



## Clinical trial results:

### A 16 Week, Single-Center, Randomized, Placebo- and Active-Controlled Proof-of-Principle Study to Assess the Efficacy and Safety of a 5% Minoxidil Topical Gel Formulation in Male Subjects with Androgenetic Alopecia

#### Summary

|                          |                  |
|--------------------------|------------------|
| EudraCT number           | 2017-000613-22   |
| Trial protocol           | DE               |
| Global end of trial date | 05 December 2019 |

#### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1 (current)     |
| This version publication date  | 20 December 2020 |
| First version publication date | 20 December 2020 |

#### Trial information

##### Trial identification

|                       |                 |
|-----------------------|-----------------|
| Sponsor protocol code | CO-150225133959 |
|-----------------------|-----------------|

##### Additional study identifiers

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

Notes:

#### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Johnson & Johnson Consumer Inc  |
| Sponsor organisation address | 199 Grandview Road, Skillman, United States, 08558                          |
| Public contact               | Global Regulatory Affairs, Johnson & Johnson Consumer Inc<br>, 215 4297845, |
| Scientific contact           | Global Regulatory Affairs, Johnson & Johnson Consumer Inc<br>, 215 4297845, |

Notes:

#### Paediatric regulatory details

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

Notes:

## Results analysis stage

|  |                  |
|--|------------------|
| Analysis stage                                       | Final            |
| Date of interim/final analysis                       | 05 December 2019 |
| Is this the analysis of the primary completion data? | No               |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 05 December 2019 |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of study was to determine the efficacy of two formulations of minoxidil, 5 percent (%) Minoxidil Topical Gel (5% MTG) and 5% Minoxidil Topical Foam (5% MTF), for hereditary hair loss in men.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices (GCP) and applicable regulatory requirements. Safety was evaluated by examining the incidence and type of adverse events, changes in clinical laboratory tests and vital signs.

Background therapy: -

Evidence for comparator: -

|   |                 |
|---|-----------------|
| Actual start date of recruitment                          | 17 January 2019 |
| Long term follow-up planned                               | No              |
| Independent data monitoring committee (IDMC) involvement? | No              |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |              |
|--------------------------------------|--------------|
| Country: Number of subjects enrolled | Germany: 140 |
| Worldwide total number of subjects   | 140          |
| EEA total number of subjects         | 140          |

Notes:

### Subjects enrolled per age group

|   |     |
|---|-----|
| In utero                                  | 0   |
| Preterm newborn - gestational age < 37 wk | 0   |
| Newborns (0-27 days)                      | 0   |
| Infants and toddlers (28 days-23 months)  | 0   |
| Children (2-11 years)                     | 0   |
| Adolescents (12-17 years)                 | 0   |
| Adults (18-64 years)                      | 140 |
| From 65 to 84 years                       | 0   |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Total of 148 subjects were screened and 140 subjects were randomized to receive one of the five study treatments.

### Period 1

|                              |                                |
|------------------------------|--------------------------------|
| Period 1 title               | Overall Study (overall period) |
| Is this the baseline period? | Yes                            |
| Allocation method            | Randomised - controlled        |
| Blinding used                | Single blind                   |
| Roles blinded                | Investigator <sup>[1]</sup>    |

Blinding implementation details:

Investigators were kept blinded during the study. Subjects that received gel did not know if they were on placebo or active. But subjects that received foam know they were on active.

### Arms

|                              |  |
|------------------------------|--|
| Are arms mutually exclusive? | Yes  |
| <b>Arm title</b>             | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) |

Arm description:

Subjects received 5 percent (%) MTG once daily until Week 16.

|  |                             |
|--|-----------------------------|
| Arm type                               | Experimental                |
| Investigational medicinal product name | Minoxidil Topical Gel (MTG) |
| Investigational medicinal product code |                             |
| Other name                             |                             |
| Pharmaceutical forms                   | Gel                         |
| Routes of administration               | Topical use                 |

Dosage and administration details:

Subjects received 5 percent (%) MTG once daily until Week 16.

|                  |                              |
|------------------|------------------------------|
| <b>Arm title</b> | Placebo Topical Gel (PTG) OD |
|------------------|------------------------------|

Arm description:

Subjects received matching PTG once daily until Week 16.

|  |                           |
|--|---------------------------|
| Arm type                               | Placebo                   |
| Investigational medicinal product name | Placebo Topical Gel (PTG) |
| Investigational medicinal product code |                           |
| Other name                             |                           |
| Pharmaceutical forms                   | Gel                       |
| Routes of administration               | Topical use               |

Dosage and administration details:

Subjects received matching PTG once daily until Week 16.

|                  |                          |
|------------------|--------------------------|
| <b>Arm title</b> | 5% MTG Twice a Day (BID) |
|------------------|--------------------------|

Arm description:

Subjects received 5 % MTG twice daily until Week 16.

|          |              |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

|   |             |
|---|-------------|
| Investigational medicinal product name              | 5% MTG      |
| Investigational medicinal product code              |             |
| Other name  |             |
| Pharmaceutical forms                                | Gel         |
| Routes of administration                            | Topical use |
| Dosage and administration details:                  |             |
| Subjects received 5% MTG twice daily until Week 16. |             |
| <b>Arm title</b>                                    | PTG BID     |

Arm description:

Subjects received matching PTG twice daily until Week 16.

|  |             |
|--|-------------|
| Arm type                               | Placebo     |
| Investigational medicinal product name | PTG         |
| Investigational medicinal product code |             |
| Other name                             |             |
| Pharmaceutical forms                   | Gel         |
| Routes of administration               | Topical use |

Dosage and administration details:

Subjects received matching PTG twice daily until Week 16.

|                  |                                     |
|------------------|-------------------------------------|
| <b>Arm title</b> | 5% Minoxidil Topical Foam (MTF) BID |
|------------------|-------------------------------------|

Arm description:

Subjects received 5 percent (%) MTF twice daily until Week 16.

|  |                   |
|--|-------------------|
| Arm type                               | Active comparator |
| Investigational medicinal product name | 5% MTF            |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Cutaneous foam    |
| Routes of administration               | Topical use       |

Dosage and administration details:

Subjects received 5 percent (%) MTF twice daily until Week 16.

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: Investigators were kept blinded during the study. Subjects that received gel did not know if they were on placebo or active. But subjects that received foam know they were on active.

| <b>Number of subjects in period 1</b> | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) | Placebo Topical Gel (PTG) OD | 5% MTG Twice a Day (BID) |
|---------------------------------------|--|------------------------------|--------------------------|
| Started                               | 41   | 20                           | 39                       |
| Completed                             | 41   | 20                           | 38                       |
| Not completed                         | 0  | 0                            | 1                        |
| Consent withdrawn by subject          | -  | -                            | 1                        |

| <b>Number of subjects in period 1</b> | PTG BID | 5% Minoxidil Topical Foam (MTF) BID |
|---------------------------------------|---------|-------------------------------------|
| Started                               | 20      | 20                                  |
| Completed                             | 18      | 19                                  |
| Not completed                         | 2       | 1                                   |
| Consent withdrawn by subject          | 2       | 1                                   |



## Baseline characteristics

### Reporting groups

|  |  |
|--|--|
| Reporting group title  | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) |
| Reporting group description:                                   |  |
| Subjects received 5 percent (%) MTG once daily until Week 16.  |  |
| Reporting group title  | Placebo Topical Gel (PTG) OD                   |
| Reporting group description:                                   |  |
| Subjects received matching PTG once daily until Week 16.       |  |
| Reporting group title  | 5% MTG Twice a Day (BID)                       |
| Reporting group description:                                   |  |
| Subjects received 5 % MTG twice daily until Week 16.           |  |
| Reporting group title  | PTG BID  |
| Reporting group description:                                   |  |
| Subjects received matching PTG twice daily until Week 16.      |  |
| Reporting group title  | 5% Minoxidil Topical Foam (MTF) BID            |
| Reporting group description:                                   |  |
| Subjects received 5 percent (%) MTF twice daily until Week 16. |  |

| Reporting group values                      | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) | Placebo Topical Gel (PTG) OD | 5% MTG Twice a Day (BID) |
|---|--|------------------------------|--------------------------|
| Number of subjects                          | 41   | 20                           | 39                       |
| Title for AgeCategorical<br>Units: subjects |  |                              |                          |
| Children (2-11 years)                       | 0  | 0                            | 0                        |
| Adolescents (12-17 years)                   | 0  | 0                            | 0                        |
| Adults (18-64 years)                        | 41   | 20                           | 39                       |
| From 65 to 84 years                         | 0  | 0                            | 0                        |
| 85 years and over                           | 0  | 0                            | 0                        |
| Title for AgeContinuous<br>Units: years     |  |                              |                          |
| arithmetic mean                             | 34.1   | 35.2                         | 33.3                     |
| standard deviation                          | ± 7.69   | ± 6.59                       | ± 7.82                   |
| Title for Gender<br>Units: subjects         |  |                              |                          |
| Male  | 41   | 20                           | 39                       |

| Reporting group values                      | PTG BID | 5% Minoxidil Topical Foam (MTF) BID | Total |
|---|---------|-------------------------------------|-------|
| Number of subjects                          | 20      | 20                                  | 140   |
| Title for AgeCategorical<br>Units: subjects |         |                                     |       |
| Children (2-11 years)                       | 0       | 0                                   | 0     |
| Adolescents (12-17 years)                   | 0       | 0                                   | 0     |
| Adults (18-64 years)                        | 20      | 20                                  | 140   |
| From 65 to 84 years                         | 0       | 0                                   | 0     |
| 85 years and over                           | 0       | 0                                   | 0     |

|  |                |                |     |
|--|----------------|----------------|-----|
| Title for AgeContinuous<br>Units: years<br>arithmetic mean<br>standard deviation | 32.2<br>± 8.36 | 32.7<br>± 5.81 | -   |
| Title for Gender<br>Units: subjects  |                |                |     |
| Male   | 20             | 20             | 140 |

## End points

### End points reporting groups

|  |  |
|--|--|
| Reporting group title  | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) |
| Reporting group description:                                   |  |
| Subjects received 5 percent (%) MTG once daily until Week 16.  |  |
| Reporting group title  | Placebo Topical Gel (PTG) OD                   |
| Reporting group description:                                   |  |
| Subjects received matching PTG once daily until Week 16.       |  |
| Reporting group title  | 5% MTG Twice a Day (BID)                       |
| Reporting group description:                                   |  |
| Subjects received 5 % MTG twice daily until Week 16.           |  |
| Reporting group title  | PTG BID  |
| Reporting group description:                                   |  |
| Subjects received matching PTG twice daily until Week 16.      |  |
| Reporting group title  | 5% Minoxidil Topical Foam (MTF) BID            |
| Reporting group description:                                   |  |
| Subjects received 5 percent (%) MTF twice daily until Week 16. |  |

### Primary: Change from Baseline in Total Non-vellus Target Area Hair Count (TAHC) at Week 16

|  |   |
|--|---|
| End point title  | Change from Baseline in Total Non-vellus Target Area Hair Count (TAHC) at Week 16 |
| End point description:   |   |
| TAHC was measured by computerized Hair Metrix <sup>SM</sup> system based on macrophotographs at Week 16. Intent-to-treat (ITT) population included all randomized subjects. Here, 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this endpoint. |   |
| End point type   | Primary   |
| End point timeframe:   |   |
| Week 16  |   |

| End point values                     | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) | Placebo Topical Gel (PTG) OD | 5% MTG Twice a Day (BID) | PTG BID         |
|--------------------------------------|--|------------------------------|--------------------------|-----------------|
| Subject group type                   | Reporting group                                | Reporting group              | Reporting group          | Reporting group |
| Number of subjects analysed          | 41   | 20                           | 37                       | 20              |
| Units: Units on a scale              |  |                              |                          |                 |
| arithmetic mean (standard deviation) | 29.0 (± 23.06)                                 | 8.1 (± 16.08)                | 43.4 (± 24.83)           | 0 (± 26.00)     |

| End point values            | 5% Minoxidil Topical Foam (MTF) BID |  |  |  |
|-----------------------------|-------------------------------------|--|--|--|
| Subject group type          | Reporting group                     |  |  |  |
| Number of subjects analysed | 19                                  |  |  |  |



|                                      |                     |  |  |  |
|--------------------------------------|---------------------|--|--|--|
| Units: Units on a scale              |                     |  |  |  |
| arithmetic mean (standard deviation) | 42.3 ( $\pm$ 40.10) |  |  |  |

## Statistical analyses

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Statistical Analysis 1  |
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD |
| Number of subjects included in analysis | 61  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.005   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Mean difference (net)   |
| Point estimate                          | -20.47  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -34.59  |
| upper limit                             | -6.34   |
| Variability estimate                    | Standard error of the mean  |
| Dispersion value                        | 7.138   |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Statistical Analysis 2  |
| Comparison groups                       | 5% MTG Twice a Day (BID) v 5% Minoxidil Topical Gel (MTG) Once Daily (OD) |
| Number of subjects included in analysis | 78  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.017   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Mean difference (net)   |
| Point estimate                          | 14.25   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 2.64  |
| upper limit                             | 25.86   |
| Variability estimate                    | Standard error of the mean  |
| Dispersion value                        | 5.869   |

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | Statistical Analysis 3   |
| Comparison groups                 | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% Minoxidil Topical Foam (MTF) BID |

|   |                            |
|---|----------------------------|
| Number of subjects included in analysis | 60                         |
| Analysis specification                  | Pre-specified              |
| Analysis type                           | superiority                |
| P-value                                 | = 0.092                    |
| Method                                  | ANCOVA                     |
| Parameter estimate                      | Mean difference (net)      |
| Point estimate                          | 12.26                      |
| Confidence interval                     |                            |
| level                                   | 95 %                       |
| sides                                   | 2-sided                    |
| lower limit                             | -2.02                      |
| upper limit                             | 26.54                      |
| Variability estimate                    | Standard error of the mean |
| Dispersion value                        | 7.218                      |

|   |                                    |
|---|------------------------------------|
| <b>Statistical analysis title</b>       | Statistical Analysis 4             |
| Comparison groups                       | 5% MTG Twice a Day (BID) v PTG BID |
| Number of subjects included in analysis | 57                                 |
| Analysis specification                  | Pre-specified                      |
| Analysis type                           | superiority                        |
| P-value                                 | < 0.001                            |
| Method                                  | ANCOVA                             |
| Parameter estimate                      | Mean difference (net)              |
| Point estimate                          | -44.52                             |
| Confidence interval                     |                                    |
| level                                   | 95 %                               |
| sides                                   | 2-sided                            |
| lower limit                             | -58.78                             |
| upper limit                             | -30.27                             |
| Variability estimate                    | Standard error of the mean         |
| Dispersion value                        | 7.203                              |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical Analysis 5   |
| Comparison groups                       | 5% MTG Twice a Day (BID) v 5% Minoxidil Topical Foam (MTF) BID |
| Number of subjects included in analysis | 56   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.788  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | -1.99  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | -16.58   |
| upper limit                             | 12.59  |

**Secondary: Change from Baseline in Total Non-vellus TAHC at Weeks 8 and 12**

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in Total Non-vellus TAHC at Weeks 8 and 12 |
|-----------------|---|

End point description:

TAHC was measured by computerized Hair Metrix<sup>SM</sup> system based on macrophotographs at Weeks 8 and 12. ITT population included all randomized subjects. Here 'n' signifies number of subjects analyzed for specific arm.

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

End point timeframe:

Weeks 8 and 12

| End point values                     | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) | Placebo Topical Gel (PTG) OD | 5% MTG Twice a Day (BID) | PTG BID         |
|--------------------------------------|--|------------------------------|--------------------------|-----------------|
| Subject group type                   | Reporting group                                | Reporting group              | Reporting group          | Reporting group |
| Number of subjects analysed          | 41   | 20                           | 39                       | 20              |
| Units: units on a scale              |  |                              |                          |                 |
| arithmetic mean (standard deviation) |  |                              |                          |                 |
| Week 8 (n=40, 20, 38, 18, 18))       | 6.9 (± 20.58)                                  | 5.9 (± 14.07)                | 22.0 (± 23.78)           | -4.8 (± 21.16)  |
| Week 12 (n=41, 20, 38, 18, 18)       | 21.8 (± 26.56)                                 | 6.3 (± 18.33)                | 39.2 (± 28.13)           | -3.9 (± 22.17)  |

| End point values                     | 5% Minoxidil Topical Foam (MTF) BID |  |  |  |
|--------------------------------------|-------------------------------------|--|--|--|
| Subject group type                   | Reporting group                     |  |  |  |
| Number of subjects analysed          | 20                                  |  |  |  |
| Units: units on a scale              |                                     |  |  |  |
| arithmetic mean (standard deviation) |                                     |  |  |  |
| Week 8 (n=40, 20, 38, 18, 18))       | 24.8 (± 25.33)                      |  |  |  |
| Week 12 (n=41, 20, 38, 18, 18)       | 41.1 (± 30.66)                      |  |  |  |

**Statistical analyses**

|                            |   |
|----------------------------|---|
| Statistical analysis title | Statistical Analysis 1 (Week 8)   |
| Comparison groups          | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD |

|   |                            |
|---|----------------------------|
| Number of subjects included in analysis | 61                         |
| Analysis specification                  | Pre-specified              |
| Analysis type                           | superiority                |
| P-value                                 | = 0.919                    |
| Method                                  | ANCOVA                     |
| Parameter estimate                      | Mean difference (net)      |
| Point estimate                          | -0.61                      |
| Confidence interval                     |                            |
| level                                   | 95 %                       |
| sides                                   | 2-sided                    |
| lower limit                             | -12.48                     |
| upper limit                             | 11.26                      |
| Variability estimate                    | Standard error of the mean |
| Dispersion value                        | 6                          |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Statistical Analysis 2 (Week 8)   |
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% MTG Twice a Day (BID) |
| Number of subjects included in analysis | 80  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.003   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Mean difference (net)   |
| Point estimate                          | 14.85   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 5.14  |
| upper limit                             | 24.56   |
| Variability estimate                    | Standard error of the mean  |
| Dispersion value                        | 4.906   |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical Analysis 3 (Week 8)  |
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% Minoxidil Topical Foam (MTF) BID |
| Number of subjects included in analysis | 61   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.005  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | 17.83  |

|                      |                            |
|----------------------|----------------------------|
| Confidence interval  |                            |
| level                | 95 %                       |
| sides                | 2-sided                    |
| lower limit          | 5.57                       |
| upper limit          | 30.09                      |
| Variability estimate | Standard error of the mean |
| Dispersion value     | 6.194                      |

|   |                                    |
|---|------------------------------------|
| <b>Statistical analysis title</b>       | Statistical Analysis 4 (Week 8)    |
| Comparison groups                       | 5% MTG Twice a Day (BID) v PTG BID |
| Number of subjects included in analysis | 59                                 |
| Analysis specification                  | Pre-specified                      |
| Analysis type                           | superiority                        |
| P-value                                 | < 0.001                            |
| Method                                  | ANCOVA                             |
| Parameter estimate                      | Mean difference (net)              |
| Point estimate                          | -26.8                              |
| Confidence interval                     |                                    |
| level                                   | 95 %                               |
| sides                                   | 2-sided                            |
| lower limit                             | -39.06                             |
| upper limit                             | -14.54                             |
| Variability estimate                    | Standard error of the mean         |
| Dispersion value                        | 6.195                              |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical Analysis 5 (Week 8)                                |
| Comparison groups                       | 5% Minoxidil Topical Foam (MTF) BID v 5% MTG Twice a Day (BID) |
| Number of subjects included in analysis | 59   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.635  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | 2.98   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | -9.42  |
| upper limit                             | 15.37  |
| Variability estimate                    | Standard error of the mean                                     |
| Dispersion value                        | 6.262  |

|                                   |                                  |
|-----------------------------------|----------------------------------|
| <b>Statistical analysis title</b> | Statistical Analysis 6 (Week 12) |
|-----------------------------------|----------------------------------|

|   |   |
|---|---|
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD |
| Number of subjects included in analysis | 61  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.034   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Mean difference (net)   |
| Point estimate                          | -15.19  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -29.23  |
| upper limit                             | -1.16   |
| Variability estimate                    | Standard error of the mean  |
| Dispersion value                        | 7.091   |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Statistical Analysis 7 (Week 12)  |
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% MTG Twice a Day (BID) |
| Number of subjects included in analysis | 80  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.004   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Mean difference (net)   |
| Point estimate                          | 16.92   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 5.47  |
| upper limit                             | 28.37   |
| Variability estimate                    | Standard error of the mean  |
| Dispersion value                        | 5.787   |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical Analysis 8 (Week 12)   |
| Comparison groups                       | 5% Minoxidil Topical Foam (MTF) BID v 5% Minoxidil Topical Gel (MTG) Once Daily (OD) |
| Number of subjects included in analysis | 61   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.014  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | 18.15  |

|                      |                            |
|----------------------|----------------------------|
| Confidence interval  |                            |
| level                | 95 %                       |
| sides                | 2-sided                    |
| lower limit          | 3.67                       |
| upper limit          | 32.63                      |
| Variability estimate | Standard error of the mean |
| Dispersion value     | 7.32                       |

|   |                                    |
|---|------------------------------------|
| <b>Statistical analysis title</b>       | Statistical Analysis 9 (Week 12)   |
| Comparison groups                       | PTG BID v 5% MTG Twice a Day (BID) |
| Number of subjects included in analysis | 59                                 |
| Analysis specification                  | Pre-specified                      |
| Analysis type                           | superiority                        |
| P-value                                 | < 0.001                            |
| Method                                  | ANCOVA                             |
| Parameter estimate                      | Mean difference (net)              |
| Point estimate                          | -43.66                             |
| Confidence interval                     |                                    |
| level                                   | 95 %                               |
| sides                                   | 2-sided                            |
| lower limit                             | -58.21                             |
| upper limit                             | -29.12                             |
| Variability estimate                    | Standard error of the mean         |
| Dispersion value                        | 7.352                              |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical Analysis 10 (Week 12)                              |
| Comparison groups                       | 5% Minoxidil Topical Foam (MTF) BID v 5% MTG Twice a Day (BID) |
| Number of subjects included in analysis | 59   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.868  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | 1.23   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | -13.47   |
| upper limit                             | 15.94  |
| Variability estimate                    | Standard error of the mean                                     |
| Dispersion value                        | 7.431  |

## Secondary: Change from Baseline in Non-vellus Target Area Hair Width (TAHW) at

**Weeks 8, 12 and 16**

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in Non-vellus Target Area Hair Width (TAHW) at Weeks 8, 12 and 16 |
|-----------------|--|

End point description:

TAHW was measured by computerized Hair Metrix<sup>SM</sup> system based on macrophotographs at Weeks 8, 12, and 16. ITT population included all randomized subjects. Here 'n' signifies number of subjects analyzed for specific arm.

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

End point timeframe:

Weeks 8, 12 and 16

| End point values                     | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) | Placebo Topical Gel (PTG) OD | 5% MTG Twice a Day (BID) | PTG BID              |
|--------------------------------------|--|------------------------------|--------------------------|----------------------|
| Subject group type                   | Reporting group                                | Reporting group              | Reporting group          | Reporting group      |
| Number of subjects analysed          | 41   | 20                           | 39                       | 20                   |
| Units: units on a scale              |  |                              |                          |                      |
| arithmetic mean (standard deviation) |  |                              |                          |                      |
| Week 8 (n=40, 20, 38, 18, 18)        | 267.87 (± 1123.266)                            | 225.98 (± 601.592)           | 1148.05 (± 1203.968)     | -248.32 (± 1057.438) |
| Week 12 (n=41, 20, 38, 18, 18)       | 10877.12 (± 4528.346)                          | 7992.00 (± 3978.613)         | 12054.63 (± 4335.559)    | 9623.74 (± 3166.357) |
| Week 16 (n=40, 20, 37, 20, 19)       | 1561.46 (± 1492.961)                           | 190.30 (± 755.771)           | 2301.72 (± 1526.758)     | -143.80 (± 1308.662) |

| End point values                     | 5% Minoxidil Topical Foam (MTF) BID |  |  |  |
|--------------------------------------|-------------------------------------|--|--|--|
| Subject group type                   | Reporting group                     |  |  |  |
| Number of subjects analysed          | 20                                  |  |  |  |
| Units: units on a scale              |                                     |  |  |  |
| arithmetic mean (standard deviation) |                                     |  |  |  |
| Week 8 (n=40, 20, 38, 18, 18)        | 1024.53 (± 1340.988)                |  |  |  |
| Week 12 (n=41, 20, 38, 18, 18)       | 10216.52 (± 4164.070)               |  |  |  |
| Week 16 (n=40, 20, 37, 20, 19)       | 2074.94 (± 2301.889)                |  |  |  |

**Statistical analyses**

|                            |   |
|----------------------------|---|
| Statistical analysis title | Statistical analysis 1 (Week 8)   |
| Comparison groups          | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD |



|   |                            |
|---|----------------------------|
| Number of subjects included in analysis | 61                         |
| Analysis specification                  | Pre-specified              |
| Analysis type                           | superiority                |
| P-value                                 | = 0.96                     |
| Method                                  | ANCOVA                     |
| Parameter estimate                      | Mean difference (net)      |
| Point estimate                          | 15.21                      |
| Confidence interval                     |                            |
| level                                   | 95 %                       |
| sides                                   | 2-sided                    |
| lower limit                             | -591.006                   |
| upper limit                             | 621.426                    |
| Variability estimate                    | Standard error of the mean |
| Dispersion value                        | 306.353                    |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Statistical analysis 2 (Week 8)   |
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% MTG Twice a Day (BID) |
| Number of subjects included in analysis | 80  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | < 0.001   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Mean difference (net)   |
| Point estimate                          | 858.748   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 362.76  |
| upper limit                             | 1354.736  |
| Variability estimate                    | Standard error of the mean  |
| Dispersion value                        | 250.648   |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical analysis 3 (Week 8)  |
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% Minoxidil Topical Foam (MTF) BID |
| Number of subjects included in analysis | 61   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.017  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | 763.563  |

|                      |                            |
|----------------------|----------------------------|
| Confidence interval  |                            |
| level                | 95 %                       |
| sides                | 2-sided                    |
| lower limit          | 136.567                    |
| upper limit          | 1390.558                   |
| Variability estimate | Standard error of the mean |
| Dispersion value     | 316.853                    |

|   |                                    |
|---|------------------------------------|
| <b>Statistical analysis title</b>       | Statistical analysis 4 (Week 8)    |
| Comparison groups                       | PTG BID v 5% MTG Twice a Day (BID) |
| Number of subjects included in analysis | 59                                 |
| Analysis specification                  | Pre-specified                      |
| Analysis type                           | superiority                        |
| P-value                                 | < 0.001                            |
| Method                                  | ANCOVA                             |
| Parameter estimate                      | Mean difference (net)              |
| Point estimate                          | -1408.135                          |
| Confidence interval                     |                                    |
| level                                   | 95 %                               |
| sides                                   | 2-sided                            |
| lower limit                             | -2034.106                          |
| upper limit                             | -782.164                           |
| Variability estimate                    | Standard error of the mean         |
| Dispersion value                        | 316.335                            |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical analysis 5 (Week 8)                                |
| Comparison groups                       | 5% MTG Twice a Day (BID) v 5% Minoxidil Topical Foam (MTF) BID |
| Number of subjects included in analysis | 59   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.766  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | -95.185  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | -727.523   |
| upper limit                             | 537.153  |
| Variability estimate                    | Standard error of the mean                                     |
| Dispersion value                        | 319.553  |

|                                   |                                  |
|-----------------------------------|----------------------------------|
| <b>Statistical analysis title</b> | Statistical analysis 6 (Week 12) |
|-----------------------------------|----------------------------------|

|   |   |
|---|---|
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD |
| Number of subjects included in analysis | 61  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.026   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Mean difference (net)   |
| Point estimate                          | -963.866  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -1807.75  |
| upper limit                             | -119.982  |
| Variability estimate                    | Standard error of the mean  |
| Dispersion value                        | 426.49  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Statistical analysis 7 (Week 12)  |
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% MTG Twice a Day (BID) |
| Number of subjects included in analysis | 80  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.01  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Mean difference (net)   |
| Point estimate                          | 907.493   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 218.819   |
| upper limit                             | 1596.167  |
| Variability estimate                    | Standard error of the mean  |
| Dispersion value                        | 348.049   |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical analysis 8 (Week 12)   |
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% Minoxidil Topical Foam (MTF) BID |
| Number of subjects included in analysis | 61   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.102  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | 725.437  |

|                      |                            |
|----------------------|----------------------------|
| Confidence interval  |                            |
| level                | 95 %                       |
| sides                | 2-sided                    |
| lower limit          | -147.175                   |
| upper limit          | 1598.049                   |
| Variability estimate | Standard error of the mean |
| Dispersion value     | 441.009                    |

|   |                                    |
|---|------------------------------------|
| <b>Statistical analysis title</b>       | Statistical analysis 9 (Week 12)   |
| Comparison groups                       | 5% MTG Twice a Day (BID) v PTG BID |
| Number of subjects included in analysis | 59                                 |
| Analysis specification                  | Pre-specified                      |
| Analysis type                           | superiority                        |
| P-value                                 | < 0.001                            |
| Method                                  | ANCOVA                             |
| Parameter estimate                      | Mean difference (net)              |
| Point estimate                          | -2514.894                          |
| Confidence interval                     |                                    |
| level                                   | 95 %                               |
| sides                                   | 2-sided                            |
| lower limit                             | -3389.491                          |
| upper limit                             | -1640.297                          |
| Variability estimate                    | Standard error of the mean         |
| Dispersion value                        | 442.013                            |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical analysis 10 (Week 12)                              |
| Comparison groups                       | 5% MTG Twice a Day (BID) v 5% Minoxidil Topical Foam (MTF) BID |
| Number of subjects included in analysis | 59   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.684  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | -182.056   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | -1065.551  |
| upper limit                             | 701.438  |
| Variability estimate                    | Standard error of the mean                                     |
| Dispersion value                        | 446.509  |

|                                   |                                   |
|-----------------------------------|-----------------------------------|
| <b>Statistical analysis title</b> | Statistical analysis 11 (Week 16) |
|-----------------------------------|-----------------------------------|

|   |   |
|---|---|
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD |
| Number of subjects included in analysis | 61  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.002   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Mean difference (net)   |
| Point estimate                          | -1300.171   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -2123.078   |
| upper limit                             | -477.264  |
| Variability estimate                    | Standard error of the mean  |
| Dispersion value                        | 415.95  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Statistical analysis 12 (Week 16)   |
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% MTG Twice a Day (BID) |
| Number of subjects included in analysis | 80  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.037   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Mean difference (net)   |
| Point estimate                          | 718.759   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 42.551  |
| upper limit                             | 1394.967  |
| Variability estimate                    | Standard error of the mean  |
| Dispersion value                        | 341.799   |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical analysis 13 (Week 16)  |
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% Minoxidil Topical Foam (MTF) BID |
| Number of subjects included in analysis | 61   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.269  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | 467.947  |

|                      |                            |
|----------------------|----------------------------|
| Confidence interval  |                            |
| level                | 95 %                       |
| sides                | 2-sided                    |
| lower limit          | -365.487                   |
| upper limit          | 1301.382                   |
| Variability estimate | Standard error of the mean |
| Dispersion value     | 421.271                    |

|   |                                    |
|---|------------------------------------|
| <b>Statistical analysis title</b>       | Statistical analysis 14 (Week 16)  |
| Comparison groups                       | 5% MTG Twice a Day (BID) v PTG BID |
| Number of subjects included in analysis | 59                                 |
| Analysis specification                  | Pre-specified                      |
| Analysis type                           | superiority                        |
| P-value                                 | < 0.001                            |
| Method                                  | ANCOVA                             |
| Parameter estimate                      | Mean difference (net)              |
| Point estimate                          | -2512.224                          |
| Confidence interval                     |                                    |
| level                                   | 95 %                               |
| sides                                   | 2-sided                            |
| lower limit                             | -3341.403                          |
| upper limit                             | -1683.045                          |
| Variability estimate                    | Standard error of the mean         |
| Dispersion value                        | 419.12                             |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical analysis 15 (Week 16)                              |
| Comparison groups                       | 5% MTG Twice a Day (BID) v 5% Minoxidil Topical Foam (MTF) BID |
| Number of subjects included in analysis | 59   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.56   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | -250.812   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | -1099.746  |
| upper limit                             | 598.123  |
| Variability estimate                    | Standard error of the mean                                     |
| Dispersion value                        | 429.106  |

## Secondary: Global Photographs Rating for Hair Loss Condition in the Vertex Region

**at Weeks 8, 12, and 16**

|                 |   |
|-----------------|---|
| End point title | Global Photographs Rating for Hair Loss Condition in the Vertex Region at Weeks 8, 12, and 16 |
|-----------------|---|

End point description:

Subject rating via global photographs of hair loss condition in the vertex region was reported at Weeks 8, 12, and 16. Hair loss condition was measured by using a 7-point scale ranging from -3 to +3: where -3 indicated significantly worse and +3 means significantly improved. ITT population included all randomized subjects. Here 'N' signifies number of subjects who were evaluable for this endpoint. Here 'n' signifies number of subjects analyzed for specific arm.

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

End point timeframe:

Weeks 8, 12, and 16

| End point values                     | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) | Placebo Topical Gel (PTG) OD | 5% MTG Twice a Day (BID) | PTG BID         |
|--------------------------------------|--|------------------------------|--------------------------|-----------------|
| Subject group type                   | Reporting group                                | Reporting group              | Reporting group          | Reporting group |
| Number of subjects analysed          | 41   | 20                           | 39                       | 20              |
| Units: units on a scale              |  |                              |                          |                 |
| arithmetic mean (standard deviation) |  |                              |                          |                 |
| Week 8 (n=41, 20, 39, 18, 19)        | 0.5 (± 0.87)                                   | 0.1 (± 0.76)                 | 0.4 (± 0.99)             | 0.3 (± 1.13)    |
| Week 12 (n=41, 20, 39, 18, 19)       | 0.7 (± 1.02)                                   | 0.4 (± 0.88)                 | 1.2 (± 1.11)             | -0.2 (± 1.26)   |
| Week 16 (n=41, 20, 38, 20, 20)       | 1.0 (± 1.08)                                   | 0.3 (± 0.73)                 | 1.1 (± 1.17)             | 0.1 (± 1.02)    |

| End point values                     | 5% Minoxidil Topical Foam (MTF) BID |  |  |  |
|--------------------------------------|-------------------------------------|--|--|--|
| Subject group type                   | Reporting group                     |  |  |  |
| Number of subjects analysed          | 20                                  |  |  |  |
| Units: units on a scale              |                                     |  |  |  |
| arithmetic mean (standard deviation) |                                     |  |  |  |
| Week 8 (n=41, 20, 39, 18, 19)        | 0.6 (± 0.90)                        |  |  |  |
| Week 12 (n=41, 20, 39, 18, 19)       | 1.3 (± 0.75)                        |  |  |  |
| Week 16 (n=41, 20, 38, 20, 20)       | 1.4 (± 0.75)                        |  |  |  |

**Statistical analyses**

|                            |   |
|----------------------------|---|
| Statistical analysis title | Statistical analysis 1 (Week 8)   |
| Comparison groups          | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD |

|   |                            |
|---|----------------------------|
| Number of subjects included in analysis | 61                         |
| Analysis specification                  | Pre-specified              |
| Analysis type                           | superiority                |
| P-value                                 | = 0.093                    |
| Method                                  | ANCOVA                     |
| Parameter estimate                      | Mean difference (net)      |
| Point estimate                          | -0.4                       |
| Confidence interval                     |                            |
| level                                   | 95 %                       |
| sides                                   | 2-sided                    |
| lower limit                             | -0.94                      |
| upper limit                             | 0.07                       |
| Variability estimate                    | Standard error of the mean |
| Dispersion value                        | 0.26                       |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Statistical analysis 2 (Week 8)   |
| Comparison groups                       | 5% MTG Twice a Day (BID) v 5% Minoxidil Topical Gel (MTG) Once Daily (OD) |
| Number of subjects included in analysis | 80  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.611   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Mean difference (net)   |
| Point estimate                          | -0.1  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -0.52   |
| upper limit                             | 0.31  |
| Variability estimate                    | Standard error of the mean  |
| Dispersion value                        | 0.21  |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical analysis 3 (Week 8)  |
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% Minoxidil Topical Foam (MTF) BID |
| Number of subjects included in analysis | 61   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.743  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | 0.1  |



|                      |                            |
|----------------------|----------------------------|
| Confidence interval  |                            |
| level                | 95 %                       |
| sides                | 2-sided                    |
| lower limit          | -0.43                      |
| upper limit          | 0.6                        |
| Variability estimate | Standard error of the mean |
| Dispersion value     | 0.26                       |

|   |                                    |
|---|------------------------------------|
| <b>Statistical analysis title</b>       | Statistical analysis 4 (Week 8)    |
| Comparison groups                       | 5% MTG Twice a Day (BID) v PTG BID |
| Number of subjects included in analysis | 59                                 |
| Analysis specification                  | Pre-specified                      |
| Analysis type                           | superiority                        |
| P-value                                 | = 0.683                            |
| Method                                  | ANCOVA                             |
| Parameter estimate                      | Mean difference (net)              |
| Point estimate                          | -0.1                               |
| Confidence interval                     |                                    |
| level                                   | 95 %                               |
| sides                                   | 2-sided                            |
| lower limit                             | -0.64                              |
| upper limit                             | 0.42                               |
| Variability estimate                    | Standard error of the mean         |
| Dispersion value                        | 0.27                               |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical analysis 5 (Week 8)                                |
| Comparison groups                       | 5% MTG Twice a Day (BID) v 5% Minoxidil Topical Foam (MTF) BID |
| Number of subjects included in analysis | 59   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.464  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | 0.2  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | -0.33  |
| upper limit                             | 0.71   |
| Variability estimate                    | Standard error of the mean                                     |
| Dispersion value                        | 0.26   |

|                                   |                                  |
|-----------------------------------|----------------------------------|
| <b>Statistical analysis title</b> | Statistical analysis 6 (Week 12) |
|-----------------------------------|----------------------------------|

|   |   |
|---|---|
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD |
| Number of subjects included in analysis | 61  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.286   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Analysis of covariance  |
| Point estimate                          | -0.3  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -0.86   |
| upper limit                             | 0.26  |
| Variability estimate                    | Standard error of the mean  |
| Dispersion value                        | 0.28  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Statistical analysis 7 (Week 12)  |
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% MTG Twice a Day (BID) |
| Number of subjects included in analysis | 80  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.036   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Mean difference (net)   |
| Point estimate                          | 0.5   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.03  |
| upper limit                             | 0.95  |
| Variability estimate                    | Standard error of the mean  |
| Dispersion value                        | 0.23  |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical analysis 8 (Week 12)   |
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% Minoxidil Topical Foam (MTF) BID |
| Number of subjects included in analysis | 61   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.025  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | 0.7  |

|                      |                            |
|----------------------|----------------------------|
| Confidence interval  |                            |
| level                | 95 %                       |
| sides                | 2-sided                    |
| lower limit          | 0.08                       |
| upper limit          | 1.22                       |
| Variability estimate | Standard error of the mean |
| Dispersion value     | 0.29                       |

|   |                                    |
|---|------------------------------------|
| <b>Statistical analysis title</b>       | Statistical analysis 9 (Week 12)   |
| Comparison groups                       | 5% MTG Twice a Day (BID) v PTG BID |
| Number of subjects included in analysis | 59                                 |
| Analysis specification                  | Pre-specified                      |
| Analysis type                           | superiority                        |
| P-value                                 | < 0.001                            |
| Method                                  | ANCOVA                             |
| Parameter estimate                      | Mean difference (net)              |
| Point estimate                          | -1.4                               |
| Confidence interval                     |                                    |
| level                                   | 95 %                               |
| sides                                   | 2-sided                            |
| lower limit                             | -1.96                              |
| upper limit                             | -0.8                               |
| Variability estimate                    | Standard error of the mean         |
| Dispersion value                        | 0.29                               |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical analysis 10 (Week 12)                              |
| Comparison groups                       | 5% MTG Twice a Day (BID) v 5% Minoxidil Topical Foam (MTF) BID |
| Number of subjects included in analysis | 59   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.582  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | 0.2  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | -0.41  |
| upper limit                             | 0.73   |
| Variability estimate                    | Standard error of the mean                                     |
| Dispersion value                        | 0.29   |

|                                   |                                   |
|-----------------------------------|-----------------------------------|
| <b>Statistical analysis title</b> | Statistical analysis 11 (Week 16) |
|-----------------------------------|-----------------------------------|

|   |   |
|---|---|
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD |
| Number of subjects included in analysis | 61  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.019   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Mean difference (net)   |
| Point estimate                          | -0.7  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -1.2  |
| upper limit                             | -0.11   |
| Variability estimate                    | Standard error of the mean  |
| Dispersion value                        | 0.28  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Statistical analysis 12 (Week 16)   |
| Comparison groups                       | 5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% MTG Twice a Day (BID) |
| Number of subjects included in analysis | 80  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.681   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Mean difference (net)   |
| Point estimate                          | 0.1   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -0.36   |
| upper limit                             | 0.54  |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical analysis 13 (Week 16)  |
| Comparison groups                       | 5% Minoxidil Topical Foam (MTF) BID v 5% Minoxidil Topical Gel (MTG) Once Daily (OD) |
| Number of subjects included in analysis | 61   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.154  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | 0.4  |

|                      |                            |
|----------------------|----------------------------|
| Confidence interval  |                            |
| level                | 95 %                       |
| sides                | 2-sided                    |
| lower limit          | -0.15                      |
| upper limit          | 0.94                       |
| Variability estimate | Standard error of the mean |
| Dispersion value     | 0.28                       |

|   |                                    |
|---|------------------------------------|
| <b>Statistical analysis title</b>       | Statistical analysis 14 (Week 16)  |
| Comparison groups                       | 5% MTG Twice a Day (BID) v PTG BID |
| Number of subjects included in analysis | 59                                 |
| Analysis specification                  | Pre-specified                      |
| Analysis type                           | superiority                        |
| P-value                                 | < 0.001                            |
| Method                                  | ANCOVA                             |
| Parameter estimate                      | Mean difference (net)              |
| Point estimate                          | -1                                 |
| Confidence interval                     |                                    |
| level                                   | 95 %                               |
| sides                                   | 2-sided                            |
| lower limit                             | -1.56                              |
| upper limit                             | -0.46                              |
| Variability estimate                    | Standard error of the mean         |
| Dispersion value                        | 0.28                               |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Statistical analysis 15 (Week 16)                              |
| Comparison groups                       | 5% Minoxidil Topical Foam (MTF) BID v 5% MTG Twice a Day (BID) |
| Number of subjects included in analysis | 59   |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.281  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Mean difference (net)  |
| Point estimate                          | 0.3  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | -0.25  |
| upper limit                             | 0.85   |
| Variability estimate                    | Standard error of the mean                                     |
| Dispersion value                        | 0.28   |

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Approximately 1 year

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 20.0 |
|--------------------|------|

### Reporting groups

|                       |            |
|-----------------------|------------|
| Reporting group title | 5% MTG(OD) |
|-----------------------|------------|

Reporting group description:

5% Minoxidil Topical Gel (F13496-121) OD

|                       |         |
|-----------------------|---------|
| Reporting group title | PTG(OD) |
|-----------------------|---------|

Reporting group description:

Placebo Topical Gel (F13496-123) OD

|                       |             |
|-----------------------|-------------|
| Reporting group title | 5% MTG(BID) |
|-----------------------|-------------|

Reporting group description:

5% Minoxidil Topical Gel (F13496-121) BID

|                       |          |
|-----------------------|----------|
| Reporting group title | PTG(BID) |
|-----------------------|----------|

Reporting group description:

Placebo Topical Gel (F13496-123) BID

|                       |             |
|-----------------------|-------------|
| Reporting group title | 5% MTF(BID) |
|-----------------------|-------------|

Reporting group description:

5% Minoxidil Topical Foam (FDS-W016140-0002) BID

| Serious adverse events  | 5% MTG(OD)     | PTG(OD)        | 5% MTG(BID)    |
|---|----------------|----------------|----------------|
| Total subjects affected by serious adverse events                   |                |                |                |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 20 (0.00%) | 0 / 39 (0.00%) |
| number of deaths (all causes)                                       | 0              | 0              | 0              |
| number of deaths resulting from adverse events                      |                |                |                |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                |                |                |
| Basal Cell Carcinoma  |                |                |                |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 20 (0.00%) | 0 / 39 (0.00%) |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 0          |

| Serious adverse events                            | PTG(BID)       | 5% MTF(BID)    |  |
|---|----------------|----------------|--|
| Total subjects affected by serious adverse events |                |                |  |
| subjects affected / exposed                       | 0 / 20 (0.00%) | 1 / 20 (5.00%) |  |
| number of deaths (all causes)                     | 0              | 0              |  |
| number of deaths resulting from                   |                |                |  |

|   |                |                |  |
|---|----------------|----------------|--|
| adverse events  |                |                |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                |                |  |
| Basal Cell Carcinoma  |                |                |  |
| subjects affected / exposed   | 0 / 20 (0.00%) | 1 / 20 (5.00%) |  |
| 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 %

| Non-serious adverse events                            | 5% MTG(OD)       | PTG(OD)          | 5% MTG(BID)      |
|---|------------------|------------------|------------------|
| Total subjects affected by non-serious adverse events |                  |                  |                  |
| subjects affected / exposed                           | 25 / 41 (60.98%) | 14 / 20 (70.00%) | 18 / 39 (46.15%) |
| Injury, poisoning and procedural complications        |                  |                  |                  |
| Contusion   |                  |                  |                  |
| subjects affected / exposed                           | 0 / 41 (0.00%)   | 1 / 20 (5.00%)   | 0 / 39 (0.00%)   |
| occurrences (all)                                     | 0                | 1                | 0                |
| Exposure to Communicable Disease                      |                  |                  |                  |
| subjects affected / exposed                           | 0 / 41 (0.00%)   | 0 / 20 (0.00%)   | 0 / 39 (0.00%)   |
| occurrences (all)                                     | 0                | 0                | 0                |
| Ligament Rupture                                      |                  |                  |                  |
| subjects affected / exposed                           | 0 / 41 (0.00%)   | 1 / 20 (5.00%)   | 0 / 39 (0.00%)   |
| occurrences (all)                                     | 0                | 1                | 0                |
| Ligament Sprain                                       |                  |                  |                  |
| subjects affected / exposed                           | 0 / 41 (0.00%)   | 1 / 20 (5.00%)   | 0 / 39 (0.00%)   |
| occurrences (all)                                     | 0                | 1                | 0                |
| Rib Fracture  |                  |                  |                  |
| subjects affected / exposed                           | 0 / 41 (0.00%)   | 1 / 20 (5.00%)   | 0 / 39 (0.00%)   |
| occurrences (all)                                     | 0                | 1                | 0                |
| Scratch   |                  |                  |                  |
| subjects affected / exposed                           | 0 / 41 (0.00%)   | 0 / 20 (0.00%)   | 0 / 39 (0.00%)   |
| occurrences (all)                                     | 0                | 0                | 0                |
| Sunburn   |                  |                  |                  |
| subjects affected / exposed                           | 0 / 41 (0.00%)   | 1 / 20 (5.00%)   | 0 / 39 (0.00%)   |
| occurrences (all)                                     | 0                | 1                | 0                |
| Cardiac disorders                                     |                  |                  |                  |

|  |  |  |  |
|--|--|--|--|
| Angina Pectoris<br>subjects affected / exposed<br>occurrences (all)  | 0 / 41 (0.00%)<br>0  | 1 / 20 (5.00%)<br>1  | 0 / 39 (0.00%)<br>0  |
| Nervous system disorders<br>Headache<br>subjects affected / exposed<br>occurrences (all)   | 8 / 41 (19.51%)<br>12  | 6 / 20 (30.00%)<br>8   | 3 / 39 (7.69%)<br>6  |
| General disorders and administration<br>site conditions<br>Application Site Pain<br>subjects affected / exposed<br>occurrences (all)<br><br>Application Site Pruritus<br>subjects affected / exposed<br>occurrences (all)<br><br>Influenza Like Illness<br>subjects affected / exposed<br>occurrences (all)                                    | 0 / 41 (0.00%)<br>0<br><br>0 / 41 (0.00%)<br>0<br><br>0 / 41 (0.00%)<br>0                            | 0 / 20 (0.00%)<br>0<br><br>0 / 20 (0.00%)<br>0<br><br>1 / 20 (5.00%)<br>1                            | 0 / 39 (0.00%)<br>0<br><br>0 / 39 (0.00%)<br>0<br><br>0 / 39 (0.00%)<br>0                            |
| Immune system disorders<br>Hypersensitivity<br>subjects affected / exposed<br>occurrences (all)  | 0 / 41 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  | 0 / 39 (0.00%)<br>0  |
| Gastrointestinal disorders<br>Abdominal Pain Upper<br>subjects affected / exposed<br>occurrences (all)<br><br>Diarrhoea<br>subjects affected / exposed<br>occurrences (all)<br><br>Food Poisoning<br>subjects affected / exposed<br>occurrences (all)<br><br>Haemorrhoids<br>subjects affected / exposed<br>occurrences (all)<br><br>Toothache | 0 / 41 (0.00%)<br>0<br><br>1 / 41 (2.44%)<br>1<br><br>2 / 41 (4.88%)<br>3<br><br>0 / 41 (0.00%)<br>0 | 0 / 20 (0.00%)<br>0<br><br>0 / 20 (0.00%)<br>0<br><br>0 / 20 (0.00%)<br>0<br><br>1 / 20 (5.00%)<br>1 | 0 / 39 (0.00%)<br>0<br><br>0 / 39 (0.00%)<br>0<br><br>0 / 39 (0.00%)<br>0<br><br>0 / 39 (0.00%)<br>0 |



|  |                     |                     |                     |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)   | 0 / 41 (0.00%)<br>0 | 0 / 20 (0.00%)<br>0 | 2 / 39 (5.13%)<br>2 |
| Respiratory, thoracic and mediastinal disorders<br>Rhinitis Allergic<br>subjects affected / exposed<br>occurrences (all) | 1 / 41 (2.44%)<br>1 | 1 / 20 (5.00%)<br>1 | 0 / 39 (0.00%)<br>0 |
| Skin and subcutaneous tissue disorders<br>Eczema<br>subjects affected / exposed<br>occurrences (all)                     | 1 / 41 (2.44%)<br>1 | 0 / 20 (0.00%)<br>0 | 0 / 39 (0.00%)<br>0 |
| Pruritus<br>subjects affected / exposed<br>occurrences (all)   | 0 / 41 (0.00%)<br>0 | 1 / 20 (5.00%)<br>1 | 0 / 39 (0.00%)<br>0 |
| Seborrhoeic Dermatitis<br>subjects affected / exposed<br>occurrences (all)   | 0 / 41 (0.00%)<br>0 | 0 / 20 (0.00%)<br>0 | 2 / 39 (5.13%)<br>2 |
| Psychiatric disorders<br>Sleep Disorder<br>subjects affected / exposed<br>occurrences (all)                              | 0 / 41 (0.00%)<br>0 | 0 / 20 (0.00%)<br>0 | 0 / 39 (0.00%)<br>0 |
| Musculoskeletal and connective tissue disorders<br>Back Pain<br>subjects affected / exposed<br>occurrences (all)         | 3 / 41 (7.32%)<br>3 | 1 / 20 (5.00%)<br>1 | 1 / 39 (2.56%)<br>1 |
| Musculoskeletal Pain<br>subjects affected / exposed<br>occurrences (all)   | 0 / 41 (0.00%)<br>0 | 1 / 20 (5.00%)<br>1 | 1 / 39 (2.56%)<br>1 |
| Musculoskeletal Stiffness<br>subjects affected / exposed<br>occurrences (all)  | 0 / 41 (0.00%)<br>0 | 1 / 20 (5.00%)<br>1 | 0 / 39 (0.00%)<br>0 |
| Tendonitis<br>subjects affected / exposed<br>occurrences (all)   | 0 / 41 (0.00%)<br>0 | 1 / 20 (5.00%)<br>1 | 1 / 39 (2.56%)<br>1 |
| Infections and infestations<br>Gastrointestinal Infection  |                     |                     |                     |

|   |                  |                 |                  |
|---|------------------|-----------------|------------------|
| subjects affected / exposed             | 0 / 41 (0.00%)   | 1 / 20 (5.00%)  | 0 / 39 (0.00%)   |
| occurrences (all)                       | 0                | 1               | 0                |
| Influenza                               |                  |                 |                  |
| subjects affected / exposed             | 0 / 41 (0.00%)   | 0 / 20 (0.00%)  | 0 / 39 (0.00%)   |
| occurrences (all)                       | 0                | 0               | 0                |
| Otitis Media                            |                  |                 |                  |
| subjects affected / exposed             | 0 / 41 (0.00%)   | 0 / 20 (0.00%)  | 1 / 39 (2.56%)   |
| occurrences (all)                       | 0                | 0               | 1                |
| Respiratory Tract Infection             |                  |                 |                  |
| subjects affected / exposed             | 0 / 41 (0.00%)   | 1 / 20 (5.00%)  | 0 / 39 (0.00%)   |
| occurrences (all)                       | 0                | 1               | 0                |
| Sinusitis                               |                  |                 |                  |
| subjects affected / exposed             | 0 / 41 (0.00%)   | 0 / 20 (0.00%)  | 2 / 39 (5.13%)   |
| occurrences (all)                       | 0                | 0               | 2                |
| Subcutaneous Abscess                    |                  |                 |                  |
| subjects affected / exposed             | 0 / 41 (0.00%)   | 1 / 20 (5.00%)  | 0 / 39 (0.00%)   |
| occurrences (all)                       | 0                | 1               | 0                |
| Upper Respiratory Tract Infection       |                  |                 |                  |
| subjects affected / exposed             | 0 / 41 (0.00%)   | 0 / 20 (0.00%)  | 0 / 39 (0.00%)   |
| occurrences (all)                       | 0                | 0               | 0                |
| Viral Upper Respiratory Tract Infection |                  |                 |                  |
| subjects affected / exposed             | 14 / 41 (34.15%) | 6 / 20 (30.00%) | 10 / 39 (25.64%) |
| occurrences (all)                       | 17               | 7               | 12               |

| <b>Non-serious adverse events</b>                     | PTG(BID)         | 5% MTF(BID)      |  |
|---|------------------|------------------|--|
| Total subjects affected by non-serious adverse events |                  |                  |  |
| subjects affected / exposed                           | 13 / 20 (65.00%) | 12 / 20 (60.00%) |  |
| Injury, poisoning and procedural complications        |                  |                  |  |
| Contusion   |                  |                  |  |
| subjects affected / exposed                           | 0 / 20 (0.00%)   | 0 / 20 (0.00%)   |  |
| occurrences (all)                                     | 0                | 0                |  |
| Exposure to Communicable Disease                      |                  |                  |  |
| subjects affected / exposed                           | 0 / 20 (0.00%)   | 1 / 20 (5.00%)   |  |
| occurrences (all)                                     | 0                | 1                |  |
| Ligament Rupture                                      |                  |                  |  |

|  |                      |                       |  |
|--|----------------------|-----------------------|--|
| subjects affected / exposed<br>occurrences (all)   | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0   |  |
| Ligament Sprain<br>subjects affected / exposed<br>occurrences (all)  | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0   |  |
| Rib Fracture<br>subjects affected / exposed<br>occurrences (all)   | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0   |  |
| Scratch<br>subjects affected / exposed<br>occurrences (all)  | 1 / 20 (5.00%)<br>1  | 0 / 20 (0.00%)<br>0   |  |
| Sunburn<br>subjects affected / exposed<br>occurrences (all)  | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0   |  |
| Cardiac disorders<br>Angina Pectoris<br>subjects affected / exposed<br>occurrences (all)   | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0   |  |
| Nervous system disorders<br>Headache<br>subjects affected / exposed<br>occurrences (all)   | 3 / 20 (15.00%)<br>3 | 5 / 20 (25.00%)<br>13 |  |
| General disorders and administration<br>site conditions<br>Application Site Pain<br>subjects affected / exposed<br>occurrences (all) | 0 / 20 (0.00%)<br>0  | 1 / 20 (5.00%)<br>1   |  |
| Application Site Pruritus<br>subjects affected / exposed<br>occurrences (all)  | 1 / 20 (5.00%)<br>1  | 0 / 20 (0.00%)<br>0   |  |
| Influenza Like Illness<br>subjects affected / exposed<br>occurrences (all)   | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0   |  |
| Immune system disorders<br>Hypersensitivity<br>subjects affected / exposed<br>occurrences (all)                                      | 1 / 20 (5.00%)<br>1  | 0 / 20 (0.00%)<br>0   |  |

|   |                             |                |                |  |
|---|-----------------------------|----------------|----------------|--|
| Gastrointestinal disorders                      | Abdominal Pain Upper        |                |                |  |
|   | subjects affected / exposed | 0 / 20 (0.00%) | 1 / 20 (5.00%) |  |
|   | occurrences (all)           | 0              | 1              |  |
|   | Diarrhoea                   |                |                |  |
|   | subjects affected / exposed | 0 / 20 (0.00%) | 1 / 20 (5.00%) |  |
|   | occurrences (all)           | 0              | 1              |  |
|   | Food Poisoning              |                |                |  |
|   | subjects affected / exposed | 0 / 20 (0.00%) | 1 / 20 (5.00%) |  |
|   | occurrences (all)           | 0              | 1              |  |
|   | Haemorrhoids                |                |                |  |
|   | subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%) |  |
|   | occurrences (all)           | 0              | 0              |  |
|   | Toothache                   |                |                |  |
|   | subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%) |  |
|   | occurrences (all)           | 0              | 0              |  |
| Respiratory, thoracic and mediastinal disorders |                             |                |                |  |
|   | Rhinitis Allergic           |                |                |  |
|   | subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%) |  |
|   | occurrences (all)           | 0              | 0              |  |
| Skin and subcutaneous tissue disorders          |                             |                |                |  |
|   | Eczema                      |                |                |  |
|   | subjects affected / exposed | 1 / 20 (5.00%) | 1 / 20 (5.00%) |  |
|   | occurrences (all)           | 1              | 2              |  |
|   | Pruritus                    |                |                |  |
|   | subjects affected / exposed | 1 / 20 (5.00%) | 0 / 20 (0.00%) |  |
|   | occurrences (all)           | 1              | 0              |  |
|   | Seborrhoeic Dermatitis      |                |                |  |
|   | subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%) |  |
|   | occurrences (all)           | 0              | 0              |  |
| Psychiatric disorders                           |                             |                |                |  |
|   | Sleep Disorder              |                |                |  |
|   | subjects affected / exposed | 0 / 20 (0.00%) | 1 / 20 (5.00%) |  |
|   | occurrences (all)           | 0              | 1              |  |
| Musculoskeletal and connective tissue disorders |                             |                |                |  |

|   |                |                |  |
|---|----------------|----------------|--|
| Back Pain                               |                |                |  |
| subjects affected / exposed             | 0 / 20 (0.00%) | 0 / 20 (0.00%) |  |
| occurrences (all)                       | 0              | 0              |  |
| Musculoskeletal Pain                    |                |                |  |
| subjects affected / exposed             | 0 / 20 (0.00%) | 0 / 20 (0.00%) |  |
| occurrences (all)                       | 0              | 0              |  |
| Musculoskeletal Stiffness               |                |                |  |
| subjects affected / exposed             | 0 / 20 (0.00%) | 0 / 20 (0.00%) |  |
| occurrences (all)                       | 0              | 0              |  |
| Tendonitis                              |                |                |  |
| subjects affected / exposed             | 0 / 20 (0.00%) | 0 / 20 (0.00%) |  |
| occurrences (all)                       | 0              | 0              |  |
| Infections and infestations             |                |                |  |
| Gastrointestinal Infection              |                |                |  |
| subjects affected / exposed             | 0 / 20 (0.00%) | 1 / 20 (5.00%) |  |
| occurrences (all)                       | 0              | 1              |  |
| Influenza                               |                |                |  |
| subjects affected / exposed             | 0 / 20 (0.00%) | 1 / 20 (5.00%) |  |
| occurrences (all)                       | 0              | 1              |  |
| Otitis Media                            |                |                |  |
| subjects affected / exposed             | 1 / 20 (5.00%) | 0 / 20 (0.00%) |  |
| occurrences (all)                       | 1              | 0              |  |
| Respiratory Tract Infection             |                |                |  |
| subjects affected / exposed             | 0 / 20 (0.00%) | 0 / 20 (0.00%) |  |
| occurrences (all)                       | 0              | 0              |  |
| Sinusitis                               |                |                |  |
| subjects affected / exposed             | 0 / 20 (0.00%) | 0 / 20 (0.00%) |  |
| occurrences (all)                       | 0              | 0              |  |
| Subcutaneous Abscess                    |                |                |  |
| subjects affected / exposed             | 0 / 20 (0.00%) | 0 / 20 (0.00%) |  |
| occurrences (all)                       | 0              | 0              |  |
| Upper Respiratory Tract Infection       |                |                |  |
| subjects affected / exposed             | 1 / 20 (5.00%) | 0 / 20 (0.00%) |  |
| occurrences (all)                       | 1              | 0              |  |
| Viral Upper Respiratory Tract Infection |                |                |  |

|                             |                 |                 |  |
|-----------------------------|-----------------|-----------------|--|
| subjects affected / exposed | 6 / 20 (30.00%) | 6 / 20 (30.00%) |  |
| occurrences (all)           | 6               | 7               |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment  |
|------------------|--|
| 03 October 2018  | Protocol Amendment-2: Protocol has been revised after comments were received from Independent Ethics Committee (IEC) in addition to some clarification added from Johnson & Johnson. |
| 23 November 2018 | Protocol Amendment 3: Protocol has been revised with some added clarifications from Johnson & Johnson as some inconsistencies were noted.  |
| 21 March 2019    | Protocol Amendment 4: Protocol has been revised with some added clarifications from Johnson & Johnson as some inconsistencies were noted.  |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported