

Table 14.2.1.1  
Summary of Hepatitis D RNA (log<sub>10</sub> IU/mL) by Dose Level and Visit  
(Efficacy Analysis Set)

Visit	50 mg/100 mg (N=13)	75 mg/100 mg (N=12)	100 mg/100 mg (N=9)	Overall (N=13)
<b>Baseline</b>				
N	13			13
Mean (SD)	4.58 ( 1.093)			4.58 ( 1.093)
Median	4.44			4.44
Min, Max	2.76, 6.28			2.76, 6.28
<b>Week 1</b>				
N	13			13
Mean (SD)	3.55 ( 1.040)			3.55 ( 1.040)
Median	3.55			3.55
Min, Max	2.13, 5.50			2.13, 5.50
<b>Change from Baseline to Week 1</b>				
N	13			13
Mean (SD)	-1.03 ( 0.599)			-1.03 ( 0.599)
Median	-1.03			-1.03
Min, Max	-1.89, -0.07			-1.89, -0.07

Baseline is the geometric mean of the Screening and Day 1 (pre-treatment) visits.  
Patients are summarized under the dose received at the corresponding visit.  
Patients during the follow-up period, after Week 24, are summarized under the last dose level received.

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<b>Week 2</b>				
N	13			13
Mean (SD)	3.57 ( 1.125)			3.57 ( 1.125)
Median	3.62			3.62
Min, Max	1.89, 5.39			1.89, 5.39
<b>Change from Baseline to Week 2</b>				
N	13			13
Mean (SD)	-1.01 ( 0.935)			-1.01 ( 0.935)
Median	-0.80			-0.80
Min, Max	-2.32, 0.84			-2.32, 0.84
<b>Week 4</b>				
N	1	12		13
Mean (SD)	3.01 ( )	3.13 ( 1.283)		3.12 ( 1.229)
Median	3.01	3.14		3.01
Min, Max	3.01, 3.01	1.11, 5.33		1.11, 5.33
<b>Change from Baseline to Week 4</b>				
N	1	12		13
Mean (SD)	-1.43 ( )	-1.47 ( 0.929)		-1.47 ( 0.890)
Median	-1.43	-1.40		-1.43
Min, Max	-1.43, -1.43	-2.91, -0.05		-2.91, -0.05

Baseline is the geometric mean of the Screening and Day 1 (pre-treatment) visits.  
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<b>Week 6</b>				
N	2	4	7	13
Mean (SD)	3.09 ( 1.025)	3.27 ( 1.310)	2.60 ( 0.856)	2.88 ( 0.994)
Median	3.09	3.29	2.38	2.73
Min, Max	2.36, 3.81	1.75, 4.76	1.30, 3.82	1.30, 4.76
<b>Change from Baseline to Week 6</b>				
N	2	4	7	13
Mean (SD)	-2.27 ( 0.276)	-1.43 ( 0.634)	-1.70 ( 1.393)	-1.70 ( 1.075)
Median	-2.27	-1.32	-1.64	-1.64
Min, Max	-2.47, -2.08	-2.29, -0.81	-3.17, 1.07	-3.17, 1.07
<b>Week 8</b>				
N	2	2	9	13
Mean (SD)	3.12 ( 0.813)	3.22 ( 0.247)	2.62 ( 1.174)	2.79 ( 1.024)
Median	3.12	3.22	2.44	3.04
Min, Max	2.54, 3.69	3.04, 3.39	1.11, 4.57	1.11, 4.57
<b>Change from Baseline to Week 8</b>				
N	2	2	9	13
Mean (SD)	-2.24 ( 0.488)	-1.96 ( 1.591)	-1.66 ( 0.746)	-1.80 ( 0.808)
Median	-2.24	-1.96	-1.63	-1.79
Min, Max	-2.59, -1.90	-3.09, -0.84	-2.87, -0.32	-3.09, -0.32

Baseline is the geometric mean of the Screening and Day 1 (pre-treatment) visits.  
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Table 14.2.1.1  
Summary of Hepatitis D RNA (log10 IU/mL) by Dose Level and Visit  
(Efficacy Analysis Set)

Visit	50 mg/100 mg (N=13)	75 mg/100 mg (N=12)	100 mg/100 mg (N=9)	Overall (N=13)
<b>Week 12</b>				
N	3	2	8	13
Mean (SD)	2.71 ( 0.928)	3.04 ( 0.785)	2.46 ( 1.397)	2.60 ( 1.175)
Median	2.95	3.04	1.76	2.48
Min, Max	1.69, 3.50	2.48, 3.59	1.11, 4.82	1.11, 4.82
<b>Change from Baseline to Week 12</b>				
N	3	2	8	13
Mean (SD)	-2.47 ( 0.508)	-2.14 ( 0.559)	-1.76 ( 0.634)	-1.98 ( 0.633)
Median	-2.75	-2.14	-1.84	-1.90
Min, Max	-2.78, -1.88	-2.54, -1.75	-2.45, -0.75	-2.78, -0.75
<b>Week 16</b>				
N	3	3	7	13
Mean (SD)	2.59 ( 1.074)	2.82 ( 0.248)	2.34 ( 1.244)	2.51 ( 1.009)
Median	2.94	2.71	1.67	2.71
Min, Max	1.38, 3.44	2.64, 3.10	1.11, 4.37	1.11, 4.37
<b>Change from Baseline to Week 16</b>				
N	3	3	7	13
Mean (SD)	-2.59 ( 0.619)	-1.60 ( 1.700)	-2.06 ( 0.656)	-2.08 ( 0.941)
Median	-2.84	-1.13	-2.17	-2.17
Min, Max	-3.06, -1.89	-3.49, -0.19	-2.92, -1.20	-3.49, -0.19

Baseline is the geometric mean of the Screening and Day 1 (pre-treatment) visits.  
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Table 14.2.1.1  
Summary of Hepatitis D RNA (log10 IU/mL) by Dose Level and Visit  
(Efficacy Analysis Set)

Visit	50 mg/100 mg (N=13)	75 mg/100 mg (N=12)	100 mg/100 mg (N=9)	Overall (N=13)
<b>Week 20</b>				
N	4	3	6	13
Mean (SD)	2.81 ( 1.059)	3.10 ( 1.244)	2.69 ( 1.566)	2.82 ( 1.260)
Median	3.22	2.40	2.45	2.75
Min, Max	1.26, 3.54	2.37, 4.54	1.11, 4.91	1.11, 4.91
<b>Change from Baseline to Week 20</b>				
N	4	3	6	13
Mean (SD)	-1.77 ( 0.647)	-1.31 ( 2.132)	-1.98 ( 0.970)	-1.76 ( 1.153)
Median	-1.47	-0.53	-2.13	-1.50
Min, Max	-2.74, -1.39	-3.73, 0.32	-3.22, -0.66	-3.73, 0.32
<b>Week 24</b>				
N	4	3	6	13
Mean (SD)	3.06 ( 1.099)	3.18 ( 1.143)	2.79 ( 1.616)	2.96 ( 1.280)
Median	3.23	3.34	2.98	3.34
Min, Max	1.67, 4.12	1.97, 4.24	0.85, 4.51	0.85, 4.51
<b>Change from Baseline to Week 24</b>				
N	4	3	6	13
Mean (SD)	-1.51 ( 0.803)	-1.23 ( 2.766)	-1.88 ( 1.017)	-1.62 ( 1.394)
Median	-1.40	-0.89	-1.60	-1.41
Min, Max	-2.55, -0.71	-4.16, 1.35	-3.48, -0.71	-4.16, 1.35

Baseline is the geometric mean of the Screening and Day 1 (pre-treatment) visits.  
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Table 14.2.1.1  
Summary of Hepatitis D RNA (log10 IU/mL) by Dose Level and Visit  
(Efficacy Analysis Set)

Visit	50 mg/100 mg (N=13)	75 mg/100 mg (N=12)	100 mg/100 mg (N=9)	Overall (N=13)
<b>Week 28</b>				
N	4	3	6	13
Mean (SD)	4.86 ( 1.955)	4.66 ( 1.476)	3.96 ( 2.065)	4.40 ( 1.811)
Median	4.67	4.29	4.67	4.29
Min, Max	2.92, 7.19	3.41, 6.29	1.26, 6.24	1.26, 7.19
<b>Change from Baseline to Week 28</b>				
N	4	3	6	13
Mean (SD)	0.29 ( 0.814)	0.25 ( 2.772)	-0.71 ( 1.551)	-0.18 ( 1.646)
Median	0.53	-0.82	-0.12	0.04
Min, Max	-0.82, 0.92	-1.84, 3.40	-3.07, 1.02	-3.07, 3.40
<b>Week 32</b>				
N	3	3	6	12
Mean (SD)	5.55 ( 2.218)	4.70 ( 0.315)	3.71 ( 1.940)	4.42 ( 1.807)
Median	5.69	4.87	3.68	4.31
Min, Max	3.26, 7.69	4.34, 4.90	1.11, 6.88	1.11, 7.69
<b>Change from Baseline to Week 32</b>				
N	3	3	6	12
Mean (SD)	0.37 ( 1.364)	0.29 ( 1.637)	-0.96 ( 1.698)	-0.32 ( 1.610)
Median	0.86	0.12	-1.22	-0.51
Min, Max	-1.18, 1.42	-1.26, 2.01	-3.22, 1.66	-3.22, 2.01

Baseline is the geometric mean of the Screening and Day 1 (pre-treatment) visits.  
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Visit	50 mg/100 mg (N=13)	75 mg/100 mg (N=12)	100 mg/100 mg (N=9)	Overall (N=13)
<b>Week 36</b>				
N	3	3	6	12
Mean (SD)	5.78 ( 1.878)	4.79 ( 1.058)	3.70 ( 1.747)	4.49 ( 1.748)
Median	6.04	4.69	3.84	4.18
Min, Max	3.79, 7.52	3.78, 5.89	1.18, 6.43	1.18, 7.52
<b>Change from Baseline to Week 36</b>				
N	3	3	6	12
Mean (SD)	0.60 ( 1.081)	0.37 ( 0.566)	-0.98 ( 1.509)	-0.24 ( 1.378)
Median	1.21	0.47	-1.23	-0.04
Min, Max	-0.65, 1.25	-0.24, 0.89	-3.15, 1.21	-3.15, 1.25
<b>Week 40</b>				
N	4	3	6	13
Mean (SD)	5.24 ( 0.946)	5.11 ( 1.193)	3.73 ( 1.852)	4.51 ( 1.569)
Median	5.08	5.31	3.88	4.60
Min, Max	4.30, 6.49	3.83, 6.19	1.18, 6.40	1.18, 6.49
<b>Change from Baseline to Week 40</b>				
N	4	3	6	13
Mean (SD)	0.66 ( 0.945)	0.70 ( 0.551)	-0.95 ( 1.599)	-0.07 ( 1.431)
Median	0.38	0.94	-1.22	0.22
Min, Max	-0.14, 2.02	0.07, 1.09	-2.60, 1.18	-2.60, 2.02

Baseline is the geometric mean of the Screening and Day 1 (pre-treatment) visits.  
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Visit	50 mg/100 mg (N=13)	75 mg/100 mg (N=12)	100 mg/100 mg (N=9)	Overall (N=13)
<b>Week 44</b>				
N	4	3	6	13
Mean (SD)	5.22 ( 1.632)	4.41 ( 0.823)	3.33 ( 1.710)	4.16 ( 1.653)
Median	4.93	4.87	3.20	3.91
Min, Max	3.85, 7.19	3.46, 4.90	1.15, 6.11	1.15, 7.19
<b>Change from Baseline to Week 44</b>				
N	4	3	6	13
Mean (SD)	0.65 ( 0.829)	-0.01 ( 1.057)	-1.34 ( 1.505)	-0.42 ( 1.467)
Median	1.01	0.57	-1.76	0.04
Min, Max	-0.59, 1.16	-1.23, 0.65	-2.85, 0.89	-2.85, 1.16
<b>Week 48</b>				
N	4	3	6	13
Mean (SD)	4.85 ( 1.539)	4.91 ( 1.432)	3.41 ( 1.770)	4.20 ( 1.679)
Median	4.52	5.70	3.47	4.45
Min, Max	3.39, 6.96	3.26, 5.78	1.11, 5.73	1.11, 6.96
<b>Change from Baseline to Week 48</b>				
N	4	3	6	13
Mean (SD)	0.27 ( 0.475)	0.50 ( 0.997)	-1.27 ( 1.595)	-0.39 ( 1.418)
Median	0.35	0.37	-1.40	0.07
Min, Max	-0.31, 0.69	-0.43, 1.56	-3.09, 0.51	-3.09, 1.56

Baseline is the geometric mean of the Screening and Day 1 (pre-treatment) visits.  
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