



Clinical trial results:

A prospective, randomized, double-blind, placebo-controlled, multicenter study with an open-label extension period to investigate the efficacy and safety of NT 201 in the combined treatment of upper facial lines (horizontal forehead lines, glabellar frown lines, and lateral periorbital lines)

Summary

EudraCT number	2011-005887-20
Trial protocol	DE GB
Global end of trial date	05 October 2013

Results information

Result version number	v1 (current)
This version publication date	23 March 2016
First version publication date	25 July 2015

Trial information

Trial identification

Sponsor protocol code	MRZ60201_3076_1
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merz Pharmaceuticals GmbH
Sponsor organisation address	Eckenheimer Landstrasse 100, Frankfurt/M, Germany, 60318
Public contact	Public Disclosure Manager, Merz Pharmaceuticals GmbH, clinicaltrials@merz.de
Scientific contact	Public Disclosure Manager, Merz Pharmaceuticals GmbH, clinicaltrials@merz.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	22 November 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 February 2013
Global end of trial reached?	Yes
Global end of trial date	05 October 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the efficacy and safety of 54 to 64 Units of NT 201 intramuscularly administered in subjects with moderate to severe upper facial lines.

Protection of trial subjects:

High medical and ethical standards were followed in accordance with Good Clinical Practice and other applicable regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 July 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects**Subjects enrolled per country**

Country: Number of subjects enrolled	United Kingdom: 24
Country: Number of subjects enrolled	France: 29
Country: Number of subjects enrolled	Germany: 103
Worldwide total number of subjects	156
EEA total number of subjects	156

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	148
From 65 to 84 years	8

85 years and over	0
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Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Screening failures were mainly caused by the FLQA-k inclusion criterion (calculated cut-off-score below 0).

Period 1

Period 1 title	Main Period (MP)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Arms

Are arms mutually exclusive?	Yes
Arm title	NT 201
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	NT 201
Investigational medicinal product code	
Other name	Botulinum neurotoxin type A free from complexing proteins, Xeomin, Bocouture, incobotulinumtoxinA
Pharmaceutical forms	Powder for solution for injection/infusion
Routes of administration	Intramuscular use

Dosage and administration details:

Dose: 54 to 64 U, mode of administration: of the total injection volume (1.35 to 1.6 mL), the following aliquots were administered intramuscularly: HFL (a flexible dose within a range of 10 to 20 Units [U] individually adjusted according to the subject's age, gender and dermal and muscular conditions [such as individual muscle mass, muscle activity, muscle looseness/compliance, brow position, and brow shape] as assessed by the investigator distributed to 5 horizontally orientated points), GFL (20 U in equal aliquots administered in 5 points), LPL (12 U in equal aliquots administered in 3 points per eye area [24 U Overall]).

Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection/infusion
Routes of administration	Intramuscular use

Dosage and administration details:

A total volume of 1.35 to 1.6 mL placebo solution were injected in the same areas and in the same manner as NT 201.

Number of subjects in period 1	NT 201	Placebo
Started	105	51
Completed	103	46
Not completed	2	5
Consent withdrawn by subject	-	1
Lost to follow-up	2	4

Period 2

Period 2 title	Open label extension (OLEX)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	NT 201
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	NT 201
Investigational medicinal product code	
Other name	Botulinum neurotoxin type A free from complexing proteins, Xeomin, Bocouture, incobotulinumtoxinA
Pharmaceutical forms	Powder for solution for injection/infusion
Routes of administration	Intramuscular use

Dosage and administration details:

Dose: 54 to 64 U, mode of administration: of the total injection volume (1.35 to 1.6 mL), the following aliquots were administered intramuscularly: HFL (a flexible dose within a range of 10 to 20 Units [U] individually adjusted according to the subject's age, gender and dermal and muscular conditions [such as individual muscle mass, muscle activity, muscle looseness/compliance, brow position, and brow shape] as assessed by the investigator distributed to 5 horizontally orientated points), GFL (20 U in equal aliquots administered in 5 points), LPL (12 U in equal aliquots administered in 3 points per eye area [24 U Overall]).

Number of subjects in period 2 ^[1]	NT 201
Started	139
Completed	132
Not completed	7
Consent withdrawn by subject	2
Lost to follow-up	5

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all subjects who completed the main period fulfilled the eligibility criteria for inclusion into the OLEX period.

Baseline characteristics

Reporting groups

Reporting group title	NT 201
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Reporting group values	NT 201	Placebo	Total
Number of subjects	105	51	156
Age categorical Units: Subjects			
Adults (18-64 years)	99	49	148
From 65-84 years	6	2	8
Age continuous Units: years			
arithmetic mean	47.4	47.5	
standard deviation	± 10.1	± 8.4	-
Gender categorical Units: Subjects			
Female	94	41	135
Male	11	10	21
Ethnic origin/race Units: Subjects			
White	102	50	152
Black or African American	2	1	3
Asian	0	0	0
Other	1	0	1

Subject analysis sets

Subject analysis set title	Full Analysis Set (FAS)
Subject analysis set type	Full analysis

Subject analysis set description:

The FAS was the subset of subjects in the safety evaluation set (SES) MP for whom the primary efficacy variables were available (i.e., all subjects who had a post-baseline value at V4 of the primary efficacy variables including imputed values).

Reporting group values	Full Analysis Set (FAS)		
Number of subjects	156		
Age categorical Units: Subjects			
Adults (18-64 years)	148		
From 65-84 years	8		
Age continuous Units: years			
arithmetic mean	47.5		
standard deviation	± 9.5		

Gender categorical			
Units: Subjects			
Female	135		
Male	21		
Ethnic origin/race			
Units: Subjects			
White	152		
Black or African American	3		
Asian	0		
Other	1		

End points

End points reporting groups

Reporting group title	NT 201
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	NT 201
Reporting group description: -	
Subject analysis set title	Full Analysis Set (FAS)
Subject analysis set type	Full analysis
Subject analysis set description:	
The FAS was the subset of subjects in the safety evaluation set (SES) MP for whom the primary efficacy variables were available (i.e., all subjects who had a post-baseline value at V4 of the primary efficacy variables including imputed values).	

Primary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D30 for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D30 for GFL
End point description:	
End point type	Primary
End point timeframe:	
Day 30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	105	51	156	
Units: Responders	87	0	87	

Statistical analyses

Statistical analysis title	Primary efficacy analysis
Comparison groups	NT 201 v Placebo
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 ^[1]
Method	Regression, Logistic

Notes:

[1] - Hierarchical test procedure: 1st step GFL, 2nd step HFL, 3rd step LPL, 4th step combined Response.

Primary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D30 for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D30 for HFL
End point description:	
End point type	Primary
End point timeframe:	
D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	105	51	156	
Units: Responders	75	1	76	

Statistical analyses

Statistical analysis title	Primary efficacy analysis
Comparison groups	NT 201 v Placebo
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 ^[2]
Method	Regression, Logistic

Notes:

[2] - Hierarchical test procedure: 1st step GFL, 2nd step HFL, 3rd step LPL, 4th step combined Response.

Primary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D30 for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D30 for LPL
End point description:	
End point type	Primary
End point timeframe:	
D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	105	51	156	
Units: Responders	67	1	68	

Statistical analyses

Statistical analysis title	Primary efficacy analysis
Comparison groups	Placebo v NT 201
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 ^[3]
Method	Regression, Logistic

Notes:

[3] - Hierarchical test procedure: 1st step GFL, 2nd step HFL, 3rd step LPL, 4th step combined Response.

Primary: Combined response defined as Investigator MAS rating sum score of 3 or lower at max. contraction at D30

End point title	Combined response defined as Investigator MAS rating sum score of 3 or lower at max. contraction at D30
End point description:	
End point type	Primary
End point timeframe:	
D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	105	51	156	
Units: Responders	57	0	57	

Statistical analyses

Statistical analysis title	Primary efficacy analysis
Comparison groups	NT 201 v Placebo
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0001 ^[4]
Method	Regression, Logistic

Notes:

[4] - Hierarchical test procedure: 1st step GFL, 2nd step HFL, 3rd step LPL, 4th step combined Response.

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D8 for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D8 for GFL
End point description:	
End point type	Secondary

End point timeframe:

D8 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	105	51	156	
Units: Responders	84	1	85	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at maximum contraction at D8 for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at maximum contraction at D8 for HFL
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End point description:

End point type	Secondary
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End point timeframe:

Day 8 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	71	1	72	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D8 for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D8 for LPL
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End point description:

End point type	Secondary
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End point timeframe:

Day 8 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	54	1	55	

Statistical analyses

No statistical analyses for this end point

Secondary: Combined response defined as Investigator MAS rating sum score of 3 or lower at max. contraction at Day 8

End point title	Combined response defined as Investigator MAS rating sum score of 3 or lower at max. contraction at Day 8
End point description:	
End point type	Secondary
End point timeframe:	
D8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	47	0	47	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D60 for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D60 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	68	0	68	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as investigator MAS rating 0 or 1 at max. contraction at D60 for HFL

End point title	Response defined as investigator MAS rating 0 or 1 at max. contraction at D60 for HFL
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End point description:

End point type	Secondary
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End point timeframe:

Day 60 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	56	2	58	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at Day 60 for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at Day 60 for LPL
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End point description:

End point type	Secondary
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End point timeframe:

Day 60 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	46	2	48	

Statistical analyses

No statistical analyses for this end point

Secondary: Combined response defined as Investigator MAS rating sum score of 3 or lower at max. contraction at Day 60

End point title	Combined response defined as Investigator MAS rating sum score of 3 or lower at max. contraction at Day 60
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End point description:

End point type	Secondary
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End point timeframe:

D60 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	34	0	34	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D90 for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D90 for GFL
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End point description:

End point type	Secondary
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End point timeframe:

Day 90 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	54	1	55	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D90 for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D90 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	38	1	39	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D90 for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D90 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	24	3	27	

Statistical analyses

No statistical analyses for this end point

Secondary: Combined response defined as Investigator MAS rating sum score of 3 or lower at max. contraction at D90

End point title	Combined response defined as Investigator MAS rating sum score of 3 or lower at max. contraction at D90
End point description:	
End point type	Secondary
End point timeframe:	
Day 90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	15	0	15	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D120 for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D120 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	14	0	14	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D120 for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D120 for HFL
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End point description:

End point type	Secondary
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End point timeframe:

Day 120 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	9	0	9	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D120 for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D120 for LPL
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End point description:

End point type	Secondary
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End point timeframe:

Day 120 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	5	0	5	

Statistical analyses

No statistical analyses for this end point

Secondary: Combined response defined as Investigator MAS rating sum score of 3 or lower at max. contraction at D120

End point title	Combined response defined as Investigator MAS rating sum score of 3 or lower at max. contraction at D120
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End point description:

End point type	Secondary
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End point timeframe:

Day 120 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	2	0	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D8 for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D8 for GFL
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End point description:

End point type	Secondary
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End point timeframe:

Day 8 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	61	0	61	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D8 for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D8 for HFL
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End point description:

End point type	Secondary
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End point timeframe:

Day 8 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	55	2	57	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D8 for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D8 for LPL
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End point description:

End point type	Secondary
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End point timeframe:

Day 8 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	38	2	40	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D30 for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D30 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	70	0	70	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D30 for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D30 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	60	3	63	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D30 for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D30 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	43	2	45	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D60 for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D60 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	47	0	47	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D60 for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D60 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	38	2	40	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D60 for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D60 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	25	3	28	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D90 for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D90 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	35	0	35	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D90 for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D90 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	25	2	27	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D90 for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D90 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	16	1	17	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D120 for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D120 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	17	0	17	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D120 for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D120 for HFL
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End point description:

End point type	Secondary
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End point timeframe:

Day 120 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	6	1	7	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D120 for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D120 for LPL
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End point description:

End point type	Secondary
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End point timeframe:

Day 120 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	7	0	7	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D8 for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D8 for GFL
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End point description:

End point type	Secondary
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End point timeframe:

Day 8 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	95	23	118	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D8 for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D8 for HFL
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End point description:

End point type	Secondary
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End point timeframe:

Day 8 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	95	20	115	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D8 for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D8 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	85	23	108	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D30 for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D30 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	97	22	119	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D30 for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D30 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	94	22	116	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D30 for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D30 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	89	20	109	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D60 for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D60 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	91	20	111	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D60 for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D60 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	91	22	113	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D60 for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D60 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	89	19	108	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D90 for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D90 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	83	21	104	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D90 for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D90 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	79	19	98	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D90 for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D90 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	78	19	97	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D120 for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D120 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	80	20	100	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D120 for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D120 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	67	23	90	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D120 for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D120 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 120 after MP	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	61	22	83	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D8 for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D8 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	76	14	90	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D8 for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D8 for HFL
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End point description:

End point type	Secondary
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End point timeframe:

Day 8 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	83	15	98	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D8 for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D8 for LPL
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End point description:

End point type	Secondary
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End point timeframe:

Day 8 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	72	9	81	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D30 for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D30 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	87	13	100	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D30 for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D30 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	87	19	106	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D30 for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D30 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	72	14	86	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D60 for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D60 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	81	8	89	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D60 for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D60 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	82	16	98	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D60 for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D60 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	74	10	84	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D90 for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D90 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	72	9	81	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D90 for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D90 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	71	16	87	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D90 for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D90 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	59	9	68	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D120 for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D120 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	63	9	72	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D120 for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D120 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	58	14	72	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D120 for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D120 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	47	10	57	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D8 for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D8 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	102	3	105	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D8 for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D8 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	97	5	102	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D8 for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D8 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	96	9	105	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D30 for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D30 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	98	3	101	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D30 for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D30 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	94	2	96	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D30 for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D30 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	96	7	103	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D60 for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D60 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Rersponders	90	5	95	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D60 for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D60 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	83	6	89	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D60 for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D60 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	82	6	88	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D90 for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D90 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	77	3	80	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D90 for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D90 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	68	5	73	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D90 for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D90 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	63	8	71	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D120 for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D120 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	43	1	44	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D120 for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D120 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
Day 120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	43	3	46	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D120 for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D120 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
Day 120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	31	7	38	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D8 for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D8 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	66	5	71	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D8 for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D8 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	80	4	84	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D8 for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D8 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	73	6	79	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D30 for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D30 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	69	5	74	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D30 for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D30 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	87	4	91	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D30 for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D30 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	81	5	86	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D60 for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D60 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	64	5	69	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D60 for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D60 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	78	7	85	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D60 for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D60 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	80	4	84	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D90 for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D90 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	55	6	61	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D90 for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D90 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	69	7	76	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D90 for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D90 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	65	7	72	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D120 for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D120 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	41	4	45	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D120 for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D120 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	47	6	53	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D120 for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D120 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	47	10	57	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D8 for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D8 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	87	12	99	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D8 for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D8 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	86	10	96	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D8 for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D8 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	82	8	90	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D30 for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D30 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	90	7	97	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D30 for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D30 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	92	6	98	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D30 for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D30 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	83	8	91	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D60 for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D60 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	87	5	92	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D60 for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D60 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	83	12	95	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D60 for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D60 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	76	10	86	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D90 for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D90 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	69	8	77	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D90 for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D90 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	73	14	87	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D90 for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D90 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	61	11	72	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D120 for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D120 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	53	8	61	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D120 for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D120 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	54	12	66	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D120 for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D120 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	51	13	64	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D8 for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D8 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	68	16	84	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D8 for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D8 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	78	9	87	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D8 for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D8 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	104	51	155	
Units: Responders	72	9	81	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D30 for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D30 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	78	14	92	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D30 for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D30 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	86	8	94	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D30 for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D30 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	76	12	88	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D60 for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D60 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	72	11	83	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D60 for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D60 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	79	8	87	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D60 for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D60 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D 60 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	102	46	148	
Units: Responders	74	9	83	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D90 for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D90 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	66	13	79	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D90 for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D90 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	68	8	76	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D90 for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D90 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D90 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	101	46	147	
Units: Responders	67	6	73	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D120 for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D120 for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	51	11	62	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D120 for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D120 for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	57	5	62	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D120 for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D120 for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	46	149	
Units: Responders	52	5	57	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator rating score of much improved (+2) or very much improved (+3) at D30 for the overall appearance of the upper face according to Global impression of Change Scale (GICS)

End point title	Response defined as Investigator rating score of much improved (+2) or very much improved (+3) at D30 for the overall appearance of the upper face according to Global impression of Change Scale (GICS)
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End point description:

End point type	Secondary
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End point timeframe:

D30 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	89	1	90	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject rating score of much improved (+2) or very much improved (+3) at D30 for the overall appearance of the upper face according to Global impression of Change Scale (GICS)

End point title	Response defined as Subject rating score of much improved (+2) or very much improved (+3) at D30 for the overall appearance of the upper face according to Global impression of Change Scale (GICS)
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End point description:

End point type	Secondary
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End point timeframe:

D30 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	103	48	151	
Units: Responders	80	1	81	

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect by D8 for GFL as reported by Subject according to diary

End point title	Onset of effect by D8 for GFL as reported by Subject according to diary
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End point description:

End point type	Secondary
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End point timeframe:

Up to D8 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	105	51	156	
Units: Onsets	90	7	97	

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect by D8 for HFL as reported by Subject according to diary

End point title	Onset of effect by D8 for HFL as reported by Subject according to diary
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End point description:

End point type	Secondary
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End point timeframe:

Up to D8 after MP injection

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	105	51	156	
Units: Onsets	95	6	101	

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect by D8 for left LPL as reported by Subject according to diary

End point title	Onset of effect by D8 for left LPL as reported by Subject according to diary
End point description:	
End point type	Secondary
End point timeframe:	
Up to D8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	105	51	156	
Units: Onsets	77	9	86	

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect by D8 for right LPL as reported by Subject according to diary

End point title	Onset of effect by D8 for right LPL as reported by Subject according to diary
End point description:	
End point type	Secondary
End point timeframe:	
Up to D8 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	105	51	156	
Units: Onsets	76	10	86	

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect between D8 and Day 30 for GFL as reported by Subject according to diary

End point title	Onset of effect between D8 and Day 30 for GFL as reported by Subject according to diary
End point description:	
End point type	Secondary
End point timeframe:	
Between D8 and D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	105	51	156	
Units: Onsets	8	0	8	

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect between D8 and D30 for HFL as reported by Subject according to diary

End point title	Onset of effect between D8 and D30 for HFL as reported by Subject according to diary
End point description:	
End point type	Secondary
End point timeframe:	
Between D8 and D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	105	51	156	
Units: Onsets	4	0	4	

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect between D8 and D30 for left LPL as reported by Subject according to diary

End point title	Onset of effect between D8 and D30 for left LPL as reported by Subject according to diary
End point description:	
End point type	Secondary
End point timeframe:	
Between D8 and D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	105	51	156	
Units: Onsets	11	1	12	

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect between D8 and D30 for right LPL as reported by Subject according to diary

End point title	Onset of effect between D8 and D30 for right LPL as reported by Subject according to diary
End point description:	
End point type	Secondary
End point timeframe:	
Between D8 and D30 after MP injection	

End point values	NT 201	Placebo	Full Analysis Set (FAS)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	105	51	156	
Units: Onsets	11	0	11	

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D8 (OLEX) for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D8 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	106	106		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D8 (OLEX) for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D8 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	106	106		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D8 (OLEX) for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D8 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	86	86		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D30 (OLEX) for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D30 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	109	109		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D30 (OLEX) for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D30 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	105	105		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D30 (OLEX) for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D30 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	91	91		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D75 (OLEX) for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D75 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	84	84		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D75 (OLEX) for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D75 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	72	72		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D75 (OLEX) for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D75 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	55	55		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D120 (OLEX) for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D120 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	48	48		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D120 (OLEX) for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D120 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	33	33		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at max. contraction at D120 (OLEX) for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at max. contraction at D120 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	19	19		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D8 (OLEX) for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D8 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	85	85		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D8 (OLEX) for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D8 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	92	92		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D8 (OLEX) for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D8 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	71	71		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D30 (OLEX) for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D30 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	82	82		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D30 (OLEX) for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D30 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	97	97		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D30 (OLEX) for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D30 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	63	63		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D75 (OLEX) for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D75 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	60	60		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D75 (OLEX) for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D75 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	49	49		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D75 (OLEX) for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D75 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	40	40		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D120 (OLEX) for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D120 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	35	35		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D120 (OLEX) for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D120 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	19	19		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at max. contraction at D120 (OLEX) for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at max. contraction at D120 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	16	16		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D8 (OLEX) for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D8 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	119	119		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D8 (OLEX) for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D8 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	129	129		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D8 (OLEX) for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D8 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	126	126		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D30 (OLEX) for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D30 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	123	123		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D30 (OLEX) for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D30 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	130	130		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D30 (OLEX) for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D30 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	125	125		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D75 (OLEX) for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D75 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	112	112		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D75 (OLEX) for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D75 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	119	119		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D75 (OLEX) for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D75 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	113	113		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D120 (OLEX) for GFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D120 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	103	103		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D120 (OLEX) for HFL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D120 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	107	107		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator MAS rating 0 or 1 at rest at D120 (OLEX) for LPL

End point title	Response defined as Investigator MAS rating 0 or 1 at rest at D120 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	95	95		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D8 (OLEX) for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D8 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	106	106		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D8 (OLEX) for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D8 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	127	127		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D8 (OLEX) for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D8 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	112	112		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D30 (OLEX) for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D30 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	116	116		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D30 (OLEX) for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D30 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	127	127		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D30 (OLEX) for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D30 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	118	118		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D75 (OLEX) for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D75 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D75 afte4r OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	101	101		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D75 (OLEX) for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D75 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	110	110		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D75 (OLEX) for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D75 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	99	99		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D120 (OLEX) for GFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D120 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	84	84		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D120 (OLEX) for HFL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D120 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	94	94		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject MAS rating 0 or 1 at rest at D120 (OLEX) for LPL

End point title	Response defined as Subject MAS rating 0 or 1 at rest at D120 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	76	76		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D8 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D8 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	127	127		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D8 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D8 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	124	124		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D8 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D8 (OLEX) for LPL
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End point description:

End point type	Secondary
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End point timeframe:

D8 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	118	118		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D30 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D30 (OLEX) for GFL
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End point description:

End point type	Secondary
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End point timeframe:

D30 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	126	126		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D30 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D30 (OLEX) for HFL
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End point description:

End point type	Secondary
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End point timeframe:

D30 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	125	125		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D30 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D30 (OLEX) for LPL
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End point description:

End point type	Secondary
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End point timeframe:

D30 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	120	120		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D75 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D75 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	110	110		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D75 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D75 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	102	102		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D75 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D75 (OLEX) for LPL
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End point description:

End point type	Secondary
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End point timeframe:

D75 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	95	95		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D120 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D120 (OLEX) for GFL
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End point description:

End point type	Secondary
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End point timeframe:

D120 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	78	78		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D120 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D120 (OLEX) for HFL
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End point description:

End point type	Secondary
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End point timeframe:

D120 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	63	63		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D120 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at max. contraction at D120 (OLEX) for LPL
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End point description:

End point type	Secondary
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End point timeframe:

D120 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	61	61		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D8 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D8 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	70	70		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D8 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D8 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	92	92		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D8 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D8 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	93	93		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D30 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D30 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	72	72		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D30 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D30 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	97	97		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D30 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D30 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	96	96		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D75 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D75 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	66	66		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D75 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D75 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	82	82		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D75 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D75 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	70	70		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D120 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D120 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	48	48		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D120 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D120 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	64	64		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Investigator MAS rating at rest at D120 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Investigator MAS rating at rest at D120 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	50	50		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D8 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D8 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	120	120		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D8 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D8 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	124	124		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D8 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D8 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	114	114		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D30 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D30 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	120	120		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D30 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D30 (OLEX) for HFL
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End point description:

End point type	Secondary
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End point timeframe:

D30 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	127	127		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D30 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D30 (OLEX) for LPL
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End point description:

End point type	Secondary
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End point timeframe:

D30 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	111	111		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D75 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D75 (OLEX) for GFL
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End point description:

End point type	Secondary
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End point timeframe:

D75 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	102	102		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D75 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D75 (OLEX) for HFL
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End point description:

End point type	Secondary
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End point timeframe:

D75 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	99	99		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D75 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D75 (OLEX) for LPL
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End point description:

End point type	Secondary
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End point timeframe:

D75 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	81	81		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D120 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D120 (OLEX) for GFL
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End point description:

End point type	Secondary
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End point timeframe:

D120 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	68	68		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D120 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D120 (OLEX) for HFL
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End point description:

End point type	Secondary
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End point timeframe:

D120 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	66	66		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D120 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at max. contraction at D120 (OLEX) for LPL
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End point description:

End point type	Secondary
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End point timeframe:

D120 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	62	62		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D8 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D8 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	87	87		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D8 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D8 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	113	113		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D8 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D8 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D8 after OLOEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	135	135		
Units: Responders	100	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D30 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D30 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	90	90		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D30 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D30 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	117	117		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D30 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D30 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D30 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	103	103		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D75 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D75 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	77	77		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D75 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D75 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	92	92		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D75 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D75 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D75 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	130	130		
Units: Responders	83	83		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D120 (OLEX) for GFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D120 (OLEX) for GFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	61	61		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D120 (OLEX) for HFL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D120 (OLEX) for HFL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	71	71		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as improvement of at least one point in Subject MAS rating at rest at D120 (OLEX) for LPL

End point title	Response defined as improvement of at least one point in Subject MAS rating at rest at D120 (OLEX) for LPL
End point description:	
End point type	Secondary
End point timeframe:	
D120 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	134	134		
Units: Responders	66	66		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Investigator rating score of much improved (+2) or very much improved (+3) at D30 (OLEX) for the overall appearance of the upper face according to Global impression of Change Scale (GICS)

End point title	Response defined as Investigator rating score of much improved (+2) or very much improved (+3) at D30 (OLEX) for the overall appearance of the upper face according to Global impression of Change Scale (GICS)
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End point description:

End point type	Secondary
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End point timeframe:

D30 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	120	120		

Statistical analyses

No statistical analyses for this end point

Secondary: Response defined as Subject rating score of much improved (+2) or very much improved (+3) at D30 (OLEX) for the overall appearance of the upper face according to Global impression of Change Scale (GICS)

End point title	Response defined as Subject rating score of much improved (+2) or very much improved (+3) at D30 (OLEX) for the overall appearance of the upper face according to Global impression of Change Scale (GICS)
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End point description:

End point type	Secondary
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End point timeframe:

D30 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	136	136		
Units: Responders	114	114		

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect by D8 (OLEX) for GFL as reported by Subject according to diary

End point title	Onset of effect by D8 (OLEX) for GFL as reported by Subject according to diary
End point description:	
End point type	Secondary
End point timeframe:	
Up to D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	139	139		
Units: Onsets	131	131		

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect by D8 (OLEX) for HFL as reported by Subject according to diary

End point title	Onset of effect by D8 (OLEX) for HFL as reported by Subject according to diary
End point description:	
End point type	Secondary
End point timeframe:	
Up to D8 after OLEX injection	

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	139	139		
Units: Onsets	133	133		

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect by D8 (OLEX) for left LPL as reported by Subject according to diary

End point title	Onset of effect by D8 (OLEX) for left LPL as reported by Subject according to diary
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End point description:

End point type	Secondary
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End point timeframe:

Up to D8 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	139	139		
Units: Onsets	121	121		

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect by D8 (OLEX) for right LPL as reported by Subject according to diary

End point title	Onset of effect by D8 (OLEX) for right LPL as reported by Subject according to diary
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End point description:

End point type	Secondary
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End point timeframe:

Up to D8 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	139	139		
Units: Onsets	123	123		

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect between D8 and Day 30 (OLEX) for GFL as reported by Subject according to diary

End point title	Onset of effect between D8 and Day 30 (OLEX) for GFL as reported by Subject according to diary
End point description:	
End point type	Secondary
End point timeframe:	Between D8 and D30 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	139	139		
Units: Onsets	3	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect between D8 and Day 30 (OLEX) for HFL as reported by Subject according to diary

End point title	Onset of effect between D8 and Day 30 (OLEX) for HFL as reported by Subject according to diary
End point description:	
End point type	Secondary
End point timeframe:	Between D8 and D30 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	139	139		
Units: Onsets	3	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect between D8 and Day 30 (OLEX) for left LPL as reported by Subject according to diary

End point title	Onset of effect between D8 and Day 30 (OLEX) for left LPL as reported by Subject according to diary
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End point description:

End point type	Secondary
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End point timeframe:

Between D8 and D30 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	139	139		
Units: Onsets	8	8		

Statistical analyses

No statistical analyses for this end point

Secondary: Onset of effect between D8 and Day 30 (OLEX) for right LPL as reported by Subject according to diary

End point title	Onset of effect between D8 and Day 30 (OLEX) for right LPL as reported by Subject according to diary
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End point description:

End point type	Secondary
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End point timeframe:

Between D8 and D30 after OLEX injection

End point values	NT 201	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	139	139		
Units: Onsets	6	6		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the timepoint of first injection until 120 +/- 7 days after last administration of injection.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	15.0
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Reporting groups

Reporting group title	NT 201 (MP)
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Reporting group description: -

Reporting group title	Placebo (MP)
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Reporting group description: -

Reporting group title	OLEX total subjects treated with NT 201
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Reporting group description: -

Serious adverse events	NT 201 (MP)	Placebo (MP)	OLEX total subjects treated with NT 201
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 105 (3.81%)	2 / 51 (3.92%)	1 / 139 (0.72%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	1 / 105 (0.95%)	0 / 51 (0.00%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	1 / 105 (0.95%)	0 / 51 (0.00%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accident			
subjects affected / exposed	0 / 105 (0.00%)	1 / 51 (1.96%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Angina pectoris			
subjects affected / exposed	1 / 105 (0.95%)	0 / 51 (0.00%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Bunion operation			
subjects affected / exposed	1 / 105 (0.95%)	0 / 51 (0.00%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myomectomy			
subjects affected / exposed	0 / 105 (0.00%)	1 / 51 (1.96%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 105 (0.00%)	0 / 51 (0.00%)	1 / 139 (0.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 105 (0.95%)	0 / 51 (0.00%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal prolapse			
subjects affected / exposed	1 / 105 (0.95%)	0 / 51 (0.00%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	1 / 105 (0.95%)	0 / 51 (0.00%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			

subjects affected / exposed	1 / 105 (0.95%)	0 / 51 (0.00%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary tract disorder			
subjects affected / exposed	1 / 105 (0.95%)	0 / 51 (0.00%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 105 (0.00%)	0 / 51 (0.00%)	1 / 139 (0.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Foot deformity			
subjects affected / exposed	1 / 105 (0.95%)	0 / 51 (0.00%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	NT 201 (MP)	Placebo (MP)	OLEX total subjects treated with NT 201
Total subjects affected by non-serious adverse events			
subjects affected / exposed	65 / 105 (61.90%)	28 / 51 (54.90%)	64 / 139 (46.04%)
Nervous system disorders			
Headache			
subjects affected / exposed	24 / 105 (22.86%)	1 / 51 (1.96%)	13 / 139 (9.35%)
occurrences (all)	27	2	14
General disorders and administration site conditions			
Injection site haematoma			
subjects affected / exposed	4 / 105 (3.81%)	3 / 51 (5.88%)	10 / 139 (7.19%)
occurrences (all)	5	5	11
Musculoskeletal and connective tissue disorders			

Back pain subjects affected / exposed occurrences (all)	1 / 105 (0.95%) 1	2 / 51 (3.92%) 2	2 / 139 (1.44%) 2
Infections and infestations			
Nasopharyngitis subjects affected / exposed occurrences (all)	20 / 105 (19.05%) 25	10 / 51 (19.61%) 12	12 / 139 (8.63%) 12
Influenza subjects affected / exposed occurrences (all)	4 / 105 (3.81%) 4	1 / 51 (1.96%) 1	4 / 139 (2.88%) 5
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 105 (1.90%) 2	2 / 51 (3.92%) 2	1 / 139 (0.72%) 1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 July 2012	Since the release of the initial protocol on 05-APR-2012, one protocol amendment was issued prior to start of enrollment on 27-JUL-2012. The main change to the protocol and the rationale for amended clinical study protocol version 2.0 (issued 18-JUL-2012) was as follows: <ul style="list-style-type: none">• The event 'dry eye' was added as an indication specific AESI for close monitoring as recommended by the German Health Authority (BfArM).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported