



## Clinical trial results:

### A Double-blind Placebo-controlled, Randomized, Parallel-group, Multicenter Clinical Trial to Evaluate Efficacy and Safety of Mometasone Furoate Nasal Spray in Children With Adenoid Hypertrophy. SNORE Study

#### Summary

|                          |                 |
|--------------------------|-----------------|
| EudraCT number           | 2014-004917-10  |
| Trial protocol           | Outside EU/EEA  |
| Global end of trial date | 25 January 2010 |

#### Results information

|                                |               |
|--------------------------------|---------------|
| Result version number          | v1            |
| This version publication date  | 01 March 2016 |
| First version publication date | 29 July 2015  |

#### Trial information

##### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | P05155 |
|-----------------------|--------|

##### Additional study identifiers

|                                    |                                    |
|------------------------------------|------------------------------------|
| ISRCTN number                      | -                                  |
| ClinicalTrials.gov id (NCT number) | NCT00552032                        |
| WHO universal trial number (UTN)   | -                                  |
| Other trial identifiers            | Merck Protocol Number: MK-0887-138 |

Notes:

#### Sponsors

|                              |                                                                                              |
|------------------------------|----------------------------------------------------------------------------------------------|
| Sponsor organisation name    | Merck Sharp & Dohme Corp.                                                                    |
| Sponsor organisation address | 2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033                               |
| Public contact               | Clinical Trials Disclosure, Merck Sharp & Dohme Corp.,<br>ClinicalTrialsDisclosure@merck.com |
| Scientific contact           | Clinical Trials Disclosure, Merck Sharp & Dohme Corp.,<br>ClinicalTrialsDisclosure@merck.com |

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? | Yes |

Notes:

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**Results analysis stage**

|                                                      |                 |
|------------------------------------------------------|-----------------|
| Analysis stage                                       | Final           |
| Date of interim/final analysis                       | 25 January 2010 |
| Is this the analysis of the primary completion data? | Yes             |
| Primary completion date                              | 25 January 2010 |
| Global end of trial reached?                         | Yes             |
| Global end of trial date                             | 25 January 2010 |
| Was the trial ended prematurely?                     | No              |

Notes:

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**General information about the trial**

Main objective of the trial:

The purpose of this study is to determine whether 8 weeks treatment with mometasone furoate nasal spray (MFNS), twice daily, is safe and effective in treating adenoid hypertrophy in children.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

|                                                           |                |
|-----------------------------------------------------------|----------------|
| Actual start date of recruitment                          | 31 August 2007 |
| Long term follow-up planned                               | No             |
| Independent data monitoring committee (IDMC) involvement? | No             |

Notes:

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

|                                      |                                      |
|--------------------------------------|--------------------------------------|
| Country: Number of subjects enrolled | Mexico: 125                          |
| Country: Number of subjects enrolled | Venezuela, Bolivarian Republic of: 7 |
| Worldwide total number of subjects   | 132                                  |
| EEA total number of subjects         | 0                                    |

Notes:

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**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)                     | 132 |
| Adolescents (12-17 years)                 | 0   |
| Adults (18-64 years)                      | 0   |
| From 65 to 84 years                       | 0   |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

This study enrolled children aged 2 to 11 years with adenoid hypertrophy (AH) with or without otitis media effusion (OME).

### Pre-assignment

Screening details:

135 participants were screened, of those, 132 were randomized in the intent-to-treat (ITT) population (MFNS n=66, placebo=66) and 96 in the per protocol (PP) population (MFNS n=49, placebo n=47).

### Period 1

|                              |                                |
|------------------------------|--------------------------------|
| Period 1 title               | Overall Study (overall period) |
| Is this the baseline period? | Yes                            |
| Allocation method            | Randomised - controlled        |
| Blinding used                | Double blind                   |
| Roles blinded                | Subject, Investigator, Carer   |

### Arms

|                              |                                |
|------------------------------|--------------------------------|
| Are arms mutually exclusive? | Yes                            |
| <b>Arm title</b>             | Mometasone Furoate nasal spray |

Arm description:

1 spray (50 mcg) in each nostril twice daily (equivalent to 200 mcg per day) administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

|                                        |                              |
|----------------------------------------|------------------------------|
| Arm type                               | Experimental                 |
| Investigational medicinal product name | mometasone furoate           |
| Investigational medicinal product code |                              |
| Other name                             | Nasonex, SCH 032088, MK-0887 |
| Pharmaceutical forms                   | Inhalation solution          |
| Routes of administration               | Inhalation use               |

Dosage and administration details:

1 spray (50 mcg) in each nostril twice daily (equivalent to 200 mcg per day) administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

|                  |                     |
|------------------|---------------------|
| <b>Arm title</b> | Placebo nasal spray |
|------------------|---------------------|

Arm description:

1 spray in each nostril twice daily administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

|                                        |                     |
|----------------------------------------|---------------------|
| Arm type                               | Placebo             |
| Investigational medicinal product name | Placebo             |
| Investigational medicinal product code |                     |
| Other name                             |                     |
| Pharmaceutical forms                   | Inhalation solution |
| Routes of administration               | Inhalation use      |

Dosage and administration details:

1 spray in each nostril twice daily administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

| <b>Number of subjects in period 1</b> | Mometasone Furoate nasal spray | Placebo nasal spray |
|---------------------------------------|--------------------------------|---------------------|
| Started                               | 66                             | 66                  |
| Completed                             | 49                             | 47                  |
| Not completed                         | 17                             | 19                  |
| Consent withdrawn by subject          | 2                              | 2                   |
| Lost to follow-up                     | 8                              | 5                   |
| Protocol deviation                    | 7                              | 12                  |

## Baseline characteristics

### Reporting groups

|                       |                                |
|-----------------------|--------------------------------|
| Reporting group title | Mometasone Furoate nasal spray |
|-----------------------|--------------------------------|

Reporting group description:

1 spray (50 mcg) in each nostril twice daily (equivalent to 200 mcg per day) administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

|                       |                     |
|-----------------------|---------------------|
| Reporting group title | Placebo nasal spray |
|-----------------------|---------------------|

Reporting group description:

1 spray in each nostril twice daily administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

| Reporting group values | Mometasone Furoate nasal spray | Placebo nasal spray | Total |
|------------------------|--------------------------------|---------------------|-------|
| Number of subjects     | 66                             | 66                  | 132   |
| Age categorical        |                                |                     |       |
| Units: Subjects        |                                |                     |       |

|                                  |        |        |    |
|----------------------------------|--------|--------|----|
| Age Continuous                   |        |        |    |
| Units: years                     |        |        |    |
| arithmetic mean                  | 5.56   | 5.36   |    |
| standard deviation               | ± 2.27 | ± 2.5  | -  |
| Gender, Male/Female              |        |        |    |
| Units: participants              |        |        |    |
| Female                           | 32     | 23     | 55 |
| Male                             | 34     | 43     | 77 |
| Adenoid/Choana (A/C) Index Grade |        |        |    |
| Units: Score on a Scale          |        |        |    |
| arithmetic mean                  | 3.3    | 3.4    |    |
| standard deviation               | ± 0.44 | ± 0.49 | -  |

## End points

### End points reporting groups

|                                                                                                                                                                                                                                              |                                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Reporting group title                                                                                                                                                                                                                        | Mometasone Furoate nasal spray |
| Reporting group description:<br>1 spray (50 mcg) in each nostril twice daily (equivalent to 200 mcg per day) administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months). |                                |
| Reporting group title                                                                                                                                                                                                                        | Placebo nasal spray            |
| Reporting group description:<br>1 spray in each nostril twice daily administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).                                          |                                |

### Primary: Change From Baseline in Adenoid/Choana (A/C) Index Grade

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Change From Baseline in Adenoid/Choana (A/C) Index Grade |
| End point description:<br>Changes in adenoid size were assessed by nasopharyngoscopic examination and were determined using the Adenoid/Choana (A/C) Index. Grades were assigned to intervals of A/C ratio percentages: grade I (0-25%), II (26-50%), III (51-75%) and IV (76-100%). Changes in adenoid size were expressed as the mean difference between grades at baseline and study visit. Positive values indicated a decrease in adenoid size, a 0 value indicated that size remained the same, and negative values indicated an increase in adenoid size. |                                                          |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Primary                                                  |
| End point timeframe:<br>Baseline (visit 2), Week 4 (visit 3), Week 8 (visit 4)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                          |

| End point values                            | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|---------------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                          | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed                 | 65 <sup>[1]</sup>              | 63 <sup>[2]</sup>   |  |  |
| Units: Score on a Scale                     |                                |                     |  |  |
| arithmetic mean (standard deviation)        |                                |                     |  |  |
| Change at Visit 3 (n=65 MFNS, n=63 Placebo) | 0.3 (± 0.6)                    | 0.2 (± 0.5)         |  |  |
| Change at Visit 4 (n=61 MFNS, n=58 Placebo) | 0.4 (± 0.7)                    | 0.3 (± 0.7)         |  |  |

Notes:

[1] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

[2] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

### Statistical analyses

|                            |                                                      |
|----------------------------|------------------------------------------------------|
| Statistical analysis title | Change from Baseline to Visit 5                      |
| Comparison groups          | Mometasone Furoate nasal spray v Placebo nasal spray |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 128           |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| P-value                                 | = 0.165       |
| Method                                  | ANCOVA        |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 0.21          |
| upper limit                             | 0.23          |

### Secondary: Total Severity Symptom Scores: Morning and Evening (AM & PM)

|                 |                                                              |
|-----------------|--------------------------------------------------------------|
| End point title | Total Severity Symptom Scores: Morning and Evening (AM & PM) |
|-----------------|--------------------------------------------------------------|

End point description:

Symptoms were assessed by whole-number linear scale to grade their severity. Scores were recorded AM & PM (12 hours later) & were based on severity within 12 hours of prior recording. The following symptoms were evaluated: Snoring; Nasal obstruction & discharge; Breathing difficulty; Oral respiration; Ear pain. Severity was graded according to the following scale: 0=absent; 1=mild; 2=moderate; 3=severe. Severity was scored individually and summed to obtain the Total Symptom Severity Score. The maximum total score possible was 36 daily; 18 for both AM (6 symptoms times max severity of 3) and PM.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

| End point values                     | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|--------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                   | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed          | 66 <sup>[3]</sup>              | 66 <sup>[4]</sup>   |  |  |
| Units: Score on a scale              |                                |                     |  |  |
| arithmetic mean (standard deviation) |                                |                     |  |  |
| Visit 2 AM (n=66 MFNS, n=66 Placebo) | 9.4 (± 2.5)                    | 9.9 (± 3.3)         |  |  |
| Visit 3 AM (n=64 MFNS, n=65 Placebo) | 5.4 (± 3.8)                    | 6.4 (± 3.7)         |  |  |
| Visit 4 AM (n=62 MFNS, n=60 Placebo) | 4.2 (± 3.6)                    | 5.5 (± 3.5)         |  |  |
| Visit 2 PM (n=66 MFNS, n=66 Placebo) | 9.9 (± 3.2)                    | 10.2 (± 2.8)        |  |  |
| Visit 3 PM (n=64 MFNS, n=65 Placebo) | 6.3 (± 3.7)                    | 7 (± 3.6)           |  |  |
| Visit 4 PM (n=62 MFNS, n=60 Placebo) | 4.8 (± 3.8)                    | 5.7 (± 3.8)         |  |  |

Notes:

[3] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

[4] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

### Statistical analyses

No statistical analyses for this end point

### Secondary: Total Frequency Symptom Scores: AM & PM

|                 |                                         |
|-----------------|-----------------------------------------|
| End point title | Total Frequency Symptom Scores: AM & PM |
|-----------------|-----------------------------------------|

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**End point description:**

Symptoms were assessed by whole-number linear scale to grade their frequency. Scores were recorded AM & PM (12). The following signs/symptoms were evaluated: Snoring; Nasal obstruction; and nasal discharge; Breathing difficulty; Oral respiration; Ear pain.

Frequency was graded according to the following scale: 0=absent; 1=intermittent; 2=persistent.

The frequency of symptoms was scored individually and summed to obtain the Total Frequency Symptom Score. The maximum total score possible was 24 daily; 12 for both AM (6 symptoms times max frequency of 2) and PM.

|                                                        |           |
|--------------------------------------------------------|-----------|
| End point type                                         | Secondary |
| End point timeframe:                                   |           |
| Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4) |           |

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| End point values                     | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|--------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                   | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed          | 66 <sup>[5]</sup>              | 66 <sup>[6]</sup>   |  |  |
| Units: Score on a scale              |                                |                     |  |  |
| arithmetic mean (standard deviation) |                                |                     |  |  |
| Visit 2 AM (n=66 MFNS, n=66 Placebo) | 7.3 (± 1.9)                    | 7.3 (± 2.4)         |  |  |
| Visit 3 AM (n=64 MFNS, n=65 Placebo) | 4.4 (± 2.7)                    | 5.4 (± 2.6)         |  |  |
| Visit 4 AM (n=62 MFNS, n=60 Placebo) | 3.7 (± 2.8)                    | 4.4 (± 2.5)         |  |  |
| Visit 2 PM (n=66 MFNS, n=66 Placebo) | 7.6 (± 2.2)                    | 8 (± 2.1)           |  |  |
| Visit 3 PM (n=64 MFNS, n=65 Placebo) | 5.3 (± 2.8)                    | 5.7 (± 2.6)         |  |  |
| Visit 4 PM (n=62 MFNS, n=60 Placebo) | 4.1 (± 2.9)                    | 4.6 (± 2.7)         |  |  |

Notes:

[5] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

[6] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

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**Statistical analyses**

No statistical analyses for this end point

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**Secondary: Number of Participants with Bilateral Tympanogram Results of: Normal, Abnormal, or Not Done**

|                 |                                                                                             |
|-----------------|---------------------------------------------------------------------------------------------|
| End point title | Number of Participants with Bilateral Tympanogram Results of: Normal, Abnormal, or Not Done |
|-----------------|---------------------------------------------------------------------------------------------|

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**End point description:**

Tympanometry was performed in children ages 2-11 by certified audiologists. Results were categorized based on audiologist's assessment as either being normal (normal pressure in the middle ear with normal mobility of the eardrum and the conduction bones), abnormal (abnormal pressure in the middle ear and/or abnormal mobility of the eardrum and the conduction bones), or tympanometry was not done (evaluation not completed). Results were assessed at baseline, Week 4 (Visit 3), and endpoint Week 8 (end of treatment).

|                                                        |           |
|--------------------------------------------------------|-----------|
| End point type                                         | Secondary |
| End point timeframe:                                   |           |
| Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4) |           |

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| End point values                            | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|---------------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                          | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed                 | 66 <sup>[7]</sup>              | 66 <sup>[8]</sup>   |  |  |
| Units: Participants                         |                                |                     |  |  |
| number (not applicable)                     |                                |                     |  |  |
| Visit 2- Normal (n=66 MFNS, n=66 Placebo)   | 35                             | 39                  |  |  |
| Visit 2- Abnormal (n=66 MFNS, n=66 Placebo) | 25                             | 22                  |  |  |
| Visit 2- Not Done (n=66 MFNS, n=66 Placebo) | 6                              | 5                   |  |  |
| Visit 3- Normal (n=65 MFNS, n=65 Placebo)   | 44                             | 33                  |  |  |
| Visit 3- Abnormal (n=65 MFNS, n=65 Placebo) | 14                             | 22                  |  |  |
| Visit 3- Not Done (n=65 MFNS, n=65 Placebo) | 7                              | 10                  |  |  |
| Visit 4- Normal (n=62 MFNS, n=60 Placebo)   | 45                             | 39                  |  |  |
| Visit 4- Abnormal (n=62 MFNS, n=60 Placebo) | 16                             | 19                  |  |  |
| Visit 4- Not Done (n=62 MFNS, n=60 Placebo) | 1                              | 2                   |  |  |

Notes:

[7] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

[8] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants With Otoloscopic Results of: Normal or Abnormal

|                 |                                                                        |
|-----------------|------------------------------------------------------------------------|
| End point title | Number of Participants With Otoloscopic Results of: Normal or Abnormal |
|-----------------|------------------------------------------------------------------------|

End point description:

Otoloscopic examination was performed of the right and left ear canals at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4). Results were categorized based on audiologist's assessment as either being normal (ear canal structures appear normal) or abnormal (ear canal structures appear abnormal).

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

| End point values                               | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|------------------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                             | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed                    | 66 <sup>[9]</sup>              | 66 <sup>[10]</sup>  |  |  |
| Units: Participants                            |                                |                     |  |  |
| number (not applicable)                        |                                |                     |  |  |
| Right Otoloscopy: Visit 2- Normal (n=66, n=66) | 50                             | 51                  |  |  |

|                                                |    |    |  |  |
|------------------------------------------------|----|----|--|--|
| Right Otoscopy: Visit 2- Abnormal (n=66, n=66) | 16 | 15 |  |  |
| Right Otoscopy Visit 3- Normal (n=65, n=65)    | 54 | 53 |  |  |
| Right Otoscopy Visit 3- Abnormal (n=65, n=65)  | 11 | 12 |  |  |
| Right Otoscopy Visit 4- Normal (n=62, n=60)    | 49 | 52 |  |  |
| Right Otoscopy Visit 4- Abnormal (n=62, n=60)  | 13 | 8  |  |  |
| Left Otoscopy: Visit 2- Normal (n=66, n=66)    | 49 | 52 |  |  |
| Left Otoscopy: Visit 2- Abnormal (n=66, n=66)  | 17 | 14 |  |  |
| Left Otoscopy Visit 3- Normal (n=65, n=65)     | 51 | 55 |  |  |
| Left Otoscopy Visit 3- Abnormal (n=65, n=65)   | 14 | 10 |  |  |
| Left Otoscopy Visit 4- Normal (n=62, n=60)     | 48 | 52 |  |  |
| Left Otoscopy Visit 4- Abnormal (n=62, n=60)   | 14 | 8  |  |  |

Notes:

[9] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

[10] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants with Rhinoscopic-Inferior Turbinates Results of: Normal, Hypertrophic, and Hypotrophic

|                 |                                                                                                               |
|-----------------|---------------------------------------------------------------------------------------------------------------|
| End point title | Number of Participants with Rhinoscopic-Inferior Turbinates Results of: Normal, Hypertrophic, and Hypotrophic |
|-----------------|---------------------------------------------------------------------------------------------------------------|

End point description:

Rhinoscopic examination of the inferior turbinates was performed at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4). Results were categorized based on investigator's assessment as either being normal appearance (normal size) , hypertrophic (swollen/normal size increased), or hypotrophic (normal size diminished).

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

| End point values                        | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|-----------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                      | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed             | 66 <sup>[11]</sup>             | 66 <sup>[12]</sup>  |  |  |
| Units: Participants                     |                                |                     |  |  |
| number (not applicable)                 |                                |                     |  |  |
| Visit 2- Normal Appearance (n=66, n=66) | 50                             | 46                  |  |  |
| Visit 2 Hypertrophic (n=66, n=66)       | 16                             | 20                  |  |  |
| Vist 2 Hypotrophic (n=66, n=66)         | 0                              | 0                   |  |  |

|                                        |    |    |  |  |
|----------------------------------------|----|----|--|--|
| Visit 3 Normal Appearance (n=65, n=65) | 46 | 48 |  |  |
| Visit 3 Hypertrophic (n=65, n=65)      | 19 | 17 |  |  |
| Visit 3 Hypotrophic (n=65, n=65)       | 0  | 0  |  |  |
| Visit 4 Normal Appearance (n=62, n=60) | 45 | 42 |  |  |
| Visit 4 Hypertrophic (n=62, n=60)      | 17 | 18 |  |  |
| Visit 4 Hypotrophic (n=62, n=60)       | 0  | 0  |  |  |

Notes:

[11] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

[12] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants With Rhinoscopic- Middle Meatus Results of: Patent, Partial Obstruction or Total Obstruction

|                 |                                                                                                                     |
|-----------------|---------------------------------------------------------------------------------------------------------------------|
| End point title | Number of Participants With Rhinoscopic- Middle Meatus Results of: Patent, Partial Obstruction or Total Obstruction |
|-----------------|---------------------------------------------------------------------------------------------------------------------|

End point description:

Rhinoscopic examination of the middle meatus was performed at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4). Results were categorized based on investigator's assessment into 3 categories: patent (easily observed), partial obstruction (partially blocked from view), or total obstruction (completely blocked from view).

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

| End point values                           | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|--------------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                         | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed                | 66 <sup>[13]</sup>             | 66 <sup>[14]</sup>  |  |  |
| Units: Participants                        |                                |                     |  |  |
| number (not applicable)                    |                                |                     |  |  |
| Visit 2- Patent (n=66, n=66)               | 62                             | 60                  |  |  |
| Visit 2- Partial Obstruction (n=66, n=66)  | 3                              | 5                   |  |  |
| Visit 2- Total Obstruction (n=66, n=66)    | 1                              | 1                   |  |  |
| Visit 3- Patent (n=65, n=65)               | 61                             | 61                  |  |  |
| Visit 3- Partial Obstruction (n=65, n=65)  | 4                              | 2                   |  |  |
| Visit 3- Total Obstruction (n=65, n=65)    | 0                              | 2                   |  |  |
| Visit 4- Patent (n=62, n=60)               | 56                             | 53                  |  |  |
| Visit 4- Partial Obstruction (n= 62, n=60) | 6                              | 4                   |  |  |
| Visit 4- Total Obstruction (n=62, n=60)    | 0                              | 3                   |  |  |

Notes:

[13] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

[14] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

## Statistical analyses

No statistical analyses for this end point

### Secondary: Rhinomanometry Results- Left and Right Nasal Fossa: Inspiratory Resistance

|                 |                                                                            |
|-----------------|----------------------------------------------------------------------------|
| End point title | Rhinomanometry Results- Left and Right Nasal Fossa: Inspiratory Resistance |
|-----------------|----------------------------------------------------------------------------|

End point description:

Rhinomanometry examination of the left & right Nasal Fossa was performed at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4) in participants ages 7-11 years.

Rhinomanometry is a test of nasal function that measures air pressure and the rate of airflow in the nasal airway during respiration by means of equipment. These findings were used to calculate inspiratory nasal airway resistance reported in Pascal/centimeter<sup>3</sup>/second (Pa/cm<sup>3</sup>/sec).

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

| End point values                        | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|-----------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                      | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed             | 19 <sup>[15]</sup>             | 20 <sup>[16]</sup>  |  |  |
| Units: Pa/cm <sup>3</sup> /sec          |                                |                     |  |  |
| arithmetic mean (standard deviation)    |                                |                     |  |  |
| Visit 2- Left Nasal Fossa (n=19, n=20)  | 2.111 (± 4.372)                | 3.28 (± 7.852)      |  |  |
| Visit 3- Left Nasal Fossa (n=18, n=18)  | 6.341 (± 22.759)               | 1.934 (± 2.234)     |  |  |
| Visit 4- Left Nasal Fossa (n=19, n=19)  | 31.074 (± 131.718)             | 54.724 (± 229.437)  |  |  |
| Visit 2- Right Nasal Fossa (n=19, n=20) | 2.985 (± 8.527)                | 6.535 (± 24.836)    |  |  |
| Visit 3- Right Nasal Fossa (n=18, n=18) | 1.823 (± 4.454)                | 3.026 (± 8.258)     |  |  |
| Visit 4- Right Nasal Fossa (n=19, n=19) | 2.56 (± 6.918)                 | 43.621 (± 174.535)  |  |  |

Notes:

[15] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

[16] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

## Statistical analyses

No statistical analyses for this end point

### Secondary: Rhinomanometry Results- Left and Right Nasal Fossa: Expiratory Resistance

|                 |                                                                           |
|-----------------|---------------------------------------------------------------------------|
| End point title | Rhinomanometry Results- Left and Right Nasal Fossa: Expiratory Resistance |
|-----------------|---------------------------------------------------------------------------|

End point description:

Rhinomanometry examination of the left & right Nasal Fossa was performed at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4) in participants ages 7-11 years.

Rhinomanometry is a test of nasal function that measures air pressure and the rate of airflow in the

nasal airway during respiration by means of equipment. These findings were used to calculate expiratory nasal airway resistance reported in Pascal/centimeter<sup>3</sup>/second (Pa/cm<sup>3</sup>/sec).

|                                                        |           |
|--------------------------------------------------------|-----------|
| End point type                                         | Secondary |
| End point timeframe:                                   |           |
| Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4) |           |

| End point values                        | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|-----------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                      | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed             | 19 <sup>[17]</sup>             | 20 <sup>[18]</sup>  |  |  |
| Units: Pa/cm <sup>3</sup> /sec          |                                |                     |  |  |
| arithmetic mean (standard deviation)    |                                |                     |  |  |
| Visit 2- Left Nasal Fossa (n=19, n=20)  | 1.771 (± 2.764)                | 3.994 (± 9.416)     |  |  |
| Visit 3- Left Nasal Fossa (n=18, n=18)  | 2.937 (± 8.196)                | 1.478 (± 1.647)     |  |  |
| Visit 4- Left Nasal Fossa (n=19, n=19)  | 13.488 (± 32.344)              | 4.148 (± 13.999)    |  |  |
| Visit 2- Right Nasal Fossa (n=19, n=20) | 2.625 (± 6.868)                | 1.083 (± 1.109)     |  |  |
| Visit 3- Right Nasal Fossa (n=18, n=18) | 2.189 (± 4.678)                | 3.646 (± 8.313)     |  |  |
| Visit 4- Right Nasal Fossa (n=19, n=19) | 0.961 (± 0.758)                | 2.792 (± 6.318)     |  |  |

Notes:

[17] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

[18] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Rhinomanometry Results- Left and Right Nasal Fossa: Inspiration Flow at 75 Pa

|                 |                                                                               |
|-----------------|-------------------------------------------------------------------------------|
| End point title | Rhinomanometry Results- Left and Right Nasal Fossa: Inspiration Flow at 75 Pa |
|-----------------|-------------------------------------------------------------------------------|

End point description:

Rhinomanometry examination of the left & right Nasal Fossa was performed at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4) in participants ages 7-11 years.

Rhinomanometry is a test of nasal function that measures air pressure and the rate of airflow in the nasal airway during respiration by means of equipment. Inspiration flow was calculated at 75 Pa.

|                                                        |           |
|--------------------------------------------------------|-----------|
| End point type                                         | Secondary |
| End point timeframe:                                   |           |
| Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4) |           |

| End point values                        | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|-----------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                      | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed             | 19 <sup>[19]</sup>             | 20 <sup>[20]</sup>  |  |  |
| Units: cm <sup>3</sup> /sec             |                                |                     |  |  |
| arithmetic mean (standard deviation)    |                                |                     |  |  |
| Visit 2- Left Nasal Fossa (n=19, n=20)  | 200.53 (± 140.492)             | 178.933 (± 129.272) |  |  |
| Visit 3- Left Nasal Fossa (n=18, n=18)  | 222.152 (± 141.74)             | 151.268 (± 130.115) |  |  |
| Visit 4- Left Nasal Fossa (n=19, n=19)  | 194.208 (± 100.746)            | 172.346 (± 102.607) |  |  |
| Visit 2- Right Nasal Fossa (n=19, n=20) | 183.562 (± 121.78)             | 161.958 (± 138.673) |  |  |
| Visit 3- Right Nasal Fossa (n=18, n=18) | 228.661 (± 149.318)            | 197.266 (± 123.763) |  |  |
| Visit 4- Right Nasal Fossa (n=19, n=19) | 215.4 (± 157.794)              | 183.368 (± 117.677) |  |  |

Notes:

[19] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

[20] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

### Statistical analyses

No statistical analyses for this end point

### Secondary: Rhinomanometry Results- Left and Right Nasal Fossa: Expiratory Flow at 75 Pa

|                 |                                                                              |
|-----------------|------------------------------------------------------------------------------|
| End point title | Rhinomanometry Results- Left and Right Nasal Fossa: Expiratory Flow at 75 Pa |
|-----------------|------------------------------------------------------------------------------|

End point description:

Rhinomanometry examination of the left & right Nasal Fossa was performed at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4) in participants ages 7-11 years.

Rhinomanometry is a test of nasal function that measures air pressure and the rate of airflow in the nasal airway during respiration by means of equipment. Expiratory flow was calculated at 75 Pa.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

| End point values                       | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|----------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                     | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed            | 19 <sup>[21]</sup>             | 20 <sup>[22]</sup>  |  |  |
| Units: cm <sup>3</sup> /sec            |                                |                     |  |  |
| arithmetic mean (standard deviation)   |                                |                     |  |  |
| Visit 2- Left Nasal Fossa (n=19, n=20) | 190.024 (± 146.067)            | 166.93 (± 116.802)  |  |  |
| Visit 3- Left Nasal Fossa (n=18, n=18) | 225.911 (± 154.83)             | 173.139 (± 151.783) |  |  |
| Visit 4- Left Nasal Fossa (n=19, n=19) | 181.026 (± 119.728)            | 192.374 (± 134.337) |  |  |

|                                         |                     |                     |  |  |
|-----------------------------------------|---------------------|---------------------|--|--|
| Visit 2- Right Nasal Fossa (n=19, n=20) | 160.531 (± 117.988) | 166.302 (± 132.754) |  |  |
| Visit 3- Right Nasal Fossa (n=18, n=18) | 209.676 (± 157.215) | 209.787 (± 151.298) |  |  |
| Visit 4- Right Nasal Fossa (n=19, n=19) | 195.108 (± 163.411) | 176.587 (± 111.421) |  |  |

Notes:

[21] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

[22] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants with Pure-Tone Audiometric Results of: Normal, Abnormal, or Not Done

|                 |                                                                                             |
|-----------------|---------------------------------------------------------------------------------------------|
| End point title | Number of Participants with Pure-Tone Audiometric Results of: Normal, Abnormal, or Not Done |
|-----------------|---------------------------------------------------------------------------------------------|

End point description:

Pure-tone audiometry was performed in children ages 7-11 by certified audiologists. Results were categorized based on audiologist's assessment as either being normal (within normal limits), abnormal (outside normal limits), or audiometry was not done (not performed). Results were assessed at baseline, Week 4 (Visit 3), and endpoint Week 8 (end of treatment).

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

| End point values                             | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|----------------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                           | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed                  | 19 <sup>[23]</sup>             | 21 <sup>[24]</sup>  |  |  |
| Units: Participants                          |                                |                     |  |  |
| number (not applicable)                      |                                |                     |  |  |
| Visit 2- Normal (n=19 MFNS, n=21 Placebo)    | 13                             | 18                  |  |  |
| Visit 2- Abnormal (n=19 MFNS, n=21 Placebo)  | 5                              | 2                   |  |  |
| Visit 2- Not Done (n=19 MFNS, n= 21 Placebo) | 1                              | 1                   |  |  |
| Visit 3- Normal (n=20 MFNS, n=21 Placebo)    | 15                             | 20                  |  |  |
| Visit 3- Abnormal (n=20 MFNS, n=21 Placebo)  | 4                              | 1                   |  |  |
| Visit 3- Not Done (n=20 MFNS, n=21 Placebo)  | 1                              | 0                   |  |  |
| Visit 4- Normal (n=19 MFNS, n=20 Placebo)    | 15                             | 18                  |  |  |
| Visit 4- Abnormal (n=19 MFNS, n=20 Placebo)  | 2                              | 2                   |  |  |
| Visit 4- Not Done (n=19 MFNS, n=20 Placebo)  | 2                              | 0                   |  |  |

Notes:

[23] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

[24] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Acoustic Rhinometry Results- Minimal Cross-Sectional Area: Left and Right Nasal Fossa

|                 |                                                                                       |
|-----------------|---------------------------------------------------------------------------------------|
| End point title | Acoustic Rhinometry Results- Minimal Cross-Sectional Area: Left and Right Nasal Fossa |
|-----------------|---------------------------------------------------------------------------------------|

End point description:

Acoustic rhinometry examination of the left & right Nasal Fossa was performed by principal investigators at baseline & each visit throughout treatment in participants ages 7-11 years. Acoustic rhinometry is a technique intended for assessment of the geometry of the nasal cavity and nasopharynx and for evaluating nasal obstruction. The technique is based on an analysis of sound waves reflected from the nasal cavities.

Measurements were taken for each side of the nose (nasopharyngeal minimum cross-sectional area) & were reported in  $\text{cm}^3$ .

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

| End point values                        | Mometasone Furoate nasal spray | Placebo nasal spray  |  |  |
|-----------------------------------------|--------------------------------|----------------------|--|--|
| Subject group type                      | Reporting group                | Reporting group      |  |  |
| Number of subjects analysed             | 19 <sup>[25]</sup>             | 20 <sup>[26]</sup>   |  |  |
| Units: $\text{cm}^3$                    |                                |                      |  |  |
| arithmetic mean (standard deviation)    |                                |                      |  |  |
| Visit 2- Left Nasal Fossa (n=19, n=20)  | 0.599 ( $\pm$ 0.567)           | 0.491 ( $\pm$ 0.265) |  |  |
| Visit 3- Left Nasal Fossa (n=18, n=18)  | 0.608 ( $\pm$ 0.485)           | 0.594 ( $\pm$ 0.403) |  |  |
| Visit 4- Left Nasal Fossa (n=19, n=19)  | 0.662 ( $\pm$ 0.444)           | 0.661 ( $\pm$ 0.444) |  |  |
| Visit 2- Right Nasal Fossa (n=19, n=20) | 0.532 ( $\pm$ 0.467)           | 0.577 ( $\pm$ 0.381) |  |  |
| Visit 3- Right Nasal Fossa (n=18, n=18) | 0.581 ( $\pm$ 0.405)           | 0.596 ( $\pm$ 0.383) |  |  |
| Visit 4- Right Nasal Fossa (n=19, n=19) | 0.734 ( $\pm$ 0.599)           | 0.814 ( $\pm$ 0.675) |  |  |

Notes:

[25] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

[26] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

## Statistical analyses

No statistical analyses for this end point

**Secondary: Acoustic Rhinometry Results- Nasopharyngeal Volume (NPV): Left and Right Nasal Fossa**

|                 |                                                                                      |
|-----------------|--------------------------------------------------------------------------------------|
| End point title | Acoustic Rhinometry Results- Nasopharyngeal Volume (NPV): Left and Right Nasal Fossa |
|-----------------|--------------------------------------------------------------------------------------|

End point description:

Acoustic rhinometry examination of the left & right Nasal Fossa was performed by principal investigators at baseline & each visit throughout treatment in participants ages 7-11 years. Acoustic rhinometry is a technique intended for assessment of the geometry of the nasal cavity and nasopharynx and for evaluating nasal obstruction. The technique is based on an analysis of sound waves reflected from the nasal cavities.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

| End point values                        | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|-----------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                      | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed             | 19 <sup>[27]</sup>             | 20 <sup>[28]</sup>  |  |  |
| Units: cm <sup>3</sup>                  |                                |                     |  |  |
| arithmetic mean (standard deviation)    |                                |                     |  |  |
| Visit 2- Left Nasal Fossa (n=19, n=20)  | 4.245 (± 1.954)                | 4.117 (± 3.554)     |  |  |
| Visit 3- Left Nasal Fossa (n=18, n=18)  | 3.725 (± 1.944)                | 3.489 (± 1.589)     |  |  |
| Visit 4- Left Nasal Fossa (n=19, n=19)  | 3.631 (± 0.905)                | 3.084 (± 1.724)     |  |  |
| Visit 2- Right Nasal Fossa (n=19, n=20) | 3.566 (± 1.629)                | 4.489 (± 2.941)     |  |  |
| Visit 3- Right Nasal Fossa (n=18, n=18) | 4.183 (± 1.341)                | 4.884 (± 3.591)     |  |  |
| Visit 4- Right Nasal Fossa (n=19, n=19) | 3.774 (± 1.24)                 | 3.275 (± 1.083)     |  |  |

Notes:

[27] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

[28] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Number of Participants with Pediatric Sleep Questionnaire (PSQ)- Impact on Health-Related Quality of Life (HRQL) Results of: Mild, Moderate, or Severe**

|                 |                                                                                                                                                        |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Number of Participants with Pediatric Sleep Questionnaire (PSQ)- Impact on Health-Related Quality of Life (HRQL) Results of: Mild, Moderate, or Severe |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

PSQ consists of 90 variables divided into 3 different factors: snoring, somnolence, and behavior. All positive Snoring and Somnolence answers scored with Yes=1 and No=0, and scores averaged to obtain a total score between 0.00 and 1.00. Behavior factor scored between 1 (never)-3 (always), and scores averaged for total score of 1 to 3. Increased scores indicate increasing abnormality of sleep. Based on determined cut-offs, participants were categorized as having mild, moderate, or severe discomfort due to interference of sleep.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

| End point values                            | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|---------------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                          | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed                 | 66 <sup>[29]</sup>             | 65 <sup>[30]</sup>  |  |  |
| Units: Participants                         |                                |                     |  |  |
| number (not applicable)                     |                                |                     |  |  |
| Visit 2- Mild (n=66 MFNS, n=65 Placebo)     | 33                             | 30                  |  |  |
| Visit 2- Moderate (n=66 MFNS, n=65 Placebo) | 17                             | 26                  |  |  |
| Visit 2- Severe (n=66 MFNS, n=65 Placebo)   | 16                             | 9                   |  |  |
| Visit 3- Mild (n=65 MFNS, n=65 Placebo)     | 50                             | 45                  |  |  |
| Visit 3- Moderate (n=65 MFNS, n=Placebo)    | 11                             | 17                  |  |  |
| Visit 3- Severe (n=65 MFNS, n=65 Placebo)   | 4                              | 3                   |  |  |
| Visit 4- Mild (n=62 MFNS, n=59 Placebo)     | 49                             | 47                  |  |  |
| Visit 4- Moderate (n=62 MFNS, n=59 Placebo) | 13                             | 10                  |  |  |
| Visit 4- Severe (n=62 MFNS, n= 59 Placebo)  | 0                              | 2                   |  |  |

Notes:

[29] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

[30] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Quality of Life Questionnaire (PedsQL) Total Score (Ages 2-4)

|                 |                                                               |
|-----------------|---------------------------------------------------------------|
| End point title | Quality of Life Questionnaire (PedsQL) Total Score (Ages 2-4) |
|-----------------|---------------------------------------------------------------|

End point description:

The impact on quality of life (QOL) was measured by a general pediatric health questionnaire. Versions were self-administered & answered by participants' parents. This modular instrument consists of 21 items using a 5-point scale: from 0 (never) to 4 (almost always). Items are reversed scored and linearly transformed to a 0-100 scale as follows: 0=100, 1=75, 2=50, 3=25, 4=0. 4 dimensions (physical, emotional, social, & school functioning) are scored. Total score is sum of all the items over the number of items answered on all the scales. Higher scores indicate a better health related QOL.

At baseline (visit 2), 52 randomized participants were between 2 and 4 years old, 23 participants in MFNS & 29 participants in Placebo group. Questionnaire was answered in accordance with the actual age of each participant at each visit.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

| End point values                     | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|--------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                   | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed          | 23 <sup>[31]</sup>             | 29 <sup>[32]</sup>  |  |  |
| Units: Score on a scale              |                                |                     |  |  |
| arithmetic mean (standard deviation) |                                |                     |  |  |
| Visit 2 (n= 23 MFNS, n=29 Placebo)   | 78.442 (± 13.114)              | 78.017 (± 14.769)   |  |  |
| Visit 3 (n=22 MFNS, n= 28 Placebo)   | 80.438 (± 15.827)              | 78.486 (± 15.707)   |  |  |
| Visit 4 (n=18 MFNS, n=25 Placebo)    | 80.137 (± 15.161)              | 82.701 (± 11.911)   |  |  |

Notes:

[31] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

[32] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Quality of Life Questionnaire (PedsQL) Total Score (Ages 5-7)

|                 |                                                               |
|-----------------|---------------------------------------------------------------|
| End point title | Quality of Life Questionnaire (PedsQL) Total Score (Ages 5-7) |
|-----------------|---------------------------------------------------------------|

End point description:

The impact on quality of life (QOL) was measured by a general pediatric health questionnaire. Versions were self-administered & answered by participants' parents. Questionnaire consists of 23 items using a 3-point scale: from 0 (not at all), 2 (sometimes), 4 (a lot). Items are reversed scored and linearly transformed to a 0-100 scale as follows: 0=100, 1=75, 2=50, 3=25, 4=0. 4 dimensions (physical, emotional, social, & school functioning) are scored. Total score is sum of all the items over the number of items answered on all the scales. Higher scores indicate a better health related QOL.

At baseline (visit 2), 52 randomized participants were between 5 and 7 years old, 28 participants in MFNS & 24 subjects in Placebo group. Questionnaire was answered in accordance with the actual age of each participant at each visit.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

| End point values                     | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|--------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                   | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed          | 28 <sup>[33]</sup>             | 24 <sup>[34]</sup>  |  |  |
| Units: Score on a scale              |                                |                     |  |  |
| arithmetic mean (standard deviation) |                                |                     |  |  |
| Visit 2 (n= 28 MFNS, n=24 Placebo)   | 78.14 (± 15.74)                | 79.03 (± 11.35)     |  |  |
| Visit 3 (n=28 MFNS, n= 23 Placebo)   | 81.56 (± 13.64)                | 84.07 (± 12.26)     |  |  |
| Visit 4 (n=28 MFNS, n=22 Placebo)    | 83.54 (± 13.63)                | 82.71 (± 13.52)     |  |  |

Notes:

[33] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

[34] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

## Statistical analyses

No statistical analyses for this end point

### Secondary: Quality of Life Questionnaire (PedsQL) Total Score (Ages 8-12)

|                 |                                                                |
|-----------------|----------------------------------------------------------------|
| End point title | Quality of Life Questionnaire (PedsQL) Total Score (Ages 8-12) |
|-----------------|----------------------------------------------------------------|

End point description:

The impact on quality of life (QOL) was measured by a general pediatric health questionnaire. Versions were self-administered & answered by participants' parents. This modular instrument consists of 23 items using a 5-point scale: from 0 (never) to 4 (almost always). Items are reversed scored and linearly transformed to a 0-100 scale as follows: 0=100, 1=75, 2=50, 3=25, 4=0. 4 dimensions (physical, emotional, social, & school functioning) are scored. Total score is sum of all the items over the number of items answered on all the scales. Higher scores indicate a better health related QOL.

At baseline (visit 2), 28 randomized participants were between 8-12 years old, 15 participants in MFNS & 13 participants in Placebo group. Questionnaire was answered in accordance with the actual age of each participant at each visit.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

| End point values                     | Mometasone Furoate nasal spray | Placebo nasal spray    |  |  |
|--------------------------------------|--------------------------------|------------------------|--|--|
| Subject group type                   | Reporting group                | Reporting group        |  |  |
| Number of subjects analysed          | 15 <sup>[35]</sup>             | 14 <sup>[36]</sup>     |  |  |
| Units: Score on a scale              |                                |                        |  |  |
| arithmetic mean (standard deviation) |                                |                        |  |  |
| Visit 2 (n= 15 MFNS, n=13 Placebo)   | 76.014 ( $\pm$ 10.266)         | 76.839 ( $\pm$ 10.828) |  |  |
| Visit 3 (n=15 MFNS, n= 14 Placebo)   | 82.971 ( $\pm$ 15.054)         | 84.006 ( $\pm$ 14.033) |  |  |
| Visit 4 (n=15 MFNS, n=13 Placebo)    | 85.725 ( $\pm$ 12.033)         | 83.946 ( $\pm$ 10.023) |  |  |

Notes:

[35] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

[36] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

## Statistical analyses

No statistical analyses for this end point

### Secondary: Obstructive Sleep Apnea-18 (OSA-18) Questionnaire Total Score

|                 |                                                               |
|-----------------|---------------------------------------------------------------|
| End point title | Obstructive Sleep Apnea-18 (OSA-18) Questionnaire Total Score |
|-----------------|---------------------------------------------------------------|

End point description:

18 items of the survey were graded on a 7-point ordinal scale. Caregivers were asked to describe how

often in the last 4 weeks had the child exhibited specific symptoms according to the following scale: 1: none of the time; 2: hardly any of the time; 3: a little of the time; 4: some of the time; 5: a good bit of the time; 6: most of the time; 7: all of the time. All scores were summed (total score: 18-126).

Grading was as follows:

- Scores < 60 suggest a slight impact on health related quality of life (HRQL)
- Scores 60-80 suggest a moderate impact
- Scores over 80 suggest a great impact

1 participant in Placebo group did not answer this questionnaire at baseline.

|                                                        |           |
|--------------------------------------------------------|-----------|
| End point type                                         | Secondary |
| End point timeframe:                                   |           |
| Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4) |           |

| End point values                     | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|--------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                   | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed          | 66 <sup>[37]</sup>             | 65 <sup>[38]</sup>  |  |  |
| Units: Score on a scale              |                                |                     |  |  |
| arithmetic mean (standard deviation) |                                |                     |  |  |
| Visit 2 (n=66 MFNS, n=65 Placebo)    | 62.742 (± 19.951)              | 60.169 (± 19.123)   |  |  |
| Visit 3 (n=65 MFNS, n= 65 Placebo)   | 47.138 (± 18.806)              | 48.769 (± 18.748)   |  |  |
| Visit 4 (n=62 MFNS, n= 59 Placebo)   | 42.742 (± 17.88)               | 43.068 (± 18.87)    |  |  |

Notes:

[37] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

[38] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants With Rhinoscopic- Septum Results of: Aligned, Non-Obstructive, or Obstructive Deviation

|                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                            | Number of Participants With Rhinoscopic- Septum Results of: Aligned, Non-Obstructive, or Obstructive Deviation |
| End point description:                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                |
| Rhinoscopic examination of the septum was performed at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4). Results were categorized based on investigator's assessment as either being aligned (septum is aligned), non-obstructive (septum is not aligned but the deviation is non-obstructive), or obstructive (septum is deviated and obstructive) deviation. |                                                                                                                |
| End point type                                                                                                                                                                                                                                                                                                                                                                             | Secondary                                                                                                      |
| End point timeframe:                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                |
| Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)                                                                                                                                                                                                                                                                                                                                     |                                                                                                                |

| End point values                                | Mometasone Furoate nasal spray | Placebo nasal spray |  |  |
|-------------------------------------------------|--------------------------------|---------------------|--|--|
| Subject group type                              | Reporting group                | Reporting group     |  |  |
| Number of subjects analysed                     | 66 <sup>[39]</sup>             | 66 <sup>[40]</sup>  |  |  |
| Units: Participants                             |                                |                     |  |  |
| number (not applicable)                         |                                |                     |  |  |
| Visit 2 Aligned (n= 66, n=66)                   | 65                             | 63                  |  |  |
| Visit 2 Non-obstructive Deviation (n= 66, n=66) | 1                              | 3                   |  |  |
| Vist 2 Obstructive Deviation (n=66, n=66)       | 0                              | 0                   |  |  |
| Visit 3 Aligned (n=65, n=65)                    | 64                             | 62                  |  |  |
| Visit 3 Non-obstructive Deviation (n=65, n=65)  | 1                              | 3                   |  |  |
| Visit 3 Obstructive Deviation (n=65, n=65)      | 0                              | 0                   |  |  |
| Visit 4 Aligned (n=62, n=60)                    | 61                             | 57                  |  |  |
| Visit 4 Non-obstructive Deviation (n=62, n=60)  | 1                              | 3                   |  |  |
| Visit 4 -Obstructive Deviation (n=62, n=60)     | 0                              | 0                   |  |  |

Notes:

[39] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

[40] - All randomized participants who took  $\geq 1$  study drug dose and were evaluable for this end point.

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Up to Week 24

|                 |            |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 13.0 |
|--------------------|------|

### Reporting groups

|                       |                     |
|-----------------------|---------------------|
| Reporting group title | Placebo nasal spray |
|-----------------------|---------------------|

Reporting group description:

1 spray in each nostril twice daily administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

|                       |                                |
|-----------------------|--------------------------------|
| Reporting group title | Mometasone Furoate nasal spray |
|-----------------------|--------------------------------|

Reporting group description:

1 spray (50 mcg) in each nostril twice daily (equivalent to 200 mcg per day) administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

| Serious adverse events                            | Placebo nasal spray | Mometasone Furoate nasal spray |  |
|---------------------------------------------------|---------------------|--------------------------------|--|
| Total subjects affected by serious adverse events |                     |                                |  |
| subjects affected / exposed                       | 3 / 66 (4.55%)      | 2 / 66 (3.03%)                 |  |
| number of deaths (all causes)                     | 0                   | 0                              |  |
| number of deaths resulting from adverse events    | 0                   | 0                              |  |
| Respiratory, thoracic and mediastinal disorders   |                     |                                |  |
| Oropharyngeal Pain                                |                     |                                |  |
| subjects affected / exposed                       | 1 / 66 (1.52%)      | 0 / 66 (0.00%)                 |  |
| occurrences causally related to treatment / all   | 0 / 1               | 0 / 0                          |  |
| deaths causally related to treatment / all        | 0 / 0               | 0 / 0                          |  |
| Pleural Effusion                                  |                     |                                |  |
| subjects affected / exposed                       | 1 / 66 (1.52%)      | 0 / 66 (0.00%)                 |  |
| occurrences causally related to treatment / all   | 0 / 1               | 0 / 0                          |  |
| deaths causally related to treatment / all        | 0 / 0               | 0 / 0                          |  |
| Infections and infestations                       |                     |                                |  |
| Appendicitis                                      |                     |                                |  |
| subjects affected / exposed                       | 0 / 66 (0.00%)      | 1 / 66 (1.52%)                 |  |
| occurrences causally related to treatment / all   | 0 / 0               | 0 / 1                          |  |
| deaths causally related to treatment / all        | 0 / 0               | 0 / 0                          |  |
| Orchitis                                          |                     |                                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 1 / 66 (1.52%) | 0 / 66 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pharyngitis                                     |                |                |  |
| subjects affected / exposed                     | 1 / 66 (1.52%) | 0 / 66 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pneumonia                                       |                |                |  |
| subjects affected / exposed                     | 1 / 66 (1.52%) | 0 / 66 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Upper Respiratory Tract Infection               |                |                |  |
| subjects affected / exposed                     | 0 / 66 (0.00%) | 1 / 66 (1.52%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |

Frequency threshold for reporting non-serious adverse events: 5 %

| <b>Non-serious adverse events</b>                     | Placebo nasal spray | Mometasone Furoate nasal spray |  |
|-------------------------------------------------------|---------------------|--------------------------------|--|
| Total subjects affected by non-serious adverse events |                     |                                |  |
| subjects affected / exposed                           | 17 / 66 (25.76%)    | 18 / 66 (27.27%)               |  |
| General disorders and administration site conditions  |                     |                                |  |
| Pyrexia                                               |                     |                                |  |
| subjects affected / exposed                           | 4 / 66 (6.06%)      | 5 / 66 (7.58%)                 |  |
| occurrences (all)                                     | 5                   | 10                             |  |
| Respiratory, thoracic and mediastinal disorders       |                     |                                |  |
| Epistaxis                                             |                     |                                |  |
| subjects affected / exposed                           | 4 / 66 (6.06%)      | 3 / 66 (4.55%)                 |  |
| occurrences (all)                                     | 14                  | 4                              |  |
| Cough                                                 |                     |                                |  |
| subjects affected / exposed                           | 4 / 66 (6.06%)      | 1 / 66 (1.52%)                 |  |
| occurrences (all)                                     | 4                   | 1                              |  |
| Infections and infestations                           |                     |                                |  |

|                             |                |                |  |
|-----------------------------|----------------|----------------|--|
| Pharyngitis                 |                |                |  |
| subjects affected / exposed | 3 / 66 (4.55%) | 4 / 66 (6.06%) |  |
| occurrences (all)           | 4              | 7              |  |
| Nasopharyngitis             |                |                |  |
| subjects affected / exposed | 4 / 66 (6.06%) | 3 / 66 (4.55%) |  |
| occurrences (all)           | 4              | 3              |  |
| Pharyngotonsillitis         |                |                |  |
| subjects affected / exposed | 4 / 66 (6.06%) | 2 / 66 (3.03%) |  |
| occurrences (all)           | 6              | 2              |  |
| Sinusitis                   |                |                |  |
| subjects affected / exposed | 2 / 66 (3.03%) | 4 / 66 (6.06%) |  |
| occurrences (all)           | 2              | 5              |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

|                                                                                                                                                                                                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The results of this study as presented are drawn from the clinical study report and should be reviewed with caution as there were inaccuracies in the database resulting from medication errors in some participants. |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Notes: