

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)
<b>Basophils (10<sup>9</sup>/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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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Laboratory Summary - Hematology  
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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)
<b>Eosinophils (10<sup>9</sup>/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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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Laboratory Summary - Hematology  
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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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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

Baseline is the last non-missing value 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)	0.178 ( 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)
<b>Erythrocytes (10<sup>12</sup>/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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)
<b>Leukocytes (10<sup>9</sup>/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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 <sup>9</sup> /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)
<b>Monocytes (10<sup>9</sup>/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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)
<b>Neutrophils Band Form (10<sup>9</sup>/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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 <sup>9</sup> /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)
<b>Platelets (10<sup>9</sup>/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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)
<b>Bilirubin (umol/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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)
<b>Blood Urea Nitrogen (mg/dL)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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)
<b>Cholesterol (mmol/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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)
<b>Creatine Kinase (IU/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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)
<b>Gamma Glutamyl Transferase (IU/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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)
<b>Indirect Bilirubin (umol/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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)
<b>Lactate Dehydrogenase (IU/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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)
<b>Magnesium (mmol/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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)
<b>Potassium (mmol/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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)
<b>Protein (g/L)</b>				
<b>Baseline</b>				
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
<b>Week 1</b>				
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
<b>Change from Baseline to Week 1</b>				
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
<b>Week 2</b>				
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	

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Baseline is the last non-missing value 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)

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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.