

**Clinical trial results:****A Multicenter, Randomized, Double-Blind Study Comparing the Efficacy and Safety of Ixekizumab Versus Placebo in Patients with Moderate-to-Severe Genital Psoriasis****Summary**

|                          |                  |
|--------------------------|------------------|
| EudraCT number           | 2015-002628-14   |
| Trial protocol           | NL AT BE         |
| Global end of trial date | 21 February 2018 |

**Results information**

|                                |               |
|--------------------------------|---------------|
| Result version number          | v1 (current)  |
| This version publication date  | 01 March 2019 |
| First version publication date | 01 March 2019 |

**Trial information****Trial identification**

|                       |             |
|-----------------------|-------------|
| Sponsor protocol code | I1F-MC-RHBQ |
|-----------------------|-------------|

**Additional study identifiers**

|                                    |                              |
|------------------------------------|------------------------------|
| ISRCTN number                      | -                            |
| ClinicalTrials.gov id (NCT number) | NCT02718898                  |
| WHO universal trial number (UTN)   | -                            |
| Other trial identifiers            | Eli Lilly and Company: 16010 |

Notes:

**Sponsors**

|                              |                                                                           |
|------------------------------|---------------------------------------------------------------------------|
| Sponsor organisation name    | Eli Lilly and Company                                                     |
| Sponsor organisation address | Lilly Corporate Center, Indianapolis, IN, United States, 46285            |
| Public contact               | Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877CTLilly, |
| Scientific contact           | Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 8772854559, |

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                       | 21 February 2018 |
| Is this the analysis of the primary completion data? | No               |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 21 February 2018 |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

The main purpose of this study is to evaluate the efficacy and safety of the study drug ixekizumab compared to placebo in participants with moderate-to-severe genital psoriasis.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

|                                                           |             |
|-----------------------------------------------------------|-------------|
| Actual start date of recruitment                          | 05 May 2016 |
| 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 | Canada: 29        |
| Country: Number of subjects enrolled | Puerto Rico: 11   |
| Country: Number of subjects enrolled | Austria: 8        |
| Country: Number of subjects enrolled | Netherlands: 5    |
| Country: Number of subjects enrolled | Turkey: 7         |
| Country: Number of subjects enrolled | Belgium: 7        |
| Country: Number of subjects enrolled | United States: 62 |
| Country: Number of subjects enrolled | Australia: 20     |
| Worldwide total number of subjects   | 149               |
| EEA total number of subjects         | 20                |

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)      | 138 |
| From 65 to 84 years       | 11  |
| 85 years and over         | 0   |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

12 week Blinded Treatment period, followed by 40 week Open Label Treatment Period, followed by 12 week Post treatment follow-up period.

### Period 1

|                              |                          |
|------------------------------|--------------------------|
| Period 1 title               | Blinded Treatment period |
| Is this the baseline period? | Yes                      |
| Allocation method            | Randomised - controlled  |
| Blinding used                | Double blind             |
| Roles blinded                | Subject, Investigator    |

### Arms

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

Arm description:

Participants received placebo subcutaneously at baseline and every 2 weeks (Q2W) from week 2 to week 10. At week 12, 160 mg Ixekizumab was given by Subcutaneous injection during blinded treatment period.

|                                        |                  |
|----------------------------------------|------------------|
| Arm type                               | Placebo          |
| Investigational medicinal product name | Ixekizumab       |
| Investigational medicinal product code |                  |
| Other name                             |                  |
| Pharmaceutical forms                   | Injection        |
| Routes of administration               | Subcutaneous use |

Dosage and administration details:

At week 12, subjects received 160 mg Ixekizumab by SC injection.

|                                        |                  |
|----------------------------------------|------------------|
| Investigational medicinal product name | Placebo          |
| Investigational medicinal product code |                  |
| Other name                             |                  |
| Pharmaceutical forms                   | Injection        |
| Routes of administration               | Subcutaneous use |

Dosage and administration details:

Subjects received placebo at baseline and every 2 weeks from week 2 to 10 by subcutaneous injection.

|                  |                                         |
|------------------|-----------------------------------------|
| <b>Arm title</b> | Ixekizumab 80mg Q2W - Blinded Treatment |
|------------------|-----------------------------------------|

Arm description:

Participants received 160 milligrams (mg) Ixekizumab subcutaneously (SC) at baseline followed by 80mg Ixekizumab every 2 weeks (Q2W) from week 2 to week 10. At week 12, 80mg Ixekizumab and placebo was given SC during blinded treatment period.

|                                        |                  |
|----------------------------------------|------------------|
| Arm type                               | Placebo          |
| Investigational medicinal product name | Ixekizumab       |
| Investigational medicinal product code |                  |
| Other name                             |                  |
| Pharmaceutical forms                   | Injection        |
| Routes of administration               | Subcutaneous use |

Dosage and administration details:

Participants received 160 milligrams (mg) Ixekizumab subcutaneously (SC) at baseline followed by 80mg Ixekizumab every 2 weeks (Q2W) from week 2 to week 10. At week 12, 80mg Ixekizumab and placebo was given SC during blinded treatment period.

| Number of subjects in period 1 | Placebo - Blinded Treatment | Ixekizumab 80mg Q2W - Blinded Treatment |
|--------------------------------|-----------------------------|-----------------------------------------|
|                                |                             |                                         |
| Started                        | 74                          | 75                                      |
| Completed                      | 65                          | 74                                      |
| Not completed                  | 9                           | 1                                       |
| Physician decision             | 1                           | -                                       |
| Adverse event, non-fatal       | 5                           | 1                                       |
| Lost to follow-up              | 2                           | -                                       |
| Lack of efficacy               | 1                           | -                                       |

## Period 2

|                              |                             |
|------------------------------|-----------------------------|
| Period 2 title               | Open Label Treatment Period |
| Is this the baseline period? | No                          |
| Allocation method            | Randomised - controlled     |
| Blinding used                | Double blind                |
| Roles blinded                | Subject, Investigator       |

## Arms

|                              |                                                           |
|------------------------------|-----------------------------------------------------------|
| Are arms mutually exclusive? | Yes                                                       |
| <b>Arm title</b>             | Placebo/Ixekizumab 80mg Q4W - Open label treatment period |

### Arm description:

Participants who received placebo in blinded treatment Period had received initial dose of 160mg Ixekizumab at week 12 followed by 80mg Ixekizumab Q4W by subcutaneous injection in open label treatment period.

Participants had an option to step-up to Q2W dosing starting at week 24 through week 40.

|                                        |                  |
|----------------------------------------|------------------|
| Arm type                               | Experimental     |
| Investigational medicinal product name | Ixekizumab       |
| Investigational medicinal product code |                  |
| Other name                             |                  |
| Pharmaceutical forms                   | Injection        |
| Routes of administration               | Subcutaneous use |

### Dosage and administration details:

Participants received 160mg Ixekizumab at week 12 followed by 80mg Ixekizumab Q4W by subcutaneous injection.

|                  |                                                                |
|------------------|----------------------------------------------------------------|
| <b>Arm title</b> | Ixekizumab 80mg Q2W/Ixekizumab 80mg Q4W - Open label treatment |
|------------------|----------------------------------------------------------------|

### Arm description:

Participants who received Ixekizumab in blinded treatment Period had received initial dose of 80mg Ixekizumab & placebo at week 12 followed by 80mg Ixekizumab Q4W by subcutaneous injection in open label treatment period.

Participants had an option to step-up to Q2W dosing starting at week 24 through week 40.

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

|                                        |                  |
|----------------------------------------|------------------|
| Investigational medicinal product name | Ixekizumab       |
| Investigational medicinal product code |                  |
| Other name                             |                  |
| Pharmaceutical forms                   | Injection        |
| Routes of administration               | Subcutaneous use |

Dosage and administration details:

Participants received 80mg Ixekizumab & placebo at week 12 followed by 80mg Ixekizumab Q4W by subcutaneous injection.

| Number of subjects in period 2                  | Placebo/Ixekizumab 80mg Q4W - Open label treatment period | Ixekizumab 80mg Q2W/Ixekizumab 80mg Q4W - Open label treatment |
|-------------------------------------------------|-----------------------------------------------------------|----------------------------------------------------------------|
| Started                                         | 65                                                        | 74                                                             |
| Completed                                       | 62                                                        | 64                                                             |
| Not completed                                   | 3                                                         | 10                                                             |
| Consent withdrawn by subject                    | 1                                                         | 3                                                              |
| Subject discontinued in OLTP                    | -                                                         | 1                                                              |
| Adverse event, non-fatal                        | 1                                                         | 1                                                              |
| Treatment of undisclosed addiction- Pt withdrew | -                                                         | 1                                                              |
| Lost to follow-up                               | -                                                         | 2                                                              |
| Lack of efficacy                                | 1                                                         | 2                                                              |

### Period 3

|                              |                                 |
|------------------------------|---------------------------------|
| Period 3 title               | Post treatment follow-up period |
| Is this the baseline period? | No                              |
| Allocation method            | Randomised - controlled         |
| Blinding used                | Double blind                    |
| Roles blinded                | Subject, Investigator           |

### Arms

|                              |                                    |
|------------------------------|------------------------------------|
| Are arms mutually exclusive? | No                                 |
| <b>Arm title</b>             | Placebo - Post treatment follow-up |

Arm description:

Participants did not receive any study treatment during post treatment follow-up period.

|                                                           |                 |
|-----------------------------------------------------------|-----------------|
| Arm type                                                  | No intervention |
| No investigational medicinal product assigned in this arm |                 |

|                  |                                                       |
|------------------|-------------------------------------------------------|
| <b>Arm title</b> | Ixekizumab 80mg Q4W - Post treatment follow-up period |
|------------------|-------------------------------------------------------|

Arm description:

Participants did not receive any study treatment during post treatment follow-up period.

|                                                           |                 |
|-----------------------------------------------------------|-----------------|
| Arm type                                                  | No intervention |
| No investigational medicinal product assigned in this arm |                 |

|                  |                                                |
|------------------|------------------------------------------------|
| <b>Arm title</b> | Ixekizumab 80mg Q2W - Post treatment follow-up |
|------------------|------------------------------------------------|

Arm description:

Participants did not receive any study treatment during post treatment follow-up period.

|          |                 |
|----------|-----------------|
| Arm type | No intervention |
|----------|-----------------|

|                                                           |
|-----------------------------------------------------------|
| No investigational medicinal product assigned in this arm |
|-----------------------------------------------------------|

| Number of subjects in period 3 | Placebo - Post treatment follow-up | Ixekizumab 80mg Q4W - Post treatment follow-up period | Ixekizumab 80mg Q2W - Post treatment follow-up |
|--------------------------------|------------------------------------|-------------------------------------------------------|------------------------------------------------|
|                                |                                    |                                                       |                                                |
| Started                        | 1                                  | 78                                                    | 49                                             |
| Completed                      | 0                                  | 67                                                    | 44                                             |
| Not completed                  | 1                                  | 11                                                    | 5                                              |
| Consent withdrawn by subject   | -                                  | 5                                                     | 3                                              |
| Adverse event, non-fatal       | -                                  | 1                                                     | 1                                              |
| Lost to follow-up              | 1                                  | 5                                                     | 1                                              |

## Baseline characteristics

### Reporting groups

|                                                                                                                                                                                                                                                    |                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| Reporting group title                                                                                                                                                                                                                              | Placebo - Blinded Treatment             |
| Reporting group description:                                                                                                                                                                                                                       |                                         |
| Participants received placebo subcutaneously at baseline and every 2 weeks (Q2W) from week 2 to week 10. At week 12, 160 mg Ixekizumab was given by Subcutaneous injection during blinded treatment period.                                        |                                         |
| Reporting group title                                                                                                                                                                                                                              | Ixekizumab 80mg Q2W - Blinded Treatment |
| Reporting group description:                                                                                                                                                                                                                       |                                         |
| Participants received 160 milligrams (mg) Ixekizumab subcutaneously (SC) at baseline followed by 80mg Ixekizumab every 2 weeks (Q2W) from week 2 to week 10. At week 12, 80mg Ixekizumab and placebo was given SC during blinded treatment period. |                                         |

| Reporting group values                             | Placebo - Blinded Treatment | Ixekizumab 80mg Q2W - Blinded Treatment | Total |
|----------------------------------------------------|-----------------------------|-----------------------------------------|-------|
| Number of subjects                                 | 74                          | 75                                      | 149   |
| Age categorical                                    |                             |                                         |       |
| Units: Subjects                                    |                             |                                         |       |
| In utero                                           |                             |                                         | 0     |
| Preterm newborn infants (gestational age < 37 wks) |                             |                                         | 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)                               |                             |                                         | 0     |
| From 65-84 years                                   |                             |                                         | 0     |
| 85 years and over                                  |                             |                                         | 0     |
| Age continuous                                     |                             |                                         |       |
| Units: years                                       |                             |                                         |       |
| arithmetic mean                                    | 44.4                        | 43.1                                    |       |
| standard deviation                                 | ± 12.55                     | ± 12.95                                 | -     |
| Gender categorical                                 |                             |                                         |       |
| Units: Subjects                                    |                             |                                         |       |
| Female                                             | 17                          | 19                                      | 36    |
| Male                                               | 57                          | 56                                      | 113   |
| Ethnicity                                          |                             |                                         |       |
| Units: Subjects                                    |                             |                                         |       |
| Hispanic or Latino                                 | 14                          | 13                                      | 27    |
| Not Hispanic or Latino                             | 57                          | 60                                      | 117   |
| Unknown or Not Reported                            | 3                           | 2                                       | 5     |
| Race                                               |                             |                                         |       |
| Units: Subjects                                    |                             |                                         |       |
| American Indian or Alaska Native                   | 0                           | 1                                       | 1     |
| Asian                                              | 7                           | 3                                       | 10    |
| Native Hawaiian or Other Pacific Islander          | 0                           | 0                                       | 0     |
| Black or African American                          | 2                           | 0                                       | 2     |
| White                                              | 64                          | 67                                      | 131   |

|                         |   |   |   |
|-------------------------|---|---|---|
| More than one race      | 1 | 4 | 5 |
| Unknown or Not Reported | 0 | 0 | 0 |

|                                                                                                                                                                                                                                                                                                                               |        |        |   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|--------|---|
| sPGA of Genitalia                                                                                                                                                                                                                                                                                                             |        |        |   |
| The Static Physician Global Assessment (sPGA) of Genitalia score is based on a combination of erythema and the secondary features (plaque elevation and/or scale). For the analysis of responses, the participant's psoriasis is assessed as follows: 0 = clear,1 = minimal,2 = mild,3 = moderate,4 = severe,5 = very severe. |        |        |   |
| Units: units on a scale                                                                                                                                                                                                                                                                                                       |        |        |   |
| arithmetic mean                                                                                                                                                                                                                                                                                                               | 3.5    | 3.4    |   |
| standard deviation                                                                                                                                                                                                                                                                                                            | ± 0.53 | ± 0.61 | - |

## End points

### End points reporting groups

|                                                                                                                                                                                                                                                                                                                                                              |                                                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|
| Reporting group title                                                                                                                                                                                                                                                                                                                                        | Placebo - Blinded Treatment                                    |
| Reporting group description:<br>Participants received placebo subcutaneously at baseline and every 2 weeks (Q2W) from week 2 to week 10. At week 12, 160 mg Ixekizumab was given by Subcutaneous injection during blinded treatment period.                                                                                                                  |                                                                |
| Reporting group title                                                                                                                                                                                                                                                                                                                                        | Ixekizumab 80mg Q2W - Blinded Treatment                        |
| Reporting group description:<br>Participants received 160 milligrams (mg) Ixekizumab subcutaneously (SC) at baseline followed by 80mg Ixekizumab every 2 weeks (Q2W) from week 2 to week 10. At week 12, 80mg Ixekizumab and placebo was given SC during blinded treatment period.                                                                           |                                                                |
| Reporting group title                                                                                                                                                                                                                                                                                                                                        | Placebo/Ixekizumab 80mg Q4W - Open label treatment period      |
| Reporting group description:<br>Participants who received placebo in blinded treatment Period had received initial dose of 160mg Ixekizumab at week 12 followed by 80mg Ixekizumab Q4W by subcutaneous injection in open label treatment period.<br><br>Participants had an option to step-up to Q2W dosing starting at week 24 through week 40.             |                                                                |
| Reporting group title                                                                                                                                                                                                                                                                                                                                        | Ixekizumab 80mg Q2W/Ixekizumab 80mg Q4W - Open label treatment |
| Reporting group description:<br>Participants who received Ixekizumab in blinded treatment Period had received initial dose of 80mg Ixekizumab & placebo at week 12 followed by 80mg Ixekizumab Q4W by subcutaneous injection in open label treatment period.<br><br>Participants had an option to step-up to Q2W dosing starting at week 24 through week 40. |                                                                |
| Reporting group title                                                                                                                                                                                                                                                                                                                                        | Placebo - Post treatment follow-up                             |
| Reporting group description:<br>Participants did not receive any study treatment during post treatment follow-up period.                                                                                                                                                                                                                                     |                                                                |
| Reporting group title                                                                                                                                                                                                                                                                                                                                        | Ixekizumab 80mg Q4W - Post treatment follow-up period          |
| Reporting group description:<br>Participants did not receive any study treatment during post treatment follow-up period.                                                                                                                                                                                                                                     |                                                                |
| Reporting group title                                                                                                                                                                                                                                                                                                                                        | Ixekizumab 80mg Q2W - Post treatment follow-up                 |
| Reporting group description:<br>Participants did not receive any study treatment during post treatment follow-up period.                                                                                                                                                                                                                                     |                                                                |

### Primary: Number of Participants Achieving Static Physician Global Assessment (sPGA) of Genitalia (0,1)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                               |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                        | Number of Participants Achieving Static Physician Global Assessment (sPGA) of Genitalia (0,1) |
| End point description:<br>sPGA of Genitalia score is based on a combination of erythema and the secondary features (plaque elevation and/or scale) in genital area. For the analysis of responses, the participant's psoriasis was assessed as follows: 0 = clear, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe, 5 = very severe. sPGA of Genitalia (0,1) : A sPGA of Genitalia assessed as either 0 or 1.<br><br>APD: All randomized participants. |                                                                                               |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                         | Primary                                                                                       |
| End point timeframe:<br>Week 12                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                               |

| <b>End point values</b>     | Placebo -<br>Blinded<br>Treatment | Ixekizumab<br>80mg Q2W -<br>Blinded<br>Treatment |  |  |
|-----------------------------|-----------------------------------|--------------------------------------------------|--|--|
| Subject group type          | Reporting group                   | Reporting group                                  |  |  |
| Number of subjects analysed | 74                                | 75                                               |  |  |
| Units: participants         | 6                                 | 55                                               |  |  |

## Statistical analyses

| <b>Statistical analysis title</b>       | Statistical Analysis 1                                                |
|-----------------------------------------|-----------------------------------------------------------------------|
| Comparison groups                       | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis | 149                                                                   |
| Analysis specification                  | Pre-specified                                                         |
| Analysis type                           | superiority                                                           |
| P-value                                 | < 0.001                                                               |
| Method                                  | Regression, Logistic                                                  |
| Parameter estimate                      | Odds ratio (OR)                                                       |
| Point estimate                          | 33.8                                                                  |
| Confidence interval                     |                                                                       |
| level                                   | 95 %                                                                  |
| sides                                   | 2-sided                                                               |
| lower limit                             | 12.39                                                                 |
| upper limit                             | 92.23                                                                 |

## Secondary: Number of Participants Achieving Overall sPGA (0,1)

|                                                                                                                                                                                                                                                                                                                                               |                                                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                               | Number of Participants Achieving Overall sPGA (0,1) |
| End point description:                                                                                                                                                                                                                                                                                                                        |                                                     |
| The overall sPGA is the physician's global assessment of the participant's psoriasis (Ps) lesions at a given time point. Plaques were assessed for induration, erythema, and scaling, and an overall rating of psoriasis severity was given using the anchors of 0 = clear, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe, 5 = very severe. |                                                     |
| Overall sPGA (0,1) : An overall sPGA assessed as either 0 or 1.                                                                                                                                                                                                                                                                               |                                                     |
| APD:All randomized participants.                                                                                                                                                                                                                                                                                                              |                                                     |
| End point type                                                                                                                                                                                                                                                                                                                                | Secondary                                           |
| End point timeframe:                                                                                                                                                                                                                                                                                                                          |                                                     |
| Week 12                                                                                                                                                                                                                                                                                                                                       |                                                     |

| <b>End point values</b>     | Placebo - Blinded Treatment | Ixekizumab 80mg Q2W - Blinded Treatment |  |  |
|-----------------------------|-----------------------------|-----------------------------------------|--|--|
| Subject group type          | Reporting group             | Reporting group                         |  |  |
| Number of subjects analysed | 74                          | 75                                      |  |  |
| Units: participants         | 2                           | 55                                      |  |  |

## Statistical analyses

| <b>Statistical analysis title</b>       | Statistical Analysis 1                                                |
|-----------------------------------------|-----------------------------------------------------------------------|
| Comparison groups                       | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis | 149                                                                   |
| Analysis specification                  | Pre-specified                                                         |
| Analysis type                           | superiority                                                           |
| P-value                                 | < 0.001                                                               |
| Method                                  | Regression, Logistic                                                  |
| Parameter estimate                      | Odds ratio (OR)                                                       |
| Point estimate                          | 102.55                                                                |
| Confidence interval                     |                                                                       |
| level                                   | 95 %                                                                  |
| sides                                   | 2-sided                                                               |
| lower limit                             | 22.79                                                                 |
| upper limit                             | 461.43                                                                |

## Secondary: Number of Participants with at Least a 3 Point Improvement in Genital Psoriasis Itch Numeric Rating Scale (NRS) Item within the Genital Psoriasis Symptom Scale (GPSS)

|                 |                                                                                                                                                                        |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Number of Participants with at Least a 3 Point Improvement in Genital Psoriasis Itch Numeric Rating Scale (NRS) Item within the Genital Psoriasis Symptom Scale (GPSS) |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### End point description:

GPSS is a participant-administered assessment of 8 symptoms: itch, pain, discomfort, stinging, burning, redness, scaling, and cracking. Each respondent was asked to answer the questions based on the psoriasis symptoms in his or her genital area. The overall severity for each individual genital psoriasis symptom is indicated by selecting the number from an Numeric Rating Scale (NRS) of 0 to 10 that best describes the worst level of each symptom in the genital area in the past 24 hours, where 0 (= no severity) and 10 (worst imaginable severity).

APD: All randomized participants with baseline GPSS Itch NRS Score  $\geq 3$ .

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Week 12              |           |

| <b>End point values</b>     | Placebo - Blinded Treatment | Ixekizumab 80mg Q2W - Blinded Treatment |  |  |
|-----------------------------|-----------------------------|-----------------------------------------|--|--|
| Subject group type          | Reporting group             | Reporting group                         |  |  |
| Number of subjects analysed | 60                          | 62                                      |  |  |
| Units: participants         | 5                           | 37                                      |  |  |

## Statistical analyses

| <b>Statistical analysis title</b>       | Statistical Analysis 1                                                |
|-----------------------------------------|-----------------------------------------------------------------------|
| Comparison groups                       | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis | 122                                                                   |
| Analysis specification                  | Pre-specified                                                         |
| Analysis type                           | superiority                                                           |
| P-value                                 | < 0.001                                                               |
| Method                                  | Regression, Logistic                                                  |
| Parameter estimate                      | Odds ratio (OR)                                                       |
| Point estimate                          | 16.27                                                                 |
| Confidence interval                     |                                                                       |
| level                                   | 95 %                                                                  |
| sides                                   | 2-sided                                                               |
| lower limit                             | 5.71                                                                  |
| upper limit                             | 46.4                                                                  |

## Secondary: Number of Participants Whose Frequency of Sexual Activity is Never or Rarely Limited by Genital Psoriasis, Utilizing the Genital Psoriasis Sexual Frequency Questionnaire (SFQ) Item 2

|                 |                                                                                                                                                                                        |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Number of Participants Whose Frequency of Sexual Activity is Never or Rarely Limited by Genital Psoriasis, Utilizing the Genital Psoriasis Sexual Frequency Questionnaire (SFQ) Item 2 |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### End point description:

The SFQ is a participant reported outcome measure to evaluate the impact of genital psoriasis symptoms on sexual frequency. It consists of 2 items that assess the impact of genital psoriasis symptoms on the frequency of sexual activity. Respondents were asked to answer the questions based on their psoriasis symptoms in the genital area. Item 2 assesses how often genital psoriasis symptoms limited the frequency of sexual activity with the following response options: 0 = never, 1 = rarely, 2 = sometimes, 3 = often, 4 = always.

\*The SFQ is also referred to as the GenPs-SFQ (genital psoriasis sexual frequency questionnaire).

APD:All randomized participants with baseline GenPs-SFQ Item 2 Score >= 2.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Week 12              |           |

| End point values            | Placebo - Blinded Treatment | Ixekizumab 80mg Q2W - Blinded Treatment |  |  |
|-----------------------------|-----------------------------|-----------------------------------------|--|--|
| Subject group type          | Reporting group             | Reporting group                         |  |  |
| Number of subjects analysed | 42                          | 37                                      |  |  |
| Units: participants         | 9                           | 29                                      |  |  |

## Statistical analyses

| Statistical analysis title              | Statistical Analysis 1                                                |
|-----------------------------------------|-----------------------------------------------------------------------|
| Comparison groups                       | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis | 79                                                                    |
| Analysis specification                  | Pre-specified                                                         |
| Analysis type                           | superiority                                                           |
| P-value                                 | < 0.001                                                               |
| Method                                  | Regression, Logistic                                                  |
| Parameter estimate                      | Odds ratio (OR)                                                       |
| Point estimate                          | 13.57                                                                 |
| Confidence interval                     |                                                                       |
| level                                   | 95 %                                                                  |
| sides                                   | 2-sided                                                               |
| lower limit                             | 4.57                                                                  |
| upper limit                             | 40.29                                                                 |

## Secondary: Number of Participants whose Frequency of Avoiding Sexual Activity is Either Never or Rarely Limited by Genital Psoriasis in the Sexual Activity Avoidance Subscale Score of the Genital Psoriasis Sexual Impact Scale (GPSIS)

|                 |                                                                                                                                                                                                                                |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Number of Participants whose Frequency of Avoiding Sexual Activity is Either Never or Rarely Limited by Genital Psoriasis in the Sexual Activity Avoidance Subscale Score of the Genital Psoriasis Sexual Impact Scale (GPSIS) |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### End point description:

GPSIS is a participant reported outcome measure to evaluate the impact of genital psoriasis symptoms on sexual activity.

The GPSIS Sexual Activity Avoidance Subscale includes 2 items:

Item 1 asks whether the participant has been sexually active in the past week. (No due to other reasons = 1, No due to genital Ps = 5)

Item 2 asks how often the participant avoided sexual activity in the past week due to Genital Psoriasis. (Never = 1, rarely = 2, Sometimes = 3, Often = 4).

APD: All randomized participants with baseline GPSIS sexual activity avoidance subscale score  $\geq 3$ .

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

### End point timeframe:

Week 12

| End point values            | Placebo - Blinded Treatment | Ixekizumab 80mg Q2W - Blinded Treatment |  |  |
|-----------------------------|-----------------------------|-----------------------------------------|--|--|
| Subject group type          | Reporting group             | Reporting group                         |  |  |
| Number of subjects analysed | 35                          | 30                                      |  |  |
| Units: participants         | 9                           | 23                                      |  |  |

## Statistical analyses

| Statistical analysis title              | Statistical Analysis 1                                                |
|-----------------------------------------|-----------------------------------------------------------------------|
| Comparison groups                       | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis | 65                                                                    |
| Analysis specification                  | Pre-specified                                                         |
| Analysis type                           | superiority                                                           |
| P-value                                 | < 0.001                                                               |
| Method                                  | Regression, Logistic                                                  |
| Parameter estimate                      | Odds ratio (OR)                                                       |
| Point estimate                          | 9.84                                                                  |
| Confidence interval                     |                                                                       |
| level                                   | 95 %                                                                  |
| sides                                   | 2-sided                                                               |
| lower limit                             | 3.08                                                                  |
| upper limit                             | 31.4                                                                  |

## Secondary: Change from Baseline in Dermatology Life Quality Index (DLQI) Total Score

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Change from Baseline in Dermatology Life Quality Index (DLQI) Total Score |
| <p>End point description:</p> <p>DLQI is a simple, participant-administered, 10 question, validated, quality-of-life questionnaire that covers 6 domains: 1) Symptoms and feelings 2) Daily activities 3) Leisure 4) Work and school 5) Personal relationships 6) Treatment.</p> <p>Response categories include:</p> <p>0 = not at all; 1 = a little; 2 = a lot; 3 = very much; "not relevant" responses scored as "0" and total score range of 0 to 30; higher scores indicate poor quality of life.</p> <p>Least Square (LS) Mean was calculated using Mixed Model Repeated Measures (MMRM) model with treatment, baseline body surface area (BSA) category, baseline value, visit, treatment-by-visit, and baseline value-by-visit interactions as fixed effects.</p> <p>APD: All randomized participants with baseline and post baseline observation for DLQI.</p> |                                                                           |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Secondary                                                                 |
| <p>End point timeframe:</p> <p>Baseline, Week 12</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                           |

| <b>End point values</b>             | Placebo - Blinded Treatment | Ixekizumab 80mg Q2W - Blinded Treatment |  |  |
|-------------------------------------|-----------------------------|-----------------------------------------|--|--|
| Subject group type                  | Reporting group             | Reporting group                         |  |  |
| Number of subjects analysed         | 70                          | 74                                      |  |  |
| Units: units on a scale             |                             |                                         |  |  |
| least squares mean (standard error) | -1.4 (± 0.62)               | -9.7 (± 0.59)                           |  |  |

## Statistical analyses

| <b>Statistical analysis title</b>       | Statistical Analysis 1                                                |
|-----------------------------------------|-----------------------------------------------------------------------|
| Comparison groups                       | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis | 144                                                                   |
| Analysis specification                  | Pre-specified                                                         |
| Analysis type                           | superiority                                                           |
| P-value                                 | < 0.001                                                               |
| Method                                  | Mixed models analysis                                                 |
| Parameter estimate                      | Mean difference (final values)                                        |
| Point estimate                          | -8.4                                                                  |
| Confidence interval                     |                                                                       |
| level                                   | 95 %                                                                  |
| sides                                   | 2-sided                                                               |
| lower limit                             | -10.1                                                                 |
| upper limit                             | -6.7                                                                  |
| Variability estimate                    | Standard error of the mean                                            |
| Dispersion value                        | 0.86                                                                  |

## Secondary: Change from Baseline in Modified Genital Psoriasis Area and Severity Index (mGPASI) Score

|                 |                                                                                           |
|-----------------|-------------------------------------------------------------------------------------------|
| End point title | Change from Baseline in Modified Genital Psoriasis Area and Severity Index (mGPASI) Score |
|-----------------|-------------------------------------------------------------------------------------------|

### End point description:

mGPASI determines participants psoriasis severity in the genital region at a given time point yielding an overall score of 0 for no psoriasis to 72 for the most severe disease. scoring index incorporates the degree of erythema (or redness), induration (or thickness), and scaling) of the genital plaques as well as erosion, fissure, and/or ulcer as a product of the genital area involved. LS Mean was calculated using MMRM model with treatment, baseline BSA category, baseline value, visit, treatment-by-visit, and baseline value-by-visit interactions as fixed effects.

APD:All randomized participants with baseline and post baseline observation for mGPASI.

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

### End point timeframe:

Baseline, Week 12

| <b>End point values</b>             | Placebo - Blinded Treatment | Ixekizumab 80mg Q2W - Blinded Treatment |  |  |
|-------------------------------------|-----------------------------|-----------------------------------------|--|--|
| Subject group type                  | Reporting group             | Reporting group                         |  |  |
| Number of subjects analysed         | 73                          | 74                                      |  |  |
| Units: units on a scale             |                             |                                         |  |  |
| least squares mean (standard error) | -3.9 (± 1.56)               | -23.9 (± 1.48)                          |  |  |

## Statistical analyses

| <b>Statistical analysis title</b>       | Statistical Analysis 1                                                |
|-----------------------------------------|-----------------------------------------------------------------------|
| Comparison groups                       | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis | 147                                                                   |
| Analysis specification                  | Pre-specified                                                         |
| Analysis type                           | superiority                                                           |
| P-value                                 | < 0.001                                                               |
| Method                                  | Mixed models analysis                                                 |
| Parameter estimate                      | Mean difference (final values)                                        |
| Point estimate                          | -20                                                                   |
| Confidence interval                     |                                                                       |
| level                                   | 95 %                                                                  |
| sides                                   | 2-sided                                                               |
| lower limit                             | -24.3                                                                 |
| upper limit                             | -15.8                                                                 |
| Variability estimate                    | Standard error of the mean                                            |
| Dispersion value                        | 2.15                                                                  |

## Secondary: Number of Participants with at least a 2-Point Change in Patient's Global Assessment of Genital Psoriasis (PatGA-Genital)

|                                                                                                                                                                                                                                                                                                                  |                                                                                                                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                  | Number of Participants with at least a 2-Point Change in Patient's Global Assessment of Genital Psoriasis (PatGA-Genital) |
| End point description:                                                                                                                                                                                                                                                                                           |                                                                                                                           |
| Patient's Global Assessment of Genital Psoriasis (PatGA-Genital) is a participant-administered, single-item scale on which participants are asked to rank the severity of their genital psoriasis "today" by circling a number on a 0 to 5 NRS, as follows: from 0 (clear), no genital psoriasis; to 5 (severe). |                                                                                                                           |
| APD: All randomized participants with baseline PatGA-Genital score $\geq 2$ .                                                                                                                                                                                                                                    |                                                                                                                           |
| End point type                                                                                                                                                                                                                                                                                                   | Secondary                                                                                                                 |
| End point timeframe:                                                                                                                                                                                                                                                                                             |                                                                                                                           |
| Week 12                                                                                                                                                                                                                                                                                                          |                                                                                                                           |

| End point values            | Placebo - Blinded Treatment | Ixekizumab 80mg Q2W - Blinded Treatment |  |  |
|-----------------------------|-----------------------------|-----------------------------------------|--|--|
| Subject group type          | Reporting group             | Reporting group                         |  |  |
| Number of subjects analysed | 73                          | 72                                      |  |  |
| Units: participants         | 11                          | 51                                      |  |  |

## Statistical analyses

| Statistical analysis title              | Statistical Analysis 1                                                |
|-----------------------------------------|-----------------------------------------------------------------------|
| Comparison groups                       | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis | 145                                                                   |
| Analysis specification                  | Pre-specified                                                         |
| Analysis type                           | superiority                                                           |
| P-value                                 | < 0.001                                                               |
| Method                                  | Regression, Logistic                                                  |
| Parameter estimate                      | Odds ratio (OR)                                                       |
| Point estimate                          | 13.95                                                                 |
| Confidence interval                     |                                                                       |
| level                                   | 95 %                                                                  |
| sides                                   | 2-sided                                                               |
| lower limit                             | 6.12                                                                  |
| upper limit                             | 31.8                                                                  |

## Secondary: Change from Baseline on the Short-Form Health Survey (SF-36) Physical Component Summary (PCS)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Change from Baseline on the Short-Form Health Survey (SF-36) Physical Component Summary (PCS) |
| End point description:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                               |
| <p>SF-36 is a participant-reported outcome measure evaluating a participant's health status. It comprises 36 items covering 8 domains: physical functioning, role physical, role emotional, bodily pain, vitality, social functioning, mental health, and general health. Items are answered on Likert scales of varying lengths. Items from 8 domains contribute to the PCS. The summary scores range from 0 to 100, with higher scores indicating better levels of function and/or better health.</p> <p>LS Mean was calculated using ANCOVA model with treatment, baseline BSA category, &amp; baseline value and mBOCF imputation method.</p> <p>All randomized participants with baseline and post baseline measurement for SF-36 PCS.</p> <p>mBOCF: Participants with or without post baseline measurement who discontinued treatment due to Adverse Event (AE) or death were imputed by their baseline observation , Participants who discontinued due to other reasons were imputed by their last observation.</p> |                                                                                               |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Secondary                                                                                     |
| End point timeframe:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                               |
| Baseline, Week 12                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                               |

| End point values                    | Placebo - Blinded Treatment | Ixekizumab 80mg Q2W - Blinded Treatment |  |  |
|-------------------------------------|-----------------------------|-----------------------------------------|--|--|
| Subject group type                  | Reporting group             | Reporting group                         |  |  |
| Number of subjects analysed         | 71                          | 72                                      |  |  |
| Units: units on a scale             |                             |                                         |  |  |
| least squares mean (standard error) | 0.687 ( $\pm$ 0.7998)       | 5.193 ( $\pm$ 0.7942)                   |  |  |

## Statistical analyses

| Statistical analysis title              | Statistical Analysis 1                                                |
|-----------------------------------------|-----------------------------------------------------------------------|
| Comparison groups                       | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis | 143                                                                   |
| Analysis specification                  | Pre-specified                                                         |
| Analysis type                           | superiority                                                           |
| P-value                                 | < 0.001                                                               |
| Method                                  | ANCOVA                                                                |
| Parameter estimate                      | Mean difference (final values)                                        |
| Point estimate                          | 4.506                                                                 |
| Confidence interval                     |                                                                       |
| level                                   | 95 %                                                                  |
| sides                                   | 2-sided                                                               |
| lower limit                             | 2.264                                                                 |
| upper limit                             | 6.748                                                                 |
| Variability estimate                    | Standard error of the mean                                            |
| Dispersion value                        | 1.1339                                                                |

## Secondary: Change from Baseline on the Short-Form Health Survey (SF-36) Mental Component Summary (MCS)

|                 |                                                                                             |
|-----------------|---------------------------------------------------------------------------------------------|
| End point title | Change from Baseline on the Short-Form Health Survey (SF-36) Mental Component Summary (MCS) |
|-----------------|---------------------------------------------------------------------------------------------|

### End point description:

SF-36 is a participant-reported outcome measure evaluating a participant's health status. It comprises 36 items covering 8 domains: physical functioning, role physical, role emotional, bodily pain, vitality, social functioning, mental health, and general health. Items are answered on Likert scales of varying lengths. Items from 8 domains contribute to the MCS. The summary scores range from 0 to 100, with higher scores indicating better levels of function and/or better health.

LS Mean was calculated using ANCOVA model with treatment, baseline BSA category, & baseline value and modified baseline observation carried forward (mBOCF) imputation method.

All randomized participants with baseline and post baseline measurement for SF-36 MCS.

mBOCF: Participants with or without post baseline measurement who discontinued treatment due to AE or death were imputed by their baseline observation, Participants who discontinued due to other reasons were imputed by their last observation.

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

### End point timeframe:

Baseline, Week 12

| <b>End point values</b>             | Placebo -<br>Blinded<br>Treatment | Ixekizumab<br>80mg Q2W -<br>Blinded<br>Treatment |  |  |
|-------------------------------------|-----------------------------------|--------------------------------------------------|--|--|
| Subject group type                  | Reporting group                   | Reporting group                                  |  |  |
| Number of subjects analysed         | 71                                | 72                                               |  |  |
| Units: units on a scale             |                                   |                                                  |  |  |
| least squares mean (standard error) | 2.186 ( $\pm$<br>0.7333)          | 3.982 ( $\pm$<br>0.7281)                         |  |  |

## Statistical analyses

| <b>Statistical analysis title</b>       | Statistical Analysis 1                                                |
|-----------------------------------------|-----------------------------------------------------------------------|
| Comparison groups                       | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis | 143                                                                   |
| Analysis specification                  | Pre-specified                                                         |
| Analysis type                           | superiority                                                           |
| P-value                                 | = 0.085                                                               |
| Method                                  | ANCOVA                                                                |
| Parameter estimate                      | Mean difference (final values)                                        |
| Point estimate                          | 1.797                                                                 |
| Confidence interval                     |                                                                       |
| level                                   | 95 %                                                                  |
| sides                                   | 2-sided                                                               |
| lower limit                             | -0.253                                                                |
| upper limit                             | 3.847                                                                 |
| Variability estimate                    | Standard error of the mean                                            |
| Dispersion value                        | 1.0367                                                                |

## Secondary: Change from Baseline in Genital Psoriasis Symptom Scale (GPSS) Total Score and Individual Items

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Change from Baseline in Genital Psoriasis Symptom Scale (GPSS) Total Score and Individual Items |
| <p>End point description:</p> <p>GPSS is a participant's-administered assessment of 8 symptoms: itch, pain, discomfort, stinging, burning, redness, scaling, and cracking. Each respondent was asked to answer the questions based on the psoriasis symptoms in his or her genital area. The overall severity for each individual genital psoriasis symptom is indicated by selecting the number from an Numeric Rating Scale (NRS) of 0 to 10 that best describes the worst level of each symptom in the genital area in the past 24 hours, where 0 (no severity) and 10 (worst imaginable severity). total score ranges from 0 (no severity) - 80 (worst imaginable severity)</p> <p>LS Mean was calculated using MMRM model with treatment, baseline BSA category, baseline value, visit, treatment-by-visit, and baseline value-by-visit interactions as fixed effects.</p> <p>APD:All randomized participants with baseline and post baseline observation for GPSS total or individual item scores.</p> |                                                                                                 |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Secondary                                                                                       |

End point timeframe:

Baseline, Week 12

| End point values                    | Placebo -<br>Blinded<br>Treatment | Ixekizumab<br>80mg Q2W -<br>Blinded<br>Treatment |  |  |
|-------------------------------------|-----------------------------------|--------------------------------------------------|--|--|
| Subject group type                  | Reporting group                   | Reporting group                                  |  |  |
| Number of subjects analysed         | 66                                | 69                                               |  |  |
| Units: units on a scale             |                                   |                                                  |  |  |
| least squares mean (standard error) |                                   |                                                  |  |  |
| Total Score                         | -2.82 (±<br>2.190)                | -31.57 (±<br>2.070)                              |  |  |
| Itch                                | -0.21 (±<br>0.290)                | -4.02 (±<br>0.274)                               |  |  |
| Pain                                | -0.34 (±<br>0.294)                | -3.84 (±<br>0.278)                               |  |  |
| Discomfort                          | -0.42 (±<br>0.298)                | -4.27 (±<br>0.282)                               |  |  |
| Stinging                            | -0.51 (±<br>0.298)                | -3.74 (±<br>0.281)                               |  |  |
| Burning                             | -0.53 (±<br>0.289)                | -3.73 (±<br>0.273)                               |  |  |
| Redness                             | -0.63 (±<br>0.287)                | -4.45 (±<br>0.272)                               |  |  |
| Scaling                             | -0.02 (±<br>0.273)                | -3.80 (±<br>0.259)                               |  |  |
| Cracking                            | -0.19 (±<br>0.280)                | -3.74 (±<br>0.264)                               |  |  |

## Statistical analyses

|                                         |                                                                       |
|-----------------------------------------|-----------------------------------------------------------------------|
| Statistical analysis title              | Statistical Analysis 1                                                |
| Statistical analysis description:       |                                                                       |
| Total Score                             |                                                                       |
| Comparison groups                       | Ixekizumab 80mg Q2W - Blinded Treatment v Placebo - Blinded Treatment |
| Number of subjects included in analysis | 135                                                                   |
| Analysis specification                  | Pre-specified                                                         |
| Analysis type                           | superiority                                                           |
| P-value                                 | < 0.001                                                               |
| Method                                  | Mixed models analysis                                                 |
| Parameter estimate                      | Mean difference (final values)                                        |
| Point estimate                          | -28.75                                                                |
| Confidence interval                     |                                                                       |
| level                                   | 95 %                                                                  |
| sides                                   | 2-sided                                                               |
| lower limit                             | -34.72                                                                |
| upper limit                             | -22.78                                                                |
| Variability estimate                    | Standard error of the mean                                            |
| Dispersion value                        | 3.015                                                                 |

|                                           |                                                                       |
|-------------------------------------------|-----------------------------------------------------------------------|
| <b>Statistical analysis title</b>         | Statistical Analysis 2                                                |
| Statistical analysis description:<br>Itch |                                                                       |
| Comparison groups                         | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis   | 135                                                                   |
| Analysis specification                    | Pre-specified                                                         |
| Analysis type                             | superiority                                                           |
| P-value                                   | < 0.001                                                               |
| Method                                    | Mixed models analysis                                                 |
| Parameter estimate                        | Mean difference (final values)                                        |
| Point estimate                            | -3.81                                                                 |
| Confidence interval                       |                                                                       |
| level                                     | 95 %                                                                  |
| sides                                     | 2-sided                                                               |
| lower limit                               | -4.6                                                                  |
| upper limit                               | -3.02                                                                 |
| Variability estimate                      | Standard error of the mean                                            |
| Dispersion value                          | 0.399                                                                 |

|                                           |                                                                       |
|-------------------------------------------|-----------------------------------------------------------------------|
| <b>Statistical analysis title</b>         | Statistical Analysis 3                                                |
| Statistical analysis description:<br>Pain |                                                                       |
| Comparison groups                         | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis   | 135                                                                   |
| Analysis specification                    | Pre-specified                                                         |
| Analysis type                             | superiority                                                           |
| P-value                                   | < 0.001                                                               |
| Method                                    | Mixed models analysis                                                 |
| Parameter estimate                        | Mean difference (final values)                                        |
| Point estimate                            | -3.5                                                                  |
| Confidence interval                       |                                                                       |
| level                                     | 95 %                                                                  |
| sides                                     | 2-sided                                                               |
| lower limit                               | -4.3                                                                  |
| upper limit                               | -2.7                                                                  |
| Variability estimate                      | Standard error of the mean                                            |
| Dispersion value                          | 0.405                                                                 |

|                                                 |                        |
|-------------------------------------------------|------------------------|
| <b>Statistical analysis title</b>               | Statistical Analysis 4 |
| Statistical analysis description:<br>Discomfort |                        |

|                                         |                                                                       |
|-----------------------------------------|-----------------------------------------------------------------------|
| Comparison groups                       | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis | 135                                                                   |
| Analysis specification                  | Pre-specified                                                         |
| Analysis type                           | superiority                                                           |
| P-value                                 | < 0.001                                                               |
| Method                                  | Mixed models analysis                                                 |
| Parameter estimate                      | Mean difference (final values)                                        |
| Point estimate                          | -3.85                                                                 |
| Confidence interval                     |                                                                       |
| level                                   | 95 %                                                                  |
| sides                                   | 2-sided                                                               |
| lower limit                             | -4.66                                                                 |
| upper limit                             | -3.04                                                                 |
| Variability estimate                    | Standard error of the mean                                            |
| Dispersion value                        | 0.41                                                                  |

|                                               |                                                                       |
|-----------------------------------------------|-----------------------------------------------------------------------|
| <b>Statistical analysis title</b>             | Statistical Analysis 5                                                |
| Statistical analysis description:<br>Stinging |                                                                       |
| Comparison groups                             | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis       | 135                                                                   |
| Analysis specification                        | Pre-specified                                                         |
| Analysis type                                 | superiority                                                           |
| P-value                                       | < 0.001                                                               |
| Method                                        | Mixed models analysis                                                 |
| Parameter estimate                            | Mean difference (final values)                                        |
| Point estimate                                | -3.23                                                                 |
| Confidence interval                           |                                                                       |
| level                                         | 95 %                                                                  |
| sides                                         | 2-sided                                                               |
| lower limit                                   | -4.04                                                                 |
| upper limit                                   | -2.42                                                                 |
| Variability estimate                          | Standard error of the mean                                            |
| Dispersion value                              | 0.41                                                                  |

|                                              |                                                                       |
|----------------------------------------------|-----------------------------------------------------------------------|
| <b>Statistical analysis title</b>            | Statistical Analysis 6                                                |
| Statistical analysis description:<br>Burning |                                                                       |
| Comparison groups                            | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |

|                                         |                                |
|-----------------------------------------|--------------------------------|
| Number of subjects included in analysis | 135                            |
| Analysis specification                  | Pre-specified                  |
| Analysis type                           | superiority                    |
| P-value                                 | < 0.001                        |
| Method                                  | Mixed models analysis          |
| Parameter estimate                      | Mean difference (final values) |
| Point estimate                          | -3.2                           |
| Confidence interval                     |                                |
| level                                   | 95 %                           |
| sides                                   | 2-sided                        |
| lower limit                             | -3.99                          |
| upper limit                             | -2.41                          |
| Variability estimate                    | Standard error of the mean     |
| Dispersion value                        | 0.397                          |

|                                         |                                                                       |
|-----------------------------------------|-----------------------------------------------------------------------|
| <b>Statistical analysis title</b>       | Statistical Analysis 7                                                |
| Statistical analysis description:       |                                                                       |
| Redness                                 |                                                                       |
| Comparison groups                       | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis | 135                                                                   |
| Analysis specification                  | Pre-specified                                                         |
| Analysis type                           | superiority                                                           |
| P-value                                 | < 0.001                                                               |
| Method                                  | Mixed models analysis                                                 |
| Parameter estimate                      | Mean difference (final values)                                        |
| Point estimate                          | -3.81                                                                 |
| Confidence interval                     |                                                                       |
| level                                   | 95 %                                                                  |
| sides                                   | 2-sided                                                               |
| lower limit                             | -4.59                                                                 |
| upper limit                             | -3.03                                                                 |
| Variability estimate                    | Standard error of the mean                                            |
| Dispersion value                        | 0.395                                                                 |

|                                         |                                                                       |
|-----------------------------------------|-----------------------------------------------------------------------|
| <b>Statistical analysis title</b>       | Statistical Analysis 8                                                |
| Statistical analysis description:       |                                                                       |
| Scaling                                 |                                                                       |
| Comparison groups                       | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis | 135                                                                   |
| Analysis specification                  | Pre-specified                                                         |
| Analysis type                           | superiority                                                           |
| P-value                                 | < 0.001                                                               |
| Method                                  | Mixed models analysis                                                 |
| Parameter estimate                      | Mean difference (final values)                                        |
| Point estimate                          | -3.78                                                                 |

|                      |                            |
|----------------------|----------------------------|
| Confidence interval  |                            |
| level                | 95 %                       |
| sides                | 2-sided                    |
| lower limit          | -4.53                      |
| upper limit          | -3.03                      |
| Variability estimate | Standard error of the mean |
| Dispersion value     | 0.377                      |

|                                   |                        |
|-----------------------------------|------------------------|
| <b>Statistical analysis title</b> | Statistical Analysis 9 |
|-----------------------------------|------------------------|

Statistical analysis description:

Cracking

|                                         |                                                                       |
|-----------------------------------------|-----------------------------------------------------------------------|
| Comparison groups                       | Placebo - Blinded Treatment v Ixekizumab 80mg Q2W - Blinded Treatment |
| Number of subjects included in analysis | 135                                                                   |
| Analysis specification                  | Pre-specified                                                         |
| Analysis type                           | superiority                                                           |
| P-value                                 | < 0.001                                                               |
| Method                                  | Mixed models analysis                                                 |
| Parameter estimate                      | Mean difference (final values)                                        |
| Point estimate                          | -3.55                                                                 |
| Confidence interval                     |                                                                       |
| level                                   | 95 %                                                                  |
| sides                                   | 2-sided                                                               |
| lower limit                             | -4.31                                                                 |
| upper limit                             | -2.79                                                                 |
| Variability estimate                    | Standard error of the mean                                            |
| Dispersion value                        | 0.385                                                                 |

### **Secondary: Number of Participants achieving sPGA of Genitalia (0,1) at Week 12 by Treatment-Emergent Anti-Drug Antibody (TE-ADA) status and by Neutralizing Antibody (NAb) status**

|                 |                                                                                                                                                                        |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Number of Participants achieving sPGA of Genitalia (0,1) at Week 12 by Treatment-Emergent Anti-Drug Antibody (TE-ADA) status and by Neutralizing Antibody (NAb) status |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

sPGA of Genitalia score is based on a combination of erythema and the secondary features (plaque elevation and/or scale). For the analysis of responses, the participant's psoriasis was assessed as follows: 0 = clear, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe, 5 = very severe.

sPGA of Genitalia (0,1) : A sPGA of Genitalia assessed as either 0 or 1.

Analysis Population Description (APD): All randomized participants who received at least one dose of study drug and either had baseline and at least 1 post-baseline evaluable samples or had no evaluable baseline and all negative post-baseline anti-drug antibody negative samples.

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

End point timeframe:

Week 12

| <b>End point values</b>     | Placebo -<br>Blinded<br>Treatment | Ixekizumab<br>80mg Q2W -<br>Blinded<br>Treatment |  |  |
|-----------------------------|-----------------------------------|--------------------------------------------------|--|--|
| Subject group type          | Reporting group                   | Reporting group                                  |  |  |
| Number of subjects analysed | 73 <sup>[1]</sup>                 | 75 <sup>[2]</sup>                                |  |  |
| Units: participants         |                                   |                                                  |  |  |
| TE-ADA positive             | 0                                 | 5                                                |  |  |
| TE-ADA negative             | 6                                 | 50                                               |  |  |
| NAb positive                | 0                                 | 0                                                |  |  |
| NAb negative                | 0                                 | 0                                                |  |  |
| NAb inconclusive            | 0                                 | 5                                                |  |  |

Notes:

[1] - Subjects analyzed (N): 0,73,0,0,0,0;

[2] - Subjects analyzed (N): 6,69,0,0,0,6;

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

I1F-MC-RHBQ

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 20.1 |
|--------------------|------|

### Reporting groups

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

Reporting group description: -

|                       |                  |
|-----------------------|------------------|
| Reporting group title | Ixekizumab 80Q2W |
|-----------------------|------------------|

Reporting group description: -

|                       |                          |
|-----------------------|--------------------------|
| Reporting group title | Placebo/Ixekizumab 80Q4W |
|-----------------------|--------------------------|

Reporting group description: -

|                       |                                   |
|-----------------------|-----------------------------------|
| Reporting group title | Ixekizumab 80Q2W/Ixekizumab 80Q4W |
|-----------------------|-----------------------------------|

Reporting group description: -

|                       |                                  |
|-----------------------|----------------------------------|
| Reporting group title | Placebo Post-Treatment Follow-up |
|-----------------------|----------------------------------|

Reporting group description: -

|                       |                                           |
|-----------------------|-------------------------------------------|
| Reporting group title | Ixekizumab 80Q2W Post-Treatment Follow-up |
|-----------------------|-------------------------------------------|

Reporting group description: -

|                       |                                           |
|-----------------------|-------------------------------------------|
| Reporting group title | Ixekizumab 80Q4W Post-Treatment Follow-up |
|-----------------------|-------------------------------------------|

Reporting group description: -

| Serious adverse events                            | Placebo        | Ixekizumab 80Q2W | Placebo/Ixekizumab 80Q4W |
|---------------------------------------------------|----------------|------------------|--------------------------|
| Total subjects affected by serious adverse events |                |                  |                          |
| subjects affected / exposed                       | 1 / 74 (1.35%) | 0 / 75 (0.00%)   | 2 / 65 (3.08%)           |
| number of deaths (all causes)                     | 0              | 0                | 0                        |
| number of deaths resulting from adverse events    | 0              | 0                | 0                        |
| Injury, poisoning and procedural complications    |                |                  |                          |
| extradural haematoma                              |                |                  |                          |
| alternative dictionary used: MedDRA 20.1          |                |                  |                          |
| subjects affected / exposed                       | 0 / 74 (0.00%) | 0 / 75 (0.00%)   | 1 / 65 (1.54%)           |
| occurrences causally related to treatment / all   | 0 / 0          | 0 / 0            | 0 / 1                    |
| deaths causally related to treatment / all        | 0 / 0          | 0 / 0            | 0 / 0                    |
| Vascular disorders                                |                |                  |                          |
| peripheral ischaemia                              |                |                  |                          |
| alternative dictionary used: MedDRA 20.1          |                |                  |                          |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 74 (0.00%) | 0 / 75 (0.00%) | 0 / 65 (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          |
| Reproductive system and breast disorders        |                |                |                |
| benign prostatic hyperplasia                    |                |                |                |
| alternative dictionary used: MedDRA 20.1        |                |                |                |
| subjects affected / exposed <sup>[1]</sup>      | 0 / 74 (0.00%) | 0 / 75 (0.00%) | 0 / 49 (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          |
| Gastrointestinal disorders                      |                |                |                |
| colitis                                         |                |                |                |
| alternative dictionary used: MedDRA 20.1        |                |                |                |
| subjects affected / exposed                     | 0 / 74 (0.00%) | 0 / 75 (0.00%) | 0 / 65 (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          |
| pancreatitis acute                              |                |                |                |
| alternative dictionary used: MedDRA 20.1        |                |                |                |
| subjects affected / exposed                     | 1 / 74 (1.35%) | 0 / 75 (0.00%) | 0 / 65 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hepatobiliary disorders                         |                |                |                |
| cholelithiasis                                  |                |                |                |
| alternative dictionary used: MedDRA 20.1        |                |                |                |
| subjects affected / exposed                     | 0 / 74 (0.00%) | 0 / 75 (0.00%) | 0 / 65 (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          |
| Psychiatric disorders                           |                |                |                |
| depression                                      |                |                |                |
| alternative dictionary used: MedDRA 20.1        |                |                |                |
| subjects affected / exposed                     | 0 / 74 (0.00%) | 0 / 75 (0.00%) | 0 / 65 (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          |
| suicide attempt                                 |                |                |                |
| alternative dictionary used: MedDRA 20.1        |                |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 74 (0.00%) | 0 / 75 (0.00%) | 0 / 65 (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          |
| Renal and urinary disorders                     |                |                |                |
| ureterolithiasis                                |                |                |                |
| alternative dictionary used: MedDRA 20.1        |                |                |                |
| subjects affected / exposed                     | 0 / 74 (0.00%) | 0 / 75 (0.00%) | 0 / 65 (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          |
| Infections and infestations                     |                |                |                |
| appendicitis                                    |                |                |                |
| alternative dictionary used: MedDRA 20.1        |                |                |                |
| subjects affected / exposed                     | 0 / 74 (0.00%) | 0 / 75 (0.00%) | 0 / 65 (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          |
| cellulitis                                      |                |                |                |
| alternative dictionary used: MedDRA 20.1        |                |                |                |
| subjects affected / exposed                     | 0 / 74 (0.00%) | 0 / 75 (0.00%) | 1 / 65 (1.54%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| escherichia bacteraemia                         |                |                |                |
| alternative dictionary used: MedDRA 20.1        |                |                |                |
| subjects affected / exposed                     | 0 / 74 (0.00%) | 0 / 75 (0.00%) | 0 / 65 (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          |
| sepsis                                          |                |                |                |
| alternative dictionary used: MedDRA 20.1        |                |                |                |
| subjects affected / exposed                     | 0 / 74 (0.00%) | 0 / 75 (0.00%) | 0 / 65 (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          |

|                                                   |                                   |                                  |                                           |
|---------------------------------------------------|-----------------------------------|----------------------------------|-------------------------------------------|
| <b>Serious adverse events</b>                     | Ixekizumab 80Q2W/Ixekizumab 80Q4W | Placebo Post-Treatment Follow-up | Ixekizumab 80Q2W Post-Treatment Follow-up |
| Total subjects affected by serious adverse events |                                   |                                  |                                           |

|                                                 |                |               |                |
|-------------------------------------------------|----------------|---------------|----------------|
| subjects affected / exposed                     | 5 / 74 (6.76%) | 0 / 1 (0.00%) | 2 / 49 (4.08%) |
| number of deaths (all causes)                   | 0              | 0             | 0              |
| number of deaths resulting from adverse events  | 0              | 0             | 0              |
| Injury, poisoning and procedural complications  |                |               |                |
| extradural haematoma                            |                |               |                |
| alternative dictionary used: MedDRA 20.1        |                |               |                |
| subjects affected / exposed                     | 0 / 74 (0.00%) | 0 / 1 (0.00%) | 0 / 49 (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          |
| Vascular disorders                              |                |               |                |
| peripheral ischaemia                            |                |               |                |
| alternative dictionary used: MedDRA 20.1        |                |               |                |
| subjects affected / exposed                     | 1 / 74 (1.35%) | 0 / 1 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Reproductive system and breast disorders        |                |               |                |
| benign prostatic hyperplasia                    |                |               |                |
| alternative dictionary used: MedDRA 20.1        |                |               |                |
| subjects affected / exposed <sup>[1]</sup>      | 1 / 56 (1.79%) | 0 / 1 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Gastrointestinal disorders                      |                |               |                |
| colitis                                         |                |               |                |
| alternative dictionary used: MedDRA 20.1        |                |               |                |
| subjects affected / exposed                     | 1 / 74 (1.35%) | 0 / 1 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| pancreatitis acute                              |                |               |                |
| alternative dictionary used: MedDRA 20.1        |                |               |                |
| subjects affected / exposed                     | 0 / 74 (0.00%) | 0 / 1 (0.00%) | 0 / 49 (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          |
| Hepatobiliary disorders                         |                |               |                |
| cholelithiasis                                  |                |               |                |
| alternative dictionary used: MedDRA 20.1        |                |               |                |

|                                                 |                |               |                |
|-------------------------------------------------|----------------|---------------|----------------|
| subjects affected / exposed                     | 1 / 74 (1.35%) | 0 / 1 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Psychiatric disorders                           |                |               |                |
| depression                                      |                |               |                |
| alternative dictionary used: MedDRA 20.1        |                |               |                |
| subjects affected / exposed                     | 0 / 74 (0.00%) | 0 / 1 (0.00%) | 0 / 49 (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          |
| suicide attempt                                 |                |               |                |
| alternative dictionary used: MedDRA 20.1        |                |               |                |
| subjects affected / exposed                     | 1 / 74 (1.35%) | 0 / 1 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Renal and urinary disorders                     |                |               |                |
| ureterolithiasis                                |                |               |                |
| alternative dictionary used: MedDRA 20.1        |                |               |                |
| subjects affected / exposed                     | 1 / 74 (1.35%) | 0 / 1 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Infections and infestations                     |                |               |                |
| appendicitis                                    |                |               |                |
| alternative dictionary used: MedDRA 20.1        |                |               |                |
| subjects affected / exposed                     | 0 / 74 (0.00%) | 0 / 1 (0.00%) | 1 / 49 (2.04%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| cellulitis                                      |                |               |                |
| alternative dictionary used: MedDRA 20.1        |                |               |                |
| subjects affected / exposed                     | 0 / 74 (0.00%) | 0 / 1 (0.00%) | 1 / 49 (2.04%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| escherichia bacteraemia                         |                |               |                |
| alternative dictionary used: MedDRA 20.1        |                |               |                |

|                                                 |                |               |                |
|-------------------------------------------------|----------------|---------------|----------------|
| subjects affected / exposed                     | 1 / 74 (1.35%) | 0 / 1 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| sepsis                                          |                |               |                |
| alternative dictionary used: MedDRA 20.1        |                |               |                |
| subjects affected / exposed                     | 1 / 74 (1.35%) | 0 / 1 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |

|                                                   |                                                 |  |  |
|---------------------------------------------------|-------------------------------------------------|--|--|
| <b>Serious adverse events</b>                     | Ixekizumab 80Q4W<br>Post-Treatment<br>Follow-up |  |  |
| Total subjects affected by serious adverse events |                                                 |  |  |
| subjects affected / exposed                       | 1 / 78 (1.28%)                                  |  |  |
| number of deaths (all causes)                     | 0                                               |  |  |
| number of deaths resulting from adverse events    | 0                                               |  |  |
| Injury, poisoning and procedural complications    |                                                 |  |  |
| extradural haematoma                              |                                                 |  |  |
| alternative dictionary used: MedDRA 20.1          |                                                 |  |  |
| subjects affected / exposed                       | 0 / 78 (0.00%)                                  |  |  |
| occurrences causally related to treatment / all   | 0 / 0                                           |  |  |
| deaths causally related to treatment / all        | 0 / 0                                           |  |  |
| Vascular disorders                                |                                                 |  |  |
| peripheral ischaemia                              |                                                 |  |  |
| alternative dictionary used: MedDRA 20.1          |                                                 |  |  |
| subjects affected / exposed                       | 0 / 78 (0.00%)                                  |  |  |
| occurrences causally related to treatment / all   | 0 / 0                                           |  |  |
| deaths causally related to treatment / all        | 0 / 0                                           |  |  |
| Reproductive system and breast disorders          |                                                 |  |  |
| benign prostatic hyperplasia                      |                                                 |  |  |
| alternative dictionary used: MedDRA 20.1          |                                                 |  |  |
| subjects affected / exposed <sup>[1]</sup>        | 0 / 78 (0.00%)                                  |  |  |
| occurrences causally related to treatment / all   | 0 / 0                                           |  |  |
| deaths causally related to treatment / all        | 0 / 0                                           |  |  |
| Gastrointestinal disorders                        |                                                 |  |  |

|                                                    |                |  |  |
|----------------------------------------------------|----------------|--|--|
| colitis                                            |                |  |  |
| alternative dictionary used:<br>MedDRA 20.1        |                |  |  |
| subjects affected / exposed                        | 0 / 78 (0.00%) |  |  |
| occurrences causally related to<br>treatment / all | 0 / 0          |  |  |
| deaths causally related to<br>treatment / all      | 0 / 0          |  |  |
| pancreatitis acute                                 |                |  |  |
| alternative dictionary used:<br>MedDRA 20.1        |                |  |  |
| subjects affected / exposed                        | 0 / 78 (0.00%) |  |  |
| occurrences causally related to<br>treatment / all | 0 / 0          |  |  |
| deaths causally related to<br>treatment / all      | 0 / 0          |  |  |
| Hepatobiliary disorders                            |                |  |  |
| cholelithiasis                                     |                |  |  |
| alternative dictionary used:<br>MedDRA 20.1        |                |  |  |
| subjects affected / exposed                        | 0 / 78 (0.00%) |  |  |
| occurrences causally related to<br>treatment / all | 0 / 0          |  |  |
| deaths causally related to<br>treatment / all      | 0 / 0          |  |  |
| Psychiatric disorders                              |                |  |  |
| depression                                         |                |  |  |
| alternative dictionary used:<br>MedDRA 20.1        |                |  |  |
| subjects affected / exposed                        | 1 / 78 (1.28%) |  |  |
| occurrences causally related to<br>treatment / all | 0 / 1          |  |  |
| deaths causally related to<br>treatment / all      | 0 / 0          |  |  |
| suicide attempt                                    |                |  |  |
| alternative dictionary used:<br>MedDRA 20.1        |                |  |  |
| subjects affected / exposed                        | 0 / 78 (0.00%) |  |  |
| occurrences causally related to<br>treatment / all | 0 / 0          |  |  |
| deaths causally related to<br>treatment / all      | 0 / 0          |  |  |
| Renal and urinary disorders                        |                |  |  |
| ureterolithiasis                                   |                |  |  |
| alternative dictionary used:<br>MedDRA 20.1        |                |  |  |
| subjects affected / exposed                        | 0 / 78 (0.00%) |  |  |
| occurrences causally related to<br>treatment / all | 0 / 0          |  |  |
| deaths causally related to<br>treatment / all      | 0 / 0          |  |  |
| Infections and infestations                        |                |  |  |

|                                                                                                                                                                                                              |                                          |  |  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--|--|
| appendicitis<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all            | <br><br>0 / 78 (0.00%)<br>0 / 0<br>0 / 0 |  |  |
| cellulitis<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all              | <br><br>0 / 78 (0.00%)<br>0 / 0<br>0 / 0 |  |  |
| escherichia bacteraemia<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all | <br><br>0 / 78 (0.00%)<br>0 / 0<br>0 / 0 |  |  |
| sepsis<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all                  | <br><br>0 / 78 (0.00%)<br>0 / 0<br>0 / 0 |  |  |

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: Gender based adverse event; Analyzed in female subjects.

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

| <b>Non-serious adverse events</b>                     | Placebo          | Ixekizumab 80Q2W | Placebo/Ixekizumab 80Q4W |
|-------------------------------------------------------|------------------|------------------|--------------------------|
| Total subjects affected by non-serious adverse events |                  |                  |                          |
| subjects affected / exposed                           | 19 / 74 (25.68%) | 21 / 75 (28.00%) | 28 / 65 (43.08%)         |
| Nervous system disorders                              |                  |                  |                          |
| headache                                              |                  |                  |                          |
| alternative dictionary used:<br>MedDRA 20.1           |                  |                  |                          |
| subjects affected / exposed                           | 4 / 74 (5.41%)   | 3 / 75 (4.00%)   | 2 / 65 (3.08%)           |
| occurrences (all)                                     | 6                | 3                | 2                        |
| General disorders and administration site conditions  |                  |                  |                          |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                   |                                                                                   |                                                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| injection site reaction<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                | 0 / 74 (0.00%)<br>0                                                               | 5 / 75 (6.67%)<br>7                                                               | 10 / 65 (15.38%)<br>24                                                            |
| Gastrointestinal disorders<br>diarrhoea<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                | 4 / 74 (5.41%)<br>4                                                               | 1 / 75 (1.33%)<br>2                                                               | 0 / 65 (0.00%)<br>0                                                               |
| Reproductive system and breast disorders<br>dysmenorrhoea<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed <sup>[2]</sup><br>occurrences (all)<br><br>vaginal haemorrhage<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed <sup>[3]</sup><br>occurrences (all)<br><br>vulvovaginal discomfort<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed <sup>[4]</sup><br>occurrences (all) | 0 / 74 (0.00%)<br>0<br><br><br>0 / 74 (0.00%)<br>0<br><br><br>0 / 74 (0.00%)<br>0 | 0 / 75 (0.00%)<br>0<br><br><br>0 / 75 (0.00%)<br>0<br><br><br>0 / 75 (0.00%)<br>0 | 0 / 16 (0.00%)<br>0<br><br><br>0 / 16 (0.00%)<br>0<br><br><br>0 / 65 (0.00%)<br>0 |
| Skin and subcutaneous tissue disorders<br>psoriasis<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                    | 4 / 74 (5.41%)<br>4                                                               | 1 / 75 (1.33%)<br>1                                                               | 0 / 65 (0.00%)<br>0                                                               |
| Musculoskeletal and connective tissue disorders<br>arthralgia<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                          | 0 / 74 (0.00%)<br>0                                                               | 0 / 75 (0.00%)<br>0                                                               | 0 / 65 (0.00%)<br>0                                                               |
| Infections and infestations<br>bacterial vaginosis<br>alternative dictionary used:<br>MedDRA 20.1                                                                                                                                                                                                                                                                                                                                                                         |                                                                                   |                                                                                   |                                                                                   |

|                                             |                |                  |                  |
|---------------------------------------------|----------------|------------------|------------------|
| subjects affected / exposed <sup>[5]</sup>  | 0 / 74 (0.00%) | 0 / 75 (0.00%)   | 0 / 16 (0.00%)   |
| occurrences (all)                           | 0              | 0                | 0                |
| nasopharyngitis                             |                |                  |                  |
| alternative dictionary used:<br>MedDRA 20.1 |                |                  |                  |
| subjects affected / exposed                 | 4 / 74 (5.41%) | 2 / 75 (2.67%)   | 9 / 65 (13.85%)  |
| occurrences (all)                           | 4              | 2                | 13               |
| upper respiratory tract infection           |                |                  |                  |
| alternative dictionary used:<br>MedDRA 20.1 |                |                  |                  |
| subjects affected / exposed                 | 5 / 74 (6.76%) | 12 / 75 (16.00%) | 10 / 65 (15.38%) |
| occurrences (all)                           | 5              | 12               | 12               |
| urinary tract infection                     |                |                  |                  |
| alternative dictionary used:<br>MedDRA 20.1 |                |                  |                  |
| subjects affected / exposed                 | 0 / 74 (0.00%) | 0 / 75 (0.00%)   | 2 / 65 (3.08%)   |
| occurrences (all)                           | 0              | 0                | 2                |
| vulvovaginal candidiasis                    |                |                  |                  |
| alternative dictionary used:<br>MedDRA 20.1 |                |                  |                  |
| subjects affected / exposed <sup>[6]</sup>  | 0 / 74 (0.00%) | 0 / 75 (0.00%)   | 1 / 16 (6.25%)   |
| occurrences (all)                           | 0              | 0                | 2                |
| vulvovaginal mycotic infection              |                |                  |                  |
| alternative dictionary used:<br>MedDRA 20.1 |                |                  |                  |
| subjects affected / exposed <sup>[7]</sup>  | 0 / 74 (0.00%) | 0 / 75 (0.00%)   | 0 / 16 (0.00%)   |
| occurrences (all)                           | 0              | 0                | 0                |

| <b>Non-serious adverse events</b>                        | Ixekizumab<br>80Q2W/Ixekizumab<br>80Q4W | Placebo Post-<br>Treatment Follow-up | Ixekizumab 80Q2W<br>Post-Treatment<br>Follow-up |
|----------------------------------------------------------|-----------------------------------------|--------------------------------------|-------------------------------------------------|
| Total subjects affected by non-serious<br>adverse events |                                         |                                      |                                                 |
| subjects affected / exposed                              | 27 / 74 (36.49%)                        | 0 / 1 (0.00%)                        | 1 / 49 (2.04%)                                  |
| Nervous system disorders                                 |                                         |                                      |                                                 |
| headache                                                 |                                         |                                      |                                                 |
| alternative dictionary used:<br>MedDRA 20.1              |                                         |                                      |                                                 |
| subjects affected / exposed                              | 6 / 74 (8.11%)                          | 0 / 1 (0.00%)                        | 0 / 49 (0.00%)                                  |
| occurrences (all)                                        | 6                                       | 0                                    | 0                                               |
| General disorders and administration<br>site conditions  |                                         |                                      |                                                 |
| injection site reaction                                  |                                         |                                      |                                                 |
| alternative dictionary used:<br>MedDRA 20.1              |                                         |                                      |                                                 |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                           |                                                                        |                                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|------------------------------------------------------------------------|---------------------------------------------------------------------------|
| subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                                                                                          | 3 / 74 (4.05%)<br>6                                                       | 0 / 1 (0.00%)<br>0                                                     | 0 / 49 (0.00%)<br>0                                                       |
| Gastrointestinal disorders<br>diarrhoea<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                | 0 / 74 (0.00%)<br>0                                                       | 0 / 1 (0.00%)<br>0                                                     | 0 / 49 (0.00%)<br>0                                                       |
| Reproductive system and breast disorders<br>dysmenorrhoea<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed <sup>[2]</sup><br>occurrences (all)<br><br>vaginal haemorrhage<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed <sup>[3]</sup><br>occurrences (all)<br><br>vulvovaginal discomfort<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed <sup>[4]</sup><br>occurrences (all) | 1 / 18 (5.56%)<br>1<br><br>1 / 18 (5.56%)<br>1<br><br>0 / 74 (0.00%)<br>0 | 0 / 1 (0.00%)<br>0<br><br>0 / 1 (0.00%)<br>0<br><br>0 / 1 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0<br><br>0 / 49 (0.00%)<br>0<br><br>1 / 11 (9.09%)<br>1 |
| Skin and subcutaneous tissue disorders<br>psoriasis<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                    | 0 / 74 (0.00%)<br>0                                                       | 0 / 1 (0.00%)<br>0                                                     | 0 / 49 (0.00%)<br>0                                                       |
| Musculoskeletal and connective tissue disorders<br>arthralgia<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                          | 5 / 74 (6.76%)<br>5                                                       | 0 / 1 (0.00%)<br>0                                                     | 0 / 49 (0.00%)<br>0                                                       |
| Infections and infestations<br>bacterial vaginosis<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed <sup>[5]</sup><br>occurrences (all)                                                                                                                                                                                                                                                                                                      | 1 / 18 (5.56%)<br>1                                                       | 0 / 1 (0.00%)<br>0                                                     | 0 / 49 (0.00%)<br>0                                                       |

|                                                                                                                                                  |                     |                    |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|---------------------|
| nasopharyngitis<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences (all)                               | 7 / 74 (9.46%)<br>8 | 0 / 1 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| upper respiratory tract infection<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences (all)             | 6 / 74 (8.11%)<br>6 | 0 / 1 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| urinary tract infection<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences (all)                       | 4 / 74 (5.41%)<br>4 | 0 / 1 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| vulvovaginal candidiasis<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed <sup>[6]</sup><br>occurrences (all)       | 0 / 18 (0.00%)<br>0 | 0 / 1 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| vulvovaginal mycotic infection<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed <sup>[7]</sup><br>occurrences (all) | 1 / 18 (5.56%)<br>1 | 0 / 1 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |

|                                                                                                                                                                                       |                                                 |  |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|--|--|
| <b>Non-serious adverse events</b>                                                                                                                                                     | Ixekizumab 80Q4W<br>Post-Treatment<br>Follow-up |  |  |
| Total subjects affected by non-serious<br>adverse events<br>subjects affected / exposed                                                                                               | 0 / 78 (0.00%)                                  |  |  |
| Nervous system disorders<br>headache<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences (all)                                               | 0 / 78 (0.00%)<br>0                             |  |  |
| General disorders and administration<br>site conditions<br>injection site reaction<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences (all) | 0 / 78 (0.00%)<br>0                             |  |  |
| Gastrointestinal disorders                                                                                                                                                            |                                                 |  |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                           |  |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|--|--|
| diarrhoea<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                              | 0 / 78 (0.00%)<br>0                                                       |  |  |
| Reproductive system and breast disorders<br>dysmenorrhoea<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed <sup>[2]</sup><br>occurrences (all)<br><br>vaginal haemorrhage<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed <sup>[3]</sup><br>occurrences (all)<br><br>vulvovaginal discomfort<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed <sup>[4]</sup><br>occurrences (all) | 0 / 78 (0.00%)<br>0<br><br>0 / 78 (0.00%)<br>0<br><br>0 / 21 (0.00%)<br>0 |  |  |
| Skin and subcutaneous tissue disorders<br>psoriasis<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                    | 0 / 78 (0.00%)<br>0                                                       |  |  |
| Musculoskeletal and connective tissue disorders<br>arthralgia<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                          | 0 / 78 (0.00%)<br>0                                                       |  |  |
| Infections and infestations<br>bacterial vaginosis<br>alternative dictionary used:<br>MedDRA 20.1<br>subjects affected / exposed <sup>[5]</sup><br>occurrences (all)<br><br>nasopharyngitis<br>alternative dictionary used:<br>MedDRA 20.1                                                                                                                                                                                                                                | 0 / 78 (0.00%)<br>0                                                       |  |  |

|                                             |                |  |  |
|---------------------------------------------|----------------|--|--|
| subjects affected / exposed                 | 0 / 78 (0.00%) |  |  |
| occurrences (all)                           | 0              |  |  |
| upper respiratory tract infection           |                |  |  |
| alternative dictionary used:<br>MedDRA 20.1 |                |  |  |
| subjects affected / exposed                 | 0 / 78 (0.00%) |  |  |
| occurrences (all)                           | 0              |  |  |
| urinary tract infection                     |                |  |  |
| alternative dictionary used:<br>MedDRA 20.1 |                |  |  |
| subjects affected / exposed                 | 0 / 78 (0.00%) |  |  |
| occurrences (all)                           | 0              |  |  |
| vulvovaginal candidiasis                    |                |  |  |
| alternative dictionary used:<br>MedDRA 20.1 |                |  |  |
| subjects affected / exposed <sup>[6]</sup>  | 0 / 78 (0.00%) |  |  |
| occurrences (all)                           | 0              |  |  |
| vulvovaginal mycotic infection              |                |  |  |
| alternative dictionary used:<br>MedDRA 20.1 |                |  |  |
| subjects affected / exposed <sup>[7]</sup>  | 0 / 78 (0.00%) |  |  |
| occurrences (all)                           | 0              |  |  |

Notes:

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender based adverse event; Analyzed in female subjects.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender based adverse event; Analyzed in female subjects.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender based adverse event; Analyzed in female subjects.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender based adverse event; Analyzed in female subjects.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender based adverse event; Analyzed in female subjects.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender based adverse event; Analyzed in female subjects.

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 22 January 2016  | Columbia–Suicide Severity Rating Scale definition was added.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 22 November 2016 | SFQ Item 2 was added into the "Major Secondary Endpoint.<br>GPSS Individual items modified to include itch.<br>Addition of sentence "For patients who have entered Period 4, psoriasis therapy is allowed, as determined appropriate by the investigator." in post treatment follow-up phase.<br>Genital Psoriasis Symptoms Scale, text to define the GPSS total and item scores at Week 12 (Visit 7) was added.<br>Genital Psoriasis Sexual Impact Scale, the Sexual Activity Avoidance Subscale scoring of the GPSIS was updated.<br>Sexual Frequency Questionnaire, text was added to define SFQ Item 2 score at Week 12.<br>Adverse Events of Special interest, text was added to include inflammatory bowel disease (IBD). |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported