# 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 |

**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 |

## 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<br>Units: Subjects | | | |
| Adults (18-64 years) | 99 | 49 | 148 |
| From 65-84 years | 6 | 2 | 8 |
| Age continuous<br>Units: years | | | |
| arithmetic mean | 47.4 | 47.5 | |
| standard deviation | ± 10.1 | ± 8.4 | - |
| Gender categorical<br>Units: Subjects | | | |
| Female | 94 | 41 | 135 |
| Male | 11 | 10 | 21 |
| Ethnic origin/race<br>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<br>Units: Subjects | | | |
| Adults (18-64 years) | 148 | | |
| From 65-84 years | 8 | | |
| Age continuous<br>Units: years | | | |
| arithmetic mean | 47.5 | | |
| standard deviation | ± 9.5 | | |

| | | | |
|---|---|---|---|
| Gender categorical<br>Units: Subjects | | | |
| Female | 135 | | |
| Male | 21 | | |
| Ethnic origin/race<br>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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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) |
|---|---|

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 | 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) |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 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 |
|---|---|

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 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 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 |
|---|---|

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 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 |
|---|---|

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 | 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 |
|---|---|

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 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 |
|---|---|

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 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 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 |
|---|---|

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 | 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) |
|---|---|

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 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) |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |
|---|---|

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 | 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 |

| Dictionary used | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 15.0 |

| Reporting groups | |
|---|---|
| Reporting group title | NT 201 (MP) |
| Reporting group description: - | |
| Reporting group title | Placebo (MP) |
| Reporting group description: - | |
| Reporting group title | OLEX total subjects treated with NT 201 |
| 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 | 1 / 105 (0.95%) | 2 / 51 (3.92%) | 2 / 139 (1.44%) |
| occurrences (all) | 1 | 2 | 2 |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 20 / 105 (19.05%) | 10 / 51 (19.61%) | 12 / 139 (8.63%) |
| occurrences (all) | 25 | 12 | 12 |
| Influenza | | | |
| subjects affected / exposed | 4 / 105 (3.81%) | 1 / 51 (1.96%) | 4 / 139 (2.88%) |
| occurrences (all) | 4 | 1 | 5 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 2 / 105 (1.90%) | 2 / 51 (3.92%) | 1 / 139 (0.72%) |
| occurrences (all) | 2 | 2 | 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:<br>• 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