13. Laboratory Evaluations 13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits OLE Population

			Overall (N=6)
Parameter (Unit)	Visit	Statistics	n (%)
Alanine aminotransferase (U/L)	V5 (OLE Week 2)	n	6
(1,7,7,7,7,7,7,7,7,7,7,7,7,7,7,7,7,7,7,7	,	No tox to No tox	6 (100.0)
	V6 (OLE Month 1)	n	6
	,	No tox to No tox	6 (100.0)
	V7 (OLE Month 2)	n	3
	,	No tox to No tox	3 (100.0)
	V8 (OLE Month 3)	n	3
		No tox to No tox	3 (100.0)
	V11 (OLE Month 12)	n	2
		No tox to No tox	2 (100.0)
	V12 (End of Taper after	c OLEn	1
	period)	No tox to No tox	1 (100.0)

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits OLE Population

			Overall (N=6)	
Parameter (Unit)	Visit	Statistics	n (%)	
Albumin (g/L)	V5 (OLE Week 2)	n	6	
		No tox to No tox	6 (100.0)	
	V6 (OLE Month 1)	n	6	
		No tox to No tox	6 (100.0)	
	V7 (OLE Month 2)	n	3	
		No tox to No tox	3 (100.0)	
	V8 (OLE Month 3)	n	3	
		No tox to No tox	3 (100.0)	
	V11 (OLE Month 12)	n	2	
		No tox to No tox	2 (100.0)	
	V12 (End of Taper after	OLEn	1	
	period)	No tox to No tox	1 (100.0)	

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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13. Laboratory Evaluations 13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits OLE Population

			Overall (N=6)	
Parameter (Unit)	Visit	Statistics	n (%)	
Alkaline phosphatase (U/L)	V5 (OLE Week 2)	n	6	
	,	No tox to No tox	6 (100.0)	
	V6 (OLE Month 1)	n	6	
		No tox to No tox	6 (100.0)	
	V7 (OLE Month 2)	n	3	
	,	No tox to No tox	3 (100.0)	
	V8 (OLE Month 3)	n	3	
		No tox to No tox	3 (100.0)	
	V11 (OLE Month 12)	n	2	
		No tox to No tox	2 (100.0)	
	V12 (End of Taper after	COLEn	1	
	period)	No tox to No tox	1 (100.0)	

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits OLE Population

			Overall (N=6)
Parameter (Unit)	Visit	Statistics	n (%)
Aspartate aminotransferase (U/L)	V5 (OLE Week 2)	n Na tau ta Na tau	6
		No tox to No tox	6 (100.0)
	V6 (OLE Month 1)	n	6
		No tox to No tox	6 (100.0)
	V7 (OLE Month 2)	n	3
		No tox to No tox	3 (100.0)
	V8 (OLE Month 3)	n	3
		No tox to No tox	3 (100.0)
	V11 (OLE Month 12)	n	2
		No tox to No tox	2 (100.0)
	V12 (End of Taper after	OLEn	1
	period)	No tox to No tox	1 (100.0)

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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13. Laboratory Evaluations 13.1. Biochemistry

OLE Population

13.1.4. Shift from Baseline Based on Toxicity Limits

			Overall (N=6)	
Parameter (Unit)	Visit	Statistics	n (%)	
Calcium (mmol/L)	V5 (OLE Week 2)	n	6	
		No tox to No tox	6 (100.0)	
	V6 (OLE Month 1)	n	6	
		No tox to No tox	6 (100.0)	
	V7 (OLE Month 2)	n	3	
		No tox to No tox	3 (100.0)	
	V8 (OLE Month 3)	n	3	
		No tox to No tox	3 (100.0)	
	V11 (OLE Month 12)	n	2	
		No tox to No tox	2 (100.0)	
	V12 (End of Taper after	OLEn	1	
	period)	No tox to No tox	1 (100.0)	

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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13. Laboratory Evaluations 13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

			Overall (N=6)
Parameter (Unit)	Visit	Statistics	n (%)
Creatinine (Jaffe) (umol/L)	V5 (OLE Week 2)	n	6
		No tox to No tox	6 (100.0)
	V6 (OLE Month 1)	n	6
		No tox to No tox	6 (100.0)
	V7 (OLE Month 2)	n	3
		No tox to No tox	3 (100.0)
	V8 (OLE Month 3)	n	3
	,	No tox to No tox	3 (100.0)
	V11 (OLE Month 12)	n	2
	,	No tox to No tox	2 (100.0)
	V12 (End of Taper after	COLEn	1
	period)	No tox to No tox	1 (100.0)

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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13. Laboratory Evaluations 13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits OLE Population

			Overall (N=6)
Parameter (Unit)	Visit	Statistics	n (%)
Gamma-glutamyl transferase (U/L)	V5 (OLE Week 2)	n	6
oanina gracanyr cranbrorade (0,1)	vo (old week 2)	No tox to No tox	5 (83.3)
		No tox to Tox	1 (16.7)
		increased	1 (10.7)
	776 (077) (1)		6
	V6 (OLE Month 1)	n	6
		No tox to No tox	5 (83.3)
		No tox to Tox	1 (16.7)
		increased	
	V7 (OLE Month 2)	n	3
		No tox to No tox	2 (66.7)
		No tox to Tox	1 (33.3)
		increased	
	V8 (OLE Month 3)	n	3
	vo (old honon b)	No tox to No tox	2 (66.7)
		No tox to Tox	1 (33.3)
		increased	1 (33.3)
	7/11 (OTE Manth 10)	_	2
	V11 (OLE Month 12)	n	2
		No tox to No tox	1 (50.0)
		No tox to Tox	1 (50.0)
		increased	

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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13. Laboratory Evaluations 13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits OLE Population

			Overall (N=6)	
Parameter (Unit)	Visit	Statistics	n (%)	
Gamma-glutamyl transferase (U/L)	V12 (End of Taper after	COLEn	1	
	period)	No tox to No tox	1 (100.0)	
Glucose (blood) (mmol/L)	V5 (OLE Week 2)	n	6	
		No tox to No tox	6 (100.0)	
	V6 (OLE Month 1)	n	6	
		No tox to No tox	6 (100.0)	
	V7 (OLE Month 2)	n	3	
		No tox to No tox	3 (100.0)	
	V8 (OLE Month 3)	n	3	
		No tox to No tox	3 (100.0)	
	V11 (OLE Month 12)	n	2	
	,	No tox to No tox	2 (100.0)	

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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13. Laboratory Evaluations 13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits OLE Population

			Overall (N=6)	
Parameter (Unit)	Visit	Statistics	n (%)	
Glucose (blood) (mmol/L)	V12 (End of Taper afte	er OLEn	1	
	period)	No tox to No tox	1 (100.0)	
HDL-cholesterol (mmol/L)	V5 (OLE Week 2)	n	6	
		No tox to No tox	5 (83.3)	
		Tox increased to No	1 (16.7)	
		tox		
	V6 (OLE Month 1)	n	6	
		No tox to No tox	5 (83.3)	
		Tox increased to No	1 (16.7)	
		tox		
	V7 (OLE Month 2)	n	3	
		No tox to No tox	3 (100.0)	
	V8 (OLE Month 3)	n	3	
		No tox to No tox	3 (100.0)	

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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13. Laboratory Evaluations 13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

			Overall (N=6)	
Parameter (Unit)	Visit	Statistics	n (%)	
HDL-cholesterol (mmol/L)	V11 (OLE Month 12)	n	2	
, , ,	,	No tox to No tox	1 (50.0)	
		Tox increased to Tox increased	1 (50.0)	
	V12 (End of Taper after	COLEn	1	
	period)	No tox to No tox	1 (100.0)	
Potassium (mmol/L)	V5 (OLE Week 2)	n	6	
		No tox to No tox	6 (100.0)	
	V6 (OLE Month 1)	n	6	
		No tox to No tox	6 (100.0)	
	V7 (OLE Month 2)	n	3	
		No tox to No tox	3 (100.0)	
	V8 (OLE Month 3)	n	3	
		No tox to No tox	3 (100.0)	

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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13. Laboratory Evaluations 13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits OLE Population

			Overall (N=6)
Parameter (Unit)	Visit	Statistics	n (%)
Potassium (mmol/L)	V11 (OLE Month 12)	n	2
		No tox to No tox	2 (100.0)
	V12 (End of Taper after	COLEn	1
	period)	No tox to No tox	1 (100.0)
Prothrombin time (plasma) (sec)	V5 (OLE Week 2)	n	5
		No tox to No tox	5 (100.0)
	V6 (OLE Month 1)	n	5
		No tox to No tox	5 (100.0)
	V7 (OLE Month 2)	n	3
		No tox to No tox	3 (100.0)
	V8 (OLE Month 3)	n	3
		No tox to No tox	3 (100.0)

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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13. Laboratory Evaluations 13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population Overall (N=6)Visit Statistics Parameter (Unit) (응) n 2 Prothrombin time (plasma) (sec) V11 (OLE Month 12) n No tox to No tox 2 (100.0) V12 (End of Taper after OLEn period) No tox to No tox 1 (100.0) Sodium (mmol/L) V5 (OLE Week 2) No tox to No tox 6 (100.0) V6 (OLE Month 1) n No tox to No tox 6 (100.0) V7 (OLE Month 2) 3 No tox to No tox 3 (100.0) 3 V8 (OLE Month 3) No tox to No tox 3 (100.0)

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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13. Laboratory Evaluations 13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

			Overall
Parameter (Unit)	Visit	Statistics	(N=6) n (%)
Sodium (mmol/L)	V11 (OLE Month 12)	n No tox to No tox	2 2 (100.0)
	V12 (End of Taper after period)	OLEn No tox to No tox	1 1 (100.0)
Total bilirubin (TBL) (blood) (umol/L)	V5 (OLE Week 2)	n No tox to No tox	6 6 (100.0)
	V6 (OLE Month 1)	n No tox to No tox	6 6 (100.0)
	V7 (OLE Month 2)	n No tox to No tox	3 3 (100.0)
	V8 (OLE Month 3)	n No tox to No tox	3 3 (100.0)

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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13. Laboratory Evaluations 13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

Parameter (Unit)	<u>-</u>		Overall (N=6)	
	Visit	Statistics	n (%)	
Total bilirubin (TBL) (blood) (umol/L)	V11 (OLE Month 12)	n	2	
	,	No tox to No tox	2 (100.0)	
	V12 (End of Taper after OLEn		1	
	period)	No tox to No tox	1 (100.0)	
Total protein (blood) (g/L)	V5 (OLE Week 2)	n	6	
		No tox to No tox	6 (100.0)	
	V6 (OLE Month 1)	n	6	
		No tox to No tox	6 (100.0)	
	V7 (OLE Month 2)	n	3	
		No tox to No tox	3 (100.0)	
	V8 (OLE Month 3)	n	3	
		No tox to No tox	3 (100.0)	

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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13. Laboratory Evaluations 13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits OLE Population

			Overall (N=6)	
Parameter (Unit)	Visit	Statistics	n (%)	
Total protein (blood) (g/L)	V11 (OLE Month 12)	n	2	
		No tox to No tox	2 (100.0)	
	V12 (End of Taper after OLEn		1	
	period)	No tox to No tox	1 (100.0)	
Urea Nitrogen (mmol/L)	V5 (OLE Week 2)	n	6	
		No tox to No tox	6 (100.0)	
	V6 (OLE Month 1)	n	6	
		No tox to No tox	6 (100.0)	
	V7 (OLE Month 2)	n	3	
		No tox to No tox	3 (100.0)	
	V8 (OLE Month 3)	n	3	
		No tox to No tox	3 (100.0)	

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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13. Laboratory Evaluations

13.1. Biochemistry

13.1.4. Shift from Baseline Based on Toxicity Limits

OLE Population

			Overall (N=6)
Parameter (Unit)	Visit	Statistics	n (%)
Urea Nitrogen (mmol/L)	V11 (OLE Month 12)	n No tox to No tox	2 2 (100.0)
	V12 (End of Taper after OLEn		1
	period)	No tox to No tox	1 (100.0)

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period.

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