



## Clinical trial results:

### A Randomized, Multicenter, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Oral Sumatriptan for the Acute Treatment of Migraine in Children and Adolescents

#### Summary

|                          |                  |
|--------------------------|------------------|
| EudraCT number           | 2015-004880-35   |
| Trial protocol           | Outside EU/EEA   |
| Global end of trial date | 03 December 2010 |

#### Results information

|                                |                 |
|--------------------------------|-----------------|
| Result version number          | v1 (current)    |
| This version publication date  | 26 January 2017 |
| First version publication date | 26 January 2017 |

#### Trial information

##### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | 111035 |
|-----------------------|--------|

##### Additional study identifiers

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

Notes:

##### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | GlaxoSmithKline  |
| Sponsor organisation address | 980 Great West Road, Brentford, Middlesex, United Kingdom, |
| Public contact               | GSK Response Center, GlaxoSmithKline, 1 866-435-7343,      |
| Scientific contact           | GSK Response Center, GlaxoSmithKline, 1 866-435-7343,      |

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                       | 04 February 2011 |
| Is this the analysis of the primary completion data? | No               |

|                                  |                  |
|----------------------------------|------------------|
| Global end of trial reached?     | Yes              |
| Global end of trial date         | 03 December 2010 |
| Was the trial ended prematurely? | No               |

Notes:

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**General information about the trial**

Main objective of the trial:

TBD

Protection of trial subjects:

Not Applicable

Background therapy: -

Evidence for comparator: -

|   |                   |
|---|-------------------|
| Actual start date of recruitment                          | 28 September 2009 |
| Long term follow-up planned                               | No                |
| Independent data monitoring committee (IDMC) involvement? | No                |

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

|                                      |            |
|--------------------------------------|------------|
| Country: Number of subjects enrolled | Japan: 178 |
| Worldwide total number of subjects   | 178        |
| 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)                     | 29  |
| Adolescents (12-17 years)                 | 149 |
| Adults (18-64 years)                      | 0   |
| From 65 to 84 years                       | 0   |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 178 participants (par.) were enrolled into the study (89 par. - Placebo arm, 44 par. - Sumatriptan 25 mg, 35 par. - Sumatriptan 50 mg). Subject disposition is presented for the Full Analysis Set, comprised of all participants who took at least one dose of investigational product and provided any post-treatment efficacy assessment.

### 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          |

### Arms

|                              |         |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes     |
| <b>Arm title</b>             | Placebo |

Arm description:

Participants took 2 tablets of placebo matched to sumatriptan 25 milligrams (mg) within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on a 5-grade, self-rating scale to assess the pain intensity of a migraine: 1 = none, 2 = mild, 3 = mild to moderate, 4 = moderate to severe, and 5 = severe.

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

Dosage and administration details:

Two tablets matching the Sumatriptan 25 mg administered orally (within 30 minutes) after development of migraine associated with score 3 or more severe pain on a 5-grade scale.

|                  |                   |
|------------------|-------------------|
| <b>Arm title</b> | Sumatriptan 25 mg |
|------------------|-------------------|

Arm description:

Participants took 1 tablet of sumatriptan 25 mg and 1 tablet of placebo matched to sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.

|  |                   |
|--|-------------------|
| Arm type                               | Active comparator |
| Investigational medicinal product name | Sumatriptan 25 mg |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Tablet            |
| Routes of administration               | Oral use          |

Dosage and administration details:

One tablet administered orally (within 30 minutes) after development of migraine associated with score 3 or more severe pain on a 5-grade scale.

|                  |                   |
|------------------|-------------------|
| <b>Arm title</b> | Sumatriptan 50 mg |
|------------------|-------------------|

Arm description:

Participants took 2 tablets of sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.

|  |                   |
|--|-------------------|
| Arm type                               | Active comparator |
| Investigational medicinal product name | Sumatriptan 50 mg |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Tablet            |
| Routes of administration               | Oral use          |

Dosage and administration details:

Two tablets of Sumatriptan 25 mg administered orally (within 30 minutes) after development of migraine associated with score 3 or more severe pain on a 5-grade scale.

| <b>Number of subjects in period 1<sup>[1]</sup></b> | Placebo | Sumatriptan 25 mg | Sumatriptan 50 mg |
|---|---------|-------------------|-------------------|
| Started   | 70      | 33                | 41                |
| Completed   | 70      | 33                | 41                |

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: A total of 178 participants (par.) were enrolled into the study (89 par. - Placebo arm, 44 par. - Sumatriptan 25 mg, 35 par. - Sumatriptan 50 mg). Subject disposition is presented for the Full Analysis Set,

## Baseline characteristics

### Reporting groups

|  |                   |
|--|-------------------|
| Reporting group title  | Placebo           |
| Reporting group description:   |                   |
| Participants took 2 tablets of placebo matched to sumatriptan 25 milligrams (mg) within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on a 5-grade, self-rating scale to assess the pain intensity of a migraine: 1 = none, 2 = mild, 3 = mild to moderate, 4 = moderate to severe, and 5 = severe. |                   |
| Reporting group title  | Sumatriptan 25 mg |
| Reporting group description:   |                   |
| Participants took 1 tablet of sumatriptan 25 mg and 1 tablet of placebo matched to sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.   |                   |
| Reporting group title  | Sumatriptan 50 mg |
| Reporting group description:   |                   |
| Participants took 2 tablets of sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.   |                   |

| Reporting group values | Placebo | Sumatriptan 25 mg | Sumatriptan 50 mg |
|------------------------|---------|-------------------|-------------------|
| Number of subjects     | 70      | 33                | 41                |
| Age categorical        |         |                   |                   |
| Units: Subjects        |         |                   |                   |

|                |  |  |  |
|----------------|--|--|--|
| Age continuous |  |  |  |
|----------------|--|--|--|

Baseline characteristics were collected in the Full Analysis Set (FAS), comprised of all participants who took at least one dose of investigational product (IP) and provided any post-treatment efficacy assessment. Participants who withdrew from the study before completion did not receive IP and thus contributed no baseline data.

|                    |        |        |        |
|--------------------|--------|--------|--------|
| Units: years       |        |        |        |
| arithmetic mean    | 13.9   | 14.5   | 14.1   |
| standard deviation | ± 2.04 | ± 2.18 | ± 1.96 |

|                    |  |  |  |
|--------------------|--|--|--|
| Gender categorical |  |  |  |
|--------------------|--|--|--|

Baseline characteristics were collected in the Full Analysis Set (FAS), comprised of all participants who took at least one dose of investigational product (IP) and provided any post-treatment efficacy assessment. Participants who withdrew from the study before completion did not receive IP and thus contributed no baseline data.

|                 |    |    |    |
|-----------------|----|----|----|
| Units: Subjects |    |    |    |
| Female          | 39 | 17 | 28 |
| Male            | 31 | 16 | 13 |

|                            |  |  |  |
|----------------------------|--|--|--|
| Race/Ethnicity, Customized |  |  |  |
|----------------------------|--|--|--|

Baseline characteristics were collected in the Full Analysis Set (FAS), comprised of all participants who took at least one dose of investigational product (IP) and provided any post-treatment efficacy assessment. Participants who withdrew from the study before completion did not receive IP and thus contributed no baseline data.

|                           |    |    |    |
|---------------------------|----|----|----|
| Units: Subjects           |    |    |    |
| Asian - Japanese Heritage | 70 | 33 | 41 |

| Reporting group values | Total |  |  |
|------------------------|-------|--|--|
| Number of subjects     | 144   |  |  |

|  |     |  |  |
|--|-----|--|--|
| Age categorical  |     |  |  |
| Units: Subjects  |     |  |  |
| Age continuous   |     |  |  |
| Baseline characteristics were collected in the Full Analysis Set (FAS), comprised of all participants who took at least one dose of investigational product (IP) and provided any post-treatment efficacy assessment. Participants who withdrew from the study before completion did not receive IP and thus contributed no baseline data. |     |  |  |
| Units: years   |     |  |  |
| arithmetic mean  |     |  |  |
| standard deviation   | -   |  |  |
| Gender categorical   |     |  |  |
| Baseline characteristics were collected in the Full Analysis Set (FAS), comprised of all participants who took at least one dose of investigational product (IP) and provided any post-treatment efficacy assessment. Participants who withdrew from the study before completion did not receive IP and thus contributed no baseline data. |     |  |  |
| Units: Subjects  |     |  |  |
| Female   | 84  |  |  |
| Male   | 60  |  |  |
| Race/Ethnicity, Customized   |     |  |  |
| Baseline characteristics were collected in the Full Analysis Set (FAS), comprised of all participants who took at least one dose of investigational product (IP) and provided any post-treatment efficacy assessment. Participants who withdrew from the study before completion did not receive IP and thus contributed no baseline data. |     |  |  |
| Units: Subjects  |     |  |  |
| Asian - Japanese Heritage  | 144 |  |  |

## End points

### End points reporting groups

|  |                    |
|--|--------------------|
| Reporting group title  | Placebo            |
| Reporting group description:<br>Participants took 2 tablets of placebo matched to sumatriptan 25 milligrams (mg) within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on a 5-grade, self-rating scale to assess the pain intensity of a migraine: 1 = none, 2 = mild, 3 = mild to moderate, 4 = moderate to severe, and 5 = severe. |                    |
| Reporting group title  | Sumatriptan 25 mg  |
| Reporting group description:<br>Participants took 1 tablet of sumatriptan 25 mg and 1 tablet of placebo matched to sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.   |                    |
| Reporting group title  | Sumatriptan 50 mg  |
| Reporting group description:<br>Participants took 2 tablets of sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.   |                    |
| Subject analysis set title   | Sumatriptan Pooled |
| Subject analysis set type  | Sub-group analysis |
| Subject analysis set description:<br>All participants receiving either sumatriptan 25 mg or 50 mg  |                    |

### Primary: Percentage of Participants Who Reported Pain Relief at 120 Minutes Post-Treatment

|  |  |
|--|--|
| End point title  | Percentage of Participants Who Reported Pain Relief at 120 Minutes Post-Treatment <sup>[1]</sup> |
| End point description:<br>Pain relief was defined as at least a 2-grade reduction in pain intensity on a 5-grade scale in participants who had not used headache rescue medication before assessment. A pain intensity score of 5 was assigned for all subsequent assessments if a participant took rescue medication (a single oral dose for the treatment of migraine pain or associated symptoms). The 5-grade scale is a participant's self-rating scale to assess the pain intensity of a migraine with the following scores: 1 = none, 2 = mild, 3 = mild to moderate, 4 = moderate to severe, and 5 = severe. |  |
| End point type   | Primary  |
| End point timeframe:<br>120 minutes post-treatment (Randomization through Final Visit [Week 6])  |  |

#### Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period.

| End point values                  | Placebo           | Sumatriptan Pooled   |  |  |
|-----------------------------------|-------------------|----------------------|--|--|
| Subject group type                | Reporting group   | Subject analysis set |  |  |
| Number of subjects analysed       | 70 <sup>[2]</sup> | 74 <sup>[3]</sup>    |  |  |
| Units: percentage of participants |                   |                      |  |  |
| number (not applicable)           | 38.6              | 31.1                 |  |  |

#### Notes:

[2] - Full Analysis Set (FAS): all participants in the Safety Population

[3] - Full Analysis Set (FAS): all participants in the Safety Population

## Statistical analyses

|  |                              |
|--|------------------------------|
| <b>Statistical analysis title</b>  | Statistical analysis 1       |
| Statistical analysis description:<br>PERCENTAGE OF PARTICIPANTS WHO REPORTED PAIN RELIEF AT 120 MINUTES POST-TREATMENT |                              |
| Comparison groups  | Placebo v Sumatriptan Pooled |
| Number of subjects included in analysis  | 144                          |
| Analysis specification   | Pre-specified                |
| Analysis type  |                              |
| P-value  | = 0.345 <sup>[4]</sup>       |
| Method   | Chi-squared                  |
| Parameter estimate   | Percent Difference           |
| Point estimate   | -7.49                        |
| Confidence interval  |                              |
| level  | 95 %                         |
| sides  | 2-sided                      |
| lower limit  | -23.02                       |
| upper limit  | 8.04                         |

Notes:

[4] - Multiplicity was not considered because the primary analysis included a single statistical comparison.

### Secondary: Percentage of Participants Who Reported Pain Relief at 30, 60, 120, and 240 Minutes Post-Treatment

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants Who Reported Pain Relief at 30, 60, 120, and 240 Minutes Post-Treatment |
|-----------------|--|

End point description:

Pain relief was defined as at least a 2-grade reduction in pain intensity on a 5-grade scale in participants who had not used headache rescue medication before assessment. A pain intensity score of 5 was assigned for all subsequent assessments if a participant took rescue medication (a single oral dose for the treatment of migraine pain or associated symptoms). The 5-grade scale is a participant's self-rating scale to assess the pain intensity of a migraine with the following scores: 1 = none, 2 = mild, 3 = mild to moderate, 4 = moderate to severe, and 5 = severe.

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

End point timeframe:

30, 60, 120, and 240 minutes post-treatment (Randomization through Final Visit [Week 6])

| End point values                  | Placebo           | Sumatriptan 25 mg | Sumatriptan 50 mg | Sumatriptan Pooled   |
|-----------------------------------|-------------------|-------------------|-------------------|----------------------|
| Subject group type                | Reporting group   | Reporting group   | Reporting group   | Subject analysis set |
| Number of subjects analysed       | 70 <sup>[5]</sup> | 33 <sup>[6]</sup> | 41 <sup>[7]</sup> | 74 <sup>[8]</sup>    |
| Units: percentage of participants |                   |                   |                   |                      |
| number (not applicable)           |                   |                   |                   |                      |
| 30 minutes post-treatment         | 4.3               | 0                 | 9.8               | 5.4                  |
| 60 minutes post-treatment         | 18.6              | 9.1               | 7.3               | 8.1                  |
| 120 minutes post-treatment        | 38.6              | 33.3              | 29.3              | 31.1                 |
| 240 minutes post-treatment        | 51.4              | 66.7              | 61                | 63.5                 |

Notes:

[5] - FAS. The analysis was performed on the LOCF dataset.

[6] - FAS. The analysis was performed on the LOCF dataset.

[7] - FAS. The analysis was performed on the LOCF dataset.

[8] - FAS. The analysis was performed on the LOCF dataset.



## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants Who Were Pain Free at 30, 60, 120, and 240 Minutes Post-Treatment

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants Who Were Pain Free at 30, 60, 120, and 240 Minutes Post-Treatment |
|-----------------|--|

End point description:

Pain free was defined as a post-treatment pain intensity score of 1 on a 5-grade scale in participants who had not used headache rescue medication before assessment. A pain intensity score of 5 was assigned for all subsequent assessments if a participant took a rescue medication. The 5-grade scale is a participant's self-rating scale to assess the pain intensity of a migraine with the following scores: 1 = none, 2 =mild, 3=mild to moderate, 4=moderate to severe, and 5=severe.

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

End point timeframe:

30, 60, 120, and 240 minutes post-treatment (Randomization through Final Visit [Week 6])

| End point values                  | Placebo           | Sumatriptan 25 mg  | Sumatriptan 50 mg  | Sumatriptan Pooled   |
|-----------------------------------|-------------------|--------------------|--------------------|----------------------|
| Subject group type                | Reporting group   | Reporting group    | Reporting group    | Subject analysis set |
| Number of subjects analysed       | 70 <sup>[9]</sup> | 33 <sup>[10]</sup> | 41 <sup>[11]</sup> | 74 <sup>[12]</sup>   |
| Units: percentage of participants |                   |                    |                    |                      |
| number (not applicable)           |                   |                    |                    |                      |
| 30 minutes post-treatment         | 2.9               | 0                  | 2.4                | 1.4                  |
| 60 minutes post-treatment         | 12.9              | 3                  | 2.4                | 2.7                  |
| 120 minutes post-treatment        | 28.6              | 24.2               | 19.5               | 21.6                 |
| 240 minutes post-treatment        | 47.1              | 63.6               | 39                 | 50                   |

Notes:

[9] - FAS. The analysis was performed on the LOCF dataset.

[10] - FAS. The analysis was performed on the LOCF dataset.

[11] - FAS. The analysis was performed on the LOCF dataset.

[12] - FAS. The analysis was performed on the LOCF dataset.

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants Who Were Photophobia Free at 30, 60, 120, and 240 Minutes Post-Treatment

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants Who Were Photophobia Free at 30, 60, 120, and 240 Minutes Post-Treatment |
|-----------------|---|

End point description:

Photophobia (sensitivity to light) is one of the associated symptoms of a migraine. A participant was assessed as photophobia free when the symptom was recorded as "absent" at each time point in his or her patient diary. Photophobia was recorded as "present" for all subsequent assessments if a participant took rescue medication.

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

End point timeframe:

30, 60, 120, and 240 minutes post-treatment (Randomization through Final Visit [Week 6])

| End point values                  | Placebo            | Sumatriptan 25 mg  | Sumatriptan 50 mg  | Sumatriptan Pooled   |
|-----------------------------------|--------------------|--------------------|--------------------|----------------------|
| Subject group type                | Reporting group    | Reporting group    | Reporting group    | Subject analysis set |
| Number of subjects analysed       | 36 <sup>[13]</sup> | 15 <sup>[14]</sup> | 13 <sup>[15]</sup> | 28 <sup>[16]</sup>   |
| Units: percentage of participants |                    |                    |                    |                      |
| number (not applicable)           |                    |                    |                    |                      |
| 30 minutes post-treatment         | 16.7               | 13.3               | 15.4               | 14.3                 |
| 60 minutes post-treatment         | 44.4               | 26.7               | 38.5               | 32.1                 |
| 120 minutes post-treatment        | 52.8               | 60                 | 46.2               | 53.6                 |
| 240 minutes post-treatment        | 69.4               | 80                 | 69.2               | 75                   |

Notes:

[13] - FAS. The analysis was performed on the LOCF dataset.

[14] - FAS. The analysis was performed on the LOCF dataset.

[15] - FAS. The analysis was performed on the LOCF dataset.

[16] - FAS. The analysis was performed on the LOCF dataset.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Who Were Phonophobia Free at 30, 60, 120, and 240 Minutes Post-Treatment

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants Who Were Phonophobia Free at 30, 60, 120, and 240 Minutes Post-Treatment |
|-----------------|---|

End point description:

Phonophobia (sensitivity to sound) is one of the associated symptoms of a migraine. A participant was assessed as phonophobia free when the symptom was recorded as "absent" at each time point in his or her patient diary. Phonophobia was recorded as "present" for all subsequent assessments if a participant took rescue medication.

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

End point timeframe:

30, 60, 120, and 240 minutes post-treatment (Randomization through Final Visit [Week 6])

| End point values                  | Placebo            | Sumatriptan 25 mg  | Sumatriptan 50 mg  | Sumatriptan Pooled   |
|-----------------------------------|--------------------|--------------------|--------------------|----------------------|
| Subject group type                | Reporting group    | Reporting group    | Reporting group    | Subject analysis set |
| Number of subjects analysed       | 22 <sup>[17]</sup> | 14 <sup>[18]</sup> | 16 <sup>[19]</sup> | 30 <sup>[20]</sup>   |
| Units: percentage of participants |                    |                    |                    |                      |
| number (not applicable)           |                    |                    |                    |                      |
| 30 minutes post-treatment         | 22.7               | 50                 | 12.5               | 30                   |
| 60 minutes post-treatment         | 45.5               | 57.1               | 25                 | 40                   |
| 120 minutes post-treatment        | 63.6               | 64.3               | 43.8               | 53.3                 |
| 240 minutes post-treatment        | 72.7               | 78.6               | 68.8               | 73.3                 |

Notes:

[17] - FAS. The analysis was performed on LOCF dataset.

[18] - FAS. The analysis was performed on LOCF dataset.

[19] - FAS. The analysis was performed on LOCF dataset.

[20] - FAS. The analysis was performed on LOCF dataset.

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants Who Were Nausea Free at 30, 60, 120, and 240 Minutes Post-Treatment

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants Who Were Nausea Free at 30, 60, 120, and 240 Minutes Post-Treatment |
|-----------------|--|

End point description:

Nausea is one of the associated symptoms of a migraine. A participant was assessed as nausea free when the symptom was recorded as "absent" at each time point in his or her patient diary. Nausea was recorded as "present" for all subsequent assessments if a participant took rescue medication.

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

End point timeframe:

30, 60, 120, and 240 minutes post-treatment (Randomization through Final Visit [Week 6])

| End point values                  | Placebo            | Sumatriptan 25 mg  | Sumatriptan 50 mg | Sumatriptan Pooled   |
|-----------------------------------|--------------------|--------------------|-------------------|----------------------|
| Subject group type                | Reporting group    | Reporting group    | Reporting group   | Subject analysis set |
| Number of subjects analysed       | 21 <sup>[21]</sup> | 10 <sup>[22]</sup> | 8 <sup>[23]</sup> | 18 <sup>[24]</sup>   |
| Units: percentage of participants |                    |                    |                   |                      |
| number (not applicable)           |                    |                    |                   |                      |
| 30 minutes post-treatment         | 47.6               | 40                 | 12.5              | 27.8                 |
| 60 minutes post-treatment         | 66.7               | 40                 | 12.5              | 27.8                 |
| 120 minutes post-treatment        | 81                 | 70                 | 50                | 61.1                 |
| 240 minutes post-treatment        | 81                 | 70                 | 50                | 61.1                 |

Notes:

[21] - FAS. The analysis was performed on the LOCF dataset.

[22] - FAS. The analysis was performed on the LOCF dataset.

[23] - FAS. The analysis was performed on the LOCF dataset.

[24] - FAS. The analysis was performed on the LOCF dataset.

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants Who Were Free of Vomiting at 30, 60, 120, and 240 Minutes Post-Treatment

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants Who Were Free of Vomiting at 30, 60, 120, and 240 Minutes Post-Treatment |
|-----------------|---|

End point description:

Vomiting is one of the associated symptoms of a migraine. A participant was assessed as being free of vomiting when the symptom was recorded as "absent" at each time point in his or her patient diary. Vomiting was recorded as "present" for all subsequent assessments if a participant took a rescue medication.

|  |           |
|--|-----------|
| End point type   | Secondary |
| End point timeframe:   |           |
| 30, 60, 120, and 240 minutes post-treatment (Randomization through Final Visit [Week 6]) |           |

| End point values                  | Placebo           | Sumatriptan 25 mg | Sumatriptan 50 mg | Sumatriptan Pooled   |
|-----------------------------------|-------------------|-------------------|-------------------|----------------------|
| Subject group type                | Reporting group   | Reporting group   | Reporting group   | Subject analysis set |
| Number of subjects analysed       | 0 <sup>[25]</sup> | 1 <sup>[26]</sup> | 0 <sup>[27]</sup> | 1 <sup>[28]</sup>    |
| Units: percentage of participants |                   |                   |                   |                      |
| number (not applicable)           |                   |                   |                   |                      |
| 30 minutes post-treatment         |                   | 0                 |                   | 0                    |
| 60 minutes post-treatment         |                   | 0                 |                   | 0                    |
| 120 minutes post-treatment        |                   | 100               |                   | 100                  |
| 240 minutes post-treatment        |                   | 100               |                   | 100                  |

Notes:

[25] - FAS. The analysis was performed on the LOCF dataset.

[26] - FAS. The analysis was performed on the LOCF dataset.

[27] - FAS. The analysis was performed on the LOCF dataset.

[28] - FAS. The analysis was performed on the LOCF dataset.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Who Used Rescue Medication Between the Time of Dosing and 240 Minutes Post-Treatment

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants Who Used Rescue Medication Between the Time of Dosing and 240 Minutes Post-Treatment |
|-----------------|---|

End point description:

Rescue medication included one of the following: a single oral dose of a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen, not to exceed the maximum recommended single dose; and anti-emetics (a drug to prevent vomiting).

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

End point timeframe:

within 240 minutes post-treatment (Randomization through Final Visit [Week 6])

| End point values                  | Placebo            | Sumatriptan 25 mg  | Sumatriptan 50 mg  | Sumatriptan Pooled   |
|-----------------------------------|--------------------|--------------------|--------------------|----------------------|
| Subject group type                | Reporting group    | Reporting group    | Reporting group    | Subject analysis set |
| Number of subjects analysed       | 70 <sup>[29]</sup> | 33 <sup>[30]</sup> | 41 <sup>[31]</sup> | 74 <sup>[32]</sup>   |
| Units: percentage of participants |                    |                    |                    |                      |
| number (not applicable)           | 12.9               | 12.1               | 14.6               | 13.5                 |

Notes:

[29] - FAS. Analysis performed on observed case dataset, a dataset without any imputation of missing data

[30] - FAS. Analysis performed on observed case dataset, a dataset without any imputation of missing data

[31] - FAS. Analysis performed on observed case dataset, a dataset without any imputation of missing data

data

[32] - FAS. Analysis performed on observed case dataset, a dataset without any imputation of missing data

## **Statistical analyses**

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No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Serious adverse events (AEs) and non-serious AEs were collected from the start of IP through follow-up contact (6 weeks plus or minus 7 days).

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

### Dictionary used

|                    |        |
|--------------------|--------|
| Dictionary name    | MedDRA |
| Dictionary version | 13.1   |

### Reporting groups

|                       |         |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Participants took 2 tablets of placebo matched to sumatriptan 25 milligrams (mg) within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on a 5-grade, self-rating scale to assess the pain intensity of a migraine: 1 = none, 2 = mild, 3 = mild to moderate, 4 = moderate to severe, and 5 = severe.

|                       |                   |
|-----------------------|-------------------|
| Reporting group title | Sumatriptan 25 mg |
|-----------------------|-------------------|

Reporting group description:

Participants took 1 tablet of sumatriptan 25 mg and 1 tablet of placebo matched to sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.

|                       |                   |
|-----------------------|-------------------|
| Reporting group title | Sumatriptan 50 mg |
|-----------------------|-------------------|

Reporting group description:

Participants took 2 tablets of sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.

|                       |                    |
|-----------------------|--------------------|
| Reporting group title | Sumatriptan Pooled |
|-----------------------|--------------------|

Reporting group description:

All participants receiving either sumatriptan 25 mg or 50 mg

| Serious adverse events                            | Placebo        | Sumatriptan 25 mg | Sumatriptan 50 mg |
|---|----------------|-------------------|-------------------|
| Total subjects affected by serious adverse events |                |                   |                   |
| subjects affected / exposed                       | 0 / 70 (0.00%) | 0 / 33 (0.00%)    | 0 / 41 (0.00%)    |
| number of deaths (all causes)                     | 0              | 0                 | 0                 |
| number of deaths resulting from adverse events    |                |                   |                   |

| Serious adverse events                            | Sumatriptan Pooled |  |  |
|---|--------------------|--|--|
| Total subjects affected by serious adverse events |                    |  |  |
| subjects affected / exposed                       | 0 / 74 (0.00%)     |  |  |
| number of deaths (all causes)                     | 0                  |  |  |
| number of deaths resulting from adverse events    |                    |  |  |

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

| <b>Non-serious adverse events</b>                     | Placebo        | Sumatriptan 25 mg | Sumatriptan 50 mg |
|---|----------------|-------------------|-------------------|
| Total subjects affected by non-serious adverse events |                |                   |                   |
| subjects affected / exposed                           | 5 / 70 (7.14%) | 2 / 33 (6.06%)    | 3 / 41 (7.32%)    |
| Investigations  |                |                   |                   |
| Blood creatine phosphokinase increased                |                |                   |                   |
| subjects affected / exposed                           | 4 / 70 (5.71%) | 0 / 33 (0.00%)    | 0 / 41 (0.00%)    |
| occurrences (all)                                     | 4              | 0                 | 0                 |
| Nervous system disorders                              |                |                   |                   |
| Somnolence  |                |                   |                   |
| subjects affected / exposed                           | 1 / 70 (1.43%) | 2 / 33 (6.06%)    | 0 / 41 (0.00%)    |
| occurrences (all)                                     | 1              | 2                 | 0                 |
| General disorders and administration site conditions  |                |                   |                   |
| Chest discomfort                                      |                |                   |                   |
| subjects affected / exposed                           | 0 / 70 (0.00%) | 0 / 33 (0.00%)    | 3 / 41 (7.32%)    |
| occurrences (all)                                     | 0              | 0                 | 3                 |

| <b>Non-serious adverse events</b>                     | Sumatriptan Pooled |  |  |
|---|--------------------|--|--|
| Total subjects affected by non-serious adverse events |                    |  |  |
| subjects affected / exposed                           | 5 / 74 (6.76%)     |  |  |
| Investigations  |                    |  |  |
| Blood creatine phosphokinase increased                |                    |  |  |
| subjects affected / exposed                           | 0 / 74 (0.00%)     |  |  |
| occurrences (all)                                     | 0                  |  |  |
| Nervous system disorders                              |                    |  |  |
| Somnolence  |                    |  |  |
| subjects affected / exposed                           | 2 / 74 (2.70%)     |  |  |
| occurrences (all)                                     | 2                  |  |  |
| General disorders and administration site conditions  |                    |  |  |
| Chest discomfort                                      |                    |  |  |
| subjects affected / exposed                           | 3 / 74 (4.05%)     |  |  |
| occurrences (all)                                     | 3                  |  |  |

## 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

None reported