Omaveloxolon (Skyclarys™)

Biogen GmbH

Anhang 4-J zu Modul 4A und 4B

Behandlung der Friedreich-Ataxie (FA) bei Erwachsenen und Jugendlichen ab 16 Jahren

Stand: 01.07.2025

Inhaltsverzeichnis

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Baseline		
N	4	7
Mean score	43.33	45.20
SD	3.050	7.151
Week 4		
N	4	7
LS mean change from baseline	0.30	-2.01
SE	1.636	1.216
95% CI	(-3.02, 3.61)	(-4.47, 0.45)
LS mean difference (Omaveloxolone-Placebo)		-2.30
SE		2.108
95% CI		(-6.58, 1.97)
p-value		0.2821
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.60
95% CI		(-1.86, 0.65)
Week 12		
N	4	7
LS mean change from baseline	-1.94	-0.61
SE	1.636	1.216
95% CI	(-5.25, 1.38)	(-3.07, 1.85)
LS mean difference (Omaveloxolone-Placebo)		1.33
SE		2.108
95% CI		(-2.95, 5.60)
p-value		0.5330
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.35
95% CI		(-0.89, 1.59)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-mfars93-mmrm-itt-pcp-byvis-gait.sas:t-mfars93-mmrm-itt-pcp-byvis-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 18		
N	4	7
LS mean change from baseline	-2.61	-3.49
SE	1.636	1.216
95% CI	(-5.93, 0.70)	(-5.95, -1.03)
LS mean difference (Omaveloxolone-Placebo)		-0.88
SE		2.108
95% CI		(-5.16, 3.40)
p-value		0.6785
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.23
95% CI		(-1.46, 1.00)
Week 24		
N	4	7
LS mean change from baseline	-0.21	0.73
SE	1.636	1.216
95% CI	(-3.53, 3.10)	(-1.74, 3.19)
LS mean difference (Omaveloxolone-Placebo)		0.94
SE		2.108
95% CI		(-3.34, 5.21)
p-value		0.6593
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.25
95% CI		(-0.99, 1.48)
Week 36		
N	4	7
LS mean change from baseline	2.33	3.74
SE	1.636	1.216
95% CI	(-0.99, 5.64)	(1.28, 6.20)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

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	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
LS mean difference (Omaveloxolone-Placebo)		1.42
SE		2.108
95% CI		(-2.86, 5.69)
p-value		0.5060
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.37
95% CI		(-0.87, 1.61)
Week 48		
N	4	6
LS mean change from baseline	2.32	2.44
SE	1.636	1.317
95% CI	(-1.00, 5.63)	(-0.22, 5.11)
LS mean difference (Omaveloxolone-Placebo)		0.13
SE		2.156
95% CI		(-4.25, 4.50)
p-value		0.9530
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.03
95% CI		(-1.23, 1.30)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

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MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Bulbar Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Baseline		
N	4	7
Mean score	0.69	0.57
SD	0.375	0.718
Week 4		
N	4	7
LS mean change from baseline	0.11	-0.23
SE	0.159	0.119
95% CI	(-0.22, 0.43)	(-0.47, 0.01)
LS mean difference (Omaveloxolone-Placebo)		-0.34
SE		0.201
95% CI		(-0.74, 0.07)
p-value		0.1043
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.92
95% CI		(-2.21, 0.36)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
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MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Bulbar Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 12		
N	4	7
LS mean change from baseline	-0.05	-0.14
SE	0.159	0.119
95% CI	(-0.37, 0.27)	(-0.38, 0.10)
LS mean difference (Omaveloxolone-Placebo)		-0.09
SE		0.201
95% CI		(-0.50, 0.32)
p-value		0.6509
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.25
95% CI		(-1.49, 0.98)
Week 18		
N	4	7
LS mean change from baseline	-0.06	0.07
SE	0.159	0.119
95% CI	(-0.38, 0.26)	(-0.17, 0.32)
LS mean difference (Omaveloxolone-Placebo)		0.13
SE		0.201
95% CI		(-0.28, 0.54)
p-value		0.5185
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.36
95% CI		(-0.88, 1.60)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
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MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Bulbar Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 24		
N	4	7
LS mean change from baseline	0.21	0.21
SE	0.159	0.119
95% CI	(-0.12, 0.53)	(-0.03, 0.45)
LS mean difference (Omaveloxolone-Placebo)		0.00
SE		0.201
95% CI		(-0.41, 0.41)
p-value		0.9875
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.01
95% CI		(-1.22, 1.24)
Week 36		
N	4	7
LS mean change from baseline	0.07	0.07
SE	0.159	0.119
95% CI	(-0.25, 0.39)	(-0.17, 0.31)
LS mean difference (Omaveloxolone-Placebo)		0.00
SE		0.201
95% CI		(-0.41, 0.41)
p-value		0.9962
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.00
95% CI		(-1.23, 1.23)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
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	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 48		
N	4	6
LS mean change from baseline	0.07	0.22
SE	0.159	0.128
95% CI	(-0.25, 0.39)	(-0.04, 0.48)
LS mean difference (Omaveloxolone-Placebo)		0.15
SE		0.208
95% CI		(-0.27, 0.57)
p-value		0.4777
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.40
95% CI		(-0.87, 1.68)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

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MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Upper Limb Coordination Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Baseline		
N	4	7
Mean score	9.94	9.57
SD	1.329	3.220
Week 4		
N	4	7
LS mean change from baseline	-0.97	-0.69
SE	1.116	0.816
95% CI	(-3.28, 1.34)	(-2.37, 0.99)
LS mean difference (Omaveloxolone-Placebo)		0.28
SE		1.455
95% CI		(-2.75, 3.31)
p-value		0.8483
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.10
95% CI		(-1.12, 1.33)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
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MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Upper Limb Coordination Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 12		
N	4	7
LS mean change from baseline	-1.23	0.67
SE	1.116	0.816
95% CI	(-3.54, 1.08)	(-1.01, 2.35)
LS mean difference (Omaveloxolone-Placebo)		1.91
SE		1.455
95% CI		(-1.13, 4.94)
p-value		0.2047
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.71
95% CI		(-0.56, 1.97)
Week 18		
N	4	7
LS mean change from baseline	-2.72	-0.40
SE	1.116	0.816
95% CI	(-5.03, -0.41)	(-2.08, 1.28)
LS mean difference (Omaveloxolone-Placebo)		2.31
SE		1.455
95% CI		(-0.72, 5.35)
p-value		0.1273
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.86
95% CI		(-0.42, 2.14)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

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	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 24		
N	4	7
LS mean change from baseline	-2.31	1.02
SE	1.116	0.816
95% CI	(-4.63, 0.00)	(-0.66, 2.70)
LS mean difference (Omaveloxolone-Placebo)		3.33
SE		1.455
95% CI		(0.30, 6.37)
p-value		0.0327
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		1.24
95% CI		(-0.10, 2.57)
Week 36		
N	4	7
LS mean change from baseline	0.85	2.04
SE	1.116	0.816
95% CI	(-1.46, 3.16)	(0.36, 3.72)
LS mean difference (Omaveloxolone-Placebo)		1.19
SE		1.455
95% CI		(-1.85, 4.22)
p-value		0.4242
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.44
95% CI		(-0.80, 1.68)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
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	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 48		
N	4	6
LS mean change from baseline	0.53	1.36
SE	1.120	0.936
95% CI	(-1.79, 2.84)	(-0.55, 3.27)
LS mean difference (Omaveloxolone-Placebo)		0.83
SE		1.558
95% CI		(-2.39, 4.06)
p-value		0.5990
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.29
95% CI		(-0.98, 1.57)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

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MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Lower Limb Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Baseline		
N	4	7
Mean score	6.63	6.43
SD	0.520	1.694
Week 4		
N	4	7
LS mean change from baseline	-0.27	-0.71
SE	0.946	0.691
95% CI	(-2.26, 1.72)	(-2.16, 0.74)
LS mean difference (Omaveloxolone-Placebo)		-0.44
SE		1.239
95% CI		(-3.06, 2.19)
p-value		0.7286
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.19
95% CI		(-1.42, 1.04)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
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	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 12		
N	4	7
LS mean change from baseline	-1.21	-1.27
SE	0.946	0.691
95% CI	(-3.20, 0.79)	(-2.72, 0.18)
LS mean difference (Omaveloxolone-Placebo)		-0.07
SE		1.239
95% CI		(-2.69, 2.56)
p-value		0.9585
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.03
95% CI		(-1.26, 1.20)
Week 18		
N	4	7
LS mean change from baseline	-1.38	-1.30
SE	0.946	0.691
95% CI	(-3.37, 0.61)	(-2.75, 0.15)
LS mean difference (Omaveloxolone-Placebo)		0.08
SE		1.239
95% CI		(-2.54, 2.70)
p-value		0.9495
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.03
95% CI		(-1.19, 1.26)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
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	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 24		
N	4	7
LS mean change from baseline	-0.26	-0.44
SE	0.946	0.691
95% CI	(-2.25, 1.74)	(-1.89, 1.01)
LS mean difference (Omaveloxolone-Placebo)		-0.18
SE		1.239
95% CI		(-2.81, 2.44)
p-value		0.8853
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.08
95% CI		(-1.31, 1.15)
Week 36		
N	4	7
LS mean change from baseline	-0.56	0.21
SE	0.946	0.691
95% CI	(-2.56, 1.43)	(-1.24, 1.66)
LS mean difference (Omaveloxolone-Placebo)		0.77
SE		1.239
95% CI		(-1.85, 3.40)
p-value		0.5404
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.33
95% CI		(-0.90, 1.57)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
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	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 48		
N	4	6
LS mean change from baseline	-0.71	-0.06
SE	0.945	0.734
95% CI	(-2.70, 1.28)	(-1.59, 1.47)
LS mean difference (Omaveloxolone-Placebo)		0.65
SE		1.265
95% CI		(-2.02, 3.32)
p-value		0.6154
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.28
95% CI		(-0.99, 1.55)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

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MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Upright Stability Domain LS Mean Change fr om Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Baseline		
N	4	7
Mean score	26.04	28.62
SD	2.123	3.685
Week 4		
N	4	7
LS mean change from baseline	1.48	-0.40
SE	1.176	0.848
95% CI	(-1.10, 4.07)	(-2.24, 1.45)
LS mean difference (Omaveloxolone-Placebo)		-1.88
SE		1.578
95% CI		(-5.37, 1.61)
p-value		0.2592
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.61
95% CI		(-1.86, 0.65)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
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MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Upright Stability Domain LS Mean Change fr om Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 12		
N	4	7
LS mean change from baseline	0.50	0.17
SE	1.176	0.848
95% CI	(-2.08, 3.08)	(-1.68, 2.02)
LS mean difference (Omaveloxolone-Placebo)		-0.33
SE		1.578
95% CI		(-3.82, 3.16)
p-value		0.8378
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.11
95% CI		(-1.34, 1.12)
Week 18		
N	4	7
LS mean change from baseline	1.63	-1.88
SE	1.176	0.848
95% CI	(-0.95, 4.21)	(-3.73, -0.04)
LS mean difference (Omaveloxolone-Placebo)		-3.52
SE		1.578
95% CI		(-7.01, -0.03)
p-value		0.0486
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-1.13
95% CI		(-2.45, 0.18)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-mfars93-d-us-mmrm-itt-pcp-gait.sas:t-mfars93-d-us-mmrm-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Upright Stability Domain LS Mean Change fr om Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 24		
N	4	7
LS mean change from baseline	1.99	0.08
SE	1.176	0.848
95% CI	(-0.59, 4.58)	(-1.77, 1.92)
LS mean difference (Omaveloxolone-Placebo)		-1.92
SE		1.578
95% CI		(-5.41, 1.58)
p-value		0.2512
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.62
95% CI		(-1.87, 0.64)
Week 36		
N	4	7
LS mean change from baseline	1.26	1.83
SE	1.176	0.848
95% CI	(-1.32, 3.84)	(-0.02, 3.67)
LS mean difference (Omaveloxolone-Placebo)		0.57
SE		1.578
95% CI		(-2.92, 4.06)
p-value		0.7247
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.18
95% CI		(-1.05, 1.41)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-mfars93-d-us-mmrm-itt-pcp-gait.sas:t-mfars93-d-us-mmrm-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Upright Stability Domain LS Mean Change fr om Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 48		
N	4	6
LS mean change from baseline	1.92	1.42
SE	1.178	0.876
95% CI	(-0.67, 4.51)	(-0.47, 3.31)
LS mean difference (Omaveloxolone-Placebo)		-0.50
SE		1.584
95% CI		(-4.00, 3.00)
p-value		0.7581
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.16
95% CI		(-1.43, 1.10)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-mfars93-d-us-mmrm-itt-pcp-gait.sas:t-mfars93-d-us-mmrm-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Summary of Proportion of Worsening in Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Total Score at Week 48 with Imputation - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Number of subjects with week 48 assessment (%)	4 (100)	6 (85.7)
Number of subjects with event (%)	3 (75.0)	5 (71.4)
RR - Relative Risk (Omaveloxolone/Placebo)		0.95
95% CI		(0.46, 1.99)
p-value		0.8964
OR - Odds Ratio (Omaveloxolone/Placebo)		0.83
95% CI		(0.05, 13.63)
ARR - Absolute Risk Reduction (Omaveloxolone-Placebo)		-0.04
95% CI		(-0.58, 0.50)

NOTE 1: Worsening if change from baseline at Week 48 >= 1.9 in mFARS Total Score. Subject without week 48 assessment will be imputed as responder with a worsening event.

NOTE 2: Cochran-Mantel-Haenszel adjusted OR and RR are calculated adjusting for pes cavus status. Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-mfars93-propw-itt-pcp-gait-imp.sas:t-mfars93-propw-itt-pcp-gait-gt2-imp.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Activities of Daily Living (ADL) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Baseline		
N	4	7
Mean score	13.63	12.21
SD	3.449	3.213
Week 24		
N	4	7
LS mean change from baseline	2.49	1.84
SE	1.334	0.984
95% CI	(-0.71, 5.69)	(-0.53, 4.20)
LS mean difference (Omaveloxolone-Placebo)		-0.65
SE		1.698
95% CI		(-4.71, 3.40)
p-value		0.7117
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.18
95% CI		(-1.41, 1.05)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-adl-mmrm-itt-pcp-gait.sas:t-adl-mmrm-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Activities of Daily Living (ADL) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 36		
N	4	7
LS mean change from baseline	2.71	3.28
SE	0.621	0.448
95% CI	(1.24, 4.18)	(2.20, 4.35)
LS mean difference (Omaveloxolone-Placebo)		0.56
SE		0.825
95% CI		(-1.37, 2.49)
p-value		0.5155
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.33
95% CI		(-0.91, 1.56)
Week 48		
N	4	6
LS mean change from baseline	2.38	2.54
SE	0.428	0.355
95% CI	(1.30, 3.47)	(1.63, 3.46)
LS mean difference (Omaveloxolone-Placebo)		0.16
SE		0.649
95% CI		(-1.47, 1.79)
p-value		0.8155
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.11
95% CI		(-1.15, 1.38)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-adl-mmrm-itt-pcp-gait.sas:t-adl-mmrm-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Patient Global Impression of Change (PGI-C) LS Mean up to Week 48 by Visit from ANCOVA+MI Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

Visit Statistic	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 12		
Number of observations per imputation	4 (100)	7 (100)
Number of imputed values per imputation	0	0
LS mean	4.25	3.75
SE	0.499	0.376
95% CI	(3.03, 5.47)	(2.83, 4.67)
LS mean difference (Omaveloxolone-Placebo)		-0.50
SE		0.656
95% CI		(-2.11, 1.11)
p-value		0.4749
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.35
95% CI		(-1.59, 0.89)
Week 24		
Number of observations per imputation	4 (100)	7 (100)
Number of imputed values per imputation	0	0
LS mean	4.79	3.13
SE	0.612	0.461
95% CI	(3.29, 6.29)	(2.00, 4.25)
LS mean difference (Omaveloxolone-Placebo)		-1.67
SE		0.805
95% CI		(-3.64, 0.30)
p-value		0.0839
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.95
95% CI		(-2.24, 0.34)

NOTE 1: LS Mean and Hedges' g are based on the ANCOVA model that includes site, treatment group.
NOTE 2: Multiple imputation including treatment, site, pes cavus status, postbaseline for the endpoint
NOTE 3: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
NOTE 4: Subject 1949208 was excluded from multiple imputation due to missing all postbaseline assessments.
Source: biib141/valueaccess/amnog/t-pgi-anc-mi-itt-pcp-gait.sas:t-pgi-anc-mi-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 15MAY2025

MOXie Part 2: Patient Global Impression of Change (PGI-C) LS Mean up to Week 48 by Visit from ANCOVA+MI Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

Visit Statistic	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 36		
Number of observations per imputation	4 (100)	7 (100)
Number of imputed values per imputation	0	0
LS mean	4.79	3.63
SE	0.748	0.563
95% CI	(2.96, 6.62)	(2.25, 5.00)
LS mean difference (Omaveloxolone-Placebo)		-1.17
SE		0.984
95% CI		(-3.57, 1.24)
p-value		0.2804
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.55
95% CI		(-1.80, 0.70)
Week 48		
Number of observations per imputation	4 (100)	6 (85.7)
Number of imputed values per imputation	0	1 (14.3)
LS mean	5.60	3.69
SE	0.859	0.670
95% CI	(3.92, 7.28)	(2.38, 5.01)
LS mean difference (Omaveloxolone-Placebo)		-1.91
SE		1.152
95% CI		(-4.17, 0.35)
p-value		0.0977
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.97
95% CI		(-2.30, 0.37)

NOTE 1: LS Mean and Hedges' g are based on the ANCOVA model that includes site, treatment group.
NOTE 2: Multiple imputation including treatment, site, pes cavus status, postbaseline for the endpoint
NOTE 3: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
NOTE 4: Subject 1949208 was excluded from multiple imputation due to missing all postbaseline assessments.
Source: biib141/valueaccess/amnog/t-pgi-anc-mi-itt-pcp-gait.sas:t-pgi-anc-mi-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 15MAY2025

MOXie Part 2: Summary of Proportion of Improvement in Patient Global Impression of Change (PGI-C) at Week 48 - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Number of subjects with week 48 assessment (%)	4 (100)	6 (100)
Number of subjects with event (%)	0	2 (33.3)
RR - Relative Risk (Omaveloxolone/Placebo)		3.57
95% CI		(0.21, 59.39)
p-value		0.3748
OR - Odds Ratio (Omaveloxolone/Placebo)		5.00
95% CI		(0.18, 136.32)
ARR - Absolute Risk Reduction (Omaveloxolone-Placebo)		0.26
95% CI		(-0.18, 0.70)

NOTE 1: Improvement if PGI-C value at Week 48 in (1,2,3).
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-pgi-propi-itt-pcp-gait.sas:t-pgi-propi-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Summary of Proportion of Improvement and Stable in Patient Global Impression of Change (PGI-C) at Week 48 - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Number of subjects with week 48 assessment (%)	4 (100)	6 (100)
Number of subjects with event (%)	0	4 (66.7)
RR - Relative Risk (Omaveloxolone/Placebo)		6.43
95% CI		(0.44, 94.41)
p-value		0.1747
OR - Odds Ratio (Omaveloxolone/Placebo)		16.20
95% CI		(0.59, 441.68)
ARR - Absolute Risk Reduction (Omaveloxolone-Placebo)		0.54
95% CI		(0.10, 0.98)

NOTE 1: Improvement and stable if PGI-C value at Week 48 in (1,2,3,4).
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-pgi-propis-itt-pcp-gait.sas:t-pgi-propis-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Summary of Proportion of Worsening in Patient Global Impression of Change (PGI-C) at Week 48 - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Number of subjects with week 48 assessment (%)	4 (100)	6 (100)
Number of subjects with event (%)	4 (100)	2 (33.3)
RR - Relative Risk (Omaveloxolone/Placebo)		0.40
95% CI		(0.14, 1.12)
p-value		0.0803
OR - Odds Ratio (Omaveloxolone/Placebo)		0.06
95% CI		(0.00, 1.68)
ARR - Absolute Risk Reduction (Omaveloxolone-Placebo)		-0.67
95% CI		(-1.04, -0.29)

NOTE 1: Worsening if PGI-C value at Week 48 in (5,6,7).
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-pgi-propw-itt-pcp-gait.sas:t-pgi-propw-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Nine-Hole Peg Test (9-HPT) Reciprocal of Average Time (1/sec) Dominant Hand LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Baseline		
N	4	7
Mean score	0.0177	0.0178
SD	0.00419	0.00494
Week 24		
N	4	7
LS mean change from baseline	-0.0019	0.0002
SE	0.00098	0.00071
95% CI	(-0.0044, 0.0006)	(-0.0016, 0.0020)
LS mean difference (Omaveloxolone-Placebo)		0.0021
SE		0.00137
95% CI		(-0.0014, 0.0056)
p-value		0.1836
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.6800
95% CI		(-0.5809, 1.9409)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-9hpt-mmrm-itt-pcp-dh-gait.sas:t-9hpt-mmrm-itt-pcp-dh-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Nine-Hole Peg Test (9-HPT) Reciprocal of Average Time (1/sec) Dominant Hand LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 48		
N	4	6
LS mean change from baseline	-0.0013	-0.0004
SE	0.00123	0.00098
95% CI	(-0.0044, 0.0019)	(-0.0029, 0.0022)
LS mean difference (Omaveloxolone-Placebo)		0.0009
SE		0.00169
95% CI		(-0.0034, 0.0051)
p-value		0.6257
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.2351
95% CI		(-1.0342, 1.5045)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-9hpt-mmrm-itt-pcp-dh-gait.sas:t-9hpt-mmrm-itt-pcp-dh-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Nine-Hole Peg Test (9-HPT) Reciprocal of Average Time (1/sec) Non-Dominant Hand LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Baseline		
N	4	7
Mean score	0.0159	0.0151
SD	0.00442	0.00629
Week 24		
N	4	7
LS mean change from baseline	-0.0006	-0.0006
SE	0.00148	0.00101
95% CI	(-0.0055, 0.0042)	(-0.0042, 0.0030)
LS mean difference (Omaveloxolone-Placebo)		0.0000
SE		0.00216
95% CI		(-0.0064, 0.0064)
p-value		0.9953
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.0024
95% CI		(-1.2309, 1.2261)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-9hpt-mmrm-itt-pcp-ndh-gait.sas:t-9hpt-mmrm-itt-pcp-ndh-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Nine-Hole Peg Test (9-HPT) Reciprocal of Average Time (1/sec) Non-Dominant Hand LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 48		
N	4	6
LS mean change from baseline	0.0001	0.0003
SE	0.00143	0.00104
95% CI	(-0.0069, 0.0071)	(-0.0052, 0.0059)
LS mean difference (Omaveloxolone-Placebo)		0.0002
SE		0.00215
95% CI		(-0.0088, 0.0093)
p-value		0.9246
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.0289
95% CI		(-1.2363, 1.2941)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-9hpt-mmrm-itt-pcp-ndh-gait.sas:t-9hpt-mmrm-itt-pcp-ndh-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Timed 25-Foot Walk Test (T25-FWT) LS Mean Change from Baseline of Reciprocal of Average Walk Time (1/sec) up to Week 48 - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Baseline		
N	4	5
Mean score	0.08	0.08
SD	0.037	0.062
Week 24		
N	4	5
LS mean change from baseline	-0.02	-0.01
SE	0.013	0.011
95% CI	(-0.05, 0.02)	(-0.04, 0.02)
LS mean difference (Omaveloxolone-Placebo)		0.01
SE		0.019
95% CI		(-0.05, 0.06)
p-value		0.7033
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.17
95% CI		(-1.14, 1.49)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-ftwk-mmrm-itt-pcp-gait.sas:t-ftwk-mmrm-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Timed 25-Foot Walk Test (T25-FWT) LS Mean Change from Baseline of Reciprocal of Average Walk Time (1/sec) up to Week 48 - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 48		
N	4	5
LS mean change from baseline	-0.03	-0.02
SE	0.018	0.016
95% CI	(-0.07, 0.01)	(-0.06, 0.01)
LS mean difference (Omaveloxolone-Placebo)		0.01
SE		0.026
95% CI		(-0.06, 0.07)
p-value		0.8170
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.12
95% CI		(-1.20, 1.43)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-ftwk-mmrm-itt-pcp-gait.sas:t-ftwk-mmrm-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Number of Falls from Baseline to Week 48 from Poisson Regression Model Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Total number of falls from baseline to week 48		
Mean	16.25	15.57
SD	13.647	17.242
Incidence rate of falls	0.05	0.05
95% CI	(0.02, 0.12)	(0.02, 0.09)
Rate ratio (Omaveloxolone/Placebo)		0.94
95% CI		(0.29, 3.12)
p-value		0.9241

NOTE 1: Incidence rate of falls and rate ratio are estimated from the Poisson model with the natural logarithm of time on study (days) as an offset term.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-fall-prm-itt-pcp-gait.sas:t-fall-prm-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: SF-36 Mental Component Summary (SF-36 MCS) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Baseline		
N	4	7
Mean score	53.09	56.48
SD	8.720	5.219
Week 24		
N	4	7
LS mean change from baseline	-12.96	9.58
SE	6.411	4.766
95% CI	(-28.13, 2.21)	(-1.76, 20.91)
LS mean difference (Omaveloxolone-Placebo)		22.53
SE		8.844
95% CI		(1.87, 43.20)
p-value		0.0363
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		1.22
95% CI		(-0.11, 2.56)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-sf36-mmrm-mcs-itt-pcp-gait.sas:t-sf36-mmrm-mcs-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 09MAY2025

MOXie Part 2: SF-36 Mental Component Summary (SF-36 MCS) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 48		
N	4	6
LS mean change from baseline	-9.04	6.90
SE	8.149	6.182
95% CI	(-28.03, 9.94)	(-7.52, 21.31)
LS mean difference (Omaveloxolone-Placebo)		15.94
SE		11.005
95% CI		(-9.32, 41.20)
p-value		0.1846
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.72
95% CI		(-0.58, 2.02)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-sf36-mmrm-mcs-itt-pcp-gait.sas:t-sf36-mmrm-mcs-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 09MAY2025

MOXie Part 2: SF-36 Physical Component Summary (SF-36 PCS) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Baseline		
N	4	7
Mean score	36.95	32.12
SD	3.765	6.871
Week 24		
N	4	7
LS mean change from baseline	-2.06	0.28
SE	4.158	2.997
95% CI	(-12.25, 8.13)	(-7.08, 7.64)
LS mean difference (Omaveloxolone-Placebo)		2.34
SE		5.797
95% CI		(-11.89, 16.56)
p-value		0.7009
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.18
95% CI		(-1.05, 1.42)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-sf36-mmrm-pcs-itt-pcp-gait.sas:t-sf36-mmrm-pcs-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 09MAY2025

MOXie Part 2: SF-36 Physical Component Summary (SF-36 PCS) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Week 48		
N	4	6
LS mean change from baseline	-7.95	-2.57
SE	4.083	3.066
95% CI	(-18.69, 2.79)	(-10.53, 5.39)
LS mean difference (Omaveloxolone-Placebo)		5.38
SE		5.702
95% CI		(-9.53, 20.30)
p-value		0.3908
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.41
95% CI		(-0.87, 1.69)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-sf36-mmrm-pcs-itt-pcp-gait.sas:t-sf36-mmrm-pcs-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 09MAY2025

MOXie Part 2: Summary of Proportion of Worsening in SF-36 Mental Component Summary (SF-36 MCS) at Week 48 - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Number of subjects with week 48 assessment	4 (100)	6 (100)
Number of subjects with event (%)	0	1 (16.7)
RR - Relative Risk (Omaveloxolone/Placebo)		2.14
95% CI		(0.11, 42.52)
p-value		0.6171
OR -Odds Ratio (Omaveloxolone/Placebo)		2.45
95% CI		(0.08, 76.13)
ARR -Absolute Risk Reduction(Omaveloxolone-Placebo)		0.11
95% CI		(-0.29, 0.52)

NOTE 1: Worsening if change from baseline at week 48 <= -9.6 in SF-36 MCS
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-sf36-propw-mcs-itt-pcp-gait.sas:t-sf36-propw-mcs-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 16MAY2025

MOXie Part 2: Summary of Proportion of Worsening in SF-36 Physical Component Summary (SF-36 PCS) at Week 48 - ITT with Pes Cavus Population of Gait Score Greater Than 2

	Placebo (N=4)	Omaveloxolone 150 mg (N=7)
Number of subjects with week 48 assessment	4 (100)	6 (100)
Number of subjects with event (%)	2 (50.0)	0
RR - Relative Risk (Omaveloxolone/Placebo)		0.14
95% CI		(0.01, 2.38)
p-value		0.1749
OR -Odds Ratio (Omaveloxolone/Placebo)		0.08
95% CI		(0.00, 2.23)
ARR -Absolute Risk Reduction(Omaveloxolone-Placebo)		-0.43
95% CI		(-0.91, 0.05)

NOTE 1: Worsening if change from baseline at week 48 <= -9.4 in SF-36 PCS.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-sf36-propw-pcs-itt-pcp-gait.sas:t-sf36-propw-pcs-itt-pcp-gait-gt2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

1. Anzahl der Patient*innen mit mindestens einem UE - ITT mit Pes Cavus Population, mit einem Gait Score größer 2

1.1. Anzahl der Patient*innen mit mindestens einem UE - ITT mit Pes Cavus Population, mit einem Gait Score größer 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem UE - ITT mit Pes Cavus Population, mit einem Gait Score größer 2					
n (%)	7 (100 %)	4 (100 %)	1,04 [0,739; 1,467] 0,8269	1,67 [0,028; 99,610] 0,8184	0,00 [0,000; 0,000] NA
Ja (%) Nein (%)	7 (100 %) 0 (0 %)	4 (100 %) 0 (0 %)			
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

2. Anzahl der Patient*innen mit mindestens einem UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score größer 2

2.1. Anzahl der Patient*innen mit mindestens einem UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score größer 2: Analyse

408-C-1402-PT2	**Behandlungsarm**		**Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert**		
	Omaveloxolon	**Placebo**			
N	**7**	**4**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score größer 2					
Infektionen und parasitäre Erkrankungen (SOC)	**2 (29 %)**	**4 (100 %)**	**0,35 [0,119; 1,011] 0,0520**	**0,05 [0,002; 1,345] 0,0742**	**-0,71 [-1,049; -0,380] < 0,0001**
Bronchitis (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Gastrointestinalinfektion (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Nasopharyngitis (PT)	0 (0 %)	2 (50 %)	0,12 [0,007; 2,104] 0,1493	0,07 [0,002; 1,913] 0,1138	-0,50 [-0,990; -0,010] 0,0451
Otitis externa (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Sinusitis (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Infektion der oberen Atemwege (PT)	0 (0 %)	3 (75 %)	0,09 [0,006; 1,389] 0,0841	0,03 [0,001; 0,894] 0,0426	-0,75 [-1,174; -0,326] 0,0006
Stoffwechsel- und	**0 (0 %)**	**1 (25 %)**	**0,21 [0,010; 4,181] 0,3097**	**0,16 [0,005; 4,865] 0,2934**	**-0,25 [-0,674; 0,174] 0,2509**

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Ernährungsstörungen (SOC)					
Hypercholesterinämie (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Psychiatrische Erkrankungen (SOC)	**0 (0 %)**	**2 (50 %)**	**0,12 [0,007; 2,104] 0,1493**	**0,07 [0,002; 1,913] 0,1138**	**-0,50 [-0,990; -0,010] 0,0451**
Depressive Verstimmung (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Depression (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Erkrankungen des Nervensystems (SOC)	**6 (86 %)**	**3 (75 %)**	**1,14 [0,602; 2,171] 0,6965**	**2,00 [0,090; 44,350] 0,6742**	**0,11 [-0,390; 0,604] 0,6859**
Ataxie (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Schwindelgefühl (PT)	1 (14 %)	2 (50 %)	0,29 [0,036; 2,247] 0,2361	0,17 [0,009; 2,984] 0,2256	-0,36 [-0,911; 0,197] 0,2083
Kopfschmerzen (PT)	4 (57 %)	1 (25 %)	2,29 [0,372; 14,031] 0,3784	4,00 [0,265; 60,325] 0,3214	0,32 [-0,239; 0,882] 0,2643
Migräne (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Spastik (PT)	2 (29 %)	0 (0 %)	3,12 [0,186; 52,601] 0,4372	4,09 [0,154; 108,938] 0,4075	0,29 [-0,049; 0,620] 0,0940
Somnolenz (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Synkope (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Erkrankungen des Ohrs und des Labyrinths (SOC)	**1 (14 %)**	**0 (0 %)**	**1,88 [0,093; 37,632] 0,6944**	**2,08 [0,068; 63,417] 0,6883**	**0,14 [-0,116; 0,402] 0,2837**
Vertigo (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Erkrankungen der Atemwege, des Brustraums und Mediastinums (SOC)	**4 (57 %)**	**1 (25 %)**	**2,29 [0,372; 14,031] 0,3784**	**4,00 [0,265; 60,325] 0,3214**	**0,32 [-0,239; 0,882] 0,2643**
Husten (PT)	2 (29 %)	1 (25 %)	1,14 [0,145; 8,987] 0,9069	1,20 [0,073; 19,631] 0,9062	0,04 [-0,505; 0,576] 0,9050
Dyspnoe (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Epistaxis (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Nasenverstopfung (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Schmerzen im Oropharynx (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Erkrankungen des Gastrointestinaltrakts (SOC)	**5 (71 %)**	**3 (75 %)**	**0,95 [0,457; 1,985] 0,9045**	**0,83 [0,051; 13,633] 0,9062**	**-0,04 [-0,576; 0,505] 0,9050**
Abdominalschmerz (PT)	1 (14 %)	1 (25 %)	0,57 [0,048; 6,856] 0,6720	0,50 [0,023; 11,088] 0,6742	-0,11 [-0,604; 0,390] 0,6859
Diarrhö (PT)	2 (29 %)	0 (0 %)	3,12 [0,186; 52,601] 0,4372	4,09 [0,154; 108,938] 0,4075	0,29 [-0,049; 0,620] 0,0940
Stuhlverfaerbung (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Flatulenz (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Gastritis (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Übelkeit (PT)	3 (43 %)	1 (25 %)	1,71 [0,256; 11,470] 0,5904	2,25 [0,149; 33,933] 0,5697	0,18 [-0,382; 0,739] 0,5436
Erbrechen (PT)	1 (14 %)	1 (25 %)	0,57 [0,048; 6,856] 0,6720	0,50 [0,023; 11,088] 0,6742	-0,11 [-0,604; 0,390] 0,6859
Erkrankungen der Haut und des Unterhautgewebes (SOC)	**2 (29 %)**	**0 (0 %)**	**3,12 [0,186; 52,601] 0,4372**	**4,09 [0,154; 108,938] 0,4075**	**0,29 [-0,049; 0,620] 0,0940**
Akne (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Urtikaria (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen (SOC)	**5 (71 %)**	**2 (50 %)**	**1,43 [0,482; 4,233] 0,5306**	**2,50 [0,194; 32,194] 0,4920**	**0,21 [-0,379; 0,808] 0,4887**
Arthralgie (PT)	1 (14 %)	1 (25 %)	0,57 [0,048; 6,856] 0,6720	0,50 [0,023; 11,088] 0,6742	-0,11 [-0,604; 0,390] 0,6859
Rückenschmerzen (PT)	2 (29 %)	1 (25 %)	1,14 [0,145; 8,987] 0,9069	1,20 [0,073; 19,631] 0,9062	0,04 [-0,505; 0,576] 0,9050
Knochenschmerzen (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Muskelspasmen (PT)	2 (29 %)	0 (0 %)	3,12 [0,186; 52,601] 0,4372	4,09 [0,154; 108,938] 0,4075	0,29 [-0,049; 0,620] 0,0940

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Schmerz in einer Extremität (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Skoliose (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Erkrankungen der Nieren und Harnwege (SOC)	**2 (29 %)**	**1 (25 %)**	**1,14 [0,145; 8,987] 0,9069**	**1,20 [0,073; 19,631] 0,9062**	**0,04 [-0,505; 0,576] 0,9050**
Pollakisurie (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Harnverhaltung (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Harninkontinenz (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Erkrankungen der Geschlechtsorgane und der Brustdrüse (SOC)	**1 (14 %)**	**0 (0 %)**	**1,88 [0,093; 37,632] 0,6944**	**2,08 [0,068; 63,417] 0,6883**	**0,14 [-0,116; 0,402] 0,2837**
Menorrhagie (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort (SOC)	**3 (43 %)**	**4 (100 %)**	**0,49 [0,210; 1,124] 0,0914**	**0,09 [0,003; 2,203] 0,1386**	**-0,57 [-0,938; -0,205] 0,0023**
Asthenie (PT)	1 (14 %)	1 (25 %)	0,57 [0,048; 6,856] 0,6720	0,50 [0,023; 11,088] 0,6742	-0,11 [-0,604; 0,390] 0,6859
Schüttelfrost (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Zyste (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Ermüdung (PT)	2 (29 %)	3 (75 %)	0,38 [0,104; 1,399] 0,1463	0,13 [0,008; 2,181] 0,1582	-0,46 [-1,005; 0,076] 0,0919
Thoraxschmerz nicht kardialen Ursprungs (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Untersuchungen (SOC)	**3 (43 %)**	**1 (25 %)**	**1,71 [0,256; 11,470] 0,5904**	**2,25 [0,149; 33,933] 0,5697**	**0,18 [-0,382; 0,739] 0,5436**
Alaninaminotransferase erhöht (PT)	3 (43 %)	0 (0 %)	4,38 [0,281; 68,058] 0,2959	7,00 [0,275; 178,466] 0,2414	0,43 [0,062; 0,795] 0,0218
Aspartataminotransferase erhöht (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Kreatinphosphokinase im Blut erhöht (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Eisen im Blut erniedrigt (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen (SOC)	**4 (57 %)**	**3 (75 %)**	**0,76 [0,324; 1,792] 0,5443**	**0,44 [0,029; 6,703] 0,5697**	**-0,18 [-0,739; 0,382] 0,5436**
Gehirnerschütterung (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Kontusion (PT)	2 (29 %)	3 (75 %)	0,38 [0,104; 1,399] 0,1463	0,13 [0,008; 2,181] 0,1582	-0,46 [-1,005; 0,076] 0,0919
Exkoriation (PT)	2 (29 %)	1 (25 %)	1,14 [0,145; 8,987] 0,9069	1,20 [0,073; 19,631] 0,9062	0,04 [-0,505; 0,576] 0,9050

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Kopfverletzung (PT)	0 (0 %)	2 (50 %)	0,12 [0,007; 2,104] 0,1493	0,07 [0,002; 1,913] 0,1138	-0,50 [-0,990; -0,010] 0,0451
Gelenksverletzung (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Risswunde (PT)	1 (14 %)	2 (50 %)	0,29 [0,036; 2,247] 0,2361	0,17 [0,009; 2,984] 0,2256	-0,36 [-0,911; 0,197] 0,2083
Bänderzerrung (PT)	2 (29 %)	1 (25 %)	1,14 [0,145; 8,987] 0,9069	1,20 [0,073; 19,631] 0,9062	0,04 [-0,505; 0,576] 0,9050
Muskelzerrung (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Zungenverletzung (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

1. Anzahl der Patient*innen mit mindestens einem milden UE - ITT mit Pes Cavus Population, mit einem Gait Score größer 2

1.1. Anzahl der Patient*innen mit mindestens einem milden UE - ITT mit Pes Cavus Population, mit einem Gait Score größer 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem milden UE - ITT mit Pes Cavus Population, mit einem Gait Score größer 2					
n (%)	7 (100 %)	4 (100 %)	1,04 [0,739; 1,467] 0,8269	1,67 [0,028; 99,610] 0,8184	0,00 [0,000; 0,000] NA
Ja (%) Nein (%)	7 (100 %) 0 (0 %)	4 (100 %) 0 (0 %)			
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

2. Anzahl der Patient*innen mit mindestens einem milden UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score größer 2

2.1. Anzahl der Patient*innen mit mindestens einem milden UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score größer 2: Analyse

408-C-1402-PT2	**Behandlungsarm**		**Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert**		
	Omaveloxolon	**Placebo**			
N	**7**	**4**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem milden UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score größer 2					
Infektionen und parasitäre Erkrankungen (SOC)	**2 (29 %)**	**4 (100 %)**	**0,35 [0,119; 1,011] 0,0520**	**0,05 [0,002; 1,345] 0,0742**	**-0,71 [-1,049; -0,380] < 0,0001**
Bronchitis (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Gastrointestinalinfektion (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Nasopharyngitis (PT)	0 (0 %)	2 (50 %)	0,12 [0,007; 2,104] 0,1493	0,07 [0,002; 1,913] 0,1138	-0,50 [-0,990; -0,010] 0,0451
Otitis externa (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Sinusitis (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Infektion der oberen Atemwege (PT)	0 (0 %)	2 (50 %)	0,12 [0,007; 2,104] 0,1493	0,07 [0,002; 1,913] 0,1138	-0,50 [-0,990; -0,010] 0,0451
Stoffwechsel- und	**0 (0 %)**	**1 (25 %)**	**0,21 [0,010; 4,181] 0,3097**	**0,16 [0,005; 4,865] 0,2934**	**-0,25 [-0,674; 0,174] 0,2509**

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Ernährungsstörungen (SOC)					
Hypercholesterinämie (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Psychiatrische Erkrankungen (SOC)	**0 (0 %)**	**2 (50 %)**	**0,12 [0,007; 2,104] 0,1493**	**0,07 [0,002; 1,913] 0,1138**	**-0,50 [-0,990; -0,010] 0,0451**
Depressive Verstimmung (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Depression (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Erkrankungen des Nervensystems (SOC)	**6 (86 %)**	**3 (75 %)**	**1,14 [0,602; 2,171] 0,6965**	**2,00 [0,090; 44,350] 0,6742**	**0,11 [-0,390; 0,604] 0,6859**
Ataxie (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Schwindelgefühl (PT)	1 (14 %)	2 (50 %)	0,29 [0,036; 2,247] 0,2361	0,17 [0,009; 2,984] 0,2256	-0,36 [-0,911; 0,197] 0,2083
Kopfschmerzen (PT)	4 (57 %)	1 (25 %)	2,29 [0,372; 14,031] 0,3784	4,00 [0,265; 60,325] 0,3214	0,32 [-0,239; 0,882] 0,2643
Spastik (PT)	2 (29 %)	0 (0 %)	3,12 [0,186; 52,601] 0,4372	4,09 [0,154; 108,938] 0,4075	0,29 [-0,049; 0,620] 0,0940
Somnolenz (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Synkope (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Erkrankungen des Ohrs und des Labyrinths (SOC)	**1 (14 %)**	**0 (0 %)**	**1,88 [0,093; 37,632] 0,6944**	**2,08 [0,068; 63,417] 0,6883**	**0,14 [-0,116; 0,402] 0,2837**

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Vertigo (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Erkrankungen der Atemwege, des Brustraums und Mediastinums (SOC)	**3 (43 %)**	**1 (25 %)**	**1,71 [0,256; 11,470] 0,5904**	**2,25 [0,149; 33,933] 0,5697**	**0,18 [-0,382; 0,739] 0,5436**
Husten (PT)	1 (14 %)	1 (25 %)	0,57 [0,048; 6,856] 0,6720	0,50 [0,023; 11,088] 0,6742	-0,11 [-0,604; 0,390] 0,6859
Dyspnoe (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Epistaxis (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Nasenverstopfung (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Schmerzen im Oropharynx (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Erkrankungen des Gastrointestinaltrakts (SOC)	**5 (71 %)**	**3 (75 %)**	**0,95 [0,457; 1,985] 0,9045**	**0,83 [0,051; 13,633] 0,9062**	**-0,04 [-0,576; 0,505] 0,9050**
Abdominalschmerz (PT)	1 (14 %)	1 (25 %)	0,57 [0,048; 6,856] 0,6720	0,50 [0,023; 11,088] 0,6742	-0,11 [-0,604; 0,390] 0,6859
Diarrhö (PT)	2 (29 %)	0 (0 %)	3,12 [0,186; 52,601] 0,4372	4,09 [0,154; 108,938] 0,4075	0,29 [-0,049; 0,620] 0,0940
Stuhlverfaerbung (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Flatulenz (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Gastritis (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Übelkeit (PT)	2 (29 %)	1 (25 %)	1,14 [0,145; 8,987] 0,9069	1,20 [0,073; 19,631] 0,9062	0,04 [-0,505; 0,576] 0,9050
Erbrechen (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Erkrankungen der Haut und des Unterhautgewebes (SOC)	**2 (29 %)**	**0 (0 %)**	**3,12 [0,186; 52,601] 0,4372**	**4,09 [0,154; 108,938] 0,4075**	**0,29 [-0,049; 0,620] 0,0940**
Akne (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Urtikaria (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen (SOC)	**5 (71 %)**	**1 (25 %)**	**2,86 [0,491; 16,621] 0,2452**	**7,50 [0,458; 122,696] 0,1582**	**0,46 [-0,076; 1,005] 0,0919**
Arthralgie (PT)	1 (14 %)	1 (25 %)	0,57 [0,048; 6,856] 0,6720	0,50 [0,023; 11,088] 0,6742	-0,11 [-0,604; 0,390] 0,6859
Rückenschmerzen (PT)	2 (29 %)	0 (0 %)	3,12 [0,186; 52,601] 0,4372	4,09 [0,154; 108,938] 0,4075	0,29 [-0,049; 0,620] 0,0940
Knochenschmerzen (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Muskelspasmen (PT)	2 (29 %)	0 (0 %)	3,12 [0,186; 52,601] 0,4372	4,09 [0,154; 108,938] 0,4075	0,29 [-0,049; 0,620] 0,0940
Schmerz in einer Extremität (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Erkrankungen der Nieren und Harnwege (SOC)	**2 (29 %)**	**1 (25 %)**	**1,14 [0,145; 8,987] 0,9069**	**1,20 [0,073; 19,631] 0,9062**	**0,04 [-0,505; 0,576] 0,9050**
Pollakisurie (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Harnverhaltung (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Harninkontinenz (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Erkrankungen der Geschlechtsorgane und der Brustdrüse (SOC)	**1 (14 %)**	**0 (0 %)**	**1,88 [0,093; 37,632] 0,6944**	**2,08 [0,068; 63,417] 0,6883**	**0,14 [-0,116; 0,402] 0,2837**
Menorrhagie (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort (SOC)	**3 (43 %)**	**3 (75 %)**	**0,57 [0,205; 1,594] 0,2886**	**0,25 [0,017; 3,770] 0,3214**	**-0,32 [-0,882; 0,239] 0,2643**
Asthenie (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Schüttelfrost (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Zyste (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Ermüdung (PT)	2 (29 %)	2 (50 %)	0,57 [0,124; 2,632] 0,4821	0,40 [0,031; 5,151] 0,4920	-0,21 [-0,808; 0,379] 0,4887

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Thoraxschmerz nicht kardialen Ursprungs (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Untersuchungen (SOC)	**3 (43 %)**	**0 (0 %)**	**4,38 [0,281; 68,058] 0,2959**	**7,00 [0,275; 178,466] 0,2414**	**0,43 [0,062; 0,795] 0,0218**
Alaninaminotransferase erhöht (PT)	3 (43 %)	0 (0 %)	4,38 [0,281; 68,058] 0,2959	7,00 [0,275; 178,466] 0,2414	0,43 [0,062; 0,795] 0,0218
Aspartataminotransferase erhöht (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Eisen im Blut erniedrigt (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen (SOC)	**3 (43 %)**	**3 (75 %)**	**0,57 [0,205; 1,594] 0,2886**	**0,25 [0,017; 3,770] 0,3214**	**-0,32 [-0,882; 0,239] 0,2643**
Gehirnerschütterung (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Kontusion (PT)	2 (29 %)	3 (75 %)	0,38 [0,104; 1,399] 0,1463	0,13 [0,008; 2,181] 0,1582	-0,46 [-1,005; 0,076] 0,0919
Exkoriation (PT)	2 (29 %)	1 (25 %)	1,14 [0,145; 8,987] 0,9069	1,20 [0,073; 19,631] 0,9062	0,04 [-0,505; 0,576] 0,9050
Kopfverletzung (PT)	0 (0 %)	2 (50 %)	0,12 [0,007; 2,104] 0,1493	0,07 [0,002; 1,913] 0,1138	-0,50 [-0,990; -0,010] 0,0451
Gelenksverletzung (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Risswunde (PT)	0 (0 %)	2 (50 %)	0,12 [0,007; 2,104] 0,1493	0,07 [0,002; 1,913] 0,1138	-0,50 [-0,990; -0,010] 0,0451

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Bänderzerrung (PT)	2 (29 %)	0 (0 %)	3,12 [0,186; 52,601] 0,4372	4,09 [0,154; 108,938] 0,4075	0,29 [-0,049; 0,620] 0,0940
Muskelzerrung (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Zungenverletzung (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

1. Anzahl der Patient*innen mit mindestens einem moderaten UE - ITT mit Pes Cavus Population, mit einem Gait Score größer 2

1.1. Anzahl der Patient*innen mit mindestens einem moderaten UE - ITT mit Pes Cavus Population, mit einem Gait Score größer 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem moderaten UE - ITT mit Pes Cavus Population, mit einem Gait Score größer 2					
n (%)	7 (100 %)	4 (100 %)	0,57 [0,205; 1,594] 0,2886	0,25 [0,017; 3,770] 0,3214	-0,32 [-0,882; 0,239] 0,2643
Ja (%) Nein (%)	3 (43 %) 4 (57 %)	3 (75 %) 1 (25 %)			
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

2. Anzahl der Patient*innen mit mindestens einem moderaten UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score größer 2

2.1. Anzahl der Patient*innen mit mindestens einem moderaten UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score größer 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem moderaten UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score größer 2					
Infektionen und parasitäre Erkrankungen (SOC)	**0 (0 %)**	**1 (25 %)**	**0,21 [0,010; 4,181] 0,3097**	**0,16 [0,005; 4,865] 0,2934**	**-0,25 [-0,674; 0,174] 0,2509**
Infektion der oberen Atemwege (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Erkrankungen des Nervensystems (SOC)	**1 (14 %)**	**1 (25 %)**	**0,57 [0,048; 6,856] 0,6720**	**0,50 [0,023; 11,088] 0,6742**	**-0,11 [-0,604; 0,390] 0,6859**
Migräne (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Synkope (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Erkrankungen der Atemwege, des Brustraums und Mediastinums (SOC)	**1 (14 %)**	**0 (0 %)**	**1,88 [0,093; 37,632] 0,6944**	**2,08 [0,068; 63,417] 0,6883**	**0,14 [-0,116; 0,402] 0,2837**
Husten (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Erkrankungen des Gastrointestinaltrakts (SOC)	**1 (14 %)**	**0 (0 %)**	**1,88 [0,093; 37,632] 0,6944**	**2,08 [0,068; 63,417] 0,6883**	**0,14 [-0,116; 0,402] 0,2837**
Übelkeit (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Erbrechen (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen (SOC)	**1 (14 %)**	**1 (25 %)**	**0,57 [0,048; 6,856] 0,6720**	**0,50 [0,023; 11,088] 0,6742**	**-0,11 [-0,604; 0,390] 0,6859**
Rückenschmerzen (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Skoliose (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort (SOC)	**0 (0 %)**	**2 (50 %)**	**0,12 [0,007; 2,104] 0,1493**	**0,07 [0,002; 1,913] 0,1138**	**-0,50 [-0,990; -0,010] 0,0451**
Asthenie (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Ermüdung (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Untersuchungen (SOC)	**0 (0 %)**	**1 (25 %)**	**0,21 [0,010; 4,181] 0,3097**	**0,16 [0,005; 4,865] 0,2934**	**-0,25 [-0,674; 0,174] 0,2509**
Kreatinphosphokinase im Blut erhöht (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	**Placebo**			
N	**7**	**4**	**RR**	**OR**	**ARR**
Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen (SOC)	**1 (14 %)**	**1 (25 %)**	**0,57 [0,048; 6,856] 0,6720**	**0,50 [0,023; 11,088] 0,6742**	**-0,11 [-0,604; 0,390] 0,6859**
Risswunde (PT)	1 (14 %)	0 (0 %)	1,88 [0,093; 37,632] 0,6944	2,08 [0,068; 63,417] 0,6883	0,14 [-0,116; 0,402] 0,2837
Bänderzerrung (PT)	0 (0 %)	1 (25 %)	0,21 [0,010; 4,181] 0,3097	0,16 [0,005; 4,865] 0,2934	-0,25 [-0,674; 0,174] 0,2509
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

1. Anzahl der Patient*innen mit mindestens einem schweren UE - ITT mit Pes Cavus Population, mit einem Gait Score größer 2

1.1. Anzahl der Patient*innen mit mindestens einem schweren UE - ITT mit Pes Cavus Population, mit einem Gait Score größer 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem schweren UE - ITT mit Pes Cavus Population, mit einem Gait Score größer 2					
Es traten keine Events auf.					
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

1. Anzahl der Patient*innen mit mindestens einem SUE - ITT mit Pes Cavus Population, mit einem Gait Score größer 2

1.1. Anzahl der Patient*innen mit mindestens einem SUE - ITT mit Pes Cavus Population, mit einem Gait Score größer 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem SUE - ITT mit Pes Cavus Population, mit einem Gait Score größer 2					
Es traten keine Events auf.					
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

1. Anzahl der Patient*innen mit Therapieabbruch aufgrund von UE nach allen SOC und PT – ITT mit Pes Cavus Population, mit einem Gait Score größer 2

1.1. Anzahl der Patient*innen mit Therapieabbruch aufgrund von UE nach allen SOC und PT – ITT mit Pes Cavus Population, mit einem Gait Score größer 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**7**	**4**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit Therapieabbruch aufgrund von UE nach allen SOC und PT – ITT mit Pes Cavus Population, mit einem Gait Score größer 2					
Es traten keine Events auf.					
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Baseline		
N	6	3
Mean score	28.33	31.50
SD	6.634	9.760
Week 4		
N	6	3
LS mean change from baseline	-2.37	-2.79
SE	1.876	2.782
95% CI	(-6.59, 1.86)	(-9.09, 3.50)
LS mean difference (Omaveloxolone-Placebo)		-0.43
SE		3.406
95% CI		(-8.15, 7.30)
p-value		0.9030
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.07
95% CI		(-1.45, 1.32)
Week 12		
N	6	3
LS mean change from baseline	-5.22	0.57
SE	1.876	2.782
95% CI	(-9.44, -0.99)	(-5.73, 6.86)
LS mean difference (Omaveloxolone-Placebo)		5.78
SE		3.406
95% CI		(-1.94, 13.51)
p-value		0.1244
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.92
95% CI		(-0.53, 2.37)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-mfars93-mmrm-itt-pcp-byvis-gait.sas:t-mfars93-mmrm-itt-pcp-byvis-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 18		
N	6	2
LS mean change from baseline	-2.31	1.73
SE	1.876	3.152
95% CI	(-6.54, 1.92)	(-5.15, 8.60)
LS mean difference (Omaveloxolone-Placebo)		4.04
SE		3.725
95% CI		(-4.18, 12.25)
p-value		0.3019
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.68
95% CI		(-0.95, 2.32)
Week 24		
N	6	2
LS mean change from baseline	-2.32	-5.63
SE	1.876	3.339
95% CI	(-6.54, 1.91)	(-12.92, 1.66)
LS mean difference (Omaveloxolone-Placebo)		-3.32
SE		3.891
95% CI		(-11.90, 5.26)
p-value		0.4124
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.54
95% CI		(-2.16, 1.08)
Week 36		
N	6	2
LS mean change from baseline	-2.78	-6.88
SE	1.876	3.426
95% CI	(-7.01, 1.45)	(-14.41, 0.66)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-mfars93-mmrm-itt-pcp-byvis-gait.sas:t-mfars93-mmrm-itt-pcp-byvis-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
LS mean difference (Omaveloxolone-Placebo)		-4.10
SE		3.971
95% CI		(-12.90, 4.70)
p-value		0.3253
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.65
95% CI		(-2.28, 0.98)
Week 48		
N	5	2
LS mean change from baseline	-0.54	-4.40
SE	2.013	3.461
95% CI	(-4.98, 3.90)	(-12.07, 3.27)
LS mean difference (Omaveloxolone-Placebo)		-3.86
SE		4.102
95% CI		(-12.94, 5.23)
p-value		0.3684
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.59
95% CI		(-2.25, 1.08)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-mfars93-mmrm-itt-pcp-byvis-gait.sas:t-mfars93-mmrm-itt-pcp-byvis-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Bulbar Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Baseline		
N	6	3
Mean score	0.33	0.67
SD	0.376	0.289
Week 4		
N	6	3
LS mean change from baseline	0.24	-0.17
SE	0.156	0.248
95% CI	(-0.13, 0.62)	(-0.78, 0.44)
LS mean difference (Omaveloxolone-Placebo)		-0.41
SE		0.311
95% CI		(-1.18, 0.35)
p-value		0.2349
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.66
95% CI		(-2.08, 0.76)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-mfars93-d-bul-mmrm-itt-pcp-gait.sas:t-mfars93-d-bul-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Bulbar Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 12		
N	6	3
LS mean change from baseline	-0.06	-0.25
SE	0.156	0.248
95% CI	(-0.43, 0.32)	(-0.86, 0.36)
LS mean difference (Omaveloxolone-Placebo)		-0.19
SE		0.311
95% CI		(-0.95, 0.58)
p-value		0.5650
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.31
95% CI		(-1.70, 1.09)
Week 18		
N	6	2
LS mean change from baseline	0.12	-0.29
SE	0.156	0.278
95% CI	(-0.26, 0.49)	(-0.93, 0.35)
LS mean difference (Omaveloxolone-Placebo)		-0.41
SE		0.338
95% CI		(-1.20, 0.38)
p-value		0.2632
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.72
95% CI		(-2.36, 0.92)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-mfars93-d-bul-mmrm-itt-pcp-gait.sas:t-mfars93-d-bul-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Bulbar Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 24		
N	6	2
LS mean change from baseline	0.20	-0.05
SE	0.156	0.284
95% CI	(-0.18, 0.57)	(-0.69, 0.60)
LS mean difference (Omaveloxolone-Placebo)		-0.24
SE		0.343
95% CI		(-1.04, 0.56)
p-value		0.5034
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.42
95% CI		(-2.03, 1.19)
Week 36		
N	6	2
LS mean change from baseline	0.04	-0.32
SE	0.156	0.282
95% CI	(-0.34, 0.41)	(-0.96, 0.33)
LS mean difference (Omaveloxolone-Placebo)		-0.35
SE		0.342
95% CI		(-1.15, 0.44)
p-value		0.3322
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.62
95% CI		(-2.25, 1.01)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-mfars93-d-bul-mmrm-itt-pcp-gait.sas:t-mfars93-d-bul-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Bulbar Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 48		
N	5	2
LS mean change from baseline	-0.02	-0.22
SE	0.211	0.322
95% CI	(-0.48, 0.44)	(-0.94, 0.49)
LS mean difference (Omaveloxolone-Placebo)		-0.20
SE		0.451
95% CI		(-1.18, 0.77)
p-value		0.6593
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.29
95% CI		(-1.93, 1.36)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-mfars93-d-bul-mmrm-itt-pcp-gait.sas:t-mfars93-d-bul-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Upper Limb Coordination Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Baseline		
N	6	3
Mean score	7.63	7.75
SD	1.571	3.683
Week 4		
N	6	3
LS mean change from baseline	-0.57	-0.54
SE	0.839	1.222
95% CI	(-2.45, 1.31)	(-3.32, 2.23)
LS mean difference (Omaveloxolone-Placebo)		0.02
SE		1.507
95% CI		(-3.41, 3.46)
p-value		0.9874
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.01
95% CI		(-1.38, 1.39)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-mfars93-d-ul-mmrm-itt-pcp-gait.sas:t-mfars93-d-ul-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Upper Limb Coordination Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 12		
N	6	3
LS mean change from baseline	-1.80	0.49
SE	0.839	1.222
95% CI	(-3.68, 0.08)	(-2.28, 3.26)
LS mean difference (Omaveloxolone-Placebo)		2.29
SE		1.507
95% CI		(-1.15, 5.72)
p-value		0.1651
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.82
95% CI		(-0.62, 2.26)
Week 18		
N	6	2
LS mean change from baseline	-0.98	1.14
SE	0.841	1.485
95% CI	(-2.87, 0.90)	(-2.05, 4.32)
LS mean difference (Omaveloxolone-Placebo)		2.12
SE		1.761
95% CI		(-1.69, 5.93)
p-value		0.2508
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.77
95% CI		(-0.87, 2.42)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-mfars93-d-ul-mmrm-itt-pcp-gait.sas:t-mfars93-d-ul-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Upper Limb Coordination Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 24		
N	6	2
LS mean change from baseline	-0.14	-1.19
SE	0.841	1.476
95% CI	(-2.02, 1.74)	(-4.35, 1.97)
LS mean difference (Omaveloxolone-Placebo)		-1.05
SE		1.751
95% CI		(-4.84, 2.74)
p-value		0.5576
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.39
95% CI		(-2.00, 1.22)
Week 36		
N	6	2
LS mean change from baseline	-0.77	-0.59
SE	0.842	1.538
95% CI	(-2.66, 1.11)	(-3.89, 2.71)
LS mean difference (Omaveloxolone-Placebo)		0.18
SE		1.812
95% CI		(-3.74, 4.11)
p-value		0.9208
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.07
95% CI		(-1.54, 1.67)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-mfars93-d-ul-mmrm-itt-pcp-gait.sas:t-mfars93-d-ul-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Upper Limb Coordination Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 48		
N	5	2
LS mean change from baseline	-0.56	0.12
SE	0.920	1.540
95% CI	(-2.57, 1.46)	(-3.18, 3.42)
LS mean difference (Omaveloxolone-Placebo)		0.68
SE		1.831
95% CI		(-3.28, 4.63)
p-value		0.7174
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.24
95% CI		(-1.41, 1.88)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-mfars93-d-ul-mmrm-itt-pcp-gait.sas:t-mfars93-d-ul-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Lower Limb Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Baseline		
N	6	3
Mean score	5.25	5.92
SD	2.168	2.428
Week 4		
N	6	3
LS mean change from baseline	-1.02	-0.02
SE	0.695	1.023
95% CI	(-2.58, 0.54)	(-2.33, 2.30)
LS mean difference (Omaveloxolone-Placebo)		1.01
SE		1.259
95% CI		(-1.85, 3.86)
p-value		0.4452
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.43
95% CI		(-0.97, 1.83)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-mfars93-d-ll-mmrm-itt-pcp-gait.sas:t-mfars93-d-ll-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Lower Limb Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 12		
N	6	3
LS mean change from baseline	-0.53	0.74
SE	0.695	1.023
95% CI	(-2.09, 1.03)	(-1.58, 3.06)
LS mean difference (Omaveloxolone-Placebo)		1.27
SE		1.259
95% CI		(-1.59, 4.12)
p-value		0.3404
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.55
95% CI		(-0.86, 1.96)
Week 18		
N	6	2
LS mean change from baseline	-0.52	3.02
SE	0.695	1.173
95% CI	(-2.08, 1.04)	(0.47, 5.58)
LS mean difference (Omaveloxolone-Placebo)		3.54
SE		1.387
95% CI		(0.49, 6.60)
p-value		0.0268
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		1.61
95% CI		(-0.17, 3.40)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-mfars93-d-ll-mmrm-itt-pcp-gait.sas:t-mfars93-d-ll-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Lower Limb Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 24		
N	6	2
LS mean change from baseline	-0.52	-0.64
SE	0.695	1.242
95% CI	(-2.08, 1.04)	(-3.35, 2.07)
LS mean difference (Omaveloxolone-Placebo)		-0.12
SE		1.449
95% CI		(-3.31, 3.08)
p-value		0.9367
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.05
95% CI		(-1.65, 1.55)
Week 36		
N	6	2
LS mean change from baseline	-1.35	-0.22
SE	0.695	1.271
95% CI	(-2.91, 0.21)	(-3.02, 2.58)
LS mean difference (Omaveloxolone-Placebo)		1.13
SE		1.476
95% CI		(-2.15, 4.40)
p-value		0.4619
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.48
95% CI		(-1.14, 2.10)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-mfars93-d-ll-mmrm-itt-pcp-gait.sas:t-mfars93-d-ll-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Lower Limb Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 48		
N	5	2
LS mean change from baseline	-1.06	1.55
SE	0.754	1.283
95% CI	(-2.72, 0.59)	(-1.30, 4.39)
LS mean difference (Omaveloxolone-Placebo)		2.61
SE		1.539
95% CI		(-0.80, 6.01)
p-value		0.1194
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		1.06
95% CI		(-0.67, 2.79)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-mfars93-d-ll-mmrm-itt-pcp-gait.sas:t-mfars93-d-ll-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Upright Stability Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Baseline		
N	6	3
Mean score	15.11	17.17
SD	4.031	3.884
Week 4		
N	6	3
LS mean change from baseline	-0.81	-2.49
SE	1.341	2.021
95% CI	(-3.96, 2.34)	(-7.27, 2.30)
LS mean difference (Omaveloxolone-Placebo)		-1.68
SE		2.483
95% CI		(-7.58, 4.22)
p-value		0.5206
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.35
95% CI		(-1.75, 1.04)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-mfars93-d-us-mmrm-itt-pcp-gait.sas:t-mfars93-d-us-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Upright Stability Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 12		
N	6	3
LS mean change from baseline	-2.62	-1.05
SE	1.341	2.021
95% CI	(-5.77, 0.53)	(-5.84, 3.73)
LS mean difference (Omaveloxolone-Placebo)		1.57
SE		2.483
95% CI		(-4.33, 7.47)
p-value		0.5477
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.33
95% CI		(-1.07, 1.72)
Week 18		
N	6	2
LS mean change from baseline	-0.66	-4.05
SE	1.341	2.200
95% CI	(-3.81, 2.50)	(-9.04, 0.94)
LS mean difference (Omaveloxolone-Placebo)		-3.39
SE		2.627
95% CI		(-9.45, 2.66)
p-value		0.2327
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.78
95% CI		(-2.42, 0.87)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-mfars93-d-us-mmrm-itt-pcp-gait.sas:t-mfars93-d-us-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Upright Stability Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 24		
N	6	2
LS mean change from baseline	-1.49	-4.34
SE	1.340	2.223
95% CI	(-4.64, 1.66)	(-9.40, 0.72)
LS mean difference (Omaveloxolone-Placebo)		-2.85
SE		2.653
95% CI		(-8.97, 3.28)
p-value		0.3149
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.65
95% CI		(-2.28, 0.98)
Week 36		
N	6	2
LS mean change from baseline	-0.63	-6.78
SE	1.340	2.439
95% CI	(-3.78, 2.52)	(-12.28, -1.29)
LS mean difference (Omaveloxolone-Placebo)		-6.15
SE		2.833
95% CI		(-12.63, 0.33)
p-value		0.0601
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-1.32
95% CI		(-3.05, 0.41)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-mfars93-d-us-mmrm-itt-pcp-gait.sas:t-mfars93-d-us-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Upright Stability Domain LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 48		
N	5	2
LS mean change from baseline	1.35	-6.73
SE	1.434	2.512
95% CI	(-1.98, 4.67)	(-12.43, -1.04)
LS mean difference (Omaveloxolone-Placebo)		-8.08
SE		2.946
95% CI		(-14.82, -1.34)
p-value		0.0242
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-1.66
95% CI		(-3.51, 0.20)

NOTE 1: LS Mean and Hedges' g are based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-mfars93-d-us-mmrm-itt-pcp-gait.sas:t-mfars93-d-us-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Summary of Proportion of Worsening in Modified Friedreich's Ataxia 93-points Rating Scale (mFARS) Total Score at Week 48 with Imputation - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Number of subjects with week 48 assessment (%)	5 (83.3)	2 (66.7)
Number of subjects with event (%)	1 (16.7)	2 (66.7)
RR - Relative Risk (Omaveloxolone/Placebo)		4.00
95% CI		(0.56, 28.40)
p-value		0.1656
OR - Odds Ratio (Omaveloxolone/Placebo)		10.00
95% CI		(0.40, 250.42)
ARR - Absolute Risk Reduction (Omaveloxolone-Placebo)		0.50
95% CI		(-0.11, 1.11)

NOTE 1: Worsening if change from baseline at Week 48 >= 1.9 in mFARS Total Score. Subject without week 48 assessment will be imputed as responder with a worsening event.

NOTE 2: Cochran-Mantel-Haenszel adjusted OR and RR are calculated adjusting for pes cavus status. Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-mfars93-propw-itt-pcp-gait-imp.sas:t-mfars93-propw-itt-pcp-gait-le2-imp.rtf **Data Tag:** FINAL **Run Date:** 07MAY2025

MOXie Part 2: Activities of Daily Living (ADL) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Baseline		
N	6	3
Mean score	7.17	12.17
SD	2.840	4.537
Week 24		
N	6	2
LS mean change from baseline	-0.75	-2.25
SE	0.876	1.608
95% CI	(-3.13, 1.63)	(-6.62, 2.12)
LS mean difference (Omaveloxolone-Placebo)		-1.50
SE		1.907
95% CI		(-6.68, 3.68)
p-value		0.4722
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.40
95% CI		(-2.02, 1.21)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-adl-mmrm-itt-pcp-gait.sas:t-adl-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Activities of Daily Living (ADL) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 36		
N	6	2
LS mean change from baseline	-0.74	-2.28
SE	0.148	0.285
95% CI	(-1.39, -0.09)	(-3.48, -1.07)
LS mean difference (Omaveloxolone-Placebo)		-1.53
SE		0.345
95% CI		(-2.97, -0.10)
p-value		0.0439
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-1.49
95% CI		(-3.25, 0.27)
Week 48		
N	6	2
LS mean change from baseline	0.89	-3.42
SE	1.000	1.835
95% CI	(-1.64, 3.42)	(-8.07, 1.22)
LS mean difference (Omaveloxolone-Placebo)		-4.31
SE		2.176
95% CI		(-9.82, 1.20)
p-value		0.1014
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-1.09
95% CI		(-2.78, 0.60)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-adl-mmrm-itt-pcp-gait.sas:t-adl-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Patient Global Impression of Change (PGI-C) LS Mean up to Week 48 by Visit from ANCOVA+MI Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

Visit Statistic	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 12		
Number of observations per imputation	6 (100)	3 (100)
Number of imputed values per imputation	0	0
LS mean	2.93	4.03
SE	0.228	0.331
95% CI	(2.29, 3.56)	(3.11, 4.94)
LS mean difference (Omaveloxolone-Placebo)		1.10
SE		0.415
95% CI		(-0.05, 2.25)
p-value		0.0571
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		1.18
95% CI		(-0.31, 2.67)
Week 24		
Number of observations per imputation	6 (100)	2 (66.7)
Number of imputed values per imputation	0	1 (33.3)
LS mean	3.32	4.13
SE	0.304	0.674
95% CI	(2.72, 3.91)	(2.80, 5.46)
LS mean difference (Omaveloxolone-Placebo)		0.81
SE		0.725
95% CI		(-0.61, 2.24)
p-value		0.2626
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.79
95% CI		(-0.85, 2.44)

NOTE 1: LS Mean and Hedges' g are based on the ANCOVA model that includes site, treatment group.
NOTE 2: Multiple imputation including treatment, site, pes cavus status, postbaseline for the endpoint
NOTE 3: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
NOTE 4: Subject 1949208 was excluded from multiple imputation due to missing all postbaseline assessments.

Source: biib141/valueaccess/amnog/t-pgi-anc-mi-itt-pcp-gait.sas:t-pgi-anc-mi-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 15MAY2025

MOXie Part 2: Patient Global Impression of Change (PGI-C) LS Mean up to Week 48 by Visit from ANCOVA+MI Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

Visit Statistic	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 36		
Number of observations per imputation	6 (100)	2 (66.7)
Number of imputed values per imputation	0	1 (33.3)
LS mean	3.80	3.45
SE	0.380	0.715
95% CI	(3.06, 4.55)	(2.05, 4.86)
LS mean difference (Omaveloxolone-Placebo)		-0.35
SE		0.808
95% CI		(-1.94, 1.23)
p-value		0.6632
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.31
95% CI		(-1.92, 1.30)
Week 48		
Number of observations per imputation	6 (100)	2 (66.7)
Number of imputed values per imputation	0	1 (33.3)
LS mean	4.02	3.26
SE	0.501	0.922
95% CI	(3.04, 5.00)	(1.45, 5.07)
LS mean difference (Omaveloxolone-Placebo)		-0.76
SE		1.050
95% CI		(-2.82, 1.30)
p-value		0.4693
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.51
95% CI		(-2.13, 1.11)

NOTE 1: LS Mean and Hedges' g are based on the ANCOVA model that includes site, treatment group.
NOTE 2: Multiple imputation including treatment, site, pes cavus status, postbaseline for the endpoint
NOTE 3: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
NOTE 4: Subject 1949208 was excluded from multiple imputation due to missing all postbaseline assessments.
Source: biib141/valueaccess/amnog/t-pgi-anc-mi-itt-pcp-gait.sas:t-pgi-anc-mi-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 15MAY2025

MOXie Part 2: Summary of Proportion of Improvement in Patient Global Impression of Change (PGI-C) at Week 48 - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Number of subjects with week 48 assessment (%)	6 (100)	2 (100)
Number of subjects with event (%)	2 (33.3)	1 (50.0)
RR - Relative Risk (Omaveloxolone/Placebo)		1.50
95% CI		(0.25, 8.98)
p-value		0.6569
OR - Odds Ratio (Omaveloxolone/Placebo)		2.00
95% CI		(0.08, 51.59)
ARR - Absolute Risk Reduction (Omaveloxolone-Placebo)		0.17
95% CI		(-0.62, 0.96)

NOTE 1: Improvement if PGI-C value at Week 48 in (1,2,3).
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-pgi-propi-itt-pcp-gait.sas:t-pgi-propi-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Summary of Proportion of Improvement and Stable in Patient Global Impression of Change (PGI-C) at Week 48 - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Number of subjects with week 48 assessment (%)	6 (100)	2 (100)
Number of subjects with event (%)	4 (66.7)	2 (100)
RR - Relative Risk (Omaveloxolone/Placebo)		1.30
95% CI		(0.61, 2.74)
p-value		0.4971
OR - Odds Ratio (Omaveloxolone/Placebo)		2.78
95% CI		(0.09, 83.84)
ARR - Absolute Risk Reduction (Omaveloxolone-Placebo)		0.33
95% CI		(-0.04, 0.71)

NOTE 1: Improvement and stable if PGI-C value at Week 48 in (1,2,3,4).
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-pgi-propis-itt-pcp-gait.sas:t-pgi-propis-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Summary of Proportion of Worsening in Patient Global Impression of Change (PGI-C) at Week 48 with Imputation - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Number of subjects with week 48 assessment (%)	6 (100)	2 (66.7)
Number of subjects with event (%)	2 (33.3)	1 (33.3)
RR - Relative Risk (Omaveloxolone/Placebo)		1.00
95% CI		(0.14, 7.10)
p-value		1.0000
OR - Odds Ratio (Omaveloxolone/Placebo)		1.00
95% CI		(0.05, 18.91)
ARR - Absolute Risk Reduction (Omaveloxolone-Placebo)		0.00
95% CI		(-0.65, 0.65)

NOTE 1: Worsening if PGI-C value at Week 48 in (5,6,7).Subject without week 48 assessment will be imputed as responder with a worsening event.

Source: biib141/valueaccess/amnog/t-pgi-propw-imp-pcp-gait.sas:t-pgi-propw-imp-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 14MAY2025

MOXie Part 2: Nine-Hole Peg Test (9-HPT) Reciprocal of Average Time (1/sec) Dominant Hand LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Baseline		
N	6	3
Mean score	0.0288	0.0323
SD	0.00812	0.01246
Week 24		
N	6	2
LS mean change from baseline	-0.0015	0.0028
SE	0.00186	0.00387
95% CI	(-0.0092, 0.0062)	(-0.0132, 0.0188)
LS mean difference (Omaveloxolone-Placebo)		0.0043
SE		0.00480
95% CI		(-0.0155, 0.0241)
p-value		0.4593
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.3033
95% CI		(-1.3039, 1.9105)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-9hpt-mmrm-itt-pcp-dh-gait.sas:t-9hpt-mmrm-itt-pcp-dh-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Nine-Hole Peg Test (9-HPT) Reciprocal of Average Time (1/sec) Dominant Hand LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 48		
N	6	2
LS mean change from baseline	-0.0002	0.0025
SE	0.00185	0.00386
95% CI	(-0.0079, 0.0075)	(-0.0135, 0.0185)
LS mean difference (Omaveloxolone-Placebo)		0.0027
SE		0.00479
95% CI		(-0.0172, 0.0225)
p-value		0.6309
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.1876
95% CI		(-1.4154, 1.7905)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-9hpt-mmrm-itt-pcp-dh-gait.sas:t-9hpt-mmrm-itt-pcp-dh-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Nine-Hole Peg Test (9-HPT) Reciprocal of Average Time (1/sec) Non-Dominant Hand LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Baseline		
N	6	3
Mean score	0.0252	0.0284
SD	0.00678	0.01108
Week 24		
N	6	2
LS mean change from baseline	-0.0017	-0.0006
SE	0.00135	0.00249
95% CI	(-0.0052, 0.0018)	(-0.0070, 0.0058)
LS mean difference (Omaveloxolone-Placebo)		0.0011
SE		0.00296
95% CI		(-0.0065, 0.0087)
p-value		0.7335
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.1950
95% CI		(-1.4081, 1.7982)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-9hpt-mmrm-itt-pcp-ndh-gait.sas:t-9hpt-mmrm-itt-pcp-ndh-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Nine-Hole Peg Test (9-HPT) Reciprocal of Average Time (1/sec) Non-Dominant Hand LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 48		
N	6	2
LS mean change from baseline	-0.0003	0.0002
SE	0.00061	0.00121
95% CI	(-0.0025, 0.0018)	(-0.0042, 0.0046)
LS mean difference (Omaveloxolone-Placebo)		0.0006
SE		0.00148
95% CI		(-0.0048, 0.0060)
p-value		0.7305
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.1478
95% CI		(-1.4541, 1.7497)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-9hpt-mmrm-itt-pcp-ndh-gait.sas:t-9hpt-mmrm-itt-pcp-ndh-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Timed 25-Foot Walk Test (T25-FWT) LS Mean Change from Baseline of Reciprocal of Average Walk Time (1/sec) up to Week 48 - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Baseline		
N	6	3
Mean score	0.19	0.17
SD	0.048	0.022
Week 24		
N	6	2
LS mean change from baseline	-0.01	0.00
SE	0.009	0.017
95% CI	(-0.05, 0.03)	(-0.07, 0.08)
LS mean difference (Omaveloxolone-Placebo)		0.01
SE		0.020
95% CI		(-0.07, 0.10)
p-value		0.6012
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.20
95% CI		(-1.40, 1.80)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-ftwk-mmrm-itt-pcp-gait.sas:t-ftwk-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Timed 25-Foot Walk Test (T25-FWT) LS Mean Change from Baseline of Reciprocal of Average Walk Time (1/sec) up to Week 48 - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 48		
N	5	2
LS mean change from baseline	-0.01	0.01
SE	0.014	0.024
95% CI	(-0.05, 0.04)	(-0.07, 0.09)
LS mean difference (Omaveloxolone-Placebo)		0.01
SE		0.029
95% CI		(-0.08, 0.11)
p-value		0.6403
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.23
95% CI		(-1.42, 1.87)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-ftwk-mmrm-itt-pcp-gait.sas:t-ftwk-mmrm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: Number of Falls from Baseline to Week 48 from Poisson Regression Model Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Total number of falls from baseline to week 48		
Mean	3.50	4.00
SD	2.811	4.583
Incidence rate of falls	0.01	0.02
95% CI	(0.00, 0.03)	(0.00, 0.06)
Rate ratio (Omaveloxolone/Placebo)		1.66
95% CI		(0.34, 8.17)
p-value		0.5358

NOTE 1: Incidence rate of falls and rate ratio are estimated from the Poisson model with the natural logarithm of time on study (days) as an offset term.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-fall-prm-itt-pcp-gait.sas:t-fall-prm-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

MOXie Part 2: SF-36 Mental Component Summary (SF-36 MCS) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Baseline		
N	6	3
Mean score	52.70	54.29
SD	10.300	9.836
Week 24		
N	6	2
LS mean change from baseline	-0.42	-18.86
SE	5.189	10.443
95% CI	(-15.62, 14.77)	(-47.79, 10.07)
LS mean difference (Omaveloxolone-Placebo)		-18.44
SE		12.816
95% CI		(-53.40, 16.53)
p-value		0.2206
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.73
95% CI		(-2.37, 0.91)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-sf36-mmrm-mcs-itt-pcp-gait.sas:t-sf36-mmrm-mcs-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 09MAY2025

MOXie Part 2: SF-36 Mental Component Summary (SF-36 MCS) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 48		
N	6	2
LS mean change from baseline	-0.24	-4.90
SE	2.598	6.681
95% CI	(-11.40, 10.92)	(-33.58, 23.78)
LS mean difference (Omaveloxolone-Placebo)		-4.66
SE		8.705
95% CI		(-42.03, 32.71)
p-value		0.6459
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-0.17
95% CI		(-1.78, 1.43)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-sf36-mmrm-mcs-itt-pcp-gait.sas:t-sf36-mmrm-mcs-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 09MAY2025

MOXie Part 2: SF-36 Physical Component Summary (SF-36 PCS) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Baseline		
N	6	3
Mean score	44.68	42.76
SD	5.787	11.385
Week 24		
N	6	2
LS mean change from baseline	1.12	3.89
SE	0.633	1.189
95% CI	(-1.22, 3.46)	(-0.37, 8.15)
LS mean difference (Omaveloxolone-Placebo)		2.77
SE		1.424
95% CI		(-2.27, 7.82)
p-value		0.1635
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		0.76
95% CI		(-0.88, 2.41)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-sf36-mmrm-pcs-itt-pcp-gait.sas:t-sf36-mmrm-pcs-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 09MAY2025

MOXie Part 2: SF-36 Physical Component Summary (SF-36 PCS) LS Mean Change from Baseline up to Week 48 by Visit from MMRM Analysis - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Week 48		
N	6	2
LS mean change from baseline	0.76	-11.21
SE	3.023	5.262
95% CI	(-7.15, 8.67)	(-24.94, 2.53)
LS mean difference (Omaveloxolone-Placebo)		-11.96
SE		6.091
95% CI		(-27.84, 3.91)
p-value		0.1094
Hedge's g standardized mean difference (Omaveloxolone-Placebo)		-1.05
95% CI		(-2.73, 0.63)

NOTE 1: LS Mean is based on the MMRM model that includes site, baseline, treatment group, time, the interaction between treatment and time, and the interaction between baseline and time.

NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.

Source: biib141/valueaccess/amnog/t-sf36-mmrm-pcs-itt-pcp-gait.sas:t-sf36-mmrm-pcs-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 09MAY2025

MOXie Part 2: Summary of Proportion of Worsening in SF-36 Mental Component Summary (SF-36 MCS) at Week 48 - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Number of subjects with week 48 assessment	6 (100)	2 (100)
Number of subjects with event (%)	0	0
RR - Relative Risk (Omaveloxolone/Placebo)		-
OR -Odds Ratio (Omaveloxolone/Placebo)		-
ARR -Absolute Risk Reduction(Omaveloxolone-Placebo)		-

NOTE 1: Worsening if change from baseline at week 48 <= -9.6 in SF-36 MCS.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-sf36-propw-mcs-itt-pcp-gait.sas:t-sf36-propw-mcs-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 16MAY2025

MOXie Part 2: Summary of Proportion of Worsening in SF-36 Physical Component Summary (SF-36 PCS) at Week 48 - ITT with Pes Cavus Population of Gait Score Less and Equal Than 2

	Placebo (N=6)	Omaveloxolone 150 mg (N=3)
Number of subjects with week 48 assessment	6 (100)	2 (100)
Number of subjects with event (%)	0	1 (50.0)
RR - Relative Risk (Omaveloxolone/Placebo)		7.00
95% CI		(0.38, 127.32)
p-value		0.1886
OR -Odds Ratio (Omaveloxolone/Placebo)		13.00
95% CI		(0.33, 505.22)
ARR -Absolute Risk Reduction(Omaveloxolone-Placebo)		0.43
95% CI		(-0.17, 1.03)

NOTE 1: Worsening if change from baseline at week 48 <= -9.4 in SF-36 PCS.
NOTE 2: Baseline Gait score is the maximum value of screening and Day 1 pre dose.
Source: biib141/valueaccess/amnog/t-sf36-propw-pcs-itt-pcp-gait.sas:t-sf36-propw-pcs-itt-pcp-gait-le2.rtf **Data Tag:** FINAL **Run Date:** 12MAY2025

1. Anzahl der Patient*innen mit mindestens einem UE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2

1.1. Anzahl der Patient*innen mit mindestens einem UE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem UE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2					
n (%)	3 (100 %)	6 (100 %)	0,94 [0,617; 1,439] 0,7956	0,54 [0,009; 33,470] 0,7815	0,00 [0,000; 0,000] NA
Ja (%) Nein (%)	3 (100 %) 0 (0 %)	6 (100 %) 0 (0 %)			
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

2. Anzahl der Patient*innen mit mindestens einem UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2

2.1. Anzahl der Patient*innen mit mindestens einem UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2					
Infektionen und parasitäre Erkrankungen (SOC)	**1 (33 %)**	**3 (50 %)**	**0,67 [0,111; 3,990] 0,6700**	**0,50 [0,028; 8,952] 0,6506**	**-0,17 [-0,833; 0,500] 0,6369**
Febrile Infektion (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Sinusitis (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Infektion der oberen Atemwege (PT)	1 (33 %)	2 (33 %)	1,00 [0,141; 7,099] 1,0000	1,00 [0,053; 18,915] 1,0000	0,00 [-0,653; 0,653] 1,0000
Virusinfektion (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Erkrankungen des Immunsystems (SOC)	**1 (33 %)**	**0 (0 %)**	**5,25 [0,273; 100,855] 0,2748**	**7,80 [0,231; 262,811] 0,2552**	**0,33 [-0,200; 0,867] 0,2227**
Allergie auf Arthropodenstich (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Psychiatrische Erkrankungen (SOC)	**1 (33 %)**	**0 (0 %)**	**5,25 [0,273; 100,855] 0,2748**	**7,80 [0,231; 262,811] 0,2552**	**0,33 [-0,200; 0,867] 0,2227**

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Schlaflosigkeit (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Erkrankungen des Nervensystems (SOC)	**2 (67 %)**	**3 (50 %)**	**1,33 [0,430; 4,134] 0,6309**	**2,00 [0,112; 35,807] 0,6506**	**0,17 [-0,500; 0,833] 0,6369**
Ataxie (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Gleichgewichtsstörung (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Schwindelgefühl (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Kopfschmerzen (PT)	1 (33 %)	1 (17 %)	2,00 [0,181; 22,056] 0,5833	2,50 [0,100; 62,605] 0,5891	0,17 [-0,444; 0,778] 0,6053
Hypoästhesie (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Parästhesie (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Tremor (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Herzerkrankungen (SOC)	**0 (0 %)**	**1 (17 %)**	**0,58 [0,030; 11,206] 0,7339**	**0,52 [0,016; 16,831] 0,7281**	**-0,17 [-0,465; 0,132] 0,2768**
Angina pectoris (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Erkrankungen des Gastrointestinaltrakts (SOC)	**1 (33 %)**	**3 (50 %)**	**0,67 [0,111; 3,990] 0,6700**	**0,50 [0,028; 8,952] 0,6506**	**-0,17 [-0,833; 0,500] 0,6369**
Abdominalschmerz (PT)	1 (33 %)	1 (17 %)	2,00 [0,181; 22,056] 0,5833	2,50 [0,100; 62,605] 0,5891	0,17 [-0,444; 0,778] 0,6053

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Diarrhö (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Übelkeit (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Erbrechen (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Erkrankungen der Haut und des Unterhautgewebes (SOC)	**1 (33 %)**	**1 (17 %)**	**2,00 [0,181; 22,056] 0,5833**	**2,50 [0,100; 62,605] 0,5891**	**0,17 [-0,444; 0,778] 0,6053**
Ausschlag (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Makulöser Ausschlag (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen (SOC)	**1 (33 %)**	**2 (33 %)**	**1,00 [0,141; 7,099] 1,0000**	**1,00 [0,053; 18,915] 1,0000**	**0,00 [-0,653; 0,653] 1,0000**
Arthralgie (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Rückenschmerzen (PT)	1 (33 %)	1 (17 %)	2,00 [0,181; 22,056] 0,5833	2,50 [0,100; 62,605] 0,5891	0,17 [-0,444; 0,778] 0,6053
Muskelspasmen (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Erkrankungen der Nieren und Harnwege (SOC)	**0 (0 %)**	**1 (17 %)**	**0,58 [0,030; 11,206] 0,7339**	**0,52 [0,016; 16,831] 0,7281**	**-0,17 [-0,465; 0,132] 0,2768**
Harnfluss vermindert (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Erkrankungen der Geschlechtsorgane und der Brustdrüse (SOC)	**1 (33 %)**	**0 (0 %)**	**5,25 [0,273; 100,855] 0,2748**	**7,80 [0,231; 262,811] 0,2552**	**0,33 [-0,200; 0,867] 0,2227**
Eierstockzyste rupturiert (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort (SOC)	**0 (0 %)**	**2 (33 %)**	**0,35 [0,022; 5,623] 0,4678**	**0,26 [0,009; 7,273] 0,4339**	**-0,33 [-0,711; 0,044] 0,0829**
Ermüdung (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Waermegefuehl (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Untersuchungen (SOC)	**2 (67 %)**	**0 (0 %)**	**8,75 [0,545; 140,584] 0,1258**	**21,67 [0,643; 730,029] 0,0862**	**0,67 [0,133; 1,200] 0,0142**
Alaninaminotransferase erhöht (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Aspartataminotransferase erhöht (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Kreatinphosphokinase im Blut erhöht (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen (SOC)	**1 (33 %)**	**3 (50 %)**	**0,67 [0,111; 3,990] 0,6700**	**0,50 [0,028; 8,952] 0,6506**	**-0,17 [-0,833; 0,500] 0,6369**
Knöchelfraktur (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Kontusion (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Exkoriation (PT)	0 (0 %)	2 (33 %)	0,35 [0,022; 5,623] 0,4678	0,26 [0,009; 7,273] 0,4339	-0,33 [-0,711; 0,044] 0,0829
Fraktur des Fußes (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Verletzung der Gliedmaßen (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Schmerzen während eines Eingriffes (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

1. Anzahl der Patient*innen mit mindestens einem milden UE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2

1.1. Anzahl der Patient*innen mit mindestens einem milden UE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem milden UE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2					
n (%)	3 (100 %)	6 (100 %)	0,94 [0,617; 1,439] 0,7956	0,54 [0,009; 33,470] 0,7815	0,00 [0,000; 0,000] NA
Ja (%) Nein (%)	3 (100 %) 0 (0 %)	6 (100 %) 0 (0 %)			
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

2. Anzahl der Patient*innen mit mindestens einem milden UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2

2.1. Anzahl der Patient*innen mit mindestens einem milden UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem milden UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2					
Infektionen und parasitäre Erkrankungen (SOC)	**1 (33 %)**	**2 (33 %)**	**1,00 [0,141; 7,099] 1,0000**	**1,00 [0,053; 18,915] 1,0000**	**0,00 [-0,653; 0,653] 1,0000**
Febrile Infektion (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Sinusitis (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Infektion der oberen Atemwege (PT)	1 (33 %)	1 (17 %)	2,00 [0,181; 22,056] 0,5833	2,50 [0,100; 62,605] 0,5891	0,17 [-0,444; 0,778] 0,6053
Erkrankungen des Immunsystems (SOC)	**1 (33 %)**	**0 (0 %)**	**5,25 [0,273; 100,855] 0,2748**	**7,80 [0,231; 262,811] 0,2552**	**0,33 [-0,200; 0,867] 0,2227**
Allergie auf Arthropodenstich (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Psychiatrische Erkrankungen (SOC)	**1 (33 %)**	**0 (0 %)**	**5,25 [0,273; 100,855] 0,2748**	**7,80 [0,231; 262,811] 0,2552**	**0,33 [-0,200; 0,867] 0,2227**

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Schlaflosigkeit (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Erkrankungen des Nervensystems (SOC)	**2 (67 %)**	**3 (50 %)**	**1,33 [0,430; 4,134] 0,6309**	**2,00 [0,112; 35,807] 0,6506**	**0,17 [-0,500; 0,833] 0,6369**
Ataxie (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Gleichgewichtsstörung (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Schwindelgefühl (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Kopfschmerzen (PT)	1 (33 %)	1 (17 %)	2,00 [0,181; 22,056] 0,5833	2,50 [0,100; 62,605] 0,5891	0,17 [-0,444; 0,778] 0,6053
Hypoästhesie (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Parästhesie (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Tremor (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Herzerkrankungen (SOC)	**0 (0 %)**	**1 (17 %)**	**0,58 [0,030; 11,206] 0,7339**	**0,52 [0,016; 16,831] 0,7281**	**-0,17 [-0,465; 0,132] 0,2768**
Angina pectoris (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Erkrankungen des Gastrointestinaltrakts (SOC)	**1 (33 %)**	**3 (50 %)**	**0,67 [0,111; 3,990] 0,6700**	**0,50 [0,028; 8,952] 0,6506**	**-0,17 [-0,833; 0,500] 0,6369**
Abdominalschmerz (PT)	1 (33 %)	1 (17 %)	2,00 [0,181; 22,056] 0,5833	2,50 [0,100; 62,605] 0,5891	0,17 [-0,444; 0,778] 0,6053

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Diarrhö (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Übelkeit (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Erbrechen (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Erkrankungen der Haut und des Unterhautgewebes (SOC)	**1 (33 %)**	**1 (17 %)**	**2,00 [0,181; 22,056] 0,5833**	**2,50 [0,100; 62,605] 0,5891**	**0,17 [-0,444; 0,778] 0,6053**
Ausschlag (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Makulöser Ausschlag (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen (SOC)	**1 (33 %)**	**2 (33 %)**	**1,00 [0,141; 7,099] 1,0000**	**1,00 [0,053; 18,915] 1,0000**	**0,00 [-0,653; 0,653] 1,0000**
Arthralgie (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Rückenschmerzen (PT)	1 (33 %)	1 (17 %)	2,00 [0,181; 22,056] 0,5833	2,50 [0,100; 62,605] 0,5891	0,17 [-0,444; 0,778] 0,6053
Muskelspasmen (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Erkrankungen der Nieren und Harnwege (SOC)	**0 (0 %)**	**1 (17 %)**	**0,58 [0,030; 11,206] 0,7339**	**0,52 [0,016; 16,831] 0,7281**	**-0,17 [-0,465; 0,132] 0,2768**
Harnfluss vermindert (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Erkrankungen der Geschlechtsorgane und der Brustdrüse (SOC)	**1 (33 %)**	**0 (0 %)**	**5,25 [0,273; 100,855] 0,2748**	**7,80 [0,231; 262,811] 0,2552**	**0,33 [-0,200; 0,867] 0,2227**
Eierstockzyste rupturiert (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort (SOC)	**0 (0 %)**	**2 (33 %)**	**0,35 [0,022; 5,623] 0,4678**	**0,26 [0,009; 7,273] 0,4339**	**-0,33 [-0,711; 0,044] 0,0829**
Ermüdung (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Waermegefuehl (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Untersuchungen (SOC)	**2 (67 %)**	**0 (0 %)**	**8,75 [0,545; 140,584] 0,1258**	**21,67 [0,643; 730,029] 0,0862**	**0,67 [0,133; 1,200] 0,0142**
Alaninaminotransferase erhöht (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Aspartataminotransferase erhöht (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Kreatinphosphokinase im Blut erhöht (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen (SOC)	**1 (33 %)**	**3 (50 %)**	**0,67 [0,111; 3,990] 0,6700**	**0,50 [0,028; 8,952] 0,6506**	**-0,17 [-0,833; 0,500] 0,6369**
Kontusion (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Exkoriation (PT)	0 (0 %)	2 (33 %)	0,35 [0,022; 5,623] 0,4678	0,26 [0,009; 7,273] 0,4339	-0,33 [-0,711; 0,044] 0,0829
Fraktur des Fußes (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Verletzung der Gliedmaßen (PT)	1 (33 %)	0 (0 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227

Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.

1. Anzahl der Patient*innen mit mindestens einem moderaten UE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2

1.1. Anzahl der Patient*innen mit mindestens einem moderaten UE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2: Analyse

408-C-1402-PT2	**Behandlungsarm**		**Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert**		
	Omaveloxolon	**Placebo**			
N	**3**	**6**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem moderaten UE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2					
n (%)	3 (100 %)	6 (100 %)	0,35 [0,022; 5,623] 0,4678	0,26 [0,009; 7,273] 0,4339	-0,33 [-0,711; 0,044] 0,0829
Ja (%) Nein (%)	0 (0 %) 3 (100 %)	2 (33 %) 4 (67 %)			
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

2. Anzahl der Patient*innen mit mindestens einem moderaten UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2

2.1. Anzahl der Patient*innen mit mindestens einem moderaten UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem moderaten UE bei mindestens 10% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2					
Infektionen und parasitäre Erkrankungen (SOC)	**0 (0 %)**	**1 (17 %)**	**0,58 [0,030; 11,206] 0,7339**	**0,52 [0,016; 16,831] 0,7281**	**-0,17 [-0,465; 0,132] 0,2768**
Infektion der oberen Atemwege (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Virusinfektion (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen (SOC)	**0 (0 %)**	**1 (17 %)**	**0,58 [0,030; 11,206] 0,7339**	**0,52 [0,016; 16,831] 0,7281**	**-0,17 [-0,465; 0,132] 0,2768**
Knöchelfraktur (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Schmerzen während eines Eingriffes (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768

Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.

1. Anzahl der Patient*innen mit mindestens einem schweren UE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2

1.1. Anzahl der Patient*innen mit mindestens einem schweren UE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	3	6	RR	OR	ARR
Anzahl der Patient*innen mit mindestens einem schweren UE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2					
Es traten keine Events auf.					
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

1. Anzahl der Patient*innen mit mindestens einem SUE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2

1.1. Anzahl der Patient*innen mit mindestens einem SUE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem SUE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2					
n (%)	3 (100 %)	6 (100 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Ja (%) Nein (%)	0 (0 %) 3 (100 %)	1 (17 %) 5 (83 %)			
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

2. Anzahl der Patient*innen mit mindestens einem SUE bei mindestens 5% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2

2.1. Anzahl der Patient*innen mit mindestens einem SUE bei mindestens 5% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit mindestens einem SUE bei mindestens 5% der Patient*innen oder mindestens 10 Patient*innen aufgetretene SOC und PT in einem Arm - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2					
Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen (SOC)	**0 (0 %)**	**1 (17 %)**	**0,58 [0,030; 11,206] 0,7339**	**0,52 [0,016; 16,831] 0,7281**	**-0,17 [-0,465; 0,132] 0,2768**
Knöchelfraktur (PT)	0 (0 %)	1 (17 %)	0,58 [0,030; 11,206] 0,7339	0,52 [0,016; 16,831] 0,7281	-0,17 [-0,465; 0,132] 0,2768
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

1. Anzahl der Patient*innen mit Therapieabbruch aufgrund von UE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2

1.1. Anzahl der Patient*innen mit Therapieabbruch aufgrund von UE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2: Analyse

408-C-1402-PT2	Behandlungsarm		Omaveloxolon vs. Placebo Effektmaß [95 %-KI] p-Wert		
	Omaveloxolon	Placebo			
N	**3**	**6**	**RR**	**OR**	**ARR**
Anzahl der Patient*innen mit Therapieabbruch aufgrund von UE - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2					
n (%)	3 (100 %)	6 (100 %)	5,25 [0,273; 100,855] 0,2748	7,80 [0,231; 262,811] 0,2552	0,33 [-0,200; 0,867] 0,2227
Ja (%) Nein (%)	1 (33 %) 2 (67 %)	0 (0 %) 6 (100 %)			
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.					

2. Anzahl der Patient*innen mit Therapieabbruch aufgrund von UE nach allen SOC und PT – deskriptive Darstellung, n (%) - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2

2.1. Anzahl der Patient*innen mit Therapieabbruch aufgrund von UE nach allen SOC und PT – deskriptive Darstellung, n (%) - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2: Analyse

408-C-1402-PT2	**Behandlungsarm**	
	Omaveloxolon	**Placebo**
N	**3**	**6**
Anzahl der Patient*innen mit Therapieabbruch aufgrund von UE nach allen SOC und PT – deskriptive Darstellung, n (%) - ITT mit Pes Cavus Population, mit einem Gait Score kleiner und gleich 2		
Untersuchungen (SOC)	**1 (33 %)**	**0 (0 %)**
Alaninaminotransferase erhöht (PT)	1 (33 %)	0 (0 %)
Aspartataminotransferase erhöht (PT)	1 (33 %)	0 (0 %)
Für die Bedeutung von Abkürzungen siehe Abkürzungsverzeichnis.		