.200, 2.430
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	0.020 (0.0183)	-0.077 (0.1332)	-0.047 (0.0395)	-0.034 (0.0702)
Median	0.020	-0.010	-0.050	-0.020
Min, Max	0.000, 0.040	-0.230, 0.010	-0.110, 0.020	-0.230, 0.040
Week 36				
N	3	3	7	13
Mean (SD)	2.393 (0.0306)	2.383 (0.1570)	2.339 (0.0430)	2.362 (0.0766)
Median	2.400	2.330	2.340	2.360
Min, Max	2.360, 2.420	2.260, 2.560	2.270, 2.400	2.260, 2.560
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	0.083 (0.0651)	0.010 (0.1572)	-0.044 (0.0476)	-0.002 (0.0941)
Median	0.080	0.080	-0.030	-0.010
Min, Max	0.020, 0.150	-0.170, 0.120	-0.100, 0.030	-0.170, 0.150

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	2.340 (0.0624)	2.360 (0.1825)	2.343 (0.0482)	2.345 (0.0832)
Median	2.370	2.270	2.330	2.340
Min, Max	2.230, 2.380	2.240, 2.570	2.300, 2.410	2.230, 2.570
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	0.032 (0.0497)	-0.013 (0.1450)	-0.040 (0.0497)	-0.011 (0.0765)
Median	0.030	-0.010	-0.040	-0.010
Min, Max	-0.040, 0.100	-0.160, 0.130	-0.130, 0.020	-0.160, 0.130
Week 44				
N	5	3	7	15
Mean (SD)	2.348 (0.0998)	2.300 (0.0755)	2.327 (0.0468)	2.329 (0.0701)
Median	2.340	2.310	2.320	2.320
Min, Max	2.200, 2.470	2.220, 2.370	2.270, 2.400	2.200, 2.470
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	0.040 (0.1125)	-0.073 (0.0451)	-0.056 (0.0276)	-0.027 (0.0819)
Median	0.010	-0.070	-0.050	-0.050
Min, Max	-0.080, 0.220	-0.120, -0.030	-0.100, -0.020	-0.120, 0.220
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	2.356 (0.0513)	2.323 (0.0379)	2.359 (0.0845)	2.351 (0.0650)
Median	2.360	2.340	2.330	2.340
Min, Max	2.290, 2.410	2.280, 2.350	2.250, 2.490	2.250, 2.490
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	0.048 (0.0769)	-0.050 (0.0700)	-0.024 (0.0635)	-0.005 (0.0758)
Median	0.060	-0.080	-0.020	-0.010
Min, Max	-0.050, 0.130	-0.100, 0.030	-0.120, 0.060	-0.120, 0.130
Early Term				
N	1		1	2
Mean (SD)	2.380 ()		2.300 ()	2.340 (0.0566)
Median	2.380		2.300	2.340
Min, Max	2.380, 2.380		2.300, 2.300	2.300, 2.380
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-0.040 ()		-0.090 ()	-0.065 (0.0354)
Median	-0.040		-0.090	-0.065
Min, Max	-0.040, -0.040		-0.090, -0.090	-0.090, -0.040

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Chloride (mmol/L)				
Baseline				
N	15			15
Mean (SD)	100.933 (2.0166)			100.933 (2.0166)
Median	101.000			101.000
Min, Max	96.000, 103.000			96.000, 103.000
Week 1				
N	15			15
Mean (SD)	100.667 (1.5887)			100.667 (1.5887)
Median	101.000			101.000
Min, Max	98.000, 104.000			98.000, 104.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.267 (1.4864)			-0.267 (1.4864)
Median	0.000			0.000
Min, Max	-3.000, 2.000			-3.000, 2.000
Week 2				
N	15			15
Mean (SD)	100.200 (2.1778)			100.200 (2.1778)
Median	101.000			101.000
Min, Max	96.000, 103.000			96.000, 103.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.733 (2.3135)			-0.733 (2.3135)
Median	-1.000			-1.000
Min, Max	-5.000, 3.000			-5.000, 3.000
Week 4				
N	2	13		15
Mean (SD)	99.000 (1.4142)	100.538 (2.7269)		100.333 (2.6095)
Median	99.000	101.000		100.000
Min, Max	98.000, 100.000	95.000, 105.000		95.000, 105.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-3.000 (0.0000)	-0.231 (3.0043)		-0.600 (2.9472)
Median	-3.000	0.000		0.000
Min, Max	-3.000, -3.000	-8.000, 4.000		-8.000, 4.000
Week 6				
N	3	5	7	15
Mean (SD)	98.333 (3.5119)	101.400 (3.2094)	100.571 (2.6992)	100.400 (3.0190)
Median	98.000	100.000	100.000	100.000
Min, Max	95.000, 102.000	99.000, 107.000	97.000, 105.000	95.000, 107.000
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-4.000 (3.6056)	1.400 (3.0496)	-0.429 (3.4572)	-0.533 (3.6814)
Median	-3.000	1.000	0.000	-1.000
Min, Max	-8.000, -1.000	-2.000, 5.000	-6.000, 5.000	-8.000, 5.000
Week 8				
N	3	2	10	15
Mean (SD)	102.333 (1.5275)	103.000 (1.4142)	100.800 (1.9322)	101.400 (1.9198)
Median	102.000	103.000	100.000	101.000
Min, Max	101.000, 104.000	102.000, 104.000	99.000, 106.000	99.000, 106.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	0.000 (2.6458)	1.500 (2.1213)	0.400 (3.0984)	0.467 (2.7740)
Median	-1.000	1.500	1.000	1.000
Min, Max	-2.000, 3.000	0.000, 3.000	-3.000, 5.000	-3.000, 5.000
Week 12				
N	3	2	8	13
Mean (SD)	102.000 (1.7321)	103.000 (1.4142)	100.625 (1.1877)	101.308 (1.5484)
Median	103.000	103.000	100.500	101.000
Min, Max	100.000, 103.000	102.000, 104.000	99.000, 103.000	99.000, 104.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	0.000 (1.0000)	1.500 (0.7071)	0.625 (2.7742)	0.615 (2.2188)
Median	0.000	1.500	0.500	1.000
Min, Max	-1.000, 1.000	1.000, 2.000	-3.000, 5.000	-3.000, 5.000
Week 16				
N	3	3	7	13
Mean (SD)	100.000 (2.6458)	101.667 (0.5774)	100.571 (2.0702)	100.692 (1.9315)
Median	101.000	102.000	101.000	101.000
Min, Max	97.000, 102.000	101.000, 102.000	97.000, 103.000	97.000, 103.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-2.000 (2.0000)	1.000 (1.0000)	0.429 (2.3705)	0.000 (2.2361)
Median	-2.000	1.000	1.000	0.000
Min, Max	-4.000, 0.000	0.000, 2.000	-4.000, 3.000	-4.000, 3.000
Week 20				
N	4	3	6	13
Mean (SD)	102.250 (2.2174)	102.000 (1.0000)	100.167 (2.3166)	101.231 (2.1662)
Median	102.000	102.000	100.500	101.000
Min, Max	100.000, 105.000	101.000, 103.000	96.000, 103.000	96.000, 105.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	0.750 (1.7078)	1.333 (0.5774)	0.000 (2.0976)	0.538 (1.7134)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	0.500	1.000	0.500	1.000
Min, Max	-1.000, 3.000	1.000, 2.000	-3.000, 2.000	-3.000, 3.000
Week 24				
N	4	3	6	13
Mean (SD)	101.750 (2.8723)	99.000 (1.0000)	100.833 (1.9408)	100.692 (2.2130)
Median	102.500	99.000	101.500	101.000
Min, Max	98.000, 104.000	98.000, 100.000	98.000, 103.000	98.000, 104.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	0.250 (2.9861)	-1.667 (1.5275)	0.667 (1.9664)	0.000 (2.2730)
Median	0.000	-2.000	1.000	0.000
Min, Max	-3.000, 4.000	-3.000, 0.000	-2.000, 3.000	-3.000, 4.000
Week 28				
N	5	3	7	15
Mean (SD)	102.000 (1.0000)	103.000 (1.7321)	100.143 (1.9518)	101.333 (1.9518)
Median	102.000	104.000	100.000	101.000
Min, Max	101.000, 103.000	101.000, 104.000	98.000, 104.000	98.000, 104.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	0.200 (1.6432)	2.333 (0.5774)	-0.286 (1.7995)	0.400 (1.8048)
Median	0.000	2.000	0.000	0.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-1.000, 3.000	2.000, 3.000	-3.000, 2.000	-3.000, 3.000
Week 32				
N	4	3	7	14
Mean (SD)	102.000 (2.4495)	102.333 (2.3094)	101.143 (1.7728)	101.643 (1.9848)
Median	102.000	101.000	101.000	101.500
Min, Max	99.000, 105.000	101.000, 105.000	99.000, 104.000	99.000, 105.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	-0.250 (2.6300)	1.667 (2.5166)	0.714 (2.4976)	0.643 (2.4371)
Median	0.500	2.000	0.000	0.500
Min, Max	-4.000, 2.000	-1.000, 4.000	-2.000, 5.000	-4.000, 5.000
Week 36				
N	3	3	7	13
Mean (SD)	102.000 (1.0000)	101.333 (1.1547)	101.714 (1.4960)	101.692 (1.2506)
Median	102.000	102.000	102.000	102.000
Min, Max	101.000, 103.000	100.000, 102.000	100.000, 104.000	100.000, 104.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	0.000 (0.0000)	0.667 (2.0817)	1.286 (2.4300)	0.846 (1.9936)
Median	0.000	0.000	1.000	0.000
Min, Max	0.000, 0.000	-1.000, 3.000	-2.000, 5.000	-2.000, 5.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	101.200 (1.9235)	101.000 (1.0000)	101.000 (3.1091)	101.067 (2.3135)
Median	101.000	101.000	101.000	101.000
Min, Max	99.000, 104.000	100.000, 102.000	97.000, 107.000	97.000, 107.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	-0.600 (1.1402)	0.333 (1.5275)	0.571 (3.8668)	0.133 (2.7220)
Median	-1.000	0.000	-1.000	-1.000
Min, Max	-2.000, 1.000	-1.000, 2.000	-3.000, 8.000	-3.000, 8.000
Week 44				
N	5	3	7	15
Mean (SD)	101.800 (1.4832)	102.667 (1.1547)	100.857 (2.3401)	101.533 (1.9223)
Median	102.000	102.000	100.000	102.000
Min, Max	100.000, 104.000	102.000, 104.000	98.000, 105.000	98.000, 105.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	0.000 (2.3452)	2.000 (1.0000)	0.429 (3.9097)	0.600 (2.9713)
Median	-1.000	2.000	1.000	1.000
Min, Max	-2.000, 3.000	1.000, 3.000	-5.000, 6.000	-5.000, 6.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	101.400 (1.9494)	101.667 (1.5275)	100.000 (1.6330)	100.800 (1.7809)
Median	102.000	102.000	101.000	101.000
Min, Max	99.000, 104.000	100.000, 103.000	98.000, 102.000	98.000, 104.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	-0.400 (2.8810)	1.000 (1.0000)	-0.429 (2.1492)	-0.133 (2.1996)
Median	-1.000	1.000	0.000	0.000
Min, Max	-4.000, 4.000	0.000, 2.000	-4.000, 2.000	-4.000, 4.000
Early Term				
N	1		1	2
Mean (SD)	104.000 ()		106.000 ()	105.000 (1.4142)
Median	104.000		106.000	105.000
Min, Max	104.000, 104.000		106.000, 106.000	104.000, 106.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	1.000 ()		4.000 ()	2.500 (2.1213)
Median	1.000		4.000	2.500
Min, Max	1.000, 1.000		4.000, 4.000	1.000, 4.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Cholesterol (mmol/L)				
Baseline				
N	15			15
Mean (SD)	4.813 (0.8254)			4.813 (0.8254)
Median	4.600			4.600
Min, Max	4.000, 6.600			4.000, 6.600
Week 1				
N	15			15
Mean (SD)	3.913 (1.0211)			3.913 (1.0211)
Median	3.600			3.600
Min, Max	2.800, 6.600			2.800, 6.600
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.900 (0.4943)			-0.900 (0.4943)
Median	-1.000			-1.000
Min, Max	-1.700, 0.000			-1.700, 0.000
Week 2				
N	15			15
Mean (SD)	3.827 (1.1411)			3.827 (1.1411)
Median	3.800			3.800
Min, Max	2.600, 6.000			2.600, 6.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.987 (0.6402)			-0.987 (0.6402)
Median	-1.000			-1.000
Min, Max	-2.000, 0.600			-2.000, 0.600
Week 4				
N	2	13		15
Mean (SD)	4.750 (1.4849)	3.815 (0.9209)		3.940 (0.9963)
Median	4.750	3.900		3.900
Min, Max	3.700, 5.800	2.800, 5.800		2.800, 5.800
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-0.900 (0.1414)	-0.869 (0.6550)		-0.873 (0.6076)
Median	-0.900	-1.000		-1.000
Min, Max	-1.000, -0.800	-1.800, 0.400		-1.800, 0.400
Week 6				
N	3	5	7	15
Mean (SD)	4.533 (0.6807)	3.660 (0.7797)	3.529 (1.2500)	3.773 (1.0333)
Median	4.300	3.900	2.900	3.900
Min, Max	4.000, 5.300	2.500, 4.500	2.600, 5.800	2.500, 5.800
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-0.700 (0.6000)	-0.920 (0.8044)	-1.271 (0.8200)	-1.040 (0.7623)
Median	-0.700	-1.200	-1.400	-1.300
Min, Max	-1.300, -0.100	-1.800, 0.300	-2.100, 0.400	-2.100, 0.400
Week 8				
N	3	2	10	15
Mean (SD)	4.700 (0.9539)	3.400 (0.9899)	3.180 (0.8626)	3.513 (1.0302)
Median	4.200	3.400	2.850	3.100
Min, Max	4.100, 5.800	2.700, 4.100	2.300, 4.700	2.300, 5.800
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-0.533 (0.2517)	-1.250 (0.9192)	-1.540 (0.4881)	-1.300 (0.6245)
Median	-0.500	-1.250	-1.650	-1.300
Min, Max	-0.800, -0.300	-1.900, -0.600	-2.300, -0.700	-2.300, -0.300
Week 12				
N	3	2	8	13
Mean (SD)	4.900 (0.7211)	4.200 (0.1414)	3.650 (1.0114)	4.023 (0.9876)
Median	4.700	4.200	3.450	4.300
Min, Max	4.300, 5.700	4.100, 4.300	2.400, 5.200	2.400, 5.700
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-0.100 (0.6928)	-0.450 (0.0707)	-1.213 (0.8659)	-0.838 (0.8790)
Median	0.300	-0.450	-1.450	-0.900
Min, Max	-0.900, 0.300	-0.500, -0.400	-2.100, 0.400	-2.100, 0.400
Week 16				
N	3	3	7	13
Mean (SD)	4.367 (0.7095)	3.633 (0.5859)	3.500 (1.1299)	3.731 (0.9560)
Median	4.500	3.400	2.900	3.600
Min, Max	3.600, 5.000	3.200, 4.300	2.400, 5.300	2.400, 5.300
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-0.633 (0.8737)	-1.167 (0.7506)	-1.329 (0.8826)	-1.131 (0.8341)
Median	-0.400	-1.200	-1.700	-1.300
Min, Max	-1.600, 0.100	-1.900, -0.400	-2.100, -0.100	-2.100, 0.100
Week 20				
N	4	3	6	13
Mean (SD)	3.975 (1.3574)	3.633 (0.2517)	3.650 (1.1432)	3.746 (1.0203)
Median	4.000	3.600	3.650	3.600
Min, Max	2.400, 5.500	3.400, 3.900	2.300, 5.100	2.300, 5.500
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-0.825 (0.8421)	-1.167 (0.4726)	-1.283 (1.0944)	-1.115 (0.8697)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-0.850	-1.000	-1.700	-1.100
Min, Max	-1.800, 0.200	-1.700, -0.800	-2.400, 0.400	-2.400, 0.400
Week 24				
N	4	3	6	13
Mean (SD)	3.975 (1.2868)	3.733 (0.1528)	3.800 (1.0139)	3.838 (0.9251)
Median	3.850	3.700	3.900	3.700
Min, Max	2.600, 5.600	3.600, 3.900	2.500, 4.800	2.500, 5.600
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-0.825 (0.6344)	-1.067 (0.3055)	-1.133 (0.9459)	-1.023 (0.7132)
Median	-0.800	-1.000	-1.350	-1.000
Min, Max	-1.600, -0.100	-1.400, -0.800	-2.000, 0.400	-2.000, 0.400
Week 28				
N	5	3	7	15
Mean (SD)	4.640 (1.0922)	4.067 (0.6110)	4.857 (1.0612)	4.627 (0.9852)
Median	4.700	4.200	4.600	4.600
Min, Max	3.300, 6.200	3.400, 4.600	3.400, 6.800	3.300, 6.800
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-0.140 (0.4393)	-0.733 (0.8737)	0.014 (0.4562)	-0.187 (0.5817)
Median	-0.200	-0.500	0.100	0.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-0.700, 0.300	-1.700, 0.000	-0.900, 0.500	-1.700, 0.500
Week 32				
N	4	3	7	14
Mean (SD)	4.700 (1.0424)	4.400 (0.5292)	4.086 (0.8821)	4.329 (0.8534)
Median	4.750	4.200	3.900	4.100
Min, Max	3.500, 5.800	4.000, 5.000	3.200, 5.900	3.200, 5.900
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	-0.225 (0.6021)	-0.400 (0.2646)	-0.757 (0.2760)	-0.529 (0.4358)
Median	-0.350	-0.500	-0.800	-0.550
Min, Max	-0.800, 0.600	-0.600, -0.100	-1.100, -0.400	-1.100, 0.600
Week 36				
N	3	3	7	13
Mean (SD)	4.667 (0.8963)	4.467 (0.3512)	4.300 (0.7234)	4.423 (0.6635)
Median	4.200	4.500	4.300	4.300
Min, Max	4.100, 5.700	4.100, 4.800	3.400, 5.700	3.400, 5.700
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	-0.333 (0.5508)	-0.333 (0.4619)	-0.543 (0.5968)	-0.446 (0.5254)
Median	-0.300	-0.600	-0.500	-0.500
Min, Max	-0.900, 0.200	-0.600, 0.200	-1.500, 0.200	-1.500, 0.200

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	4.480 (0.8075)	4.567 (0.2517)	4.586 (1.0270)	4.547 (0.8061)
Median	4.400	4.600	4.400	4.400
Min, Max	3.600, 5.800	4.300, 4.800	3.600, 6.800	3.600, 6.800
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	-0.300 (0.3317)	-0.233 (0.3786)	-0.257 (0.7413)	-0.267 (0.5367)
Median	-0.300	-0.400	0.100	-0.300
Min, Max	-0.800, 0.000	-0.500, 0.200	-1.800, 0.300	-1.800, 0.300
Week 44				
N	5	3	7	15
Mean (SD)	4.720 (0.7294)	4.267 (0.1528)	4.400 (0.6880)	4.480 (0.6259)
Median	4.400	4.300	4.200	4.300
Min, Max	4.200, 6.000	4.100, 4.400	3.700, 5.800	3.700, 6.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	-0.060 (0.4775)	-0.533 (0.2082)	-0.443 (0.3994)	-0.333 (0.4254)
Median	0.000	-0.600	-0.300	-0.300
Min, Max	-0.600, 0.400	-0.700, -0.300	-1.100, -0.100	-1.100, 0.400
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	4.480 (0.8983)	4.467 (0.2887)	4.443 (0.6949)	4.460 (0.6706)
Median	4.200	4.300	4.200	4.300
Min, Max	3.700, 6.000	4.300, 4.800	3.700, 5.600	3.700, 6.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	-0.300 (0.3536)	-0.333 (0.0577)	-0.400 (0.6506)	-0.353 (0.4688)
Median	-0.400	-0.300	-0.400	-0.400
Min, Max	-0.600, 0.300	-0.400, -0.300	-1.400, 0.400	-1.400, 0.400
Early Term				
N	1		1	2
Mean (SD)	4.200 ()		2.500 ()	3.350 (1.2021)
Median	4.200		2.500	3.350
Min, Max	4.200, 4.200		2.500, 2.500	2.500, 4.200
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-0.500 ()		-1.800 ()	-1.150 (0.9192)
Median	-0.500		-1.800	-1.150
Min, Max	-0.500, -0.500		-1.800, -1.800	-1.800, -0.500

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Creatine Kinase (IU/L)				
Baseline				
N	15			15
Mean (SD)	135.800 (57.3264)			135.800 (57.3264)
Median	120.000			120.000
Min, Max	70.000, 280.000			70.000, 280.000
Week 1				
N	15			15
Mean (SD)	149.867 (55.7685)			149.867 (55.7685)
Median	145.000			145.000
Min, Max	88.000, 261.000			88.000, 261.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	14.067 (18.7634)			14.067 (18.7634)
Median	16.000			16.000
Min, Max	-20.000, 40.000			-20.000, 40.000
Week 2				
N	15			15
Mean (SD)	135.667 (68.6385)			135.667 (68.6385)
Median	109.000			109.000
Min, Max	76.000, 330.000			76.000, 330.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.133 (30.9859)			-0.133 (30.9859)
Median	3.000			3.000
Min, Max	-47.000, 50.000			-47.000, 50.000
Week 4				
N	2	13		15
Mean (SD)	198.000 (101.8234)	140.692 (89.5623)		148.333 (89.5693)
Median	198.000	117.000		117.000
Min, Max	126.000, 270.000	73.000, 424.000		73.000, 424.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-2.000 (11.3137)	14.769 (64.9476)		12.533 (60.4942)
Median	-2.000	2.000		2.000
Min, Max	-10.000, 6.000	-65.000, 205.000		-65.000, 205.000
Week 6				
N	3	5	7	15
Mean (SD)	117.333 (51.8298)	140.200 (28.8652)	135.857 (57.8977)	133.600 (46.1872)
Median	128.000	141.000	110.000	122.000
Min, Max	61.000, 163.000	109.000, 183.000	90.000, 231.000	61.000, 231.000
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-39.667 (67.5747)	3.200 (43.1880)	10.000 (60.1360)	-2.200 (55.8636)
Median	-10.000	12.000	19.000	8.000
Min, Max	-117.000, 8.000	-70.000, 36.000	-86.000, 92.000	-117.000, 92.000
Week 8				
N	3	2	10	15
Mean (SD)	124.000 (65.5973)	195.000 (91.9239)	160.400 (64.8129)	157.733 (66.0762)
Median	101.000	195.000	139.000	130.000
Min, Max	73.000, 198.000	130.000, 260.000	82.000, 261.000	73.000, 261.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-33.000 (43.7150)	33.000 (11.3137)	36.200 (51.7876)	21.933 (53.0639)
Median	-19.000	33.000	20.000	12.000
Min, Max	-82.000, 2.000	25.000, 41.000	-27.000, 141.000	-82.000, 141.000
Week 12				
N	3	2	8	13
Mean (SD)	96.667 (62.4286)	97.000 (15.5563)	203.875 (238.3457)	162.692 (191.6974)
Median	70.000	97.000	121.000	108.000
Min, Max	52.000, 168.000	86.000, 108.000	61.000, 779.000	52.000, 779.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-43.667 (59.7857)	-65.000 (65.0538)	68.000 (234.1880)	21.769 (191.5486)
Median	-18.000	-65.000	-13.000	-19.000
Min, Max	-112.000, -1.000	-111.000, -19.000	-62.000, 638.000	-112.000, 638.000
Week 16				
N	3	3	7	13
Mean (SD)	102.000 (27.4955)	127.000 (32.1870)	123.714 (34.4757)	119.462 (31.5267)
Median	96.000	131.000	112.000	112.000
Min, Max	78.000, 132.000	93.000, 157.000	85.000, 165.000	78.000, 165.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-38.333 (95.4481)	-30.000 (27.7849)	-10.571 (36.1426)	-21.462 (49.5860)
Median	7.000	-16.000	-11.000	-12.000
Min, Max	-148.000, 26.000	-62.000, -12.000	-70.000, 36.000	-148.000, 36.000
Week 20				
N	4	3	6	13
Mean (SD)	103.250 (27.5000)	117.000 (40.0375)	131.167 (54.4589)	119.308 (43.0066)
Median	98.500	98.000	113.000	99.000
Min, Max	75.000, 141.000	90.000, 163.000	84.000, 224.000	75.000, 224.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-30.500 (78.9325)	-40.000 (21.9317)	-6.500 (28.6409)	-21.615 (46.9531)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-6.000	-49.000	-5.500	-15.000
Min, Max	-139.000, 29.000	-56.000, -15.000	-37.000, 42.000	-139.000, 42.000
Week 24				
N	4	3	6	13
Mean (SD)	112.750 (48.1067)	135.000 (16.6433)	163.333 (123.3607)	141.231 (86.5440)
Median	97.500	128.000	116.500	123.000
Min, Max	74.000, 182.000	123.000, 154.000	78.000, 407.000	74.000, 407.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-21.000 (52.2622)	-22.000 (44.0341)	25.667 (98.8123)	0.308 (75.3098)
Median	-1.500	-24.000	-6.000	-7.000
Min, Max	-98.000, 17.000	-65.000, 23.000	-38.000, 225.000	-98.000, 225.000
Week 28				
N	5	3	7	15
Mean (SD)	124.400 (49.7323)	180.333 (59.0452)	109.143 (32.0855)	128.467 (49.1425)
Median	134.000	183.000	115.000	128.000
Min, Max	72.000, 184.000	120.000, 238.000	74.000, 152.000	72.000, 238.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-6.600 (68.0867)	23.333 (52.6340)	-21.000 (31.7122)	-7.333 (49.4609)
Median	4.000	19.000	-30.000	-5.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-96.000, 87.000	-27.000, 78.000	-67.000, 24.000	-96.000, 87.000
Week 32				
N	4	3	7	14
Mean (SD)	126.000 (51.5170)	339.667 (346.2258)	142.714 (30.7556)	180.143 (164.3771)
Median	114.500	170.000	150.000	136.000
Min, Max	77.000, 198.000	111.000, 738.000	109.000, 187.000	77.000, 738.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	-9.250 (55.6499)	182.667 (291.3972)	12.571 (34.9230)	42.786 (142.0602)
Median	-3.500	23.000	-9.000	6.000
Min, Max	-82.000, 52.000	6.000, 519.000	-19.000, 66.000	-82.000, 519.000
Week 36				
N	3	3	7	13
Mean (SD)	111.000 (64.0859)	154.667 (47.4377)	123.000 (38.7857)	127.538 (45.5643)
Median	74.000	172.000	119.000	119.000
Min, Max	74.000, 185.000	101.000, 191.000	81.000, 194.000	74.000, 194.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	-29.333 (56.8712)	-2.333 (45.5229)	-7.143 (33.1030)	-11.154 (39.2913)
Median	3.000	-4.000	-10.000	-4.000
Min, Max	-95.000, 4.000	-47.000, 44.000	-46.000, 36.000	-95.000, 44.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	113.000 (47.6917)	150.000 (57.7148)	139.857 (40.0018)	132.933 (45.1639)
Median	102.000	125.000	131.000	125.000
Min, Max	75.000, 195.000	109.000, 216.000	83.000, 197.000	75.000, 216.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	-18.000 (47.1328)	-7.000 (13.4536)	9.714 (37.5087)	-2.867 (37.7905)
Median	-6.000	-3.000	15.000	4.000
Min, Max	-85.000, 32.000	-22.000, 4.000	-58.000, 54.000	-85.000, 54.000
Week 44				
N	5	3	7	15
Mean (SD)	128.400 (61.5979)	177.667 (116.9031)	139.571 (46.8788)	143.467 (65.7081)
Median	90.000	122.000	128.000	122.000
Min, Max	77.000, 202.000	99.000, 312.000	83.000, 194.000	77.000, 312.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	-2.600 (74.2415)	20.667 (63.3588)	9.429 (54.7140)	7.667 (59.2171)
Median	-30.000	-6.000	-2.000	-6.000
Min, Max	-78.000, 119.000	-25.000, 93.000	-52.000, 101.000	-78.000, 119.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	133.000 (52.9858)	258.667 (160.6124)	128.143 (35.0591)	155.867 (88.5985)
Median	119.000	206.000	119.000	131.000
Min, Max	78.000, 207.000	131.000, 439.000	70.000, 168.000	70.000, 439.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	2.000 (91.6761)	101.667 (103.7995)	-2.000 (20.8407)	20.067 (76.8993)
Median	-1.000	59.000	1.000	3.000
Min, Max	-114.000, 137.000	26.000, 220.000	-29.000, 26.000	-114.000, 220.000
Early Term				
N	1		1	2
Mean (SD)	111.000 ()		103.000 ()	107.000 (5.6569)
Median	111.000		103.000	107.000
Min, Max	111.000, 111.000		103.000, 103.000	103.000, 111.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-9.000 ()		18.000 ()	4.500 (19.0919)
Median	-9.000		18.000	4.500
Min, Max	-9.000, -9.000		18.000, 18.000	-9.000, 18.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Creatinine (umol/L)				
Baseline				
N	15			15
Mean (SD)	73.733 (12.7865)			73.733 (12.7865)
Median	75.000			75.000
Min, Max	54.000, 98.000			54.000, 98.000
Week 1				
N	15			15
Mean (SD)	78.733 (12.1859)			78.733 (12.1859)
Median	80.000			80.000
Min, Max	63.000, 105.000			63.000, 105.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	5.000 (9.0238)			5.000 (9.0238)
Median	2.000			2.000
Min, Max	-9.000, 20.000			-9.000, 20.000
Week 2				
N	15			15
Mean (SD)	79.133 (12.0289)			79.133 (12.0289)
Median	76.000			76.000
Min, Max	63.000, 103.000			63.000, 103.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	5.400 (11.1854)			5.400 (11.1854)
Median	5.000			5.000
Min, Max	-14.000, 22.000			-14.000, 22.000
Week 4				
N	2	13		15
Mean (SD)	75.000 (8.4853)	81.000 (14.2712)		80.200 (13.5710)
Median	75.000	75.000		75.000
Min, Max	69.000, 81.000	61.000, 113.000		61.000, 113.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	21.000 (8.4853)	4.231 (12.6369)		6.467 (13.2980)
Median	21.000	4.000		5.000
Min, Max	15.000, 27.000	-11.000, 28.000		-11.000, 28.000
Week 6				
N	3	5	7	15
Mean (SD)	72.333 (16.2583)	92.000 (14.1951)	77.000 (10.0333)	81.067 (14.3451)
Median	78.000	93.000	79.000	80.000
Min, Max	54.000, 85.000	78.000, 114.000	60.000, 90.000	54.000, 114.000
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	18.000 (15.8745)	7.200 (13.8636)	2.857 (7.7337)	7.333 (12.2863)
Median	24.000	3.000	3.000	3.000
Min, Max	0.000, 30.000	-5.000, 29.000	-11.000, 14.000	-11.000, 30.000
Week 8				
N	3	2	10	15
Mean (SD)	61.667 (3.2146)	97.500 (0.7071)	84.500 (16.3044)	81.667 (17.3109)
Median	63.000	97.500	80.500	78.000
Min, Max	58.000, 64.000	97.000, 98.000	64.000, 116.000	58.000, 116.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	7.333 (2.8868)	6.000 (8.4853)	8.500 (16.7813)	7.933 (13.7189)
Median	9.000	6.000	5.000	6.000
Min, Max	4.000, 9.000	0.000, 12.000	-14.000, 38.000	-14.000, 38.000
Week 12				
N	3	2	8	13
Mean (SD)	65.000 (12.7671)	93.000 (1.4142)	79.250 (10.8200)	78.077 (13.2820)
Median	68.000	93.000	76.500	76.000
Min, Max	51.000, 76.000	92.000, 94.000	65.000, 102.000	51.000, 102.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	5.667 (9.0738)	1.500 (7.7782)	3.125 (14.4364)	3.462 (11.9277)
Median	7.000	1.500	-4.000	-4.000
Min, Max	-4.000, 14.000	-4.000, 7.000	-10.000, 32.000	-10.000, 32.000
Week 16				
N	3	3	7	13
Mean (SD)	70.333 (9.8658)	90.000 (8.6603)	78.571 (13.8547)	79.308 (13.1807)
Median	75.000	95.000	78.000	78.000
Min, Max	59.000, 77.000	80.000, 95.000	64.000, 105.000	59.000, 105.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	11.000 (10.4403)	4.000 (6.5574)	2.286 (14.5913)	4.692 (12.0512)
Median	6.000	5.000	-2.000	0.000
Min, Max	4.000, 23.000	-3.000, 10.000	-7.000, 35.000	-7.000, 35.000
Week 20				
N	4	3	6	13
Mean (SD)	90.250 (46.7074)	82.333 (6.0277)	75.333 (8.4063)	81.538 (25.0120)
Median	71.000	83.000	73.000	76.000
Min, Max	60.000, 159.000	76.000, 88.000	66.000, 86.000	60.000, 159.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	28.250 (40.5740)	-3.667 (9.8658)	-2.000 (6.2929)	6.923 (25.7632)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	9.500	1.000	0.000	1.000
Min, Max	5.000, 89.000	-15.000, 3.000	-11.000, 6.000	-15.000, 89.000
Week 24				
N	4	3	6	13
Mean (SD)	82.250 (27.7293)	94.333 (2.8868)	77.667 (3.1411)	82.923 (15.6283)
Median	72.500	96.000	78.000	80.000
Min, Max	61.000, 123.000	91.000, 96.000	73.000, 81.000	61.000, 123.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	20.250 (22.5000)	8.333 (11.6762)	0.333 (9.0921)	8.308 (16.2193)
Median	11.500	6.000	0.000	5.000
Min, Max	5.000, 53.000	-2.000, 21.000	-10.000, 15.000	-10.000, 53.000
Week 28				
N	5	3	7	15
Mean (SD)	69.400 (25.8612)	86.000 (10.1489)	76.000 (8.0000)	75.800 (16.4369)
Median	58.000	88.000	77.000	75.000
Min, Max	48.000, 113.000	75.000, 95.000	63.000, 87.000	48.000, 113.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	9.000 (19.5064)	0.000 (3.0000)	-2.000 (6.3246)	2.067 (12.3893)
Median	3.000	0.000	-3.000	2.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-7.000, 43.000	-3.000, 3.000	-9.000, 6.000	-9.000, 43.000
Week 32				
N	4	3	7	14
Mean (SD)	62.000 (5.2915)	81.667 (13.2035)	78.571 (8.9043)	74.500 (11.7784)
Median	61.000	79.000	80.000	74.000
Min, Max	57.000, 69.000	70.000, 96.000	65.000, 93.000	57.000, 96.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	4.000 (3.7417)	-4.333 (2.0817)	0.571 (5.7982)	0.500 (5.3457)
Median	3.500	-5.000	0.000	0.000
Min, Max	0.000, 9.000	-6.000, -2.000	-7.000, 11.000	-7.000, 11.000
Week 36				
N	3	3	7	13
Mean (SD)	61.000 (1.0000)	81.667 (12.5033)	74.429 (6.7542)	73.000 (10.2470)
Median	61.000	76.000	75.000	73.000
Min, Max	60.000, 62.000	73.000, 96.000	68.000, 85.000	60.000, 96.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	1.667 (9.2916)	-4.333 (4.0415)	-3.571 (5.8838)	-2.538 (6.3458)
Median	6.000	-2.000	-3.000	-3.000
Min, Max	-9.000, 8.000	-9.000, -2.000	-15.000, 3.000	-15.000, 8.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	72.400 (24.8052)	81.000 (5.2915)	79.143 (7.7766)	77.267 (14.7961)
Median	60.000	83.000	78.000	76.000
Min, Max	54.000, 115.000	75.000, 85.000	69.000, 89.000	54.000, 115.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	12.000 (18.5876)	-5.000 (8.6603)	1.143 (4.7056)	3.533 (12.7664)
Median	5.000	0.000	3.000	3.000
Min, Max	0.000, 45.000	-15.000, 0.000	-6.000, 7.000	-15.000, 45.000
Week 44				
N	5	3	7	15
Mean (SD)	72.400 (25.6768)	83.000 (10.8167)	80.143 (8.8587)	78.133 (16.0484)
Median	64.000	80.000	81.000	77.000
Min, Max	51.000, 116.000	74.000, 95.000	66.000, 92.000	51.000, 116.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	12.000 (19.6469)	-3.000 (8.0000)	2.143 (9.2273)	4.400 (13.8141)
Median	4.000	-3.000	-3.000	4.000
Min, Max	-4.000, 46.000	-11.000, 5.000	-6.000, 16.000	-11.000, 46.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	72.600 (25.9287)	91.333 (17.0098)	79.714 (9.9115)	79.667 (17.9589)
Median	65.000	92.000	80.000	79.000
Min, Max	53.000, 117.000	74.000, 108.000	62.000, 90.000	53.000, 117.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	12.200 (19.9800)	5.333 (5.6862)	1.714 (5.9642)	5.933 (12.5269)
Median	3.000	7.000	2.000	3.000
Min, Max	-1.000, 47.000	-1.000, 10.000	-5.000, 10.000	-5.000, 47.000
Early Term				
N	1		1	2
Mean (SD)	66.000 ()		89.000 ()	77.500 (16.2635)
Median	66.000		89.000	77.500
Min, Max	66.000, 66.000		89.000, 89.000	66.000, 89.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	12.000 ()		7.000 ()	9.500 (3.5355)
Median	12.000		7.000	9.500
Min, Max	12.000, 12.000		7.000, 7.000	7.000, 12.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Direct Bilirubin (umol/L)				
Baseline				
N	15			15
Mean (SD)	3.600 (1.4041)			3.600 (1.4041)
Median	3.000			3.000
Min, Max	2.000, 6.000			2.000, 6.000
Week 1				
N	15			15
Mean (SD)	3.533 (1.0601)			3.533 (1.0601)
Median	4.000			4.000
Min, Max	2.000, 5.000			2.000, 5.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.067 (1.1629)			-0.067 (1.1629)
Median	0.000			0.000
Min, Max	-2.000, 2.000			-2.000, 2.000
Week 2				
N	15			15
Mean (SD)	3.200 (0.9411)			3.200 (0.9411)
Median	3.000			3.000
Min, Max	2.000, 5.000			2.000, 5.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.400 (0.9103)			-0.400 (0.9103)
Median	0.000			0.000
Min, Max	-2.000, 1.000			-2.000, 1.000
Week 4				
N	2	13		15
Mean (SD)	3.000 (1.4142)	3.308 (1.1821)		3.267 (1.1629)
Median	3.000	3.000		3.000
Min, Max	2.000, 4.000	2.000, 6.000		2.000, 6.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	0.500 (0.7071)	-0.462 (1.1266)		-0.333 (1.1127)
Median	0.500	0.000		0.000
Min, Max	0.000, 1.000	-2.000, 1.000		-2.000, 1.000
Week 6				
N	3	5	7	15
Mean (SD)	3.000 (1.0000)	3.600 (2.0736)	2.857 (0.8997)	3.133 (1.3558)
Median	3.000	3.000	3.000	3.000
Min, Max	2.000, 4.000	2.000, 7.000	2.000, 4.000	2.000, 7.000
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	0.333 (0.5774)	-0.400 (1.1402)	-0.857 (1.3452)	-0.467 (1.1872)
Median	0.000	0.000	-1.000	0.000
Min, Max	0.000, 1.000	-2.000, 1.000	-3.000, 1.000	-3.000, 1.000
Week 8				
N	3	2	10	15
Mean (SD)	2.667 (0.5774)	2.500 (0.7071)	3.400 (0.9661)	3.133 (0.9155)
Median	3.000	2.500	3.500	3.000
Min, Max	2.000, 3.000	2.000, 3.000	2.000, 5.000	2.000, 5.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	0.000 (0.0000)	0.000 (1.4142)	-0.700 (1.1595)	-0.467 (1.0601)
Median	0.000	0.000	-1.000	0.000
Min, Max	0.000, 0.000	-1.000, 1.000	-2.000, 1.000	-2.000, 1.000
Week 12				
N	3	2	8	13
Mean (SD)	4.000 (1.0000)	2.000 (0.0000)	3.500 (1.0690)	3.385 (1.1209)
Median	4.000	2.000	3.000	3.000
Min, Max	3.000, 5.000	2.000, 2.000	2.000, 5.000	2.000, 5.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	0.667 (0.5774)	-0.500 (0.7071)	-0.625 (1.4079)	-0.308 (1.2506)
Median	1.000	-0.500	-0.500	0.000
Min, Max	0.000, 1.000	-1.000, 0.000	-3.000, 1.000	-3.000, 1.000
Week 16				
N	3	3	7	13
Mean (SD)	3.667 (1.5275)	3.000 (1.7321)	3.000 (1.2910)	3.154 (1.3445)
Median	4.000	2.000	2.000	2.000
Min, Max	2.000, 5.000	2.000, 5.000	2.000, 5.000	2.000, 5.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	0.333 (1.5275)	-0.333 (0.5774)	-1.000 (1.1547)	-0.538 (1.1983)
Median	0.000	0.000	-1.000	0.000
Min, Max	-1.000, 2.000	-1.000, 0.000	-3.000, 0.000	-3.000, 2.000
Week 20				
N	4	3	6	13
Mean (SD)	3.250 (0.9574)	3.000 (1.0000)	3.000 (0.6325)	3.077 (0.7596)
Median	3.500	3.000	3.000	3.000
Min, Max	2.000, 4.000	2.000, 4.000	2.000, 4.000	2.000, 4.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-0.250 (0.5000)	-0.333 (0.5774)	-1.000 (1.7889)	-0.615 (1.2609)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	0.000	0.000	-1.000	0.000
Min, Max	-1.000, 0.000	-1.000, 0.000	-3.000, 1.000	-3.000, 1.000
Week 24				
N	4	3	6	13
Mean (SD)	4.500 (2.5166)	2.667 (0.5774)	3.333 (1.0328)	3.538 (1.6132)
Median	4.000	3.000	3.000	3.000
Min, Max	2.000, 8.000	2.000, 3.000	2.000, 5.000	2.000, 8.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	1.000 (2.7080)	-0.667 (1.5275)	-0.667 (1.3663)	-0.154 (1.9081)
Median	0.000	-1.000	-1.000	-1.000
Min, Max	-1.000, 5.000	-2.000, 1.000	-2.000, 1.000	-2.000, 5.000
Week 28				
N	5	3	7	15
Mean (SD)	4.200 (1.7889)	7.000 (6.9282)	3.000 (1.2910)	4.200 (3.2994)
Median	3.000	3.000	2.000	3.000
Min, Max	3.000, 7.000	3.000, 15.000	2.000, 5.000	2.000, 15.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	1.000 (1.5811)	3.667 (5.5076)	-1.000 (1.1547)	0.600 (2.9952)
Median	1.000	1.000	-1.000	0.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-1.000, 3.000	0.000, 10.000	-3.000, 0.000	-3.000, 10.000
Week 32				
N	4	3	7	14
Mean (SD)	3.500 (0.5774)	4.000 (1.0000)	3.714 (1.7043)	3.714 (1.2666)
Median	3.500	4.000	3.000	3.500
Min, Max	3.000, 4.000	3.000, 5.000	2.000, 6.000	2.000, 6.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	0.500 (0.5774)	0.667 (0.5774)	-0.286 (0.7559)	0.143 (0.7703)
Median	0.500	1.000	0.000	0.000
Min, Max	0.000, 1.000	0.000, 1.000	-1.000, 1.000	-1.000, 1.000
Week 36				
N	3	3	7	13
Mean (SD)	3.333 (0.5774)	3.333 (0.5774)	4.143 (2.1157)	3.769 (1.5892)
Median	3.000	3.000	4.000	3.000
Min, Max	3.000, 4.000	3.000, 4.000	2.000, 7.000	2.000, 7.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	0.000 (1.0000)	0.000 (1.0000)	0.143 (0.8997)	0.077 (0.8623)
Median	0.000	0.000	0.000	0.000
Min, Max	-1.000, 1.000	-1.000, 1.000	-1.000, 1.000	-1.000, 1.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	3.000 (1.0000)	2.667 (1.1547)	3.857 (1.3452)	3.333 (1.2344)
Median	3.000	2.000	4.000	3.000
Min, Max	2.000, 4.000	2.000, 4.000	2.000, 6.000	2.000, 6.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	-0.200 (0.8367)	-0.667 (0.5774)	-0.143 (1.5736)	-0.267 (1.1629)
Median	0.000	-1.000	0.000	0.000
Min, Max	-1.000, 1.000	-1.000, 0.000	-3.000, 2.000	-3.000, 2.000
Week 44				
N	5	3	7	15
Mean (SD)	4.400 (1.8166)	3.000 (0.0000)	3.571 (1.9024)	3.733 (1.6676)
Median	5.000	3.000	3.000	3.000
Min, Max	2.000, 6.000	3.000, 3.000	2.000, 7.000	2.000, 7.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	1.200 (1.9235)	-0.333 (1.5275)	-0.429 (1.1339)	0.133 (1.5976)
Median	1.000	0.000	-1.000	0.000
Min, Max	-1.000, 4.000	-2.000, 1.000	-2.000, 1.000	-2.000, 4.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	3.400 (0.8944)	3.333 (1.1547)	4.000 (2.0000)	3.667 (1.4960)
Median	3.000	4.000	3.000	3.000
Min, Max	3.000, 5.000	2.000, 4.000	2.000, 8.000	2.000, 8.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	0.200 (0.8367)	0.000 (1.0000)	0.000 (1.1547)	0.067 (0.9612)
Median	0.000	0.000	0.000	0.000
Min, Max	-1.000, 1.000	-1.000, 1.000	-1.000, 2.000	-1.000, 2.000
Early Term				
N	1		1	2
Mean (SD)	2.000 ()		3.000 ()	2.500 (0.7071)
Median	2.000		3.000	2.500
Min, Max	2.000, 2.000		3.000, 3.000	2.000, 3.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	0.000 ()		-1.000 ()	-0.500 (0.7071)
Median	0.000		-1.000	-0.500
Min, Max	0.000, 0.000		-1.000, -1.000	-1.000, 0.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Gamma Glutamyl Transferase (IU/L)				
Baseline				
N	15			15
Mean (SD)	58.333 (43.6605)			58.333 (43.6605)
Median	54.000			54.000
Min, Max	16.000, 186.000			16.000, 186.000
Week 1				
N	15			15
Mean (SD)	57.867 (34.1945)			57.867 (34.1945)
Median	53.000			53.000
Min, Max	12.000, 136.000			12.000, 136.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.467 (24.1450)			-0.467 (24.1450)
Median	-3.000			-3.000
Min, Max	-50.000, 72.000			-50.000, 72.000
Week 2				
N	15			15
Mean (SD)	55.600 (30.0495)			55.600 (30.0495)
Median	49.000			49.000
Min, Max	16.000, 114.000			16.000, 114.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-2.733 (34.2355)			-2.733 (34.2355)
Median	-2.000			-2.000
Min, Max	-86.000, 89.000			-86.000, 89.000
Week 4				
N	2	13		15
Mean (SD)	34.000 (4.2426)	56.462 (32.0952)		53.467 (30.7684)
Median	34.000	51.000		47.000
Min, Max	31.000, 37.000	16.000, 131.000		16.000, 131.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	4.000 (0.0000)	-6.231 (47.9221)		-4.867 (44.5130)
Median	4.000	-8.000		0.000
Min, Max	4.000, 4.000	-113.000, 106.000		-113.000, 106.000
Week 6				
N	3	5	7	15
Mean (SD)	45.333 (15.5671)	59.000 (27.2764)	52.429 (37.3044)	53.200 (29.4817)
Median	47.000	54.000	38.000	47.000
Min, Max	29.000, 60.000	24.000, 92.000	14.000, 113.000	14.000, 113.000
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	4.333 (8.7369)	-32.800 (44.1101)	10.571 (36.4457)	-5.133 (39.3952)
Median	2.000	-16.000	-2.000	-2.000
Min, Max	-3.000, 14.000	-94.000, 10.000	-17.000, 88.000	-94.000, 88.000
Week 8				
N	3	2	10	15
Mean (SD)	40.667 (13.6504)	53.500 (21.9203)	52.700 (39.4350)	50.400 (32.9562)
Median	47.000	53.500	43.000	47.000
Min, Max	25.000, 50.000	38.000, 69.000	11.000, 139.000	11.000, 139.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-0.333 (16.5630)	-12.000 (15.5563)	-9.400 (60.1723)	-7.933 (48.9934)
Median	-2.000	-12.000	-8.000	-5.000
Min, Max	-16.000, 17.000	-23.000, -1.000	-123.000, 114.000	-123.000, 114.000
Week 12				
N	3	2	8	13
Mean (SD)	51.333 (21.7332)	51.500 (20.5061)	51.375 (37.1827)	51.385 (30.3357)
Median	55.000	51.500	41.500	43.000
Min, Max	28.000, 71.000	37.000, 66.000	12.000, 119.000	12.000, 119.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	11.000 (41.6053)	-14.000 (14.1421)	-20.000 (43.9090)	-11.923 (40.0676)
Median	22.000	-14.000	-12.000	-10.000
Min, Max	-35.000, 46.000	-24.000, -4.000	-91.000, 49.000	-91.000, 49.000
Week 16				
N	3	3	7	13
Mean (SD)	50.667 (27.5741)	51.333 (9.8658)	52.143 (46.4594)	51.615 (34.9656)
Median	53.000	56.000	30.000	44.000
Min, Max	22.000, 77.000	40.000, 58.000	12.000, 120.000	12.000, 120.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	10.333 (45.1700)	-31.333 (39.9291)	-12.714 (33.3052)	-11.692 (37.1313)
Median	28.000	-14.000	-15.000	-14.000
Min, Max	-41.000, 44.000	-77.000, -3.000	-66.000, 47.000	-77.000, 47.000
Week 20				
N	4	3	6	13
Mean (SD)	37.500 (21.2053)	47.000 (5.5678)	54.333 (46.6505)	47.462 (32.8801)
Median	36.500	48.000	30.500	41.000
Min, Max	17.000, 60.000	41.000, 52.000	15.000, 116.000	15.000, 116.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-1.000 (33.3567)	-35.667 (28.8848)	-15.833 (36.5208)	-15.846 (33.8325)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	5.000	-20.000	-19.000	-18.000
Min, Max	-41.000, 27.000	-69.000, -18.000	-70.000, 42.000	-70.000, 42.000
Week 24				
N	4	3	6	13
Mean (SD)	75.500 (84.4650)	49.000 (9.8489)	68.500 (67.0723)	66.154 (61.4788)
Median	41.000	46.000	35.000	41.000
Min, Max	21.000, 199.000	41.000, 60.000	17.000, 179.000	17.000, 199.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	37.000 (91.8041)	-33.667 (20.3060)	-1.667 (28.7449)	2.846 (57.0290)
Median	12.000	-24.000	-10.500	-14.000
Min, Max	-42.000, 166.000	-57.000, -20.000	-25.000, 54.000	-57.000, 166.000
Week 28				
N	5	3	7	15
Mean (SD)	58.800 (64.7433)	108.333 (119.9847)	101.286 (139.5919)	88.533 (109.9382)
Median	32.000	53.000	53.000	40.000
Min, Max	23.000, 174.000	26.000, 246.000	17.000, 410.000	17.000, 410.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	22.600 (67.0545)	25.667 (89.9407)	37.571 (84.1781)	30.200 (74.3594)
Median	-4.000	-17.000	1.000	-1.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-23.000, 141.000	-35.000, 129.000	-15.000, 224.000	-35.000, 224.000
Week 32				
N	4	3	7	14
Mean (SD)	67.750 (64.2878)	96.333 (54.4273)	103.286 (109.0424)	91.643 (84.5637)
Median	43.000	76.000	72.000	63.500
Min, Max	23.000, 162.000	55.000, 158.000	17.000, 318.000	17.000, 318.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	30.750 (65.7641)	13.667 (28.0238)	39.571 (61.3212)	31.500 (54.4338)
Median	1.000	15.000	8.000	7.000
Min, Max	-8.000, 129.000	-15.000, 41.000	-9.000, 132.000	-15.000, 132.000
Week 36				
N	3	3	7	13
Mean (SD)	107.667 (8.9629)	63.667 (10.1160)	96.143 (68.1700)	91.308 (51.2403)
Median	103.000	69.000	69.000	70.000
Min, Max	102.000, 118.000	52.000, 70.000	26.000, 212.000	26.000, 212.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	67.333 (24.7857)	-19.000 (28.5132)	32.429 (38.7679)	28.615 (44.0389)
Median	78.000	-18.000	14.000	14.000
Min, Max	39.000, 85.000	-48.000, 9.000	-1.000, 111.000	-48.000, 111.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	62.200 (29.9533)	65.000 (8.1854)	68.429 (47.4934)	65.667 (35.2251)
Median	78.000	63.000	56.000	63.000
Min, Max	30.000, 93.000	58.000, 74.000	23.000, 160.000	23.000, 160.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	26.000 (21.1424)	-17.667 (33.8575)	4.714 (22.4255)	7.333 (27.7274)
Median	30.000	-12.000	6.000	6.000
Min, Max	3.000, 47.000	-54.000, 13.000	-26.000, 46.000	-54.000, 47.000
Week 44				
N	5	3	7	15
Mean (SD)	120.200 (124.2204)	58.667 (8.6217)	61.286 (52.0792)	80.400 (80.1960)
Median	81.000	57.000	43.000	57.000
Min, Max	29.000, 338.000	51.000, 68.000	18.000, 172.000	18.000, 338.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	84.000 (127.8652)	-24.000 (37.7227)	-2.429 (13.6609)	22.067 (84.1380)
Median	31.000	-13.000	-10.000	4.000
Min, Max	4.000, 311.000	-66.000, 7.000	-14.000, 20.000	-66.000, 311.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	72.800 (57.9068)	75.000 (16.6433)	59.286 (46.7251)	66.933 (44.5958)
Median	54.000	68.000	35.000	60.000
Min, Max	24.000, 172.000	63.000, 94.000	26.000, 153.000	24.000, 172.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	36.600 (61.1130)	-7.667 (13.4288)	-4.429 (21.4543)	8.600 (41.3725)
Median	11.000	-2.000	-10.000	2.000
Min, Max	-1.000, 145.000	-23.000, 2.000	-33.000, 31.000	-33.000, 145.000
Early Term				
N	1		1	2
Mean (SD)	20.000 ()		26.000 ()	23.000 (4.2426)
Median	20.000		26.000	23.000
Min, Max	20.000, 20.000		26.000, 26.000	20.000, 26.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-7.000 ()		1.000 ()	-3.000 (5.6569)
Median	-7.000		1.000	-3.000
Min, Max	-7.000, -7.000		1.000, 1.000	-7.000, 1.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Globulin (g/L)				
Baseline				
N	15			15
Mean (SD)	30.933 (4.3337)			30.933 (4.3337)
Median	31.000			31.000
Min, Max	24.000, 40.000			24.000, 40.000
Week 1				
N	15			15
Mean (SD)	32.133 (3.6227)			32.133 (3.6227)
Median	32.000			32.000
Min, Max	26.000, 39.000			26.000, 39.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	1.200 (1.7403)			1.200 (1.7403)
Median	1.000			1.000
Min, Max	-1.000, 4.000			-1.000, 4.000
Week 2				
N	15			15
Mean (SD)	31.400 (3.6214)			31.400 (3.6214)
Median	31.000			31.000
Min, Max	24.000, 37.000			24.000, 37.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	0.467 (1.8465)			0.467 (1.8465)
Median	1.000			1.000
Min, Max	-3.000, 4.000			-3.000, 4.000
Week 4				
N	2	13		15
Mean (SD)	35.000 (8.4853)	31.385 (3.4044)		31.867 (4.0860)
Median	35.000	31.000		31.000
Min, Max	29.000, 41.000	24.000, 37.000		24.000, 41.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	5.000 (0.0000)	0.308 (2.4285)		0.933 (2.7894)
Median	5.000	0.000		0.000
Min, Max	5.000, 5.000	-3.000, 5.000		-3.000, 5.000
Week 6				
N	3	5	7	15
Mean (SD)	32.333 (6.0277)	32.600 (6.3875)	29.857 (2.6726)	31.267 (4.6670)
Median	33.000	31.000	31.000	31.000
Min, Max	26.000, 38.000	25.000, 41.000	25.000, 32.000	25.000, 41.000
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	1.000 (1.7321)	0.200 (4.0866)	0.143 (1.9518)	0.333 (2.6367)
Median	2.000	0.000	1.000	0.000
Min, Max	-1.000, 2.000	-3.000, 7.000	-3.000, 2.000	-3.000, 7.000
Week 8				
N	3	2	10	15
Mean (SD)	31.333 (4.5092)	26.500 (0.7071)	31.800 (4.0770)	31.000 (4.1231)
Median	31.000	26.500	31.000	31.000
Min, Max	27.000, 36.000	26.000, 27.000	28.000, 41.000	26.000, 41.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	0.000 (3.0000)	-5.000 (1.4142)	1.100 (3.2128)	0.067 (3.5349)
Median	0.000	-5.000	0.500	0.000
Min, Max	-3.000, 3.000	-6.000, -4.000	-4.000, 7.000	-6.000, 7.000
Week 12				
N	3	2	8	13
Mean (SD)	25.000 (2.0000)	28.500 (0.7071)	31.250 (3.5757)	29.385 (3.9272)
Median	25.000	28.500	30.500	28.000
Min, Max	23.000, 27.000	28.000, 29.000	28.000, 37.000	23.000, 37.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-4.333 (4.6188)	-3.000 (1.4142)	-0.250 (3.1510)	-1.615 (3.5949)
Median	-7.000	-3.000	0.000	-2.000
Min, Max	-7.000, 1.000	-4.000, -2.000	-4.000, 4.000	-7.000, 4.000
Week 16				
N	3	3	7	13
Mean (SD)	28.667 (2.8868)	30.000 (1.7321)	30.286 (3.4503)	29.846 (2.8823)
Median	27.000	29.000	30.000	29.000
Min, Max	27.000, 32.000	29.000, 32.000	25.000, 36.000	25.000, 36.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-0.667 (3.2146)	-4.333 (3.2146)	0.000 (2.1602)	-1.154 (3.0234)
Median	-2.000	-3.000	0.000	-2.000
Min, Max	-3.000, 3.000	-8.000, -2.000	-3.000, 3.000	-8.000, 3.000
Week 20				
N	4	3	6	13
Mean (SD)	27.000 (2.8284)	29.000 (4.3589)	30.833 (3.9200)	29.231 (3.8113)
Median	26.000	27.000	30.500	27.000
Min, Max	25.000, 31.000	26.000, 34.000	27.000, 37.000	25.000, 37.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-1.000 (2.3094)	-5.333 (0.5774)	-0.500 (3.4496)	-1.769 (3.2443)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-1.000	-5.000	0.000	-3.000
Min, Max	-3.000, 1.000	-6.000, -5.000	-5.000, 3.000	-6.000, 3.000
Week 24				
N	4	3	6	13
Mean (SD)	29.250 (4.9917)	31.000 (5.1962)	30.833 (4.2622)	30.385 (4.3501)
Median	31.000	28.000	31.500	31.000
Min, Max	22.000, 33.000	28.000, 37.000	26.000, 37.000	22.000, 37.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	1.250 (5.2520)	-3.333 (0.5774)	-0.500 (3.9875)	-0.615 (4.0731)
Median	-1.000	-3.000	1.000	-2.000
Min, Max	-2.000, 9.000	-4.000, -3.000	-6.000, 3.000	-6.000, 9.000
Week 28				
N	5	3	7	15
Mean (SD)	30.400 (4.3359)	32.333 (7.5719)	31.571 (4.9281)	31.333 (4.9522)
Median	29.000	29.000	31.000	29.000
Min, Max	27.000, 38.000	27.000, 41.000	26.000, 41.000	26.000, 41.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	0.800 (3.8987)	-2.000 (3.0000)	1.143 (4.0999)	0.400 (3.7947)
Median	2.000	-2.000	1.000	1.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-5.000, 5.000	-5.000, 1.000	-5.000, 7.000	-5.000, 7.000
Week 32				
N	4	3	7	14
Mean (SD)	33.500 (3.0000)	36.667 (8.3267)	30.857 (5.6988)	32.857 (5.7760)
Median	33.000	34.000	29.000	31.000
Min, Max	31.000, 37.000	30.000, 46.000	26.000, 42.000	26.000, 46.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	2.500 (4.4347)	2.333 (3.5119)	0.429 (4.0766)	1.429 (3.8970)
Median	3.000	2.000	-1.000	1.000
Min, Max	-3.000, 7.000	-1.000, 6.000	-4.000, 8.000	-4.000, 8.000
Week 36				
N	3	3	7	13
Mean (SD)	33.000 (2.6458)	36.667 (5.0332)	34.857 (5.6988)	34.846 (4.8278)
Median	34.000	36.000	32.000	34.000
Min, Max	30.000, 35.000	32.000, 42.000	29.000, 43.000	29.000, 43.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	3.667 (3.2146)	2.333 (1.5275)	4.429 (4.5774)	3.769 (3.6550)
Median	5.000	2.000	5.000	4.000
Min, Max	0.000, 6.000	1.000, 4.000	-2.000, 12.000	-2.000, 12.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	31.800 (4.5497)	34.667 (2.3094)	33.000 (3.9158)	32.933 (3.7885)
Median	33.000	36.000	31.000	33.000
Min, Max	25.000, 37.000	32.000, 36.000	30.000, 39.000	25.000, 39.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	2.200 (2.7749)	0.333 (4.0415)	2.571 (2.8785)	2.000 (2.9761)
Median	1.000	1.000	2.000	1.000
Min, Max	-1.000, 6.000	-4.000, 4.000	-1.000, 7.000	-4.000, 7.000
Week 44				
N	5	3	7	15
Mean (SD)	32.200 (7.5631)	33.000 (4.3589)	30.429 (3.8668)	31.533 (5.1667)
Median	34.000	31.000	30.000	31.000
Min, Max	24.000, 43.000	30.000, 38.000	27.000, 38.000	24.000, 43.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	2.600 (2.9665)	-1.333 (1.1547)	0.000 (3.4157)	0.600 (3.1803)
Median	2.000	-2.000	0.000	0.000
Min, Max	0.000, 7.000	-2.000, 0.000	-4.000, 5.000	-4.000, 7.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	33.600 (6.6558)	33.000 (1.7321)	30.714 (3.9036)	32.133 (4.6425)
Median	31.000	32.000	31.000	32.000
Min, Max	27.000, 44.000	32.000, 35.000	27.000, 38.000	27.000, 44.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	4.000 (2.9155)	-1.333 (3.2146)	0.286 (3.3523)	1.200 (3.6489)
Median	3.000	0.000	0.000	1.000
Min, Max	1.000, 8.000	-5.000, 1.000	-4.000, 6.000	-5.000, 8.000
Early Term				
N	1		1	2
Mean (SD)	35.000 ()		25.000 ()	30.000 (7.0711)
Median	35.000		25.000	30.000
Min, Max	35.000, 35.000		25.000, 25.000	25.000, 35.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-1.000 ()		0.000 ()	-0.500 (0.7071)
Median	-1.000		0.000	-0.500
Min, Max	-1.000, -1.000		0.000, 0.000	-1.000, 0.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Glucose (mmol/L)				
Baseline				
N	15			15
Mean (SD)	5.533 (2.9208)			5.533 (2.9208)
Median	4.800			4.800
Min, Max	3.600, 15.800			3.600, 15.800
Week 1				
N	15			15
Mean (SD)	5.000 (0.8375)			5.000 (0.8375)
Median	4.900			4.900
Min, Max	3.300, 6.500			3.300, 6.500
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.533 (2.5883)			-0.533 (2.5883)
Median	0.100			0.100
Min, Max	-9.600, 1.100			-9.600, 1.100
Week 2				
N	15			15
Mean (SD)	4.967 (0.9796)			4.967 (0.9796)
Median	4.800			4.800
Min, Max	3.200, 7.000			3.200, 7.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.567 (2.7694)			-0.567 (2.7694)
Median	0.000			0.000
Min, Max	-10.200, 1.500			-10.200, 1.500
Week 4				
N	2	13		15
Mean (SD)	5.500 (0.2828)	5.115 (1.2674)		5.167 (1.1836)
Median	5.500	4.900		5.100
Min, Max	5.300, 5.700	3.500, 8.900		3.500, 8.900
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	0.600 (0.0000)	-0.515 (3.0841)		-0.367 (2.8821)
Median	0.600	-0.100		0.100
Min, Max	0.600, 0.600	-10.400, 2.700		-10.400, 2.700
Week 6				
N	3	5	7	15
Mean (SD)	5.333 (0.7638)	5.400 (0.8775)	5.229 (0.8036)	5.307 (0.7658)
Median	5.500	5.100	5.200	5.200
Min, Max	4.500, 6.000	4.700, 6.900	4.000, 6.200	4.000, 6.900
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	0.600 (0.4359)	0.320 (1.2755)	-0.971 (4.3092)	-0.227 (2.9968)
Median	0.800	0.100	0.400	0.300
Min, Max	0.100, 0.900	-1.100, 2.400	-10.600, 1.400	-10.600, 2.400
Week 8				
N	3	2	10	15
Mean (SD)	5.200 (0.5292)	4.250 (1.0607)	5.010 (0.4012)	4.947 (0.5566)
Median	5.400	4.250	5.050	5.000
Min, Max	4.600, 5.600	3.500, 5.000	4.500, 5.600	3.500, 5.600
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	0.467 (0.2517)	-0.400 (1.2728)	-0.940 (3.4063)	-0.587 (2.8135)
Median	0.500	-0.400	0.300	0.300
Min, Max	0.200, 0.700	-1.300, 0.500	-10.400, 1.100	-10.400, 1.100
Week 12				
N	3	2	8	13
Mean (SD)	4.933 (0.2517)	4.900 (0.1414)	5.000 (0.7191)	4.969 (0.5618)
Median	4.900	4.900	4.950	4.900
Min, Max	4.700, 5.200	4.800, 5.000	4.000, 6.000	4.000, 6.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	0.700 (0.5292)	0.250 (0.3536)	-1.338 (4.3154)	-0.623 (3.4388)
Median	0.500	0.250	-0.100	0.200
Min, Max	0.300, 1.300	0.000, 0.500	-11.800, 1.500	-11.800, 1.500
Week 16				
N	3	3	7	13
Mean (SD)	5.367 (1.1150)	4.867 (0.3215)	5.486 (1.1437)	5.315 (0.9728)
Median	5.800	5.000	5.100	5.100
Min, Max	4.100, 6.200	4.500, 5.100	4.800, 8.000	4.100, 8.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	1.133 (0.6506)	0.200 (0.4583)	-1.086 (3.0824)	-0.277 (2.4066)
Median	1.100	0.300	0.300	0.500
Min, Max	0.500, 1.800	-0.300, 0.600	-7.800, 0.800	-7.800, 1.800
Week 20				
N	4	3	6	13
Mean (SD)	5.125 (2.0402)	4.500 (0.8185)	4.917 (0.4401)	4.885 (1.1357)
Median	4.700	4.700	4.800	4.800
Min, Max	3.200, 7.900	3.600, 5.200	4.400, 5.500	3.200, 7.900
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-2.000 (3.9590)	-0.167 (0.9609)	-0.117 (1.0944)	-0.708 (2.3186)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-0.350	0.000	0.000	0.000
Min, Max	-7.900, 0.600	-1.200, 0.700	-1.800, 1.500	-7.900, 1.500
Week 24				
N	4	3	6	13
Mean (SD)	4.025 (0.3594)	4.567 (0.3055)	4.750 (0.2811)	4.485 (0.4337)
Median	4.150	4.500	4.700	4.500
Min, Max	3.500, 4.300	4.300, 4.900	4.500, 5.300	3.500, 5.300
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-3.100 (5.7347)	-0.100 (0.2646)	-0.283 (0.7731)	-1.108 (3.2248)
Median	-0.300	-0.200	-0.150	-0.200
Min, Max	-11.700, -0.100	-0.300, 0.200	-1.500, 0.700	-11.700, 0.700
Week 28				
N	5	3	7	15
Mean (SD)	4.580 (0.8701)	4.667 (0.7506)	5.171 (0.7365)	4.873 (0.7833)
Median	4.600	4.700	5.300	4.700
Min, Max	3.300, 5.700	3.900, 5.400	4.200, 6.400	3.300, 6.400
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-2.140 (4.4658)	0.000 (0.6557)	0.114 (1.1202)	-0.660 (2.7336)
Median	-0.300	-0.100	-0.100	-0.100

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-10.100, 0.200	-0.600, 0.700	-1.500, 1.600	-10.100, 1.600
Week 32				
N	4	3	7	14
Mean (SD)	4.850 (0.6608)	4.367 (0.2082)	5.214 (0.6694)	4.929 (0.6580)
Median	5.100	4.300	5.100	4.900
Min, Max	3.900, 5.300	4.200, 4.600	4.500, 6.300	3.900, 6.300
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	0.400 (0.3367)	-0.300 (0.3464)	0.157 (1.2528)	0.129 (0.9135)
Median	0.250	-0.500	0.500	0.200
Min, Max	0.200, 0.900	-0.500, 0.100	-1.700, 2.000	-1.700, 2.000
Week 36				
N	3	3	7	13
Mean (SD)	5.467 (0.2309)	3.933 (1.0693)	4.671 (0.4990)	4.685 (0.7862)
Median	5.600	4.500	4.500	4.600
Min, Max	5.200, 5.600	2.700, 4.600	4.000, 5.300	2.700, 5.600
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	1.233 (0.7506)	-0.733 (0.9238)	-0.386 (0.7904)	-0.092 (1.0681)
Median	1.200	-0.200	-0.300	-0.200
Min, Max	0.500, 2.000	-1.800, -0.200	-1.600, 0.800	-1.800, 2.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	5.520 (1.6843)	4.367 (0.2517)	4.800 (0.3464)	4.953 (1.0350)
Median	5.000	4.400	4.700	4.700
Min, Max	3.900, 8.200	4.100, 4.600	4.300, 5.200	3.900, 8.200
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	-1.200 (3.7623)	-0.300 (0.3464)	-0.257 (0.8080)	-0.580 (2.1325)
Median	-0.200	-0.100	-0.300	-0.200
Min, Max	-7.600, 2.400	-0.700, -0.100	-1.500, 0.700	-7.600, 2.400
Week 44				
N	5	3	7	15
Mean (SD)	5.080 (1.8431)	4.833 (0.2082)	5.286 (1.3359)	5.127 (1.3317)
Median	4.700	4.900	4.700	4.700
Min, Max	3.300, 8.200	4.600, 5.000	3.900, 8.000	3.300, 8.200
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	-1.640 (3.4004)	0.167 (0.3512)	0.229 (1.3622)	-0.407 (2.2208)
Median	-0.300	0.200	-0.100	-0.100
Min, Max	-7.600, 0.800	-0.200, 0.500	-0.900, 3.200	-7.600, 3.200
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	4.780 (1.6574)	4.433 (0.5132)	5.157 (0.5318)	4.887 (1.0141)
Median	4.500	4.300	5.000	4.900
Min, Max	2.800, 7.300	4.000, 5.000	4.400, 5.900	2.800, 7.300
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	-1.940 (3.7514)	-0.233 (0.5508)	0.100 (0.8185)	-0.647 (2.2944)
Median	-0.200	-0.200	0.200	-0.200
Min, Max	-8.500, 0.500	-0.800, 0.300	-1.300, 1.100	-8.500, 1.100
Early Term				
N	1		1	2
Mean (SD)	4.800 ()		7.100 ()	5.950 (1.6263)
Median	4.800		7.100	5.950
Min, Max	4.800, 4.800		7.100, 7.100	4.800, 7.100
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-0.300 ()		1.900 ()	0.800 (1.5556)
Median	-0.300		1.900	0.800
Min, Max	-0.300, -0.300		1.900, 1.900	-0.300, 1.900

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Indirect Bilirubin (umol/L)				
Baseline				
N	15			15
Mean (SD)	5.533 (2.4746)			5.533 (2.4746)
Median	4.000			4.000
Min, Max	2.000, 9.000			2.000, 9.000
Week 1				
N	15			15
Mean (SD)	5.533 (1.9591)			5.533 (1.9591)
Median	6.000			6.000
Min, Max	2.000, 8.000			2.000, 8.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	0.000 (1.6475)			0.000 (1.6475)
Median	0.000			0.000
Min, Max	-2.000, 4.000			-2.000, 4.000
Week 2				
N	13			13
Mean (SD)	4.538 (0.7763)			4.538 (0.7763)
Median	5.000			5.000
Min, Max	3.000, 6.000			3.000, 6.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	13			13
Mean (SD)	-1.385 (2.2560)			-1.385 (2.2560)
Median	0.000			0.000
Min, Max	-6.000, 1.000			-6.000, 1.000
Week 4				
N	2	11		13
Mean (SD)	4.500 (2.1213)	4.545 (2.5045)		4.538 (2.3670)
Median	4.500	4.000		4.000
Min, Max	3.000, 6.000	2.000, 11.000		2.000, 11.000
Change from Baseline to Week 4				
N	2	11		13
Mean (SD)	1.000 (1.4142)	-1.818 (2.9264)		-1.385 (2.9023)
Median	1.000	-1.000		-1.000
Min, Max	0.000, 2.000	-7.000, 2.000		-7.000, 2.000
Week 6				
N	2	4	6	12
Mean (SD)	4.500 (0.7071)	5.500 (5.0000)	4.167 (0.7528)	4.667 (2.7414)
Median	4.500	3.000	4.000	4.000
Min, Max	4.000, 5.000	3.000, 13.000	3.000, 5.000	3.000, 13.000
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	2	4	6	12
Mean (SD)	0.500 (0.7071)	-2.000 (4.5461)	-1.833 (2.8577)	-1.500 (3.2051)
Median	0.500	-3.000	-1.500	-0.500
Min, Max	0.000, 1.000	-6.000, 4.000	-5.000, 1.000	-6.000, 4.000
Week 8				
N	2	2	8	12
Mean (SD)	2.500 (0.7071)	3.000 (0.0000)	4.375 (0.9161)	3.833 (1.1146)
Median	2.500	3.000	5.000	3.500
Min, Max	2.000, 3.000	3.000, 3.000	3.000, 5.000	2.000, 5.000
Change from Baseline to Week 8				
N	2	2	8	12
Mean (SD)	-1.500 (0.7071)	-1.000 (0.0000)	-2.875 (2.4165)	-2.333 (2.1034)
Median	-1.500	-1.000	-3.500	-2.000
Min, Max	-2.000, -1.000	-1.000, -1.000	-6.000, 1.000	-6.000, 1.000
Week 12				
N	3	2	7	12
Mean (SD)	4.667 (2.5166)	2.500 (0.7071)	5.143 (1.6762)	4.583 (1.9287)
Median	5.000	2.500	5.000	5.000
Min, Max	2.000, 7.000	2.000, 3.000	3.000, 7.000	2.000, 7.000
Change from Baseline to Week 12				
N	3	2	7	12

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	0.667 (2.5166)	-1.500 (0.7071)	-2.000 (2.2361)	-1.250 (2.3012)
Median	1.000	-1.500	-2.000	-2.000
Min, Max	-2.000, 3.000	-2.000, -1.000	-5.000, 2.000	-5.000, 3.000
Week 16				
N	2	2	6	10
Mean (SD)	5.000 (0.0000)	4.000 (0.0000)	4.333 (2.3381)	4.400 (1.7764)
Median	5.000	4.000	3.500	4.000
Min, Max	5.000, 5.000	4.000, 4.000	3.000, 9.000	3.000, 9.000
Change from Baseline to Week 16				
N	2	2	6	10
Mean (SD)	1.000 (0.0000)	-2.500 (3.5355)	-2.500 (2.1679)	-1.800 (2.4855)
Median	1.000	-2.500	-2.000	-1.000
Min, Max	1.000, 1.000	-5.000, 0.000	-5.000, 0.000	-5.000, 1.000
Week 20				
N	3	2	5	10
Mean (SD)	3.667 (0.5774)	3.000 (0.0000)	4.400 (1.3416)	3.900 (1.1005)
Median	4.000	3.000	5.000	3.500
Min, Max	3.000, 4.000	3.000, 3.000	3.000, 6.000	3.000, 6.000
Change from Baseline to Week 20				
N	3	2	5	10
Mean (SD)	-1.333 (2.3094)	-3.500 (3.5355)	-2.400 (2.4083)	-2.300 (2.4060)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	0.000	-3.500	-3.000	-2.000
Min, Max	-4.000, 0.000	-6.000, -1.000	-5.000, 1.000	-6.000, 1.000
Week 24				
N	4	3	5	12
Mean (SD)	4.000 (1.4142)	3.667 (0.5774)	4.400 (1.6733)	4.083 (1.3114)
Median	3.500	4.000	4.000	4.000
Min, Max	3.000, 6.000	3.000, 4.000	3.000, 7.000	3.000, 7.000
Change from Baseline to Week 24				
N	4	3	5	12
Mean (SD)	-0.750 (2.5000)	-2.000 (2.6458)	-2.400 (2.0736)	-1.750 (2.2613)
Median	-0.500	-1.000	-2.000	-1.000
Min, Max	-4.000, 2.000	-5.000, 0.000	-5.000, 0.000	-5.000, 2.000
Week 28				
N	5	3	5	13
Mean (SD)	5.000 (2.8284)	4.333 (0.5774)	5.400 (1.8166)	5.000 (2.0000)
Median	4.000	4.000	6.000	4.000
Min, Max	3.000, 10.000	4.000, 5.000	3.000, 7.000	3.000, 10.000
Change from Baseline to Week 28				
N	5	3	5	13
Mean (SD)	0.600 (3.2863)	-1.333 (2.3094)	-2.200 (1.9235)	-0.923 (2.7222)
Median	0.000	0.000	-2.000	0.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-3.000, 6.000	-4.000, 0.000	-5.000, 0.000	-5.000, 6.000
Week 32				
N	4	3	7	14
Mean (SD)	4.500 (2.3805)	4.000 (1.0000)	5.143 (2.5448)	4.714 (2.1636)
Median	3.500	4.000	4.000	4.000
Min, Max	3.000, 8.000	3.000, 5.000	2.000, 9.000	2.000, 9.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	0.750 (2.2174)	-1.667 (3.0551)	-1.143 (1.4639)	-0.714 (2.1278)
Median	0.000	-1.000	-1.000	-0.500
Min, Max	-1.000, 4.000	-5.000, 1.000	-4.000, 0.000	-5.000, 4.000
Week 36				
N	3	3	5	11
Mean (SD)	5.333 (0.5774)	4.667 (0.5774)	6.400 (3.7815)	5.636 (2.5406)
Median	5.000	5.000	5.000	5.000
Min, Max	5.000, 6.000	4.000, 5.000	4.000, 13.000	4.000, 13.000
Change from Baseline to Week 36				
N	3	3	5	11
Mean (SD)	1.333 (0.5774)	-1.000 (2.6458)	-1.200 (3.2711)	-0.455 (2.6595)
Median	1.000	0.000	-3.000	0.000
Min, Max	1.000, 2.000	-4.000, 1.000	-4.000, 4.000	-4.000, 4.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	6	14
Mean (SD)	4.800 (2.2804)	3.000 (1.0000)	6.333 (2.0656)	5.071 (2.2690)
Median	4.000	3.000	6.000	5.000
Min, Max	2.000, 8.000	2.000, 4.000	3.000, 9.000	2.000, 9.000
Change from Baseline to Week 40				
N	5	3	6	14
Mean (SD)	0.400 (2.7019)	-2.667 (2.0817)	-0.667 (2.8752)	-0.714 (2.7296)
Median	0.000	-2.000	-1.500	-1.000
Min, Max	-3.000, 4.000	-5.000, -1.000	-3.000, 5.000	-5.000, 5.000
Week 44				
N	5	3	7	15
Mean (SD)	6.400 (2.9665)	3.333 (0.5774)	6.286 (3.3022)	5.733 (2.9633)
Median	6.000	3.000	6.000	5.000
Min, Max	3.000, 11.000	3.000, 4.000	2.000, 12.000	2.000, 12.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	2.000 (3.4641)	-2.333 (2.3094)	0.000 (1.7321)	0.200 (2.8335)
Median	1.000	-1.000	0.000	0.000
Min, Max	-1.000, 7.000	-5.000, -1.000	-2.000, 3.000	-5.000, 7.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	4.000 (1.5811)	4.000 (2.0000)	6.143 (5.0143)	5.000 (3.6450)
Median	4.000	4.000	5.000	4.000
Min, Max	2.000, 6.000	2.000, 6.000	3.000, 17.000	2.000, 17.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	-0.400 (2.5100)	-1.667 (1.5275)	-0.143 (4.2594)	-0.533 (3.2042)
Median	1.000	-2.000	-1.000	-1.000
Min, Max	-4.000, 2.000	-3.000, 0.000	-5.000, 8.000	-5.000, 8.000
Early Term				
N	1		1	2
Mean (SD)	4.000 ()		4.000 ()	4.000 (0.0000)
Median	4.000		4.000	4.000
Min, Max	4.000, 4.000		4.000, 4.000	4.000, 4.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	1.000 ()		-4.000 ()	-1.500 (3.5355)
Median	1.000		-4.000	-1.500
Min, Max	1.000, 1.000		-4.000, -4.000	-4.000, 1.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Lactate Dehydrogenase (IU/L)				
Baseline				
N	15			15
Mean (SD)	186.533 (29.6090)			186.533 (29.6090)
Median	192.000			192.000
Min, Max	126.000, 228.000			126.000, 228.000
Week 1				
N	15			15
Mean (SD)	176.133 (25.1279)			176.133 (25.1279)
Median	178.000			178.000
Min, Max	130.000, 223.000			130.000, 223.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-10.400 (15.9006)			-10.400 (15.9006)
Median	-6.000			-6.000
Min, Max	-50.000, 18.000			-50.000, 18.000
Week 2				
N	15			15
Mean (SD)	172.667 (24.8701)			172.667 (24.8701)
Median	175.000			175.000
Min, Max	130.000, 233.000			130.000, 233.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-13.867 (19.2014)			-13.867 (19.2014)
Median	-16.000			-16.000
Min, Max	-48.000, 19.000			-48.000, 19.000
Week 4				
N	2	13		15
Mean (SD)	230.000 (103.2376)	175.000 (22.9420)		182.333 (39.8366)
Median	230.000	178.000		178.000
Min, Max	157.000, 303.000	136.000, 218.000		136.000, 303.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	36.000 (55.1543)	-10.385 (25.9664)		-4.200 (32.5822)
Median	36.000	-14.000		-4.000
Min, Max	-3.000, 75.000	-52.000, 37.000		-52.000, 75.000
Week 6				
N	3	5	7	15
Mean (SD)	205.667 (72.8309)	169.600 (18.1052)	185.286 (17.0364)	184.133 (33.9303)
Median	193.000	173.000	179.000	177.000
Min, Max	140.000, 284.000	145.000, 193.000	171.000, 220.000	140.000, 284.000

Change from Baseline to Week 6

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	22.667 (38.8501)	5.400 (16.8464)	-18.714 (20.6778)	-2.400 (27.7381)
Median	32.000	10.000	-9.000	-3.000
Min, Max	-20.000, 56.000	-24.000, 19.000	-48.000, 2.000	-48.000, 56.000
Week 8				
N	3	2	10	15
Mean (SD)	193.000 (59.7327)	181.500 (40.3051)	184.400 (14.4006)	185.733 (27.8246)
Median	169.000	181.500	185.500	184.000
Min, Max	149.000, 261.000	153.000, 210.000	156.000, 210.000	149.000, 261.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	10.000 (22.0681)	9.500 (27.5772)	-6.100 (23.8628)	-0.800 (23.4557)
Median	8.000	9.500	-9.000	-8.000
Min, Max	-11.000, 33.000	-10.000, 29.000	-35.000, 51.000	-35.000, 51.000
Week 12				
N	3	2	8	13
Mean (SD)	213.000 (45.9239)	154.500 (23.3345)	181.625 (19.4858)	184.692 (31.2554)
Median	188.000	154.500	186.000	185.000
Min, Max	185.000, 266.000	138.000, 171.000	152.000, 214.000	138.000, 266.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	10.000 (37.0405)	-17.500 (10.6066)	-13.250 (14.9451)	-8.538 (21.9644)
Median	24.000	-17.500	-7.500	-10.000
Min, Max	-32.000, 38.000	-25.000, -10.000	-35.000, 2.000	-35.000, 38.000
Week 16				
N	3	3	7	13
Mean (SD)	227.667 (65.8584)	181.667 (24.4199)	176.143 (23.8008)	189.308 (39.8631)
Median	199.000	174.000	179.000	180.000
Min, Max	181.000, 303.000	162.000, 209.000	139.000, 208.000	139.000, 303.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	24.667 (58.1578)	0.000 (27.5136)	-17.857 (20.1199)	-3.923 (34.8388)
Median	38.000	-1.000	-13.000	-11.000
Min, Max	-39.000, 75.000	-27.000, 28.000	-53.000, 9.000	-53.000, 75.000
Week 20				
N	4	3	6	13
Mean (SD)	196.000 (47.5044)	177.000 (15.3948)	185.667 (18.9491)	186.846 (28.3926)
Median	188.000	181.000	191.500	189.000
Min, Max	148.000, 260.000	160.000, 190.000	161.000, 210.000	148.000, 260.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-4.750 (45.9810)	-4.667 (14.5717)	-8.333 (16.8958)	-6.385 (26.1997)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-5.500	-3.000	-12.000	-3.000
Min, Max	-46.000, 38.000	-20.000, 9.000	-24.000, 11.000	-46.000, 38.000
Week 24				
N	4	3	6	13
Mean (SD)	228.250 (112.5000)	192.333 (21.9393)	200.667 (24.0222)	207.231 (60.9018)
Median	178.500	185.000	202.500	195.000
Min, Max	160.000, 396.000	175.000, 217.000	161.000, 235.000	160.000, 396.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	27.500 (100.4307)	10.667 (26.0256)	6.667 (25.9204)	14.000 (54.8164)
Median	1.000	12.000	12.000	12.000
Min, Max	-60.000, 168.000	-16.000, 36.000	-25.000, 45.000	-60.000, 168.000
Week 28				
N	5	3	7	15
Mean (SD)	221.800 (38.9320)	223.333 (45.0814)	202.000 (36.4234)	212.867 (37.4564)
Median	225.000	203.000	219.000	219.000
Min, Max	176.000, 281.000	192.000, 275.000	127.000, 229.000	127.000, 281.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	29.200 (27.8424)	41.667 (28.2194)	17.714 (25.9853)	26.333 (26.7413)
Median	16.000	29.000	10.000	22.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	5.000, 65.000	22.000, 74.000	-4.000, 69.000	-4.000, 74.000
Week 32				
N	4	3	7	14
Mean (SD)	206.250 (43.7674)	204.333 (41.0163)	223.286 (43.9989)	214.357 (40.9964)
Median	204.000	203.000	216.000	209.500
Min, Max	155.000, 262.000	164.000, 246.000	172.000, 311.000	155.000, 311.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	14.000 (28.2017)	22.667 (36.6652)	39.000 (34.4915)	28.357 (32.7311)
Median	14.500	2.000	46.000	27.000
Min, Max	-15.000, 42.000	1.000, 65.000	-2.000, 92.000	-15.000, 92.000
Week 36				
N	3	3	7	13
Mean (SD)	254.000 (3.6056)	187.000 (6.5574)	192.429 (37.5626)	205.385 (38.5758)
Median	253.000	186.000	191.000	194.000
Min, Max	251.000, 258.000	181.000, 194.000	132.000, 247.000	132.000, 258.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	51.000 (33.8083)	5.333 (17.7858)	8.143 (24.2173)	17.385 (30.0847)
Median	33.000	13.000	6.000	13.000
Min, Max	30.000, 90.000	-15.000, 18.000	-27.000, 48.000	-27.000, 90.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	211.400 (28.5184)	194.333 (22.0076)	184.429 (27.2327)	195.400 (27.7715)
Median	204.000	195.000	194.000	195.000
Min, Max	185.000, 254.000	172.000, 216.000	140.000, 214.000	140.000, 254.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	18.800 (19.5883)	12.667 (20.7445)	0.143 (15.6037)	8.867 (18.7573)
Median	26.000	9.000	7.000	11.000
Min, Max	-16.000, 31.000	-6.000, 35.000	-25.000, 15.000	-25.000, 35.000
Week 44				
N	5	3	7	15
Mean (SD)	224.000 (22.4833)	189.667 (13.7961)	186.000 (25.5995)	199.400 (27.9049)
Median	218.000	195.000	178.000	200.000
Min, Max	203.000, 252.000	174.000, 200.000	145.000, 222.000	145.000, 252.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	31.400 (20.0823)	8.000 (12.7671)	1.714 (30.2749)	12.867 (26.8564)
Median	32.000	11.000	-5.000	11.000
Min, Max	9.000, 58.000	-6.000, 19.000	-41.000, 52.000	-41.000, 58.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	209.200 (18.8600)	195.333 (23.6714)	173.143 (30.0079)	189.600 (29.1077)
Median	206.000	209.000	168.000	201.000
Min, Max	187.000, 238.000	168.000, 209.000	133.000, 214.000	133.000, 238.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	16.600 (20.2929)	13.667 (12.5033)	-11.143 (24.8424)	3.067 (24.3911)
Median	20.000	8.000	-9.000	7.000
Min, Max	-14.000, 40.000	5.000, 28.000	-51.000, 22.000	-51.000, 40.000
Early Term				
N	1		1	2
Mean (SD)	143.000 ()		149.000 ()	146.000 (4.2426)
Median	143.000		149.000	146.000
Min, Max	143.000, 143.000		149.000, 149.000	143.000, 149.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-17.000 ()		23.000 ()	3.000 (28.2843)
Median	-17.000		23.000	3.000
Min, Max	-17.000, -17.000		23.000, 23.000	-17.000, 23.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Magnesium (mmol/L)				
Baseline				
N	15			15
Mean (SD)	0.857 (0.0468)			0.857 (0.0468)
Median	0.860			0.860
Min, Max	0.760, 0.940			0.760, 0.940
Week 1				
N	15			15
Mean (SD)	0.843 (0.0324)			0.843 (0.0324)
Median	0.840			0.840
Min, Max	0.750, 0.890			0.750, 0.890
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.014 (0.0405)			-0.014 (0.0405)
Median	-0.010			-0.010
Min, Max	-0.100, 0.050			-0.100, 0.050
Week 2				
N	15			15
Mean (SD)	0.841 (0.0324)			0.841 (0.0324)
Median	0.850			0.850
Min, Max	0.770, 0.890			0.770, 0.890

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.017 (0.0559)			-0.017 (0.0559)
Median	-0.010			-0.010
Min, Max	-0.120, 0.120			-0.120, 0.120
Week 4				
N	2	13		15
Mean (SD)	0.815 (0.0778)	0.840 (0.0476)		0.837 (0.0495)
Median	0.815	0.850		0.850
Min, Max	0.760, 0.870	0.740, 0.910		0.740, 0.910
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-0.055 (0.0495)	-0.015 (0.0672)		-0.021 (0.0651)
Median	-0.055	-0.020		-0.020
Min, Max	-0.090, -0.020	-0.120, 0.090		-0.120, 0.090
Week 6				
N	3	5	7	15
Mean (SD)	0.817 (0.0651)	0.818 (0.0502)	0.833 (0.0685)	0.825 (0.0583)
Median	0.820	0.840	0.820	0.820
Min, Max	0.750, 0.880	0.750, 0.860	0.730, 0.940	0.730, 0.940
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-0.047 (0.0473)	-0.010 (0.0520)	-0.043 (0.0927)	-0.033 (0.0711)
Median	-0.030	-0.020	-0.050	-0.040
Min, Max	-0.100, -0.010	-0.050, 0.080	-0.210, 0.090	-0.210, 0.090
Week 8				
N	3	2	10	15
Mean (SD)	0.887 (0.0321)	0.860 (0.0141)	0.829 (0.0384)	0.845 (0.0412)
Median	0.900	0.860	0.825	0.850
Min, Max	0.850, 0.910	0.850, 0.870	0.780, 0.890	0.780, 0.910
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	0.023 (0.0321)	0.020 (0.1131)	-0.030 (0.0383)	-0.013 (0.0515)
Median	0.010	0.020	-0.030	0.000
Min, Max	0.000, 0.060	-0.060, 0.100	-0.090, 0.020	-0.090, 0.100
Week 12				
N	3	2	8	13
Mean (SD)	0.813 (0.0351)	0.855 (0.0354)	0.793 (0.0440)	0.807 (0.0444)
Median	0.810	0.855	0.790	0.810
Min, Max	0.780, 0.850	0.830, 0.880	0.720, 0.840	0.720, 0.880
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-0.040 (0.0300)	0.015 (0.0636)	-0.079 (0.0419)	-0.055 (0.0525)
Median	-0.040	0.015	-0.070	-0.040
Min, Max	-0.070, -0.010	-0.030, 0.060	-0.140, -0.040	-0.140, 0.060
Week 16				
N	3	3	7	13
Mean (SD)	0.807 (0.0379)	0.860 (0.0794)	0.837 (0.0206)	0.835 (0.0431)
Median	0.790	0.890	0.840	0.840
Min, Max	0.780, 0.850	0.770, 0.920	0.810, 0.860	0.770, 0.920
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-0.047 (0.0321)	0.027 (0.0862)	-0.041 (0.0313)	-0.027 (0.0533)
Median	-0.060	0.010	-0.030	-0.030
Min, Max	-0.070, -0.010	-0.050, 0.120	-0.100, -0.010	-0.100, 0.120
Week 20				
N	4	3	6	13
Mean (SD)	0.855 (0.0332)	0.830 (0.0436)	0.843 (0.0554)	0.844 (0.0443)
Median	0.860	0.850	0.845	0.860
Min, Max	0.810, 0.890	0.780, 0.860	0.780, 0.920	0.780, 0.920
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	0.003 (0.0330)	-0.003 (0.0723)	-0.040 (0.0569)	-0.018 (0.0541)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	0.005	-0.040	-0.060	-0.040
Min, Max	-0.040, 0.040	-0.050, 0.080	-0.100, 0.040	-0.100, 0.080
Week 24				
N	4	3	6	13
Mean (SD)	0.833 (0.0263)	0.807 (0.0551)	0.830 (0.0374)	0.825 (0.0371)
Median	0.825	0.780	0.820	0.820
Min, Max	0.810, 0.870	0.770, 0.870	0.790, 0.880	0.770, 0.880
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-0.020 (0.0271)	-0.027 (0.0231)	-0.053 (0.0446)	-0.037 (0.0368)
Median	-0.030	-0.040	-0.065	-0.040
Min, Max	-0.040, 0.020	-0.040, 0.000	-0.110, 0.000	-0.110, 0.020
Week 28				
N	5	3	7	15
Mean (SD)	0.852 (0.0492)	0.870 (0.0557)	0.819 (0.0227)	0.840 (0.0428)
Median	0.850	0.880	0.820	0.820
Min, Max	0.790, 0.910	0.810, 0.920	0.780, 0.850	0.780, 0.920
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-0.008 (0.0396)	0.037 (0.0252)	-0.047 (0.0377)	-0.017 (0.0474)
Median	-0.010	0.040	-0.060	-0.020

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-0.060, 0.040	0.010, 0.060	-0.100, 0.020	-0.100, 0.060
Week 32				
N	4	3	7	14
Mean (SD)	0.860 (0.0294)	0.870 (0.0346)	0.856 (0.0670)	0.860 (0.0499)
Median	0.865	0.850	0.870	0.865
Min, Max	0.820, 0.890	0.850, 0.910	0.760, 0.960	0.760, 0.960
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	-0.003 (0.0340)	0.037 (0.0404)	-0.010 (0.0630)	0.002 (0.0521)
Median	-0.010	0.030	0.000	0.005
Min, Max	-0.030, 0.040	0.000, 0.080	-0.100, 0.080	-0.100, 0.080
Week 36				
N	3	3	7	13
Mean (SD)	0.827 (0.0306)	0.833 (0.0737)	0.839 (0.0481)	0.835 (0.0474)
Median	0.820	0.860	0.840	0.840
Min, Max	0.800, 0.860	0.750, 0.890	0.760, 0.910	0.750, 0.910
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	-0.027 (0.0321)	0.000 (0.0346)	-0.027 (0.0522)	-0.021 (0.0433)
Median	-0.040	-0.020	-0.020	-0.020
Min, Max	-0.050, 0.010	-0.020, 0.040	-0.130, 0.040	-0.130, 0.040

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	0.818 (0.0581)	0.890 (0.0265)	0.847 (0.0373)	0.846 (0.0485)
Median	0.790	0.880	0.840	0.840
Min, Max	0.770, 0.910	0.870, 0.920	0.800, 0.900	0.770, 0.920
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	-0.042 (0.0444)	0.057 (0.0503)	-0.019 (0.0505)	-0.011 (0.0580)
Median	-0.070	0.050	-0.010	-0.010
Min, Max	-0.080, 0.020	0.010, 0.110	-0.100, 0.040	-0.100, 0.110
Week 44				
N	5	3	7	15
Mean (SD)	0.842 (0.0327)	0.823 (0.0643)	0.829 (0.0279)	0.832 (0.0359)
Median	0.830	0.850	0.820	0.830
Min, Max	0.820, 0.900	0.750, 0.870	0.800, 0.880	0.750, 0.900
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	-0.018 (0.0164)	-0.010 (0.0361)	-0.037 (0.0562)	-0.025 (0.0419)
Median	-0.020	-0.020	-0.040	-0.020
Min, Max	-0.030, 0.010	-0.040, 0.030	-0.130, 0.050	-0.130, 0.050
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	0.826 (0.0344)	0.923 (0.0451)	0.860 (0.0469)	0.861 (0.0533)
Median	0.840	0.920	0.870	0.860
Min, Max	0.780, 0.860	0.880, 0.970	0.770, 0.910	0.770, 0.970
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	-0.034 (0.0261)	0.090 (0.0265)	-0.006 (0.0553)	0.004 (0.0613)
Median	-0.030	0.100	0.000	-0.010
Min, Max	-0.070, -0.010	0.060, 0.110	-0.090, 0.080	-0.090, 0.110
Early Term				
N	1		1	2
Mean (SD)	0.790 ()		0.810 ()	0.800 (0.0141)
Median	0.790		0.810	0.800
Min, Max	0.790, 0.790		0.810, 0.810	0.790, 0.810
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-0.100 ()		0.050 ()	-0.025 (0.1061)
Median	-0.100		0.050	-0.025
Min, Max	-0.100, -0.100		0.050, 0.050	-0.100, 0.050

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Phosphate (mmol/L)				
Baseline				
N	15			15
Mean (SD)	1.032 (0.2306)			1.032 (0.2306)
Median	1.010			1.010
Min, Max	0.630, 1.390			0.630, 1.390
Week 1				
N	15			15
Mean (SD)	0.975 (0.1554)			0.975 (0.1554)
Median	0.980			0.980
Min, Max	0.600, 1.180			0.600, 1.180
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.057 (0.1293)			-0.057 (0.1293)
Median	-0.080			-0.080
Min, Max	-0.260, 0.180			-0.260, 0.180
Week 2				
N	15			15
Mean (SD)	0.942 (0.1734)			0.942 (0.1734)
Median	0.950			0.950
Min, Max	0.590, 1.190			0.590, 1.190

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	-0.090 (0.2252)			-0.090 (0.2252)
Median	-0.060			-0.060
Min, Max	-0.590, 0.220			-0.590, 0.220
Week 4				
N	2	13		15
Mean (SD)	1.160 (0.0566)	0.980 (0.1306)		1.004 (0.1373)
Median	1.160	0.960		1.030
Min, Max	1.120, 1.200	0.740, 1.190		0.740, 1.200
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-0.060 (0.0424)	-0.023 (0.2028)		-0.028 (0.1886)
Median	-0.060	0.030		-0.020
Min, Max	-0.090, -0.030	-0.450, 0.310		-0.450, 0.310
Week 6				
N	3	5	7	15
Mean (SD)	1.147 (0.0850)	0.938 (0.1720)	0.987 (0.1854)	1.003 (0.1740)
Median	1.180	0.940	0.910	0.970
Min, Max	1.050, 1.210	0.680, 1.130	0.780, 1.260	0.680, 1.260
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-0.080 (0.0985)	-0.140 (0.1306)	0.071 (0.2325)	-0.029 (0.1985)
Median	-0.050	-0.120	0.100	-0.050
Min, Max	-0.190, 0.000	-0.280, 0.030	-0.260, 0.370	-0.280, 0.370
Week 8				
N	3	2	10	15
Mean (SD)	1.293 (0.0929)	0.995 (0.1202)	1.016 (0.1852)	1.069 (0.1946)
Median	1.250	0.995	1.005	1.080
Min, Max	1.230, 1.400	0.910, 1.080	0.780, 1.420	0.780, 1.420
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	0.067 (0.0896)	-0.130 (0.2546)	0.061 (0.2285)	0.037 (0.2096)
Median	0.020	-0.130	0.070	0.040
Min, Max	0.010, 0.170	-0.310, 0.050	-0.250, 0.410	-0.310, 0.410
Week 12				
N	3	2	8	13
Mean (SD)	1.187 (0.0764)	1.095 (0.2475)	1.014 (0.1639)	1.066 (0.1654)
Median	1.170	1.095	0.940	1.120
Min, Max	1.120, 1.270	0.920, 1.270	0.860, 1.240	0.860, 1.270
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	0.123 (0.2914)	-0.030 (0.1273)	0.010 (0.1695)	0.030 (0.1879)
Median	0.030	-0.030	0.010	0.030
Min, Max	-0.110, 0.450	-0.120, 0.060	-0.200, 0.250	-0.200, 0.450
Week 16				
N	3	3	7	13
Mean (SD)	1.133 (0.1815)	1.057 (0.2346)	0.897 (0.1616)	0.988 (0.1975)
Median	1.060	1.110	0.970	1.000
Min, Max	1.000, 1.340	0.800, 1.260	0.670, 1.100	0.670, 1.340
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	0.070 (0.2265)	-0.137 (0.4239)	-0.060 (0.1256)	-0.048 (0.2279)
Median	0.100	-0.070	-0.060	-0.060
Min, Max	-0.170, 0.280	-0.590, 0.250	-0.250, 0.120	-0.590, 0.280
Week 20				
N	4	3	6	13
Mean (SD)	0.980 (0.1817)	0.910 (0.1400)	0.978 (0.2725)	0.963 (0.2083)
Median	0.965	0.910	0.985	0.910
Min, Max	0.800, 1.190	0.770, 1.050	0.700, 1.260	0.700, 1.260
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	0.025 (0.1682)	-0.283 (0.1950)	-0.033 (0.2856)	-0.073 (0.2499)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	0.015	-0.280	-0.040	-0.090
Min, Max	-0.160, 0.230	-0.480, -0.090	-0.360, 0.290	-0.480, 0.290
Week 24				
N	4	3	6	13
Mean (SD)	1.088 (0.2079)	0.983 (0.1677)	1.053 (0.1462)	1.048 (0.1612)
Median	1.075	1.070	1.050	1.060
Min, Max	0.850, 1.350	0.790, 1.090	0.800, 1.240	0.790, 1.350
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	0.133 (0.2089)	-0.210 (0.1277)	0.042 (0.2068)	0.012 (0.2215)
Median	0.120	-0.240	0.030	-0.070
Min, Max	-0.110, 0.400	-0.320, -0.070	-0.200, 0.350	-0.320, 0.400
Week 28				
N	5	3	7	15
Mean (SD)	1.050 (0.2887)	0.927 (0.0611)	1.047 (0.2687)	1.024 (0.2405)
Median	1.190	0.940	1.130	1.100
Min, Max	0.540, 1.210	0.860, 0.980	0.690, 1.320	0.540, 1.320
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	0.044 (0.2481)	-0.267 (0.3350)	0.066 (0.2148)	-0.008 (0.2672)
Median	-0.030	-0.450	0.110	0.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-0.180, 0.470	-0.470, 0.120	-0.270, 0.290	-0.470, 0.470
Week 32				
N	4	3	7	14
Mean (SD)	1.085 (0.2082)	1.017 (0.1858)	0.903 (0.2212)	0.979 (0.2117)
Median	1.160	0.930	0.960	0.970
Min, Max	0.780, 1.240	0.890, 1.230	0.510, 1.130	0.510, 1.240
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	-0.015 (0.0597)	-0.177 (0.2554)	-0.079 (0.2306)	-0.081 (0.1971)
Median	-0.020	-0.160	0.000	-0.020
Min, Max	-0.080, 0.060	-0.440, 0.070	-0.490, 0.160	-0.490, 0.160
Week 36				
N	3	3	7	13
Mean (SD)	1.230 (0.0693)	0.823 (0.1365)	0.951 (0.2338)	0.986 (0.2311)
Median	1.270	0.760	0.930	0.970
Min, Max	1.150, 1.270	0.730, 0.980	0.560, 1.290	0.560, 1.290
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	0.167 (0.3365)	-0.370 (0.2524)	-0.030 (0.1581)	-0.063 (0.2817)
Median	0.030	-0.410	0.000	-0.080
Min, Max	-0.080, 0.550	-0.600, -0.100	-0.330, 0.160	-0.600, 0.550

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	1.040 (0.3018)	0.873 (0.0551)	0.931 (0.1558)	0.956 (0.2029)
Median	1.120	0.900	0.930	0.910
Min, Max	0.650, 1.370	0.810, 0.910	0.770, 1.180	0.650, 1.370
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	0.034 (0.1246)	-0.320 (0.3291)	-0.050 (0.1456)	-0.076 (0.2154)
Median	0.040	-0.430	-0.030	-0.030
Min, Max	-0.110, 0.180	-0.580, 0.050	-0.360, 0.080	-0.580, 0.180
Week 44				
N	5	3	7	15
Mean (SD)	1.068 (0.1760)	0.920 (0.0529)	0.970 (0.1097)	0.993 (0.1335)
Median	1.140	0.940	1.000	0.960
Min, Max	0.850, 1.270	0.860, 0.960	0.740, 1.060	0.740, 1.270
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	0.062 (0.1527)	-0.273 (0.3163)	-0.011 (0.1592)	-0.039 (0.2182)
Median	0.030	-0.370	-0.060	-0.050
Min, Max	-0.090, 0.290	-0.530, 0.080	-0.260, 0.160	-0.530, 0.290
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	1.042 (0.1918)	1.013 (0.1701)	0.939 (0.2111)	0.988 (0.1901)
Median	1.030	1.020	0.940	0.980
Min, Max	0.820, 1.240	0.840, 1.180	0.630, 1.320	0.630, 1.320
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	0.036 (0.1701)	-0.180 (0.1473)	-0.043 (0.2358)	-0.044 (0.2036)
Median	0.020	-0.210	-0.010	-0.010
Min, Max	-0.210, 0.260	-0.310, -0.020	-0.530, 0.190	-0.530, 0.260
Early Term				
N	1		1	2
Mean (SD)	1.400 ()		0.970 ()	1.185 (0.3041)
Median	1.400		0.970	1.185
Min, Max	1.400, 1.400		0.970, 0.970	0.970, 1.400
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	0.190 ()		0.170 ()	0.180 (0.0141)
Median	0.190		0.170	0.180
Min, Max	0.190, 0.190		0.170, 0.170	0.170, 0.190

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Potassium (mmol/L)				
Baseline				
N	15			15
Mean (SD)	4.393 (0.3615)			4.393 (0.3615)
Median	4.200			4.200
Min, Max	3.900, 5.300			3.900, 5.300
Week 1				
N	15			15
Mean (SD)	4.493 (0.4026)			4.493 (0.4026)
Median	4.400			4.400
Min, Max	3.900, 5.300			3.900, 5.300
Change from Baseline to Week 1				
N	15			15
Mean (SD)	0.100 (0.3723)			0.100 (0.3723)
Median	0.100			0.100
Min, Max	-0.500, 1.000			-0.500, 1.000
Week 2				
N	15			15
Mean (SD)	4.413 (0.3357)			4.413 (0.3357)
Median	4.400			4.400
Min, Max	3.800, 5.000			3.800, 5.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	0.020 (0.4144)			0.020 (0.4144)
Median	0.000			0.000
Min, Max	-0.600, 0.800			-0.600, 0.800
Week 4				
N	2	13		15
Mean (SD)	4.300 (0.7071)	4.231 (0.3199)		4.240 (0.3521)
Median	4.300	4.200		4.200
Min, Max	3.800, 4.800	3.400, 4.700		3.400, 4.800
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-0.450 (0.0707)	-0.108 (0.3546)		-0.153 (0.3502)
Median	-0.450	-0.100		-0.300
Min, Max	-0.500, -0.400	-0.800, 0.500		-0.800, 0.500
Week 6				
N	3	5	7	15
Mean (SD)	3.900 (0.6083)	4.300 (0.5148)	4.114 (0.3388)	4.133 (0.4467)
Median	4.200	4.300	4.200	4.200
Min, Max	3.200, 4.300	3.500, 4.800	3.600, 4.500	3.200, 4.800
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-0.667 (0.5774)	-0.060 (0.6189)	-0.229 (0.5314)	-0.260 (0.5730)
Median	-1.000	0.000	-0.200	-0.200
Min, Max	-1.000, 0.000	-0.900, 0.800	-1.200, 0.300	-1.200, 0.800
Week 8				
N	3	2	10	15
Mean (SD)	4.367 (0.9074)	4.200 (0.1414)	4.130 (0.3917)	4.187 (0.4764)
Median	4.500	4.200	4.200	4.300
Min, Max	3.400, 5.200	4.100, 4.300	3.500, 4.600	3.400, 5.200
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-0.200 (0.5568)	-0.100 (0.2828)	-0.230 (0.5376)	-0.207 (0.4877)
Median	-0.100	-0.100	-0.050	-0.100
Min, Max	-0.800, 0.300	-0.300, 0.100	-1.300, 0.300	-1.300, 0.300
Week 12				
N	3	2	8	13
Mean (SD)	4.200 (0.2646)	4.300 (0.2828)	4.075 (0.4496)	4.138 (0.3798)
Median	4.100	4.300	4.100	4.100
Min, Max	4.000, 4.500	4.100, 4.500	3.400, 4.800	3.400, 4.800
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-0.367 (0.7638)	0.000 (0.4243)	-0.250 (0.5682)	-0.238 (0.5606)
Median	-0.200	0.000	-0.550	-0.300
Min, Max	-1.200, 0.300	-0.300, 0.300	-0.900, 0.600	-1.200, 0.600
Week 16				
N	3	3	7	13
Mean (SD)	4.400 (0.3464)	4.600 (0.7000)	4.171 (0.5823)	4.323 (0.5525)
Median	4.200	4.600	4.300	4.300
Min, Max	4.200, 4.800	3.900, 5.300	3.500, 5.000	3.500, 5.300
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	-0.167 (0.8622)	0.233 (0.8505)	-0.129 (0.7825)	-0.054 (0.7601)
Median	0.000	0.200	0.000	0.000
Min, Max	-1.100, 0.600	-0.600, 1.100	-1.200, 0.800	-1.200, 1.100
Week 20				
N	4	3	6	13
Mean (SD)	4.100 (0.4899)	4.300 (0.3606)	4.283 (0.2401)	4.231 (0.3376)
Median	4.100	4.200	4.300	4.200
Min, Max	3.500, 4.700	4.000, 4.700	4.000, 4.700	3.500, 4.700
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-0.325 (0.2630)	-0.067 (0.5132)	-0.067 (0.4227)	-0.146 (0.3886)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-0.300	-0.200	-0.200	-0.200
Min, Max	-0.600, -0.100	-0.500, 0.500	-0.500, 0.500	-0.600, 0.500
Week 24				
N	4	3	6	13
Mean (SD)	4.325 (0.2754)	3.933 (0.2517)	4.200 (0.3033)	4.177 (0.3004)
Median	4.350	3.900	4.100	4.200
Min, Max	4.000, 4.600	3.700, 4.200	3.900, 4.700	3.700, 4.700
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-0.100 (0.5292)	-0.433 (0.3786)	-0.150 (0.4764)	-0.200 (0.4546)
Median	0.000	-0.600	-0.100	-0.200
Min, Max	-0.800, 0.400	-0.700, 0.000	-0.900, 0.500	-0.900, 0.500
Week 28				
N	5	3	7	15
Mean (SD)	4.460 (0.3050)	4.400 (0.2646)	4.357 (0.2637)	4.400 (0.2619)
Median	4.300	4.300	4.400	4.300
Min, Max	4.300, 5.000	4.200, 4.700	3.900, 4.700	3.900, 5.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	0.080 (0.2280)	0.033 (0.4041)	-0.057 (0.4721)	0.007 (0.3712)
Median	0.100	-0.200	-0.200	0.100

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-0.300, 0.300	-0.200, 0.500	-0.700, 0.500	-0.700, 0.500
Week 32				
N	4	3	7	14
Mean (SD)	4.675 (0.3304)	4.333 (0.1155)	4.386 (0.2193)	4.457 (0.2652)
Median	4.650	4.400	4.500	4.450
Min, Max	4.300, 5.100	4.200, 4.400	3.900, 4.500	3.900, 5.100
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	0.200 (0.3162)	-0.033 (0.2082)	-0.029 (0.3861)	0.036 (0.3319)
Median	0.250	-0.100	-0.200	0.000
Min, Max	-0.200, 0.500	-0.200, 0.200	-0.500, 0.500	-0.500, 0.500
Week 36				
N	3	3	7	13
Mean (SD)	4.667 (0.3786)	4.433 (0.0577)	4.386 (0.2268)	4.462 (0.2534)
Median	4.500	4.400	4.400	4.400
Min, Max	4.400, 5.100	4.400, 4.500	4.100, 4.700	4.100, 5.100
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	0.100 (0.2646)	0.067 (0.1528)	-0.029 (0.3251)	0.023 (0.2682)
Median	0.200	0.100	0.000	0.100
Min, Max	-0.200, 0.300	-0.100, 0.200	-0.500, 0.300	-0.500, 0.300

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	4.500 (0.4301)	4.633 (0.2082)	4.714 (0.1574)	4.627 (0.2815)
Median	4.300	4.700	4.700	4.700
Min, Max	4.000, 5.000	4.400, 4.800	4.500, 4.900	4.000, 5.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	0.120 (0.4025)	0.267 (0.3055)	0.300 (0.3109)	0.233 (0.3288)
Median	0.100	0.200	0.300	0.200
Min, Max	-0.300, 0.700	0.000, 0.600	-0.100, 0.700	-0.300, 0.700
Week 44				
N	5	3	7	15
Mean (SD)	4.380 (0.2775)	4.433 (0.1528)	4.486 (0.2734)	4.440 (0.2444)
Median	4.300	4.400	4.500	4.500
Min, Max	4.100, 4.800	4.300, 4.600	4.100, 4.900	4.100, 4.900
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	0.000 (0.3162)	0.067 (0.0577)	0.071 (0.3352)	0.047 (0.2800)
Median	0.100	0.100	0.300	0.100
Min, Max	-0.500, 0.300	0.000, 0.100	-0.500, 0.300	-0.500, 0.300
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	4.360 (0.6348)	4.600 (0.1000)	4.443 (0.2760)	4.447 (0.3962)
Median	4.400	4.600	4.500	4.500
Min, Max	3.400, 5.100	4.500, 4.700	4.100, 4.800	3.400, 5.100
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	-0.020 (0.5495)	0.233 (0.0577)	0.029 (0.3773)	0.053 (0.3962)
Median	0.000	0.200	0.000	0.200
Min, Max	-0.800, 0.700	0.200, 0.300	-0.600, 0.500	-0.800, 0.700
Early Term				
N	1		1	2
Mean (SD)	4.200 ()		3.600 ()	3.900 (0.4243)
Median	4.200		3.600	3.900
Min, Max	4.200, 4.200		3.600, 3.600	3.600, 4.200
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	0.000 ()		-1.200 ()	-0.600 (0.8485)
Median	0.000		-1.200	-0.600
Min, Max	0.000, 0.000		-1.200, -1.200	-1.200, 0.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Protein (g/L)				
Baseline				
N	15			15
Mean (SD)	75.067 (5.7379)			75.067 (5.7379)
Median	76.000			76.000
Min, Max	65.000, 86.000			65.000, 86.000
Week 1				
N	15			15
Mean (SD)	76.467 (4.6731)			76.467 (4.6731)
Median	77.000			77.000
Min, Max	67.000, 82.000			67.000, 82.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	1.400 (2.5014)			1.400 (2.5014)
Median	2.000			2.000
Min, Max	-5.000, 5.000			-5.000, 5.000
Week 2				
N	15			15
Mean (SD)	75.400 (5.0398)			75.400 (5.0398)
Median	78.000			78.000
Min, Max	66.000, 82.000			66.000, 82.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	0.333 (3.0628)			0.333 (3.0628)
Median	0.000			0.000
Min, Max	-8.000, 6.000			-8.000, 6.000
Week 4				
N	2	13		15
Mean (SD)	79.000 (8.4853)	74.462 (4.0746)		75.067 (4.6823)
Median	79.000	75.000		75.000
Min, Max	73.000, 85.000	65.000, 80.000		65.000, 85.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	4.500 (2.1213)	-0.692 (3.4973)		0.000 (3.7607)
Median	4.500	0.000		1.000
Min, Max	3.000, 6.000	-9.000, 3.000		-9.000, 6.000
Week 6				
N	3	5	7	15
Mean (SD)	75.667 (5.7735)	75.000 (9.0277)	74.571 (5.6526)	74.933 (6.4749)
Median	79.000	73.000	75.000	75.000
Min, Max	69.000, 79.000	67.000, 88.000	64.000, 81.000	64.000, 88.000
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	0.667 (3.2146)	-1.200 (6.0166)	0.286 (2.8702)	-0.133 (3.9976)
Median	2.000	-3.000	0.000	-1.000
Min, Max	-3.000, 3.000	-6.000, 9.000	-4.000, 4.000	-6.000, 9.000
Week 8				
N	3	2	10	15
Mean (SD)	73.333 (5.1316)	66.000 (5.6569)	75.200 (5.3500)	73.600 (5.8773)
Median	72.000	66.000	75.500	73.000
Min, Max	69.000, 79.000	62.000, 70.000	69.000, 87.000	62.000, 87.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-1.667 (3.2146)	-7.000 (1.4142)	-0.300 (4.7854)	-1.467 (4.6578)
Median	-3.000	-7.000	-1.000	-2.000
Min, Max	-4.000, 2.000	-8.000, -6.000	-7.000, 8.000	-8.000, 8.000
Week 12				
N	3	2	8	13
Mean (SD)	69.000 (1.0000)	69.000 (2.8284)	75.000 (3.7796)	72.692 (4.2892)
Median	69.000	69.000	74.500	73.000
Min, Max	68.000, 70.000	67.000, 71.000	69.000, 82.000	67.000, 82.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-2.667 (3.5119)	-4.000 (4.2426)	-1.625 (3.7773)	-2.231 (3.5626)
Median	-3.000	-4.000	-2.500	-3.000
Min, Max	-6.000, 1.000	-7.000, -1.000	-8.000, 4.000	-8.000, 4.000
Week 16				
N	3	3	7	13
Mean (SD)	72.333 (3.2146)	72.667 (3.2146)	74.000 (5.7446)	73.308 (4.5348)
Median	71.000	74.000	75.000	74.000
Min, Max	70.000, 76.000	69.000, 75.000	63.000, 82.000	63.000, 82.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	0.667 (3.0551)	-4.667 (6.0277)	-1.286 (2.8115)	-1.615 (3.9059)
Median	0.000	-4.000	-2.000	-2.000
Min, Max	-2.000, 4.000	-11.000, 1.000	-4.000, 3.000	-11.000, 4.000
Week 20				
N	4	3	6	13
Mean (SD)	69.250 (5.0580)	70.333 (7.5056)	75.833 (3.9707)	72.538 (5.7099)
Median	68.500	70.000	75.000	73.000
Min, Max	65.000, 75.000	63.000, 78.000	72.000, 83.000	63.000, 83.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-0.750 (0.9574)	-7.000 (1.7321)	-1.167 (3.7103)	-2.385 (3.6638)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	-0.500	-8.000	-1.000	-2.000
Min, Max	-2.000, 0.000	-8.000, -5.000	-5.000, 4.000	-8.000, 4.000
Week 24				
N	4	3	6	13
Mean (SD)	70.250 (6.8981)	74.333 (6.6583)	76.167 (4.1673)	73.923 (5.7946)
Median	73.000	76.000	75.000	74.000
Min, Max	60.000, 75.000	67.000, 80.000	73.000, 84.000	60.000, 84.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	0.250 (4.5735)	-3.000 (2.6458)	-0.833 (3.8166)	-1.000 (3.7417)
Median	0.000	-2.000	-1.000	-1.000
Min, Max	-5.000, 6.000	-6.000, -1.000	-5.000, 5.000	-6.000, 6.000
Week 28				
N	5	3	7	15
Mean (SD)	73.400 (7.0214)	72.667 (6.4291)	76.000 (5.3229)	74.467 (5.8660)
Median	74.000	70.000	75.000	74.000
Min, Max	67.000, 84.000	68.000, 80.000	70.000, 84.000	67.000, 84.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	1.000 (2.0000)	-4.667 (4.1633)	0.000 (3.9581)	-0.600 (3.8693)
Median	2.000	-6.000	0.000	0.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-2.000, 3.000	-8.000, 0.000	-5.000, 5.000	-8.000, 5.000
Week 32				
N	4	3	7	14
Mean (SD)	75.750 (4.1130)	77.000 (7.0000)	74.429 (6.7788)	75.357 (5.8125)
Median	75.500	77.000	72.000	73.500
Min, Max	71.000, 81.000	70.000, 84.000	68.000, 86.000	68.000, 86.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	1.500 (2.8868)	-0.333 (2.0817)	-1.571 (5.1916)	-0.429 (4.1084)
Median	1.500	-1.000	-3.000	-1.000
Min, Max	-1.000, 4.000	-2.000, 2.000	-7.000, 7.000	-7.000, 7.000
Week 36				
N	3	3	7	13
Mean (SD)	76.333 (4.6188)	78.333 (6.0277)	77.857 (6.1489)	77.615 (5.3935)
Median	79.000	79.000	77.000	79.000
Min, Max	71.000, 79.000	72.000, 84.000	70.000, 85.000	70.000, 85.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	4.667 (2.0817)	1.000 (3.0000)	1.857 (4.1404)	2.308 (3.5680)
Median	4.000	1.000	0.000	3.000
Min, Max	3.000, 7.000	-2.000, 4.000	-4.000, 7.000	-4.000, 7.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	74.800 (5.3572)	76.667 (4.9329)	77.286 (4.3861)	76.333 (4.6085)
Median	76.000	79.000	78.000	77.000
Min, Max	69.000, 82.000	71.000, 80.000	71.000, 83.000	69.000, 83.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	2.400 (2.3022)	-0.667 (5.5076)	1.286 (3.1472)	1.267 (3.3693)
Median	3.000	2.000	1.000	2.000
Min, Max	0.000, 5.000	-7.000, 3.000	-5.000, 5.000	-7.000, 5.000
Week 44				
N	5	3	7	15
Mean (SD)	76.800 (8.4380)	74.667 (4.7258)	75.286 (4.7157)	75.667 (5.8146)
Median	79.000	73.000	73.000	73.000
Min, Max	67.000, 86.000	71.000, 80.000	71.000, 84.000	67.000, 86.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	4.400 (3.7815)	-2.667 (4.9329)	-0.714 (3.3523)	0.600 (4.5482)
Median	3.000	-5.000	0.000	1.000
Min, Max	2.000, 11.000	-6.000, 3.000	-5.000, 5.000	-6.000, 11.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	77.000 (7.2801)	76.333 (2.5166)	75.571 (5.3497)	76.200 (5.3612)
Median	77.000	76.000	75.000	76.000
Min, Max	68.000, 88.000	74.000, 79.000	69.000, 85.000	68.000, 88.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	4.600 (3.5071)	-1.000 (6.5574)	-0.429 (4.1576)	1.133 (4.8531)
Median	6.000	-2.000	-1.000	1.000
Min, Max	1.000, 9.000	-7.000, 6.000	-5.000, 7.000	-7.000, 9.000
Early Term				
N	1		1	2
Mean (SD)	77.000 ()		62.000 ()	69.500 (10.6066)
Median	77.000		62.000	69.500
Min, Max	77.000, 77.000		62.000, 62.000	62.000, 77.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-5.000 ()		-8.000 ()	-6.500 (2.1213)
Median	-5.000		-8.000	-6.500
Min, Max	-5.000, -5.000		-8.000, -8.000	-8.000, -5.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Sodium (mmol/L)				
Baseline				
N	15			15
Mean (SD)	140.267 (1.6676)			140.267 (1.6676)
Median	140.000			140.000
Min, Max	137.000, 143.000			137.000, 143.000
Week 1				
N	15			15
Mean (SD)	139.267 (2.3135)			139.267 (2.3135)
Median	140.000			140.000
Min, Max	136.000, 142.000			136.000, 142.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-1.000 (2.0354)			-1.000 (2.0354)
Median	-1.000			-1.000
Min, Max	-5.000, 2.000			-5.000, 2.000
Week 2				
N	15			15
Mean (SD)	140.267 (1.7099)			140.267 (1.7099)
Median	141.000			141.000
Min, Max	137.000, 142.000			137.000, 142.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	0.000 (1.9640)			0.000 (1.9640)
Median	0.000			0.000
Min, Max	-3.000, 3.000			-3.000, 3.000
Week 4				
N	2	13		15
Mean (SD)	137.500 (0.7071)	140.154 (2.2674)		139.800 (2.3053)
Median	137.500	140.000		140.000
Min, Max	137.000, 138.000	135.000, 143.000		135.000, 143.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-3.000 (1.4142)	-0.077 (1.9774)		-0.467 (2.1336)
Median	-3.000	0.000		-1.000
Min, Max	-4.000, -2.000	-3.000, 3.000		-4.000, 3.000
Week 6				
N	3	5	7	15
Mean (SD)	139.333 (0.5774)	139.800 (2.9496)	139.714 (1.2536)	139.667 (1.7995)
Median	139.000	140.000	140.000	140.000
Min, Max	139.000, 140.000	135.000, 143.000	138.000, 141.000	135.000, 143.000

Change from Baseline to Week 6

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	-1.667 (0.5774)	-0.400 (1.6733)	-0.286 (1.8898)	-0.600 (1.6388)
Median	-2.000	0.000	0.000	0.000
Min, Max	-2.000, -1.000	-2.000, 2.000	-4.000, 2.000	-4.000, 2.000
Week 8				
N	3	2	10	15
Mean (SD)	142.000 (2.6458)	141.000 (2.8284)	139.600 (2.1705)	140.267 (2.3745)
Median	143.000	141.000	140.000	140.000
Min, Max	139.000, 144.000	139.000, 143.000	135.000, 142.000	135.000, 144.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	1.000 (3.0000)	0.500 (0.7071)	-0.400 (1.3499)	0.000 (1.6903)
Median	1.000	0.500	0.000	0.000
Min, Max	-2.000, 4.000	0.000, 1.000	-2.000, 2.000	-2.000, 4.000
Week 12				
N	3	2	8	13
Mean (SD)	141.000 (1.0000)	142.000 (0.0000)	140.000 (1.8516)	140.538 (1.6641)
Median	141.000	142.000	140.500	141.000
Min, Max	140.000, 142.000	142.000, 142.000	137.000, 142.000	137.000, 142.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	0.000 (0.0000)	1.500 (2.1213)	0.500 (2.0702)	0.538 (1.7614)
Median	0.000	1.500	0.000	0.000
Min, Max	0.000, 0.000	0.000, 3.000	-2.000, 4.000	-2.000, 4.000
Week 16				
N	3	3	7	13
Mean (SD)	142.000 (1.0000)	140.667 (1.5275)	140.000 (2.3094)	140.615 (1.9807)
Median	142.000	141.000	140.000	141.000
Min, Max	141.000, 143.000	139.000, 142.000	137.000, 143.000	137.000, 143.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	1.000 (1.0000)	0.333 (3.0551)	0.571 (2.3705)	0.615 (2.1424)
Median	1.000	1.000	0.000	1.000
Min, Max	0.000, 2.000	-3.000, 3.000	-2.000, 5.000	-3.000, 5.000
Week 20				
N	4	3	6	13
Mean (SD)	142.000 (1.4142)	140.667 (1.5275)	140.500 (1.8708)	141.000 (1.6833)
Median	142.500	141.000	141.000	141.000
Min, Max	140.000, 143.000	139.000, 142.000	137.000, 142.000	137.000, 143.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	1.500 (0.5774)	0.333 (0.5774)	1.000 (1.6733)	1.000 (1.2247)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	1.500	0.000	0.000	1.000
Min, Max	1.000, 2.000	0.000, 1.000	0.000, 4.000	0.000, 4.000
Week 24				
N	4	3	6	13
Mean (SD)	141.750 (2.5000)	138.667 (1.1547)	140.500 (2.1679)	140.462 (2.2589)
Median	141.500	138.000	141.000	141.000
Min, Max	139.000, 145.000	138.000, 140.000	137.000, 143.000	137.000, 145.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	1.250 (2.0616)	-1.667 (2.0817)	1.000 (2.0000)	0.462 (2.2217)
Median	1.500	-1.000	1.000	0.000
Min, Max	-1.000, 3.000	-4.000, 0.000	-2.000, 3.000	-4.000, 3.000
Week 28				
N	5	3	7	15
Mean (SD)	142.000 (1.5811)	139.667 (2.3094)	139.714 (1.9760)	140.467 (2.0999)
Median	142.000	141.000	141.000	141.000
Min, Max	140.000, 144.000	137.000, 141.000	136.000, 141.000	136.000, 144.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	1.400 (1.6733)	-0.667 (2.5166)	-0.286 (1.7043)	0.200 (1.9346)
Median	1.000	-1.000	-1.000	0.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	0.000, 4.000	-3.000, 2.000	-2.000, 3.000	-3.000, 4.000
Week 32				
N	4	3	7	14
Mean (SD)	141.750 (2.7538)	140.667 (2.8868)	140.571 (2.0702)	140.929 (2.3027)
Median	141.500	139.000	141.000	140.500
Min, Max	139.000, 145.000	139.000, 144.000	137.000, 143.000	137.000, 145.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	0.750 (2.6300)	0.333 (1.5275)	0.571 (1.6183)	0.571 (1.7852)
Median	1.000	0.000	0.000	0.000
Min, Max	-2.000, 3.000	-1.000, 2.000	-2.000, 3.000	-2.000, 3.000
Week 36				
N	3	3	7	13
Mean (SD)	143.333 (0.5774)	141.000 (2.0000)	140.857 (2.4103)	141.462 (2.1839)
Median	143.000	141.000	141.000	142.000
Min, Max	143.000, 144.000	139.000, 143.000	136.000, 143.000	136.000, 144.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	2.333 (0.5774)	0.667 (2.8868)	0.857 (2.3401)	1.154 (2.1543)
Median	2.000	-1.000	1.000	1.000
Min, Max	2.000, 3.000	-1.000, 4.000	-3.000, 4.000	-3.000, 4.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	142.000 (2.2361)	140.333 (0.5774)	141.571 (2.3705)	141.467 (2.0656)
Median	142.000	140.000	141.000	141.000
Min, Max	139.000, 145.000	140.000, 141.000	138.000, 145.000	138.000, 145.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	1.400 (1.9494)	0.000 (1.0000)	1.571 (2.6367)	1.200 (2.1448)
Median	0.000	0.000	1.000	0.000
Min, Max	0.000, 4.000	-1.000, 1.000	-2.000, 6.000	-2.000, 6.000
Week 44				
N	5	3	7	15
Mean (SD)	141.400 (1.8166)	140.333 (1.5275)	140.286 (2.4976)	140.667 (2.0587)
Median	142.000	140.000	142.000	142.000
Min, Max	139.000, 143.000	139.000, 142.000	137.000, 143.000	137.000, 143.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	0.800 (2.2804)	0.000 (2.0000)	0.286 (3.5456)	0.400 (2.7464)
Median	1.000	0.000	1.000	1.000
Min, Max	-2.000, 3.000	-2.000, 2.000	-5.000, 4.000	-5.000, 4.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	142.200 (3.2711)	141.000 (1.0000)	140.571 (2.2254)	141.200 (2.4260)
Median	142.000	141.000	140.000	142.000
Min, Max	137.000, 145.000	140.000, 142.000	137.000, 143.000	137.000, 145.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	1.600 (3.6469)	0.667 (1.1547)	0.571 (1.3973)	0.933 (2.2509)
Median	2.000	0.000	1.000	1.000
Min, Max	-4.000, 6.000	0.000, 2.000	-2.000, 2.000	-4.000, 6.000
Early Term				
N	1		1	2
Mean (SD)	140.000 ()		145.000 ()	142.500 (3.5355)
Median	140.000		145.000	142.500
Min, Max	140.000, 140.000		145.000, 145.000	140.000, 145.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-1.000 ()		2.000 ()	0.500 (2.1213)
Median	-1.000		2.000	0.500
Min, Max	-1.000, -1.000		2.000, 2.000	-1.000, 2.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Thyrotropin (mIU/L)				
Baseline				
N	15			15
Mean (SD)	1.655 (0.8351)			1.655 (0.8351)
Median	1.470			1.470
Min, Max	0.930, 3.850			0.930, 3.850

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Thyroxine (nmol/L)				
Baseline				
N	15			15
Mean (SD)	112.333 (27.9148)			112.333 (27.9148)
Median	111.000			111.000
Min, Max	73.000, 176.000			73.000, 176.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Triglycerides (mmol/L)				
Baseline				
N	15			15
Mean (SD)	1.247 (0.5718)			1.247 (0.5718)
Median	1.000			1.000
Min, Max	0.700, 2.900			0.700, 2.900
Week 1				
N	15			15
Mean (SD)	1.160 (0.3776)			1.160 (0.3776)
Median	1.100			1.100
Min, Max	0.600, 2.200			0.600, 2.200
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.087 (0.4240)			-0.087 (0.4240)
Median	-0.100			-0.100
Min, Max	-0.700, 0.700			-0.700, 0.700
Week 2				
N	15			15
Mean (SD)	1.327 (0.5483)			1.327 (0.5483)
Median	1.200			1.200
Min, Max	0.700, 2.700			0.700, 2.700

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	0.080 (0.6538)			0.080 (0.6538)
Median	-0.100			-0.100
Min, Max	-0.800, 1.800			-0.800, 1.800
Week 4				
N	2	13		15
Mean (SD)	1.300 (0.2828)	1.477 (0.8064)		1.453 (0.7530)
Median	1.300	1.300		1.300
Min, Max	1.100, 1.500	0.600, 3.300		0.600, 3.300
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	-0.100 (0.4243)	0.254 (0.5441)		0.207 (0.5311)
Median	-0.100	0.100		0.100
Min, Max	-0.400, 0.200	-0.400, 1.600		-0.400, 1.600
Week 6				
N	3	5	7	15
Mean (SD)	1.467 (0.5508)	1.040 (0.1817)	1.400 (0.4865)	1.293 (0.4350)
Median	1.200	1.100	1.500	1.200
Min, Max	1.100, 2.100	0.800, 1.200	0.700, 2.200	0.700, 2.200
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	0.300 (0.1000)	0.040 (0.2074)	-0.057 (0.5094)	0.047 (0.3796)
Median	0.300	0.000	-0.100	0.000
Min, Max	0.200, 0.400	-0.100, 0.400	-0.700, 0.700	-0.700, 0.700
Week 8				
N	3	2	10	15
Mean (SD)	1.133 (0.2082)	0.900 (0.7071)	1.110 (0.3755)	1.087 (0.3720)
Median	1.200	0.900	1.100	1.100
Min, Max	0.900, 1.300	0.400, 1.400	0.600, 1.900	0.400, 1.900
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	-0.033 (0.4933)	-0.250 (0.4950)	-0.180 (0.4780)	-0.160 (0.4517)
Median	0.200	-0.250	-0.050	0.000
Min, Max	-0.600, 0.300	-0.600, 0.100	-1.000, 0.600	-1.000, 0.600
Week 12				
N	3	2	8	13
Mean (SD)	1.400 (0.3464)	1.100 (0.1414)	1.163 (0.3335)	1.208 (0.3148)
Median	1.600	1.100	1.100	1.100
Min, Max	1.000, 1.600	1.000, 1.200	0.800, 1.800	0.800, 1.800
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	0.300 (0.4000)	-0.050 (0.0707)	-0.100 (0.5318)	0.000 (0.4708)
Median	0.300	-0.050	0.000	0.000
Min, Max	-0.100, 0.700	-0.100, 0.000	-1.100, 0.600	-1.100, 0.700
Week 16				
N	3	3	7	13
Mean (SD)	1.267 (0.2082)	0.867 (0.4619)	1.257 (0.3645)	1.169 (0.3728)
Median	1.200	0.600	1.200	1.200
Min, Max	1.100, 1.500	0.600, 1.400	0.900, 2.000	0.600, 2.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	0.167 (0.3215)	-0.167 (0.2517)	-0.071 (0.4821)	-0.038 (0.3990)
Median	0.300	-0.200	0.000	0.000
Min, Max	-0.200, 0.400	-0.400, 0.100	-0.900, 0.600	-0.900, 0.600
Week 20				
N	4	3	6	13
Mean (SD)	1.150 (0.1915)	0.867 (0.3055)	1.367 (0.5955)	1.185 (0.4634)
Median	1.200	0.800	1.300	1.200
Min, Max	0.900, 1.300	0.600, 1.200	0.700, 2.200	0.600, 2.200
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	-0.050 (0.5260)	-0.167 (0.2082)	0.067 (0.6653)	-0.023 (0.5199)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	0.000	-0.100	-0.050	-0.100
Min, Max	-0.600, 0.400	-0.400, 0.000	-0.700, 1.100	-0.700, 1.100
Week 24				
N	4	3	6	13
Mean (SD)	1.050 (0.1915)	1.033 (0.2517)	1.400 (0.7183)	1.208 (0.5188)
Median	1.100	1.000	1.200	1.000
Min, Max	0.800, 1.200	0.800, 1.300	0.800, 2.600	0.800, 2.600
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	-0.150 (0.5260)	0.000 (0.2000)	0.100 (0.5657)	0.000 (0.4708)
Median	-0.100	0.000	-0.150	-0.100
Min, Max	-0.700, 0.300	-0.200, 0.200	-0.400, 1.000	-0.700, 1.000
Week 28				
N	5	3	7	15
Mean (SD)	1.300 (0.4359)	0.833 (0.2082)	1.671 (0.6626)	1.380 (0.5979)
Median	1.200	0.900	1.600	1.200
Min, Max	0.900, 2.000	0.600, 1.000	1.000, 2.900	0.600, 2.900
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	-0.040 (0.5727)	-0.200 (0.3464)	0.400 (0.5164)	0.133 (0.5434)
Median	0.300	-0.400	0.500	0.200

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-0.800, 0.500	-0.400, 0.200	-0.200, 1.300	-0.800, 1.300
Week 32				
N	4	3	7	14
Mean (SD)	1.175 (0.2217)	1.067 (0.3215)	1.229 (0.6626)	1.179 (0.4839)
Median	1.200	1.200	1.000	1.100
Min, Max	0.900, 1.400	0.700, 1.300	0.800, 2.700	0.700, 2.700
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	-0.125 (0.3775)	0.033 (0.4163)	-0.043 (0.2225)	-0.050 (0.2929)
Median	-0.100	-0.100	0.000	-0.050
Min, Max	-0.500, 0.200	-0.300, 0.500	-0.400, 0.300	-0.500, 0.500
Week 36				
N	3	3	7	13
Mean (SD)	0.933 (0.0577)	1.000 (0.1000)	1.343 (0.4036)	1.169 (0.3497)
Median	0.900	1.000	1.300	1.000
Min, Max	0.900, 1.000	0.900, 1.100	0.900, 2.100	0.900, 2.100
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	-0.167 (0.5508)	-0.033 (0.2309)	0.071 (0.4821)	-0.008 (0.4310)
Median	0.100	0.100	0.200	0.100
Min, Max	-0.800, 0.200	-0.300, 0.100	-0.800, 0.600	-0.800, 0.600

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	1.600 (0.7649)	1.100 (0.4583)	1.271 (0.5345)	1.347 (0.5986)
Median	1.200	1.000	1.200	1.200
Min, Max	1.000, 2.700	0.700, 1.600	0.500, 2.200	0.500, 2.700
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	0.260 (0.4722)	0.067 (0.2082)	0.000 (0.5538)	0.100 (0.4645)
Median	0.200	0.000	0.100	0.100
Min, Max	-0.300, 1.000	-0.100, 0.300	-0.700, 0.800	-0.700, 1.000
Week 44				
N	5	3	7	15
Mean (SD)	1.320 (0.3347)	0.867 (0.2517)	1.014 (0.3716)	1.087 (0.3642)
Median	1.300	0.900	0.900	1.000
Min, Max	0.900, 1.700	0.600, 1.100	0.500, 1.600	0.500, 1.700
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	-0.020 (0.3347)	-0.167 (0.2517)	-0.257 (0.5287)	-0.160 (0.4154)
Median	0.000	-0.200	-0.200	-0.200
Min, Max	-0.400, 0.400	-0.400, 0.100	-1.300, 0.400	-1.300, 0.400
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	1.120 (0.3962)	1.067 (0.3215)	1.329 (0.5345)	1.207 (0.4431)
Median	0.900	1.200	1.000	1.000
Min, Max	0.800, 1.600	0.700, 1.300	0.800, 2.300	0.700, 2.300
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	-0.220 (0.4438)	0.033 (0.3512)	0.057 (0.4995)	-0.040 (0.4453)
Median	-0.100	0.000	0.000	0.000
Min, Max	-0.900, 0.200	-0.300, 0.400	-0.600, 0.700	-0.900, 0.700
Early Term				
N	1		1	2
Mean (SD)	1.600 ()		1.200 ()	1.400 (0.2828)
Median	1.600		1.200	1.400
Min, Max	1.600, 1.600		1.200, 1.200	1.200, 1.600
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	-0.300 ()		0.100 ()	-0.100 (0.2828)
Median	-0.300		0.100	-0.100
Min, Max	-0.300, -0.300		0.100, 0.100	-0.300, 0.100

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Triiodothyronine (nmol/L)				
Baseline				
N	15			15
Mean (SD)	2.253 (0.5927)			2.253 (0.5927)
Median	2.300			2.300
Min, Max	1.200, 3.200			1.200, 3.200

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Urea (mmol/L)				
Baseline				
N	15			15
Mean (SD)	4.693 (1.4563)			4.693 (1.4563)
Median	4.600			4.600
Min, Max	2.000, 7.600			2.000, 7.600
Week 1				
N	15			15
Mean (SD)	4.993 (1.4786)			4.993 (1.4786)
Median	4.500			4.500
Min, Max	2.900, 7.700			2.900, 7.700
Change from Baseline to Week 1				
N	15			15
Mean (SD)	0.300 (1.2048)			0.300 (1.2048)
Median	0.500			0.500
Min, Max	-1.600, 2.400			-1.600, 2.400
Week 2				
N	15			15
Mean (SD)	4.900 (1.1225)			4.900 (1.1225)
Median	4.800			4.800
Min, Max	3.000, 7.300			3.000, 7.300

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	0.207 (1.1222)			0.207 (1.1222)
Median	0.100			0.100
Min, Max	-1.600, 2.700			-1.600, 2.700
Week 4				
N	2	13		15
Mean (SD)	4.850 (1.0607)	5.023 (1.7408)		5.000 (1.6375)
Median	4.850	4.400		4.400
Min, Max	4.100, 5.600	3.300, 9.300		3.300, 9.300
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	0.700 (1.9799)	0.246 (1.0453)		0.307 (1.1145)
Median	0.700	0.400		0.400
Min, Max	-0.700, 2.100	-1.100, 2.600		-1.100, 2.600
Week 6				
N	3	5	7	15
Mean (SD)	4.133 (0.9018)	4.680 (1.1735)	4.786 (1.5192)	4.620 (1.2508)
Median	4.200	4.600	4.400	4.400
Min, Max	3.200, 5.000	3.300, 6.400	2.900, 7.000	2.900, 7.000
Change from Baseline to Week 6				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	0.033 (1.2583)	-0.440 (0.4930)	0.143 (1.7615)	-0.073 (1.3035)
Median	0.200	-0.300	0.300	-0.200
Min, Max	-1.300, 1.200	-1.200, 0.100	-2.400, 3.000	-2.400, 3.000
Week 8				
N	3	2	10	15
Mean (SD)	4.100 (0.7810)	3.850 (2.3335)	5.220 (1.3911)	4.813 (1.4422)
Median	3.700	3.850	5.100	5.000
Min, Max	3.600, 5.000	2.200, 5.500	3.100, 7.400	2.200, 7.400
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	0.000 (1.5395)	-1.750 (0.4950)	0.530 (1.7334)	0.120 (1.7060)
Median	-0.400	-1.750	0.150	-0.200
Min, Max	-1.300, 1.700	-2.100, -1.400	-1.400, 4.900	-2.100, 4.900
Week 12				
N	3	2	8	13
Mean (SD)	4.300 (0.3606)	5.250 (2.3335)	4.750 (1.8739)	4.723 (1.6172)
Median	4.200	5.250	4.250	4.200
Min, Max	4.000, 4.700	3.600, 6.900	2.800, 8.500	2.800, 8.500
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-0.500 (0.9644)	-0.350 (0.4950)	0.025 (1.8813)	-0.154 (1.5158)
Median	-0.100	-0.350	-0.450	-0.300
Min, Max	-1.600, 0.200	-0.700, 0.000	-2.200, 3.400	-2.200, 3.400
Week 16				
N	3	3	7	13
Mean (SD)	5.033 (2.0984)	4.133 (1.6503)	4.543 (1.4593)	4.562 (1.5344)
Median	4.300	4.600	4.000	4.300
Min, Max	3.400, 7.400	2.300, 5.500	3.100, 6.800	2.300, 7.400
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	0.233 (2.7465)	-1.133 (1.0599)	-0.200 (2.0380)	-0.315 (1.9420)
Median	-0.600	-1.300	-0.800	-0.800
Min, Max	-2.000, 3.300	-2.100, 0.000	-1.600, 4.300	-2.100, 4.300
Week 20				
N	4	3	6	13
Mean (SD)	5.975 (3.4645)	5.100 (1.5000)	4.867 (1.3171)	5.262 (2.0863)
Median	4.600	5.100	4.700	4.800
Min, Max	3.600, 11.100	3.600, 6.600	3.200, 7.200	3.200, 11.100
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	1.750 (4.7290)	-0.167 (0.7638)	-0.250 (0.7556)	0.385 (2.6124)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	0.250	0.000	-0.100	0.000
Min, Max	-2.100, 8.600	-1.000, 0.500	-1.300, 0.500	-2.100, 8.600
Week 24				
N	4	3	6	13
Mean (SD)	5.350 (1.4083)	4.300 (1.3892)	5.100 (2.2935)	4.992 (1.7825)
Median	4.900	3.600	5.000	4.800
Min, Max	4.200, 7.400	3.400, 5.900	2.600, 8.100	2.600, 8.100
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	1.125 (2.8756)	-0.967 (0.7506)	-0.017 (2.1498)	0.115 (2.1744)
Median	0.850	-1.000	-0.300	-0.200
Min, Max	-2.100, 4.900	-1.700, -0.200	-2.300, 3.300	-2.300, 4.900
Week 28				
N	5	3	7	15
Mean (SD)	4.080 (0.9257)	4.367 (1.5144)	5.557 (2.4589)	4.827 (1.9170)
Median	3.600	3.700	4.700	4.500
Min, Max	3.300, 5.600	3.300, 6.100	3.700, 11.000	3.300, 11.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	0.300 (1.9532)	-0.900 (0.8718)	0.457 (1.7709)	0.133 (1.6834)
Median	-0.400	-1.300	0.100	-0.200

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-2.000, 3.100	-1.500, 0.100	-0.900, 4.300	-2.000, 4.300
Week 32				
N	4	3	7	14
Mean (SD)	4.475 (0.9287)	4.900 (2.0075)	4.343 (0.6803)	4.500 (1.0407)
Median	4.650	4.000	3.900	4.250
Min, Max	3.200, 5.400	3.500, 7.200	3.700, 5.400	3.200, 7.200
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	0.375 (1.4660)	-0.367 (0.7506)	-0.757 (0.6079)	-0.350 (1.0021)
Median	1.000	-0.400	-0.700	-0.500
Min, Max	-1.800, 1.300	-1.100, 0.400	-1.600, 0.200	-1.800, 1.300
Week 36				
N	3	3	7	13
Mean (SD)	4.100 (0.7810)	4.667 (1.0017)	4.657 (0.7323)	4.531 (0.7729)
Median	3.700	4.300	4.500	4.400
Min, Max	3.600, 5.000	3.900, 5.800	3.800, 5.700	3.600, 5.800
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	-0.700 (0.5196)	-0.600 (1.2530)	-0.443 (1.1487)	-0.538 (0.9896)
Median	-0.400	-0.700	-0.400	-0.400
Min, Max	-1.300, -0.400	-1.800, 0.700	-2.200, 1.200	-2.200, 1.200

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	4.920 (2.1776)	4.633 (0.8963)	4.057 (0.5127)	4.460 (1.3211)
Median	4.700	5.100	4.100	4.200
Min, Max	3.100, 8.600	3.600, 5.200	3.300, 4.900	3.100, 8.600
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	1.140 (2.9720)	-0.633 (1.6442)	-1.043 (0.8886)	-0.233 (2.0697)
Median	0.700	0.000	-1.200	-0.600
Min, Max	-1.600, 6.100	-2.500, 0.600	-2.700, 0.100	-2.700, 6.100
Week 44				
N	5	3	7	15
Mean (SD)	5.060 (1.4571)	4.667 (2.3756)	3.986 (0.9703)	4.480 (1.4374)
Median	5.900	3.500	4.100	4.100
Min, Max	2.800, 6.300	3.100, 7.400	2.700, 5.800	2.700, 7.400
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	1.280 (1.6162)	-0.600 (0.7810)	-1.114 (1.0991)	-0.213 (1.6080)
Median	0.800	-0.200	-1.200	-0.400
Min, Max	-0.400, 3.800	-1.500, -0.100	-2.600, 0.800	-2.600, 3.800
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	4.800 (1.3509)	5.133 (2.0984)	4.457 (0.6779)	4.707 (1.1919)
Median	5.600	4.400	4.200	4.400
Min, Max	3.000, 5.900	3.500, 7.500	3.400, 5.500	3.000, 7.500
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	1.020 (1.6453)	-0.133 (0.9504)	-0.643 (0.5442)	0.013 (1.2693)
Median	1.000	-0.100	-0.600	-0.300
Min, Max	-0.700, 3.400	-1.100, 0.800	-1.200, 0.200	-1.200, 3.400
Early Term				
N	1		1	2
Mean (SD)	4.300 ()		5.900 ()	5.100 (1.1314)
Median	4.300		5.900	5.100
Min, Max	4.300, 4.300		5.900, 5.900	4.300, 5.900
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	2.300 ()		0.900 ()	1.600 (0.9899)
Median	2.300		0.900	1.600
Min, Max	2.300, 2.300		0.900, 0.900	0.900, 2.300

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Uric acid (umol/L)				
Baseline				
N	15			15
Mean (SD)	309.000 (46.7027)			309.000 (46.7027)
Median	302.000			302.000
Min, Max	210.000, 369.000			210.000, 369.000
Week 1				
N	15			15
Mean (SD)	308.200 (51.3659)			308.200 (51.3659)
Median	308.000			308.000
Min, Max	199.000, 415.000			199.000, 415.000
Change from Baseline to Week 1				
N	15			15
Mean (SD)	-0.800 (47.6808)			-0.800 (47.6808)
Median	-6.000			-6.000
Min, Max	-63.000, 116.000			-63.000, 116.000
Week 2				
N	15			15
Mean (SD)	310.000 (54.1532)			310.000 (54.1532)
Median	316.000			316.000
Min, Max	210.000, 397.000			210.000, 397.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Change from Baseline to Week 2				
N	15			15
Mean (SD)	1.000 (43.9821)			1.000 (43.9821)
Median	-6.000			-6.000
Min, Max	-52.000, 109.000			-52.000, 109.000
Week 4				
N	2	13		15
Mean (SD)	275.500 (86.9741)	319.923 (60.6952)		314.000 (62.7876)
Median	275.500	298.000		298.000
Min, Max	214.000, 337.000	237.000, 434.000		214.000, 434.000
Change from Baseline to Week 4				
N	2	13		15
Mean (SD)	27.000 (32.5269)	1.615 (61.7529)		5.000 (58.5150)
Median	27.000	-25.000		-3.000
Min, Max	4.000, 50.000	-92.000, 136.000		-92.000, 136.000
Week 6				
N	3	5	7	15
Mean (SD)	320.667 (123.7794)	351.400 (77.7515)	304.143 (70.4685)	323.200 (80.6918)
Median	360.000	339.000	321.000	339.000
Min, Max	182.000, 420.000	268.000, 474.000	218.000, 394.000	182.000, 474.000

Change from Baseline to Week 6

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	3	5	7	15
Mean (SD)	60.333 (82.7305)	26.000 (55.7763)	-14.000 (71.6426)	14.200 (70.4964)
Median	73.000	39.000	-38.000	1.000
Min, Max	-28.000, 136.000	-34.000, 105.000	-117.000, 113.000	-117.000, 136.000
Week 8				
N	3	2	10	15
Mean (SD)	275.000 (67.0149)	304.500 (12.0208)	337.100 (106.6234)	320.333 (92.9367)
Median	296.000	304.500	316.000	296.000
Min, Max	200.000, 329.000	296.000, 313.000	220.000, 550.000	200.000, 550.000
Change from Baseline to Week 8				
N	3	2	10	15
Mean (SD)	14.667 (27.9344)	-24.500 (10.6066)	17.500 (121.0246)	11.333 (98.7339)
Median	9.000	-24.500	-21.500	-17.000
Min, Max	-10.000, 45.000	-32.000, -17.000	-127.000, 296.000	-127.000, 296.000
Week 12				
N	3	2	8	13
Mean (SD)	279.000 (14.0000)	262.500 (4.9497)	311.875 (89.6253)	296.692 (71.7442)
Median	273.000	262.500	308.500	283.000
Min, Max	269.000, 295.000	259.000, 266.000	175.000, 414.000	175.000, 414.000
Change from Baseline to Week 12				
N	3	2	8	13

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Mean (SD)	-6.333 (12.5033)	-66.500 (6.3640)	-14.750 (89.9345)	-20.769 (71.9191)
Median	-12.000	-66.500	-26.000	-15.000
Min, Max	-15.000, 8.000	-71.000, -62.000	-144.000, 143.000	-144.000, 143.000
Week 16				
N	3	3	7	13
Mean (SD)	319.000 (25.7099)	321.667 (97.3875)	287.571 (66.5704)	302.692 (64.7809)
Median	328.000	270.000	296.000	296.000
Min, Max	290.000, 339.000	261.000, 434.000	187.000, 363.000	187.000, 434.000
Change from Baseline to Week 16				
N	3	3	7	13
Mean (SD)	33.667 (24.3790)	-20.667 (74.2720)	-33.000 (78.0000)	-14.769 (69.6385)
Median	43.000	-60.000	-54.000	-20.000
Min, Max	6.000, 52.000	-67.000, 65.000	-135.000, 108.000	-135.000, 108.000
Week 20				
N	4	3	6	13
Mean (SD)	345.250 (97.1301)	294.000 (52.1153)	279.667 (59.6378)	303.154 (71.9767)
Median	335.500	268.000	299.500	295.000
Min, Max	244.000, 466.000	260.000, 354.000	189.000, 336.000	189.000, 466.000
Change from Baseline to Week 20				
N	4	3	6	13
Mean (SD)	67.750 (110.3460)	-48.333 (29.2973)	-52.000 (46.3897)	-14.308 (85.6041)

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Median	49.500	-60.000	-47.500	-38.000
Min, Max	-40.000, 212.000	-70.000, -15.000	-128.000, 7.000	-128.000, 212.000
Week 24				
N	4	3	6	13
Mean (SD)	316.000 (45.4459)	341.000 (60.5558)	275.167 (48.9997)	302.923 (54.1533)
Median	310.000	338.000	282.500	307.000
Min, Max	273.000, 371.000	282.000, 403.000	211.000, 333.000	211.000, 403.000
Change from Baseline to Week 24				
N	4	3	6	13
Mean (SD)	38.500 (51.0979)	-1.333 (40.8085)	-56.500 (46.0641)	-14.538 (60.6309)
Median	41.000	8.000	-55.500	-12.000
Min, Max	-12.000, 84.000	-46.000, 34.000	-122.000, 9.000	-122.000, 84.000
Week 28				
N	5	3	7	15
Mean (SD)	311.600 (42.2706)	334.333 (28.2902)	307.857 (58.9447)	314.400 (47.1514)
Median	323.000	339.000	330.000	330.000
Min, Max	255.000, 351.000	304.000, 360.000	177.000, 342.000	177.000, 360.000
Change from Baseline to Week 28				
N	5	3	7	15
Mean (SD)	47.600 (36.3291)	-8.000 (33.0454)	-19.000 (42.8719)	5.400 (47.8850)
Median	45.000	-24.000	-20.000	-3.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Min, Max	-3.000, 97.000	-30.000, 30.000	-85.000, 36.000	-85.000, 97.000
Week 32				
N	4	3	7	14
Mean (SD)	304.750 (66.0776)	354.667 (78.3092)	322.857 (63.9751)	324.500 (64.5872)
Median	328.500	313.000	339.000	336.500
Min, Max	210.000, 352.000	306.000, 445.000	190.000, 383.000	190.000, 445.000
Change from Baseline to Week 32				
N	4	3	7	14
Mean (SD)	38.250 (31.4470)	12.333 (55.1936)	-4.000 (42.5754)	11.571 (43.3957)
Median	44.000	-17.000	5.000	10.500
Min, Max	0.000, 65.000	-22.000, 76.000	-72.000, 41.000	-72.000, 76.000
Week 36				
N	3	3	7	13
Mean (SD)	312.000 (25.1197)	336.667 (36.0185)	321.429 (55.2173)	322.769 (43.8656)
Median	298.000	338.000	326.000	326.000
Min, Max	297.000, 341.000	300.000, 372.000	205.000, 374.000	205.000, 374.000
Change from Baseline to Week 36				
N	3	3	7	13
Mean (SD)	26.667 (23.6925)	-5.667 (19.5021)	-5.429 (31.6694)	1.923 (29.2816)
Median	14.000	3.000	4.000	7.000
Min, Max	12.000, 54.000	-28.000, 8.000	-57.000, 34.000	-57.000, 54.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Week 40				
N	5	3	7	15
Mean (SD)	302.600 (50.8163)	338.000 (52.8488)	311.714 (60.8734)	313.933 (53.8271)
Median	305.000	309.000	329.000	322.000
Min, Max	233.000, 371.000	306.000, 399.000	189.000, 380.000	189.000, 399.000
Change from Baseline to Week 40				
N	5	3	7	15
Mean (SD)	38.600 (46.0033)	-4.333 (29.7377)	-15.143 (44.0546)	4.933 (46.7707)
Median	23.000	-21.000	-11.000	18.000
Min, Max	-2.000, 117.000	-22.000, 30.000	-73.000, 31.000	-73.000, 117.000
Week 44				
N	5	3	7	15
Mean (SD)	312.800 (39.2135)	311.333 (42.9224)	318.286 (63.5471)	315.067 (49.4288)
Median	293.000	326.000	336.000	326.000
Min, Max	284.000, 375.000	263.000, 345.000	183.000, 377.000	183.000, 377.000
Change from Baseline to Week 44				
N	5	3	7	15
Mean (SD)	48.800 (50.2364)	-31.000 (31.0966)	-8.571 (38.4918)	6.067 (50.4770)
Median	43.000	-24.000	5.000	5.000
Min, Max	0.000, 121.000	-65.000, -4.000	-79.000, 38.000	-79.000, 121.000
Week 48				

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.

Table 14.4.3.2
Laboratory Summary - Clinical Chemistry
(Safety Analysis Set)

Parameter (unit) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
N	5	3	7	15
Mean (SD)	300.000 (47.0478)	353.000 (44.2380)	316.286 (53.1028)	318.200 (50.0017)
Median	323.000	365.000	339.000	326.000
Min, Max	226.000, 343.000	304.000, 390.000	217.000, 374.000	217.000, 390.000
Change from Baseline to Week 48				
N	5	3	7	15
Mean (SD)	36.000 (34.1541)	10.667 (30.8275)	-10.571 (43.2044)	9.200 (41.4904)
Median	38.000	21.000	-3.000	16.000
Min, Max	-2.000, 89.000	-24.000, 35.000	-69.000, 41.000	-69.000, 89.000
Early Term				
N	1		1	2
Mean (SD)	249.000 ()		368.000 ()	308.500 (84.1457)
Median	249.000		368.000	308.500
Min, Max	249.000, 249.000		368.000, 368.000	249.000, 368.000
Change from Baseline to Early Term				
N	1		1	2
Mean (SD)	39.000 ()		70.000 ()	54.500 (21.9203)
Median	39.000		70.000	54.500
Min, Max	39.000, 39.000		70.000, 70.000	39.000, 70.000

Baseline is the last non-missing value obtained prior to the first dose of study drug.
Patients are summarized under the dose received at the corresponding visit.