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13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Alanine aminotransferase (U/L)	Baseline	n	6
		Mean (SD)	21.50 (8.24)
		Median	20.00
		Q1 ; Q3	15.00 ; 26.00
		Min ; Max	13.0 ; 35.0
	V5 (OLE Week 2)	n	6
		Mean (SD)	25.00 (10.10)
		Median	23.00
		Q1 ; Q3	18.00 ; 34.00
		Min ; Max	13.0 ; 39.0
	V6 (OLE Month 1)	n	6
		Mean (SD)	42.33 (27.16)
		Median	34.50
		Q1 ; Q3	24.00 ; 69.00
		Min ; Max	12.0 ; 80.0
	V7 (OLE Month 2)	n	3
		Mean (SD)	36.00 (12.29)
		Median	31.00
		Q1 ; Q3	27.00 ; 50.00
		Min ; Max	27.0 ; 50.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Alanine aminotransferase (U/L)	V8 (OLE Month 3)	n	3
		Mean (SD)	25.00 (8.19)
		Median	27.00
		Q1 ; Q3	16.00 ; 32.00
		Min ; Max	16.0 ; 32.0
	V11 (OLE Month 12)	n	2
		Mean (SD)	22.00 (8.49)
		Median	22.00
		Q1 ; Q3	16.00 ; 28.00
		Min ; Max	16.0 ; 28.0
	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	15.00
		Median	15.00
		Q1 ; Q3	15.00 ; 15.00
		Min ; Max	15.0 ; 15.0
Albumin (g/L)	Baseline	n	6
		Mean (SD)	43.67 (2.34)
		Median	44.00
		Q1 ; Q3	41.00 ; 45.00
		Min ; Max	41.0 ; 47.0

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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Parameter (Unit)	Visit	Statistics	Overall (N=6)
Albumin (g/L)	V5 (OLE Week 2)	n	6
		Mean (SD)	45.83 (3.97)
		Median	48.00
		Q1 ; Q3	43.00 ; 48.00
		Min ; Max	39.0 ; 49.0
	V6 (OLE Month 1)	n	6
		Mean (SD)	45.33 (3.20)
		Median	46.00
		Q1 ; Q3	42.00 ; 48.00
		Min ; Max	41.0 ; 49.0
	V7 (OLE Month 2)	n	3
		Mean (SD)	45.33 (1.53)
		Median	45.00
		Q1 ; Q3	44.00 ; 47.00
		Min ; Max	44.0 ; 47.0
	V8 (OLE Month 3)	n	3
		Mean (SD)	45.33 (0.58)
		Median	45.00
		Q1 ; Q3	45.00 ; 46.00
		Min ; Max	45.0 ; 46.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Albumin (g/L)	V11 (OLE Month 12)	n	2
		Mean (SD)	45.50 (2.12)
		Median	45.50
		Q1 ; Q3	44.00 ; 47.00
		Min ; Max	44.0 ; 47.0
	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	45.00
		Median	45.00
		Q1 ; Q3	45.00 ; 45.00
		Min ; Max	45.0 ; 45.0
Alkaline phosphatase (U/L)	Baseline	n	6
		Mean (SD)	51.00 (20.30)
		Median	48.50
		Q1 ; Q3	36.00 ; 56.00
		Min ; Max	30.0 ; 87.0
	V5 (OLE Week 2)	n	6
		Mean (SD)	69.00 (30.98)
		Median	58.00
		Q1 ; Q3	44.00 ; 102.00
		Min ; Max	39.0 ; 113.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Alkaline phosphatase (U/L)	V6 (OLE Month 1)	n	6
		Mean (SD)	71.33 (30.57)
		Median	56.50
		Q1 ; Q3	53.00 ; 100.00
		Min ; Max	43.0 ; 119.0
	V7 (OLE Month 2)	n	3
		Mean (SD)	71.33 (20.50)
		Median	60.00
		Q1 ; Q3	59.00 ; 95.00
		Min ; Max	59.0 ; 95.0
	V8 (OLE Month 3)	n	3
		Mean (SD)	79.67 (23.25)
		Median	71.00
		Q1 ; Q3	62.00 ; 106.00
		Min ; Max	62.0 ; 106.0
	V11 (OLE Month 12)	n	2
		Mean (SD)	66.50 (14.85)
		Median	66.50
		Q1 ; Q3	56.00 ; 77.00
		Min ; Max	56.0 ; 77.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Alkaline phosphatase (U/L)	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	57.00
		Median	57.00
		Q1 ; Q3	57.00 ; 57.00
		Min ; Max	57.0 ; 57.0
Aspartate aminotransferase (U/L)	Baseline	n	6
		Mean (SD)	21.33 (5.35)
		Median	19.00
		Q1 ; Q3	18.00 ; 27.00
		Min ; Max	16.0 ; 29.0
	V5 (OLE Week 2)	n	6
		Mean (SD)	23.17 (6.43)
		Median	22.00
		Q1 ; Q3	20.00 ; 24.00
		Min ; Max	16.0 ; 35.0
	V6 (OLE Month 1)	n	6
		Mean (SD)	36.83 (13.14)
		Median	39.00
		Q1 ; Q3	24.00 ; 43.00
		Min ; Max	20.0 ; 56.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Aspartate aminotransferase (U/L)	V7 (OLE Month 2)	n	3
		Mean (SD)	30.00 (11.36)
		Median	25.00
		Q1 ; Q3	22.00 ; 43.00
		Min ; Max	22.0 ; 43.0
	V8 (OLE Month 3)	n	3
		Mean (SD)	21.67 (2.89)
		Median	20.00
		Q1 ; Q3	20.00 ; 25.00
		Min ; Max	20.0 ; 25.0
	V11 (OLE Month 12)	n	2
		Mean (SD)	24.50 (0.71)
		Median	24.50
		Q1 ; Q3	24.00 ; 25.00
		Min ; Max	24.0 ; 25.0
	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	17.00
		Median	17.00
		Q1 ; Q3	17.00 ; 17.00
		Min ; Max	17.0 ; 17.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Calcium (mmol/L)	Baseline	n	6
		Mean (SD)	2.28 (0.07)
		Median	2.27
		Q1 ; Q3	2.24 ; 2.28
		Min ; Max	2.2 ; 2.4
	V5 (OLE Week 2)	n	6
		Mean (SD)	2.34 (0.04)
		Median	2.36
		Q1 ; Q3	2.32 ; 2.37
		Min ; Max	2.3 ; 2.4
	V6 (OLE Month 1)	n	6
		Mean (SD)	2.35 (0.05)
		Median	2.35
		Q1 ; Q3	2.30 ; 2.40
		Min ; Max	2.3 ; 2.4
	V7 (OLE Month 2)	n	3
		Mean (SD)	2.29 (0.10)
		Median	2.26
		Q1 ; Q3	2.21 ; 2.40
		Min ; Max	2.2 ; 2.4

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Calcium (mmol/L)	V8 (OLE Month 3)	n	3
		Mean (SD)	2.34 (0.05)
		Median	2.35
		Q1 ; Q3	2.29 ; 2.38
		Min ; Max	2.3 ; 2.4
	V11 (OLE Month 12)	n	2
		Mean (SD)	2.37 (0.06)
		Median	2.37
		Q1 ; Q3	2.33 ; 2.41
		Min ; Max	2.3 ; 2.4
	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	2.28
		Median	2.28
		Q1 ; Q3	2.28 ; 2.28
		Min ; Max	2.3 ; 2.3
Creatinine (Jaffe) (umol/L)	Baseline	n	6
		Mean (SD)	70.83 (13.76)
		Median	70.00
		Q1 ; Q3	61.00 ; 76.00
		Min ; Max	54.0 ; 94.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Creatinine (Jaffe) (umol/L)	V5 (OLE Week 2)	n	6
		Mean (SD)	72.50 (12.01)
		Median	71.00
		Q1 ; Q3	66.00 ; 76.00
		Min ; Max	58.0 ; 93.0
	V6 (OLE Month 1)	n	6
		Mean (SD)	72.83 (17.14)
		Median	72.00
		Q1 ; Q3	61.00 ; 86.00
		Min ; Max	49.0 ; 97.0
	V7 (OLE Month 2)	n	3
		Mean (SD)	72.33 (4.51)
		Median	72.00
		Q1 ; Q3	68.00 ; 77.00
		Min ; Max	68.0 ; 77.0
	V8 (OLE Month 3)	n	3
		Mean (SD)	67.33 (7.09)
		Median	66.00
		Q1 ; Q3	61.00 ; 75.00
		Min ; Max	61.0 ; 75.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Creatinine (Jaffe) (umol/L)	V11 (OLE Month 12)	n	2
		Mean (SD)	81.50 (12.02)
		Median	81.50
		Q1 ; Q3	73.00 ; 90.00
		Min ; Max	73.0 ; 90.0
	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	93.00
		Median	93.00
		Q1 ; Q3	93.00 ; 93.00
		Min ; Max	93.0 ; 93.0
Gamma-glutamyl transferase (U/L)	Baseline	n	6
		Mean (SD)	31.00 (20.72)
		Median	28.50
		Q1 ; Q3	13.00 ; 42.00
		Min ; Max	11.0 ; 63.0
	V5 (OLE Week 2)	n	6
		Mean (SD)	58.33 (68.47)
		Median	28.50
		Q1 ; Q3	20.00 ; 75.00
		Min ; Max	8.0 ; 190.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Gamma-glutamyl transferase (U/L)	V6 (OLE Month 1)	n	6
		Mean (SD)	64.50 (54.45)
		Median	60.00
		Q1 ; Q3	21.00 ; 74.00
		Min ; Max	9.0 ; 163.0
	V7 (OLE Month 2)	n	3
		Mean (SD)	110.67 (154.95)
		Median	34.00
		Q1 ; Q3	9.00 ; 289.00
		Min ; Max	9.0 ; 289.0
	V8 (OLE Month 3)	n	3
		Mean (SD)	95.33 (135.15)
		Median	27.00
		Q1 ; Q3	8.00 ; 251.00
		Min ; Max	8.0 ; 251.0
	V11 (OLE Month 12)	n	2
		Mean (SD)	61.00 (63.64)
		Median	61.00
		Q1 ; Q3	16.00 ; 106.00
		Min ; Max	16.0 ; 106.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Gamma-glutamyl transferase (U/L)	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	19.00
		Median	19.00
		Q1 ; Q3	19.00 ; 19.00
		Min ; Max	19.0 ; 19.0
Glucose (blood) (mmol/L)	Baseline	n	6
		Mean (SD)	4.93 (0.65)
		Median	4.95
		Q1 ; Q3	4.70 ; 5.30
		Min ; Max	3.9 ; 5.8
	V5 (OLE Week 2)	n	6
		Mean (SD)	4.73 (0.42)
		Median	4.95
		Q1 ; Q3	4.30 ; 5.00
		Min ; Max	4.1 ; 5.1
	V6 (OLE Month 1)	n	6
		Mean (SD)	4.97 (0.50)
		Median	5.00
		Q1 ; Q3	4.80 ; 5.40
		Min ; Max	4.1 ; 5.5

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Glucose (blood) (mmol/L)	V7 (OLE Month 2)	n	3
		Mean (SD)	5.50 (0.70)
		Median	5.20
		Q1 ; Q3	5.00 ; 6.30
		Min ; Max	5.0 ; 6.3
	V8 (OLE Month 3)	n	3
		Mean (SD)	5.23 (0.42)
		Median	5.10
		Q1 ; Q3	4.90 ; 5.70
		Min ; Max	4.9 ; 5.7
	V11 (OLE Month 12)	n	2
		Mean (SD)	4.70 (0.42)
		Median	4.70
		Q1 ; Q3	4.40 ; 5.00
		Min ; Max	4.4 ; 5.0
	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	5.30
		Median	5.30
		Q1 ; Q3	5.30 ; 5.30
		Min ; Max	5.3 ; 5.3

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
HDL-cholesterol (mmol/L)	Baseline	n	6
		Mean (SD)	1.50 (0.49)
		Median	1.30
		Q1 ; Q3	1.30 ; 1.40
		Min ; Max	1.2 ; 2.5
	V5 (OLE Week 2)	n	6
		Mean (SD)	1.55 (0.21)
		Median	1.55
		Q1 ; Q3	1.40 ; 1.60
		Min ; Max	1.3 ; 1.9
	V6 (OLE Month 1)	n	6
		Mean (SD)	1.52 (0.47)
		Median	1.45
		Q1 ; Q3	1.30 ; 1.50
		Min ; Max	1.0 ; 2.4
	V7 (OLE Month 2)	n	3
		Mean (SD)	1.23 (0.12)
		Median	1.30
		Q1 ; Q3	1.10 ; 1.30
		Min ; Max	1.1 ; 1.3

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
HDL-cholesterol (mmol/L)	V8 (OLE Month 3)	n	3
		Mean (SD)	1.30 (0.17)
		Median	1.20
		Q1 ; Q3	1.20 ; 1.50
		Min ; Max	1.2 ; 1.5
	V11 (OLE Month 12)	n	2
		Mean (SD)	2.25 (0.92)
		Median	2.25
		Q1 ; Q3	1.60 ; 2.90
		Min ; Max	1.6 ; 2.9
	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	1.20
		Median	1.20
		Q1 ; Q3	1.20 ; 1.20
		Min ; Max	1.2 ; 1.2
International normalized ratio	Baseline	n	6
		Mean (SD)	1.01 (0.04)
		Median	1.01
		Q1 ; Q3	0.97 ; 1.02
		Min ; Max	1.0 ; 1.1

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
International normalized ratio	V5 (OLE Week 2)	n	5
		Mean (SD)	0.98 (0.05)
		Median	1.00
		Q1 ; Q3	0.97 ; 1.01
		Min ; Max	0.9 ; 1.0
	V6 (OLE Month 1)	n	5
		Mean (SD)	0.97 (0.03)
		Median	0.97
		Q1 ; Q3	0.97 ; 0.98
		Min ; Max	0.9 ; 1.0
	V7 (OLE Month 2)	n	3
		Mean (SD)	1.01 (0.04)
		Median	1.01
		Q1 ; Q3	0.97 ; 1.04
		Min ; Max	1.0 ; 1.0
	V8 (OLE Month 3)	n	3
		Mean (SD)	0.98 (0.02)
		Median	0.97
		Q1 ; Q3	0.96 ; 1.00
		Min ; Max	1.0 ; 1.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
International normalized ratio	V11 (OLE Month 12)	n	2
		Mean (SD)	1.04 (0.05)
		Median	1.04
		Q1 ; Q3	1.00 ; 1.07
		Min ; Max	1.0 ; 1.1
	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	1.03
		Median	1.03
		Q1 ; Q3	1.03 ; 1.03
		Min ; Max	1.0 ; 1.0
Potassium (mmol/L)	Baseline	n	6
		Mean (SD)	4.30 (0.28)
		Median	4.35
		Q1 ; Q3	4.10 ; 4.40
		Min ; Max	3.9 ; 4.7
	V5 (OLE Week 2)	n	6
		Mean (SD)	4.48 (0.16)
		Median	4.55
		Q1 ; Q3	4.40 ; 4.60
		Min ; Max	4.2 ; 4.6

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Potassium (mmol/L)	V6 (OLE Month 1)	n	6
		Mean (SD)	4.43 (0.16)
		Median	4.40
		Q1 ; Q3	4.40 ; 4.50
		Min ; Max	4.2 ; 4.7
	V7 (OLE Month 2)	n	3
		Mean (SD)	4.47 (0.31)
		Median	4.40
		Q1 ; Q3	4.20 ; 4.80
		Min ; Max	4.2 ; 4.8
	V8 (OLE Month 3)	n	3
		Mean (SD)	4.27 (0.12)
		Median	4.20
		Q1 ; Q3	4.20 ; 4.40
		Min ; Max	4.2 ; 4.4
	V11 (OLE Month 12)	n	2
		Mean (SD)	4.30 (0.14)
		Median	4.30
		Q1 ; Q3	4.20 ; 4.40
		Min ; Max	4.2 ; 4.4

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.

Output ID: T-CHEMVAL 02AUG17

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13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Potassium (mmol/L)	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	4.00
		Median	4.00
		Q1 ; Q3	4.00 ; 4.00
		Min ; Max	4.0 ; 4.0
Prolactin (mIU/L)	Baseline	n	6
		Mean (SD)	228.80 (117.12)
		Median	194.95
		Q1 ; Q3	160.00 ; 215.40
		Min ; Max	145.8 ; 461.7
	V5 (OLE Week 2)	n	6
		Mean (SD)	127.58 (30.76)
		Median	126.05
		Q1 ; Q3	110.20 ; 154.90
		Min ; Max	81.4 ; 166.9
	V6 (OLE Month 1)	n	6
		Mean (SD)	160.98 (28.23)
		Median	163.35
		Q1 ; Q3	154.40 ; 172.10
		Min ; Max	113.8 ; 198.9

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Prolactin (mIU/L)	V7 (OLE Month 2)	n	3
		Mean (SD)	138.03 (3.57)
		Median	139.30
		Q1 ; Q3	134.00 ; 140.80
		Min ; Max	134.0 ; 140.8
	V8 (OLE Month 3)	n	3
		Mean (SD)	136.23 (22.75)
		Median	123.30
		Q1 ; Q3	122.90 ; 162.50
		Min ; Max	122.9 ; 162.5
	V11 (OLE Month 12)	n	2
		Mean (SD)	96.65 (18.31)
		Median	96.65
		Q1 ; Q3	83.70 ; 109.60
		Min ; Max	83.7 ; 109.6
	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	169.80
		Median	169.80
		Q1 ; Q3	169.80 ; 169.80
		Min ; Max	169.8 ; 169.8

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Prothrombin time (plasma) (sec)	Baseline	n	6
		Mean (SD)	10.88 (0.43)
		Median	10.90
		Q1 ; Q3	10.50 ; 11.00
		Min ; Max	10.4 ; 11.6
	V5 (OLE Week 2)	n	5
		Mean (SD)	10.58 (0.53)
		Median	10.80
		Q1 ; Q3	10.50 ; 10.90
		Min ; Max	9.7 ; 11.0
	V6 (OLE Month 1)	n	5
		Mean (SD)	10.46 (0.36)
		Median	10.50
		Q1 ; Q3	10.40 ; 10.60
		Min ; Max	9.9 ; 10.9
	V7 (OLE Month 2)	n	3
		Mean (SD)	10.87 (0.35)
		Median	10.90
		Q1 ; Q3	10.50 ; 11.20
		Min ; Max	10.5 ; 11.2

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Prothrombin time (plasma) (sec)	V8 (OLE Month 3)	n	3
		Mean (SD)	10.57 (0.21)
		Median	10.50
		Q1 ; Q3	10.40 ; 10.80
		Min ; Max	10.4 ; 10.8
	V11 (OLE Month 12)	n	2
		Mean (SD)	11.15 (0.49)
		Median	11.15
		Q1 ; Q3	10.80 ; 11.50
		Min ; Max	10.8 ; 11.5
	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	11.10
		Median	11.10
		Q1 ; Q3	11.10 ; 11.10
		Min ; Max	11.1 ; 11.1
Sodium (mmol/L)	Baseline	n	6
		Mean (SD)	142.17 (2.14)
		Median	142.00
		Q1 ; Q3	140.00 ; 144.00
		Min ; Max	140.0 ; 145.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Sodium (mmol/L)	V5 (OLE Week 2)	n	6
		Mean (SD)	143.67 (1.97)
		Median	143.00
		Q1 ; Q3	142.00 ; 145.00
		Min ; Max	142.0 ; 147.0
	V6 (OLE Month 1)	n	6
		Mean (SD)	143.50 (1.52)
		Median	143.50
		Q1 ; Q3	142.00 ; 144.00
		Min ; Max	142.0 ; 146.0
	V7 (OLE Month 2)	n	3
		Mean (SD)	143.00 (1.73)
		Median	144.00
		Q1 ; Q3	141.00 ; 144.00
		Min ; Max	141.0 ; 144.0
	V8 (OLE Month 3)	n	3
		Mean (SD)	142.00 (2.00)
		Median	142.00
		Q1 ; Q3	140.00 ; 144.00
		Min ; Max	140.0 ; 144.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Sodium (mmol/L)	V11 (OLE Month 12)	n	2
		Mean (SD)	142.50 (0.71)
		Median	142.50
		Q1 ; Q3	142.00 ; 143.00
		Min ; Max	142.0 ; 143.0
	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	143.00
		Median	143.00
		Q1 ; Q3	143.00 ; 143.00
		Min ; Max	143.0 ; 143.0
Total bilirubin (TBL) (blood) (umol/L)	Baseline	n	6
		Mean (SD)	6.42 (1.41)
		Median	6.35
		Q1 ; Q3	5.10 ; 7.30
		Min ; Max	4.8 ; 8.6
	V5 (OLE Week 2)	n	6
		Mean (SD)	6.43 (1.09)
		Median	6.30
		Q1 ; Q3	5.50 ; 7.60
		Min ; Max	5.2 ; 7.7

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Total bilirubin (TBL) (blood) (umol/L)	V6 (OLE Month 1)	n	6
		Mean (SD)	5.90 (1.77)
		Median	5.85
		Q1 ; Q3	4.10 ; 7.80
		Min ; Max	3.8 ; 8.0
	V7 (OLE Month 2)	n	3
		Mean (SD)	6.73 (2.56)
		Median	6.50
		Q1 ; Q3	4.30 ; 9.40
		Min ; Max	4.3 ; 9.4
	V8 (OLE Month 3)	n	3
		Mean (SD)	5.43 (1.15)
		Median	5.40
		Q1 ; Q3	4.30 ; 6.60
		Min ; Max	4.3 ; 6.6
	V11 (OLE Month 12)	n	2
		Mean (SD)	7.30 (2.55)
		Median	7.30
		Q1 ; Q3	5.50 ; 9.10
		Min ; Max	5.5 ; 9.1

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Total bilirubin (TBL) (blood) (umol/L)	V12 (End of Taper after OLEn period)	n	6
		Mean (SD)	3.80
		Median	3.80
		Q1 ; Q3	3.80 ; 3.80
		Min ; Max	3.8 ; 3.8
Total protein (blood) (g/L)	Baseline	n	6
		Mean (SD)	68.17 (4.26)
		Median	68.50
		Q1 ; Q3	64.00 ; 71.00
		Min ; Max	63.0 ; 74.0
	V5 (OLE Week 2)	n	6
		Mean (SD)	71.67 (3.72)
		Median	70.50
		Q1 ; Q3	69.00 ; 74.00
		Min ; Max	68.0 ; 78.0
	V6 (OLE Month 1)	n	6
		Mean (SD)	70.67 (7.31)
		Median	69.00
		Q1 ; Q3	64.00 ; 75.00
		Min ; Max	64.0 ; 83.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Total protein (blood) (g/L)	V7 (OLE Month 2)	n	3
		Mean (SD)	71.33 (3.79)
		Median	73.00
		Q1 ; Q3	67.00 ; 74.00
		Min ; Max	67.0 ; 74.0
	V8 (OLE Month 3)	n	3
		Mean (SD)	70.67 (2.89)
		Median	69.00
		Q1 ; Q3	69.00 ; 74.00
		Min ; Max	69.0 ; 74.0
	V11 (OLE Month 12)	n	2
		Mean (SD)	71.00 (4.24)
		Median	71.00
		Q1 ; Q3	68.00 ; 74.00
		Min ; Max	68.0 ; 74.0
	V12 (End of Taper after OLE period)	n	1
		Mean (SD)	66.00
		Median	66.00
		Q1 ; Q3	66.00 ; 66.00
		Min ; Max	66.0 ; 66.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Triglycerides (mmol/L)	Baseline	n	6
		Mean (SD)	1.10 (0.48)
		Median	1.11
		Q1 ; Q3	0.71 ; 1.24
		Min ; Max	0.5 ; 1.9
	V5 (OLE Week 2)	n	6
		Mean (SD)	1.47 (0.82)
		Median	1.25
		Q1 ; Q3	0.84 ; 1.70
		Min ; Max	0.8 ; 3.0
	V6 (OLE Month 1)	n	6
		Mean (SD)	1.34 (0.25)
		Median	1.34
		Q1 ; Q3	1.11 ; 1.45
		Min ; Max	1.1 ; 1.7
	V7 (OLE Month 2)	n	3
		Mean (SD)	1.68 (1.14)
		Median	1.17
		Q1 ; Q3	0.89 ; 2.99
		Min ; Max	0.9 ; 3.0

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Triglycerides (mmol/L)	V8 (OLE Month 3)	n	3
		Mean (SD)	1.39 (0.30)
		Median	1.22
		Q1 ; Q3	1.22 ; 1.74
		Min ; Max	1.2 ; 1.7
	V11 (OLE Month 12)	n	2
		Mean (SD)	0.91 (0.16)
		Median	0.91
		Q1 ; Q3	0.80 ; 1.02
		Min ; Max	0.8 ; 1.0
	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	1.64
		Median	1.64
		Q1 ; Q3	1.64 ; 1.64
		Min ; Max	1.6 ; 1.6
Urea Nitrogen (mmol/L)	Baseline	n	6
		Mean (SD)	5.47 (1.14)
		Median	5.20
		Q1 ; Q3	5.00 ; 5.80
		Min ; Max	4.1 ; 7.5

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Urea Nitrogen (mmol/L)	V5 (OLE Week 2)	n	6
		Mean (SD)	4.82 (1.54)
		Median	4.45
		Q1 ; Q3	3.60 ; 5.50
		Min ; Max	3.4 ; 7.5
	V6 (OLE Month 1)	n	6
		Mean (SD)	4.95 (1.10)
		Median	4.85
		Q1 ; Q3	4.30 ; 6.00
		Min ; Max	3.4 ; 6.3
	V7 (OLE Month 2)	n	3
		Mean (SD)	4.07 (1.12)
		Median	3.80
		Q1 ; Q3	3.10 ; 5.30
		Min ; Max	3.1 ; 5.3
	V8 (OLE Month 3)	n	3
		Mean (SD)	4.47 (1.44)
		Median	3.90
		Q1 ; Q3	3.40 ; 6.10
		Min ; Max	3.4 ; 6.1

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

13.1.1. Value by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Urea Nitrogen (mmol/L)	V11 (OLE Month 12)	n	2
		Mean (SD)	5.75 (0.35)
		Median	5.75
		Q1 ; Q3	5.50 ; 6.00
		Min ; Max	5.5 ; 6.0
	V12 (End of Taper after OLEn period)	n	1
		Mean (SD)	5.40
		Median	5.40
		Q1 ; Q3	5.40 ; 5.40
		Min ; Max	5.4 ; 5.4

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.

Output ID: T-CHEMVAL 02AUG17

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