



## Clinical trial results:

**A randomised, double-blind, placebo-controlled, parallel-group, dose-range trial to investigate the efficacy and safety of FE 999302 as add-on treatment to follitropin delta (REKOVELLE) in women undergoing controlled ovarian stimulation in a long GnRH agonist protocol**

### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2017-003810-13 |
| Trial protocol           | CZ DK BE GB ES |
| Global end of trial date |                |

### Results information

|                                |                 |
|--------------------------------|-----------------|
| Result version number          | v1 (current)    |
| This version publication date  | 07 January 2021 |
| First version publication date | 07 January 2021 |

### Trial information

#### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | 000289 |
|-----------------------|--------|

#### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT03564509 |
| WHO universal trial number (UTN)   | -           |

Notes:

### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Ferring Pharmaceuticals A/S   |
| Sponsor organisation address | International PharmaScience Center, Kay Fiskers Plads 11, Copenhagen S, Denmark, 2300 |
| Public contact               | Global Clinical Compliance, Ferring Pharmaceuticals, DK0-Disclosure@ferring.com       |
| Scientific contact           | Global Clinical Compliance, Ferring Pharmaceuticals, DK0-Disclosure@ferring.com       |

Notes:

### Paediatric regulatory details

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

Notes:

## Results analysis stage

|  |                 |
|--|-----------------|
| Analysis stage                                       | Interim         |
| Date of interim/final analysis                       | 30 January 2020 |
| Is this the analysis of the primary completion data? | Yes             |
| Primary completion date                              | 21 October 2019 |
| Global end of trial reached?                         | No              |

Notes:

## General information about the trial

Main objective of the trial:

To investigate the effects of FE 999302 on parameters influencing pregnancy rates in women undergoing Controlled Ovarian Stimulation (COS) with follitropin delta in a long gonadotropin releasing hormone (GnRH) agonist protocol.

Protection of trial subjects:

The trial was performed in accordance with the version of Declaration of Helsinki in force at the initiation of the trial. The trial was performed in compliance with International Council for Harmonisation Good Clinical Practice (ICH GCP).

Background therapy: -

Evidence for comparator: -

|   |             |
|---|-------------|
| Actual start date of recruitment                          | 14 May 2018 |
| Long term follow-up planned                               | No          |
| Independent data monitoring committee (IDMC) involvement? | Yes         |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                    |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | United Kingdom: 60 |
| Country: Number of subjects enrolled | Spain: 297         |
| Country: Number of subjects enrolled | Belgium: 34        |
| Country: Number of subjects enrolled | Czechia: 170       |
| Country: Number of subjects enrolled | Denmark: 59        |
| Worldwide total number of subjects   | 620                |
| EEA total number of subjects         | 620                |

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)                      | 620 |
| From 65 to 84 years                       | 0   |

|                   |   |
|-------------------|---|
| 85 years and over | 0 |
|-------------------|---|

## Subject disposition

### Recruitment

Recruitment details:

The trial was performed in 5 countries, and a total of 20 sites randomised subjects to the trial (2 in Belgium, 4 in Czech Republic, 4 in Denmark, 6 in Spain, and 4 in United Kingdom) between May 2018 to Jan 2020.

### Pre-assignment

Screening details:

In total, 773 subjects were screened of which 620 subjects were randomised. Of the randomised subjects, 619 subjects were exposed to investigational medicinal product (IMP): 515 to FE 999302 and 104 to placebo. The number of subjects exposed to each of the dose levels were: 104, 101, 99, 107, and 104 to 1, 2, 4, 8, and 12 µg, respectively.

### Period 1

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

Blinding implementation details:

FE 999302 and placebo were identical in appearance and the trial was considered double-blind as neither the subject nor the investigator knew whether the subject was receiving FE 999302 or placebo.

### Arms

|                              |  |
|------------------------------|--|
| Are arms mutually exclusive? | Yes                                    |
| <b>Arm title</b>             | FE 999302 (1 µg) and Follitropin Delta |

Arm description:

Dose 1 µg of FE 999302, a recombinant human choriogonadotropin (rhCG) solution for subcutaneous injection; individualised follitropin delta dose

|  |                                   |
|--|-----------------------------------|
| Arm type                               | Experimental and add-on treatment |
| Investigational medicinal product name | FE 999302 (1 µg)                  |
| Investigational medicinal product code | FE 999302                         |
| Other name                             |                                   |
| Pharmaceutical forms                   | Solution for injection            |
| Routes of administration               | Subcutaneous use                  |

Dosage and administration details:

Dose 1 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

|                  |  |
|------------------|--|
| <b>Arm title</b> | FE 999302 (2 µg) and Follitropin Delta |
|------------------|--|

Arm description:

Dose 2 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

|  |                                   |
|--|-----------------------------------|
| Arm type                               | Experimental and add-on treatment |
| Investigational medicinal product name | FE 999302 (2 µg)                  |
| Investigational medicinal product code | FE 999302                         |
| Other name                             |                                   |
| Pharmaceutical forms                   | Solution for injection            |
| Routes of administration               | Subcutaneous use                  |

Dosage and administration details:

Dose 2 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

|                  |  |
|------------------|--|
| <b>Arm title</b> | FE 999302 (4 µg) and Follitropin Delta |
|------------------|--|

Arm description:

Dose 4 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

|  |                                   |
|--|-----------------------------------|
| Arm type                               | Experimental and add-on treatment |
| Investigational medicinal product name | FE 999302 (4 µg)                  |
| Investigational medicinal product code | FE 999302                         |
| Other name                             |                                   |
| Pharmaceutical forms                   | Solution for injection            |
| Routes of administration               | Subcutaneous use                  |

Dosage and administration details:

Dose 4 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

|                  |  |
|------------------|--|
| <b>Arm title</b> | FE 999302 (8 µg) and Follitropin Delta |
|------------------|--|

Arm description:

Dose 8 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

|  |                                   |
|--|-----------------------------------|
| Arm type                               | Experimental and add-on treatment |
| Investigational medicinal product name | FE 999302 (8 µg)                  |
| Investigational medicinal product code | FE 999302                         |
| Other name                             |                                   |
| Pharmaceutical forms                   | Solution for injection            |
| Routes of administration               | Subcutaneous use                  |

Dosage and administration details:

Dose 8 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

|                  |   |
|------------------|---|
| <b>Arm title</b> | FE 999302 (12 µg) and Follitropin Delta |
|------------------|---|

Arm description:

Dose 12 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

|  |                                   |
|--|-----------------------------------|
| Arm type                               | Experimental and add-on treatment |
| Investigational medicinal product name | FE 999302 (12 µg)                 |
| Investigational medicinal product code | FE 999302                         |
| Other name                             |                                   |
| Pharmaceutical forms                   | Solution for injection            |
| Routes of administration               | Subcutaneous use                  |

Dosage and administration details:

Dose 12 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

|                  |                               |
|------------------|-------------------------------|
| <b>Arm title</b> | Placebo and Follitropin Delta |
|------------------|-------------------------------|

Arm description:

Placebo and individualised follitropin delta dose

|  |                              |
|--|------------------------------|
| Arm type                               | Placebo and add-on treatment |
| Investigational medicinal product name | Placebo                      |
| Investigational medicinal product code |                              |
| Other name                             |                              |
| Pharmaceutical forms                   | Solution for injection       |
| Routes of administration               | Subcutaneous use             |

Dosage and administration details:

Placebo and individualised follitropin delta dose

| <b>Number of subjects in period 1<sup>[1]</sup></b> | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta |
|---|--|--|--|
| Started   | 104                                    | 101                                    | 99                                     |
| Completed   | 101                                    | 99                                     | 94                                     |
| Not completed                                       | 3                                      | 2                                      | 5                                      |
| Consent withdrawn by subject                        | -                                      | 1                                      | 1                                      |
| Adverse event, non-fatal                            | 1                                      | 1                                      | 3                                      |
| Other   | 1                                      | -                                      | 1                                      |
| Lost to follow-up                                   | 1                                      | -                                      | -                                      |

| <b>Number of subjects in period 1<sup>[1]</sup></b> | FE 999302 (8 µg) and Follitropin Delta | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |
|---|--|---|-------------------------------|
| Started   | 107                                    | 104                                     | 104                           |
| Completed   | 99                                     | 100                                     | 98                            |
| Not completed                                       | 8                                      | 4                                       | 6                             |
| Consent withdrawn by subject                        | -                                      | -                                       | -                             |
| Adverse event, non-fatal                            | 7                                      | 4                                       | 5                             |
| Other   | -                                      | -                                       | -                             |
| Lost to follow-up                                   | 1                                      | -                                       | 1                             |

Notes:

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

Justification: In total, 773 subjects were screened. Of these, 153 were screening failures and 620 were randomised. Of the 620 randomised subjects, 619 subjects were exposed to IMP. The subject that was not exposed to IMP fulfilled exclusion criterion 6 (abnormal karyotype) and should not have been randomised.

## Baseline characteristics

### Reporting groups

|  |   |
|--|---|
| Reporting group title  | FE 999302 (1 µg) and Follitropin Delta  |
| Reporting group description:   |   |
| Dose 1 µg of FE 999302, a recombinant human choriogonadotropin (rhCG) solution for subcutaneous injection; individualised follitropin delta dose |   |
| Reporting group title  | FE 999302 (2 µg) and Follitropin Delta  |
| Reporting group description:   |   |
| Dose 2 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose  |   |
| Reporting group title  | FE 999302 (4 µg) and Follitropin Delta  |
| Reporting group description:   |   |
| Dose 4 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose  |   |
| Reporting group title  | FE 999302 (8 µg) and Follitropin Delta  |
| Reporting group description:   |   |
| Dose 8 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose  |   |
| Reporting group title  | FE 999302 (12 µg) and Follitropin Delta |
| Reporting group description:   |   |
| Dose 12 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose                                       |   |
| Reporting group title  | Placebo and Follitropin Delta           |
| Reporting group description:   |   |
| Placebo and individualised follitropin delta dose  |   |

| Reporting group values           | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta |
|----------------------------------|--|--|--|
| Number of subjects               | 104                                    | 101                                    | 99                                     |
| Age categorical                  |  |  |  |
| Units: Subjects                  |  |  |  |
| 30-37 years                      | 73                                     | 71                                     | 68                                     |
| 38-42 years                      | 31                                     | 30                                     | 31                                     |
| Age continuous                   |  |  |  |
| Units: years                     |  |  |  |
| arithmetic mean                  | 35.6                                   | 35.6                                   | 35.5                                   |
| standard deviation               | ± 3.3                                  | ± 3.4                                  | ± 3.2                                  |
| Gender categorical               |  |  |  |
| Units: Subjects                  |  |  |  |
| Female                           | 104                                    | 101                                    | 99                                     |
| Male                             | 0                                      | 0                                      | 0                                      |
| Race                             |  |  |  |
| Units: Subjects                  |  |  |  |
| American Indian or Alaska Native | 1                                      | 0                                      | 0                                      |
| Asian                            | 2                                      | 2                                      | 3                                      |
| Black or African American        | 0                                      | 2                                      | 0                                      |
| Multiple                         | 0                                      | 0                                      | 0                                      |
| White                            | 101                                    | 97                                     | 96                                     |
| Ethnicity                        |  |  |  |
| Units: Subjects                  |  |  |  |
| Hispanic or Latino               | 2                                      | 5                                      | 1                                      |
| Not Hispanic or Latino           | 102                                    | 96                                     | 98                                     |

|                          |       |       |       |
|--------------------------|-------|-------|-------|
| Body mass index (BMI)    |       |       |       |
| Units: kg/m <sup>2</sup> |       |       |       |
| arithmetic mean          | 24.1  | 23.6  | 23.7  |
| standard deviation       | ± 3.5 | ± 3.3 | ± 3.7 |

| <b>Reporting group values</b>    | FE 999302 (8 µg)<br>and Follitropin Delta | FE 999302 (12 µg)<br>and Follitropin Delta | Placebo and<br>Follitropin Delta |
|----------------------------------|---|--|----------------------------------|
| Number of subjects               | 107                                       | 104  | 104                              |
| Age categorical                  |   |  |                                  |
| Units: Subjects                  |   |  |                                  |
| 30-37 years                      | 71  | 71   | 72                               |
| 38-42 years                      | 36  | 33   | 32                               |
| Age continuous                   |   |  |                                  |
| Units: years                     |   |  |                                  |
| arithmetic mean                  | 35.7                                      | 35.3                                       | 35.6                             |
| standard deviation               | ± 3.5                                     | ± 3.5                                      | ± 3.2                            |
| Gender categorical               |   |  |                                  |
| Units: Subjects                  |   |  |                                  |
| Female                           | 107                                       | 104  | 104                              |
| Male                             | 0   | 0  | 0                                |
| Race                             |   |  |                                  |
| Units: Subjects                  |   |  |                                  |
| American Indian or Alaska Native | 0   | 0  | 2                                |
| Asian                            | 2   | 2  | 2                                |
| Black or African American        | 0   | 2  | 0                                |
| Multiple                         | 1   | 0  | 0                                |
| White                            | 104                                       | 100  | 100                              |
| Ethnicity                        |   |  |                                  |
| Units: Subjects                  |   |  |                                  |
| Hispanic or Latino               | 0   | 1  | 2                                |
| Not Hispanic or Latino           | 107                                       | 103  | 102                              |
| Body mass index (BMI)            |   |  |                                  |
| Units: kg/m <sup>2</sup>         |   |  |                                  |
| arithmetic mean                  | 24.5                                      | 24.2                                       | 23.6                             |
| standard deviation               | ± 3.8                                     | ± 3.8                                      | ± 3.1                            |

| <b>Reporting group values</b> | Total |  |  |
|-------------------------------|-------|--|--|
| Number of subjects            | 619   |  |  |
| Age categorical               |       |  |  |
| Units: Subjects               |       |  |  |
| 30-37 years                   | 426   |  |  |
| 38-42 years                   | 193   |  |  |
| Age continuous                |       |  |  |
| Units: years                  |       |  |  |
| arithmetic mean               |       |  |  |
| standard deviation            | -     |  |  |
| Gender categorical            |       |  |  |
| Units: Subjects               |       |  |  |
| Female                        | 619   |  |  |
| Male                          | 0     |  |  |



|                                  |     |  |  |
|----------------------------------|-----|--|--|
| Race                             |     |  |  |
| Units: Subjects                  |     |  |  |
| American Indian or Alaska Native | 3   |  |  |
| Asian                            | 13  |  |  |
| Black or African American        | 4   |  |  |
| Multiple                         | 1   |  |  |
| White                            | 598 |  |  |
| Ethnicity                        |     |  |  |
| Units: Subjects                  |     |  |  |
| Hispanic or Latino               | 11  |  |  |
| Not Hispanic or Latino           | 608 |  |  |
| Body mass index (BMI)            |     |  |  |
| Units: kg/m <sup>2</sup>         |     |  |  |
| arithmetic mean                  |     |  |  |
| standard deviation               | -   |  |  |

## End points

### End points reporting groups

|  |   |
|--|---|
| Reporting group title  | FE 999302 (1 µg) and Follitropin Delta  |
| Reporting group description:<br>Dose 1 µg of FE 999302, a recombinant human choriogonadotropin (rhCG) solution for subcutaneous injection; individualised follitropin delta dose |   |
| Reporting group title  | FE 999302 (2 µg) and Follitropin Delta  |
| Reporting group description:<br>Dose 2 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose  |   |
| Reporting group title  | FE 999302 (4 µg) and Follitropin Delta  |
| Reporting group description:<br>Dose 4 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose  |   |
| Reporting group title  | FE 999302 (8 µg) and Follitropin Delta  |
| Reporting group description:<br>Dose 8 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose  |   |
| Reporting group title  | FE 999302 (12 µg) and Follitropin Delta |
| Reporting group description:<br>Dose 12 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose                                       |   |
| Reporting group title  | Placebo and Follitropin Delta           |
| Reporting group description:<br>Placebo and individualised follitropin delta dose  |   |

### Primary: Number of good-quality blastocysts on day 5 after oocyte retrieval (grade 3BB or higher)

|   |  |
|---|--|
| End point title   | Number of good-quality blastocysts on day 5 after oocyte retrieval (grade 3BB or higher) |
| End point description:<br>Quality of blastocysts was assessed by blastocyst expansion and hatching status, blastocyst inner cell mass grading, and trophectoderm grading. The scoring was based on the classification system by Gardner and Schoolcraft, with additional categories for inner cell mass (degenerative or no inner cell mass) and trophectoderm (degenerative or very large cells).<br><br>The analysis population included the full analysis set (FAS) which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received. |  |
| End point type  | Primary  |
| End point timeframe:<br>On day 5 after oocyte retrieval   |  |

| End point values                     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed          | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: Number of blastocysts         |  |  |  |  |
| arithmetic mean (standard deviation) | 2.3 (± 2.1)                            | 3.0 (± 2.8)                            | 2.3 (± 2.5)                            | 2.6 (± 2.5)                            |

|                                      |   |                               |  |  |
|--------------------------------------|---|-------------------------------|--|--|
| <b>End point values</b>              | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
| Subject group type                   | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed          | 104                                     | 104                           |  |  |
| Units: Number of blastocysts         |   |                               |  |  |
| arithmetic mean (standard deviation) | 2.2 (± 2.4)                             | 3.3 (± 2.9)                   |  |  |

## Statistical analyses

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[1]</sup>   |
| P-value                                 | = 0.0012   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.65   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.5  |
| upper limit                             | 0.85   |

Notes:

[1] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and anti-Müllerian hormone (AMH) group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[2]</sup>   |
| P-value                                 | = 0.3822   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.89   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.69   |
| upper limit                             | 1.15   |

Notes:

[2] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[3]</sup>   |
| P-value                                 | = 0.0021   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.66   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.51   |
| upper limit                             | 0.86   |

Notes:

[3] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[4]</sup>   |
| P-value                                 | = 0.0491   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.78   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.6  |
| upper limit                             | 1  |

Notes:

[4] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[5]</sup>  |
| P-value                                 | = 0.0005  |
| Method                                  | Negative binomial regression model                                      |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 0.63  |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.48    |
| upper limit         | 0.82    |

Notes:

[5] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

### Secondary: Number and quality of embryos on day 3 after oocyte retrieval

|                 |   |
|-----------------|---|
| End point title | Number and quality of embryos on day 3 after oocyte retrieval |
|-----------------|---|

End point description:

Number of embryos (total and good-quality) on Day 3. A good-quality embryo was defined as an embryo with  $\geq 6$  cells and  $\leq 25\%$  fragmentation, or with embryo stage classified as compacting/compacted.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

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

End point timeframe:

On day 3 after oocyte retrieval

| End point values                     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed          | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: Number of embryos             |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Number of embryos                    | 6.1 (± 3.6)                            | 6.2 (± 3.9)                            | 5.7 (± 3.7)                            | 6.0 (± 3.6)                            |
| Number of good-quality embryos       | 4.9 (± 3.2)                            | 5.2 (± 3.5)                            | 4.4 (± 3.3)                            | 4.9 (± 3.1)                            |

| End point values                     | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|--------------------------------------|---|-------------------------------|--|--|
| Subject group type                   | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed          | 104                                     | 104                           |  |  |
| Units: Number of embryos             |   |                               |  |  |
| arithmetic mean (standard deviation) |   |                               |  |  |
| Number of embryos                    | 5.2 (± 3.7)                             | 7.4 (± 4.2)                   |  |  |
| Number of good-quality embryos       | 4.3 (± 3.5)                             | 6.0 (± 3.7)                   |  |  |

### Statistical analyses

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Statistical analysis description:       |  |
| Treatment comparison: Number of embryos |  |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[6]</sup>   |
| P-value                                 | = 0.007  |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.8  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.68   |
| upper limit                             | 0.94   |

Notes:

[6] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Statistical analysis description:       |  |
| Treatment comparison: Number of embryos |  |
| Comparison groups                       | Placebo and Follitropin Delta v FE 999302 (2 µg) and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[7]</sup>   |
| P-value                                 | = 0.0183   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.82   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.7  |
| upper limit                             | 0.97   |

Notes:

[7] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Statistical analysis description:       |  |
| Treatment comparison: Number of embryos |  |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                                    |
|---|------------------------------------|
| Number of subjects included in analysis | 203                                |
| Analysis specification                  | Pre-specified                      |
| Analysis type                           | other <sup>[8]</sup>               |
| P-value                                 | = 0.0005                           |
| Method                                  | Negative binomial regression model |
| Parameter estimate                      | Ratio vs Placebo                   |
| Point estimate                          | 0.75                               |
| Confidence interval                     |                                    |
| level                                   | 95 %                               |
| sides                                   | 2-sided                            |
| lower limit                             | 0.63                               |
| upper limit                             | 0.88                               |

Notes:

[8] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|                                   |                    |
|-----------------------------------|--------------------|
| <b>Statistical analysis title</b> | FE 999302, Placebo |
|-----------------------------------|--------------------|

Statistical analysis description:

Treatment comparison: Number of embryos

|   |  |
|---|--|
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[9]</sup>   |
| P-value                                 | = 0.0069   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.8  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.68   |
| upper limit                             | 0.94   |

Notes:

[9] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|                                   |                    |
|-----------------------------------|--------------------|
| <b>Statistical analysis title</b> | FE 999302, Placebo |
|-----------------------------------|--------------------|

Statistical analysis description:

Treatment comparison: Number of embryos

|   |   |
|---|---|
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[10]</sup>   |
| P-value                                 | < 0.0001  |
| Method                                  | Negative binomial regression model                                      |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 0.69  |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.58    |
| upper limit         | 0.81    |

Notes:

[10] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|                                   |                    |
|-----------------------------------|--------------------|
| <b>Statistical analysis title</b> | FE 999302, Placebo |
|-----------------------------------|--------------------|

Statistical analysis description:

Treatment comparison: Number of good-quality embryos

|   |  |
|---|--|
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[11]</sup>  |
| P-value                                 | = 0.0055   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.78   |

Confidence interval

|             |         |
|-------------|---------|
| level       | 95 %    |
| sides       | 2-sided |
| lower limit | 0.65    |
| upper limit | 0.93    |

Notes:

[11] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|                                   |                    |
|-----------------------------------|--------------------|
| <b>Statistical analysis title</b> | FE 999302, Placebo |
|-----------------------------------|--------------------|

Statistical analysis description:

Treatment comparison: Number of good-quality embryos

|   |  |
|---|--|
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[12]</sup>  |
| P-value                                 | = 0.0593   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.84   |

Confidence interval

|             |         |
|-------------|---------|
| level       | 95 %    |
| sides       | 2-sided |
| lower limit | 0.7     |
| upper limit | 1.01    |

Notes:

[12] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|                                   |                    |
|-----------------------------------|--------------------|
| <b>Statistical analysis title</b> | FE 999302, Placebo |
|-----------------------------------|--------------------|



|  |  |
|--|--|
| Statistical analysis description:                    |  |
| Treatment comparison: Number of good-quality embryos |  |
| Comparison groups                                    | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis              | 203  |
| Analysis specification                               | Pre-specified  |
| Analysis type  | other <sup>[13]</sup>  |
| P-value  | = 0.0002   |
| Method   | Negative binomial regression model                                     |
| Parameter estimate                                   | Ratio vs Placebo   |
| Point estimate                                       | 0.71   |
| Confidence interval                                  |  |
| level  | 95 %   |
| sides  | 2-sided  |
| lower limit  | 0.59   |
| upper limit  | 0.85   |

Notes:

[13] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|  |  |
|--|--|
| <b>Statistical analysis title</b>                    | FE 999302, Placebo   |
| Statistical analysis description:                    |  |
| Treatment comparison: Number of good-quality embryos |  |
| Comparison groups                                    | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis              | 211  |
| Analysis specification                               | Pre-specified  |
| Analysis type  | other <sup>[14]</sup>  |
| P-value  | = 0.0096   |
| Method   | Negative binomial regression model                                     |
| Parameter estimate                                   | Ratio vs Placebo   |
| Point estimate                                       | 0.79   |
| Confidence interval                                  |  |
| level  | 95 %   |
| sides  | 2-sided  |
| lower limit  | 0.66   |
| upper limit  | 0.94   |

Notes:

[14] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|  |   |
|--|---|
| <b>Statistical analysis title</b>                    | FE 999302, Placebo  |
| Statistical analysis description:                    |   |
| Treatment comparison: Number of good-quality embryos |   |
| Comparison groups                                    | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis              | 208   |
| Analysis specification                               | Pre-specified   |
| Analysis type  | other <sup>[15]</sup>   |
| P-value  | < 0.0001  |
| Method   | Negative binomial regression model                                      |
| Parameter estimate                                   | Ratio vs Placebo  |
| Point estimate                                       | 0.68  |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.57    |
| upper limit         | 0.82    |

Notes:

[15] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

### Secondary: Number and quality of blastocysts on day 5 after oocyte retrieval

|                 |   |
|-----------------|---|
| End point title | Number and quality of blastocysts on day 5 after oocyte retrieval |
|-----------------|---|

End point description:

Number of blastocysts (total and good-quality) on Day 5. Blastocyst quality was assessed by blastocyst expansion and hatching status, blastocyst inner cell mass grading, and trophectoderm grading. The scoring was based on the classification system by Gardner and Schoolcraft, with additional categories for inner cell mass (degenerative or no inner cell mass) and trophectoderm (degenerative or very large cells).

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

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

End point timeframe:

On day 5 after oocyte retrieval

| End point values                     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed          | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: Number of blastocysts         |  |  |  |  |
| arithmetic mean (standard deviation) | 4.1 (± 3.0)                            | 4.7 (± 3.5)                            | 3.8 (± 3.0)                            | 4.3 (± 3.4)                            |

| End point values                     | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|--------------------------------------|---|-------------------------------|--|--|
| Subject group type                   | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed          | 104                                     | 104                           |  |  |
| Units: Number of blastocysts         |   |                               |  |  |
| arithmetic mean (standard deviation) | 3.6 (± 3.3)                             | 5.3 (± 3.8)                   |  |  |

### Statistical analyses

|                            |  |
|----------------------------|--|
| Statistical analysis title | FE 999302, Placebo   |
| Comparison groups          | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                                    |
|---|------------------------------------|
| Number of subjects included in analysis | 208                                |
| Analysis specification                  | Pre-specified                      |
| Analysis type                           | other <sup>[16]</sup>              |
| P-value                                 | = 0.0068                           |
| Method                                  | Negative binomial regression model |
| Parameter estimate                      | Ratio vs Placebo                   |
| Point estimate                          | 0.75                               |
| Confidence interval                     |                                    |
| level                                   | 95 %                               |
| sides                                   | 2-sided                            |
| lower limit                             | 0.61                               |
| upper limit                             | 0.92                               |

Notes:

[16] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[17]</sup>  |
| P-value                                 | = 0.1553   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.86   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.7  |
| upper limit                             | 1.06   |

Notes:

[17] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[18]</sup>  |
| P-value                                 | = 0.0005   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.68   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.55   |
| upper limit                             | 0.85   |

Notes:

[18] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[19]</sup>  |
| P-value                                 | = 0.0235   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.79   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.64   |
| upper limit                             | 0.97   |

Notes:

[19] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[20]</sup>   |
| P-value                                 | < 0.0001  |
| Method                                  | Negative binomial regression model                                      |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 0.65  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.53  |
| upper limit                             | 0.81  |

Notes:

[20] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

### **Secondary: Changes in serum hormone (progesterone) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval**

|                 |   |
|-----------------|---|
| End point title | Changes in serum hormone (progesterone) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval |
|-----------------|---|

End point description:

Blood samples for analysis of serum hormone levels were drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, end-of-stimulation, and at oocyte retrieval.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12

µg), Placebo

Stimulation day 6: n=104, n=99, n=97, n=105, n=104, n=103

Stimulation day 8: n=102, n=97, n=95, n=103, n=100, n=100

End-of-stimulation: n=104, n=99, n=99, n=104, n=103, n=102

Oocyte retrieval: n=103, n=100, n=98, n=106, n=102, n=101

|  |           |
|--|-----------|
| End point type   | Secondary |
| End point timeframe:   |           |
| Stimulation Day 1 (baseline), Stimulation Day 6, stimulation Day 8, end-of-stimulation (up to 20 stimulation days), and oocyte retrieval |           |

| End point values                     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed          | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: nmol/L                        |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Stimulation Day 6                    | 0.094 (± 0.486)                        | 0.050 (± 0.320)                        | 0.306 (± 2.454)                        | 0.187 (± 0.361)                        |
| Stimulation Day 8                    | 0.599 (± 2.887)                        | 0.317 (± 0.407)                        | 0.377 (± 0.562)                        | 0.620 (± 0.702)                        |
| End-of-stimulation visit             | 1.327 (± 1.001)                        | 1.429 (± 0.984)                        | 1.687 (± 1.636)                        | 2.407 (± 1.608)                        |
| Oocyte retrieval visit               | 28.304 (± 16.381)                      | 26.426 (± 15.671)                      | 23.680 (± 16.108)                      | 23.666 (± 12.553)                      |

| End point values                     | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|--------------------------------------|---|-------------------------------|--|--|
| Subject group type                   | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed          | 104                                     | 104                           |  |  |
| Units: nmol/L                        |   |                               |  |  |
| arithmetic mean (standard deviation) |   |                               |  |  |
| Stimulation Day 6                    | 0.268 (± 0.450)                         | -0.215 (± 2.691)              |  |  |
| Stimulation Day 8                    | 0.691 (± 0.638)                         | 0.022 (± 2.734)               |  |  |
| End-of-stimulation visit             | 2.555 (± 1.571)                         | 1.090 (± 2.797)               |  |  |
| Oocyte retrieval visit               | 21.818 (± 10.590)                       | 31.154 (± 16.586)             |  |  |

## Statistical analyses

|                            |  |
|----------------------------|--|
| Statistical analysis title | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups          | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                       |
|---|-----------------------|
| Number of subjects included in analysis | 208                   |
| Analysis specification                  | Pre-specified         |
| Analysis type                           | other <sup>[21]</sup> |
| P-value                                 | = 0.4287              |
| Method                                  | ANCOVA                |
| Parameter estimate                      | Ratio vs Placebo      |
| Point estimate                          | 1.08                  |
| Confidence interval                     |                       |
| level                                   | 95 %                  |
| sides                                   | 2-sided               |
| lower limit                             | 0.9                   |
| upper limit                             | 1.3                   |

Notes:

[21] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[22]</sup>  |
| P-value                                 | = 0.4301   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.08   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.89   |
| upper limit                             | 1.3  |

Notes:

[22] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[23]</sup>  |
| P-value                                 | = 0.1019   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.17   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.97   |
| upper limit                             | 1.41   |

Notes:

[23] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[24]</sup>  |
| P-value                                 | = 0.0046   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.31   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.09   |
| upper limit                             | 1.57   |

Notes:

[24] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[25]</sup>   |
| P-value                                 | < 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 1.54  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 1.28  |
| upper limit                             | 1.85  |

Notes:

[25] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[26]</sup>  |
| P-value                                 | = 0.8375   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.02   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.83    |
| upper limit         | 1.25    |

Notes:

[26] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[27]</sup>  |
| P-value                                 | = 0.9139   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.01   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.83   |
| upper limit                             | 1.24   |

Notes:

[27] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[28]</sup>  |
| P-value                                 | = 0.2647   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.12   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.92   |
| upper limit                             | 1.38   |

Notes:

[28] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                 | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |



|   |                       |
|---|-----------------------|
| Number of subjects included in analysis | 211                   |
| Analysis specification                  | Pre-specified         |
| Analysis type                           | other <sup>[29]</sup> |
| P-value                                 | = 0.0007              |
| Method                                  | ANCOVA                |
| Parameter estimate                      | Ratio vs Placebo      |
| Point estimate                          | 1.42                  |
| Confidence interval                     |                       |
| level                                   | 95 %                  |
| sides                                   | 2-sided               |
| lower limit                             | 1.16                  |
| upper limit                             | 1.74                  |

Notes:

[29] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[30]</sup>   |
| P-value                                 | < 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 1.59  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 1.3   |
| upper limit                             | 1.95  |

Notes:

[30] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[31]</sup>  |
| P-value                                 | = 0.8069   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.98   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.83   |
| upper limit                             | 1.16   |

Notes:

[31] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[32]</sup>  |
| P-value                                 | = 0.4818   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.06   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.9  |
| upper limit                             | 1.26   |

Notes:

[32] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[33]</sup>  |
| P-value                                 | = 0.0754   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.17   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.98   |
| upper limit                             | 1.39   |

Notes:

[33] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[34]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.65   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 1.39    |
| upper limit         | 1.96    |

Notes:

[34] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                 |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[35]</sup>   |
| P-value                                 | < 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 1.82  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 1.54  |
| upper limit                             | 2.16  |

Notes:

[35] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[36]</sup>  |
| P-value                                 | = 0.0885   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.86   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.73   |
| upper limit                             | 1.02   |

Notes:

[36] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                 | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                       |
|---|-----------------------|
| Number of subjects included in analysis | 205                   |
| Analysis specification                  | Pre-specified         |
| Analysis type                           | other <sup>[37]</sup> |
| P-value                                 | = 0.0146              |
| Method                                  | ANCOVA                |
| Parameter estimate                      | Ratio vs Placebo      |
| Point estimate                          | 0.81                  |
| Confidence interval                     |                       |
| level                                   | 95 %                  |
| sides                                   | 2-sided               |
| lower limit                             | 0.68                  |
| upper limit                             | 0.96                  |

Notes:

[37] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[38]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.71   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.6  |
| upper limit                             | 0.84   |

Notes:

[38] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[39]</sup>  |
| P-value                                 | = 0.0006   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.74   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.63   |
| upper limit                             | 0.88   |

Notes:

[39] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                   |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[40]</sup>   |
| P-value                                 | < 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 0.71  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.6   |
| upper limit                             | 0.84  |

Notes:

[40] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation day 1 as a covariate.

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**Secondary: Changes in serum hormone (17-OH-progesterone) levels of from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval**

|                 |  |
|-----------------|--|
| End point title | Changes in serum hormone (17-OH-progesterone) levels of from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval |
|-----------------|--|

End point description:

Blood samples for analysis of serum hormone levels were drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, end-of-stimulation, and at oocyte retrieval.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12 µg), Placebo

Stimulation day 6: n=103, n=99, n=97, n=105, n=104, n=102

Stimulation day 8: n=101, n=97, n=96, n=102, n=101, n=100

End-of-stimulation: n=102, n=99, n=99, n=104, n=104, n=101

Oocyte retrieval: n=102, n=99, n=98, n=106, n=103, n=98

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

End point timeframe:

Stimulation Day 1 (baseline), stimulation Day 6, stimulation Day 8, end-of-stimulation (up to 20 stimulation days), and oocyte retrieval

---

| End point values                     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed          | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: nmol/L                        |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Stimulation Day 6                    | 0.716 (± 0.612)                        | 0.855 (± 1.052)                        | 1.121 (± 0.835)                        | 1.622 (± 1.251)                        |
| Stimulation Day 8                    | 1.542 (± 1.132)                        | 2.026 (± 1.443)                        | 2.594 (± 1.973)                        | 3.701 (± 2.739)                        |
| End-of-stimulation visit             | 4.840 (± 2.934)                        | 5.559 (± 3.362)                        | 7.025 (± 5.274)                        | 10.022 (± 6.007)                       |
| Oocyte retrieval visit               | 22.518 (± 10.417)                      | 24.565 (± 12.943)                      | 25.505 (± 14.471)                      | 42.227 (± 144.990)                     |

| End point values                     | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|--------------------------------------|---|-------------------------------|--|--|
| Subject group type                   | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed          | 104                                     | 104                           |  |  |
| Units: nmol/L                        |   |                               |  |  |
| arithmetic mean (standard deviation) |   |                               |  |  |
| Stimulation Day 6                    | 1.940 (± 1.428)                         | 0.335 (± 0.585)               |  |  |
| Stimulation Day 8                    | 4.123 (± 2.716)                         | 1.076 (± 1.161)               |  |  |
| End-of-stimulation visit             | 10.605 (± 5.849)                        | 3.635 (± 2.425)               |  |  |
| Oocyte retrieval visit               | 27.218 (± 13.283)                       | 18.278 (± 8.826)              |  |  |

## Statistical analyses

|   |  |
|---|--|
| Statistical analysis title              | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[41]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.43   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.25   |
| upper limit                             | 1.64   |

Notes:

[41] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[42]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.68   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.46   |
| upper limit                             | 1.93   |

Notes:

[42] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[43]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.84   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.6  |
| upper limit                             | 2.12   |

Notes:

[43] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[44]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 2.45   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 2.14    |
| upper limit         | 2.81    |

Notes:

[44] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[45]</sup>   |
| P-value                                 | < 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 2.71  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 2.37  |
| upper limit                             | 3.11  |

Notes:

[45] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[46]</sup>  |
| P-value                                 | = 0.0008   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.3  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.12   |
| upper limit                             | 1.52   |

Notes:

[46] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                 | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |



|   |                       |
|---|-----------------------|
| Number of subjects included in analysis | 205                   |
| Analysis specification                  | Pre-specified         |
| Analysis type                           | other <sup>[47]</sup> |
| P-value                                 | < 0.0001              |
| Method                                  | ANCOVA                |
| Parameter estimate                      | Ratio vs Placebo      |
| Point estimate                          | 1.59                  |
| Confidence interval                     |                       |
| level                                   | 95 %                  |
| sides                                   | 2-sided               |
| lower limit                             | 1.36                  |
| upper limit                             | 1.86                  |

Notes:

[47] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[48]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.85   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.58   |
| upper limit                             | 2.16   |

Notes:

[48] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[49]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 2.57   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 2.2  |
| upper limit                             | 2.99   |

Notes:

[49] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[50]</sup>   |
| P-value                                 | < 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 2.81  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 2.41  |
| upper limit                             | 3.28  |

Notes:

[50] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[51]</sup>  |
| P-value                                 | = 0.0025   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.27   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.09   |
| upper limit                             | 1.47   |

Notes:

[51] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[52]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.48   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 1.27    |
| upper limit         | 1.72    |

Notes:

[52] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[53]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.75   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.5  |
| upper limit                             | 2.04   |

Notes:

[53] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[54]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 2.55   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 2.19   |
| upper limit                             | 2.96   |

Notes:

[54] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | FE 999302, Placebo (End-of-stimulation)                                 |
| Comparison groups                 | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                       |
|---|-----------------------|
| Number of subjects included in analysis | 208                   |
| Analysis specification                  | Pre-specified         |
| Analysis type                           | other <sup>[55]</sup> |
| P-value                                 | < 0.0001              |
| Method                                  | ANCOVA                |
| Parameter estimate                      | Ratio vs Placebo      |
| Point estimate                          | 2.7                   |
| Confidence interval                     |                       |
| level                                   | 95 %                  |
| sides                                   | 2-sided               |
| lower limit                             | 2.32                  |
| upper limit                             | 3.14                  |

Notes:

[55] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[56]</sup>  |
| P-value                                 | = 0.0198   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.19   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.03   |
| upper limit                             | 1.37   |

Notes:

[56] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[57]</sup>  |
| P-value                                 | = 0.0003   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.31   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.13   |
| upper limit                             | 1.51   |

Notes:

[57] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[58]</sup>  |
| P-value                                 | = 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.33   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.15   |
| upper limit                             | 1.54   |

Notes:

[58] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[59]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.58   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.37   |
| upper limit                             | 1.83   |

Notes:

[59] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                   |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[60]</sup>   |
| P-value                                 | < 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 1.48  |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 1.28    |
| upper limit         | 1.71    |

Notes:

[60] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

## Secondary: Changes in serum hormone (androstenedione) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval

|                 |  |
|-----------------|--|
| End point title | Changes in serum hormone (androstenedione) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval |
|-----------------|--|

End point description:

Blood samples for analysis of serum hormone levels were drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, end-of-stimulation, and at oocyte retrieval.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12 µg), Placebo

Stimulation day 6: n=104, n=100, n=97, n=105, n=103, n=103

Stimulation day 8: n=102, n=97, n=95, n=103, n=100, n=101

End-of-stimulation: n=104, n=99, n=99, n=104, n=103, n=102

Oocyte retrieval: n=103, n=100, n=98, n=106, n=102, n=101

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

End point timeframe:

Stimulation Day 1 (baseline), stimulation Day 6, stimulation Day 8, end-of-stimulation (up to 20 stimulation days), and oocyte retrieval

| End point values                     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed          | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: nmol/L                        |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Stimulation Day 6                    | 0.91 (± 0.97)                          | 1.26 (± 1.23)                          | 1.29 (± 1.21)                          | 1.86 (± 1.48)                          |
| Stimulation Day 8                    | 2.02 (± 1.44)                          | 2.77 (± 2.12)                          | 3.19 (± 2.12)                          | 4.44 (± 3.09)                          |
| End-of-stimulation visit             | 5.48 (± 2.97)                          | 6.37 (± 3.73)                          | 7.64 (± 4.64)                          | 9.99 (± 5.39)                          |
| Oocyte retrieval visit               | 6.50 (± 3.49)                          | 7.17 (± 4.01)                          | 8.58 (± 3.88)                          | 10.76 (± 5.48)                         |

|                  |   |                               |  |  |
|------------------|---|-------------------------------|--|--|
| End point values | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|------------------|---|-------------------------------|--|--|

|                                      |                     |                    |  |  |
|--------------------------------------|---------------------|--------------------|--|--|
| Subject group type                   | Reporting group     | Reporting group    |  |  |
| Number of subjects analysed          | 104                 | 104                |  |  |
| Units: nmol/L                        |                     |                    |  |  |
| arithmetic mean (standard deviation) |                     |                    |  |  |
| Stimulation Day 6                    | 2.17 ( $\pm$ 1.60)  | 0.35 ( $\pm$ 0.95) |  |  |
| Stimulation Day 8                    | 4.65 ( $\pm$ 2.82)  | 1.22 ( $\pm$ 1.51) |  |  |
| End-of-stimulation visit             | 9.66 ( $\pm$ 5.01)  | 3.03 ( $\pm$ 2.13) |  |  |
| Oocyte retrieval visit               | 10.34 ( $\pm$ 5.10) | 4.06 ( $\pm$ 2.54) |  |  |

## Statistical analyses

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[61]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.18   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.09   |
| upper limit                             | 1.28   |

Notes:

[61] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[62]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.29   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.19   |
| upper limit                             | 1.4  |

Notes:

[62] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo (Stimulation Day 6)                           |
| Comparison groups                 | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin |

|   |                       |
|---|-----------------------|
|   | Delta                 |
| Number of subjects included in analysis | 203                   |
| Analysis specification                  | Pre-specified         |
| Analysis type                           | other <sup>[63]</sup> |
| P-value                                 | < 0.0001              |
| Method                                  | ANCOVA                |
| Parameter estimate                      | Ratio vs Placebo      |
| Point estimate                          | 1.32                  |
| Confidence interval                     |                       |
| level                                   | 95 %                  |
| sides                                   | 2-sided               |
| lower limit                             | 1.21                  |
| upper limit                             | 1.43                  |

Notes:

[63] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[64]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.5  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.39   |
| upper limit                             | 1.63   |

Notes:

[64] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[65]</sup>   |
| P-value                                 | < 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 1.59  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 1.47  |
| upper limit                             | 1.72  |



Notes:

[65] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[66]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.23   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.11   |
| upper limit                             | 1.35   |

Notes:

[66] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[67]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.38   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.25   |
| upper limit                             | 1.52   |

Notes:

[67] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[68]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.51   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 1.37    |
| upper limit         | 1.67    |

Notes:

[68] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[69]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.83   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.67   |
| upper limit                             | 2.02   |

Notes:

[69] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[70]</sup>   |
| P-value                                 | < 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 1.87  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 1.7   |
| upper limit                             | 2.06  |

Notes:

[70] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                 | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                       |
|---|-----------------------|
| Number of subjects included in analysis | 208                   |
| Analysis specification                  | Pre-specified         |
| Analysis type                           | other <sup>[71]</sup> |
| P-value                                 | < 0.0001              |
| Method                                  | ANCOVA                |
| Parameter estimate                      | Ratio vs Placebo      |
| Point estimate                          | 1.41                  |
| Confidence interval                     |                       |
| level                                   | 95 %                  |
| sides                                   | 2-sided               |
| lower limit                             | 1.27                  |
| upper limit                             | 1.56                  |

Notes:

[71] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[72]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.57   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.41   |
| upper limit                             | 1.74   |

Notes:

[72] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[73]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.78   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.6  |
| upper limit                             | 1.98   |

Notes:

[73] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[74]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 2.21   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 2  |
| upper limit                             | 2.45   |

Notes:

[74] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                 |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[75]</sup>   |
| P-value                                 | < 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 2.17  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 1.96  |
| upper limit                             | 2.41  |

Notes:

[75] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[76]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.34   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 1.21    |
| upper limit         | 1.48    |

Notes:

[76] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[77]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.44   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.31   |
| upper limit                             | 1.59   |

Notes:

[77] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[78]</sup>  |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.69   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.53   |
| upper limit                             | 1.87   |

Notes:

[78] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                 | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                       |
|---|-----------------------|
| Number of subjects included in analysis | 211                   |
| Analysis specification                  | Pre-specified         |
| Analysis type                           | other <sup>[79]</sup> |
| P-value                                 | < 0.0001              |
| Method                                  | ANCOVA                |
| Parameter estimate                      | Ratio vs Placebo      |
| Point estimate                          | 1.99                  |
| Confidence interval                     |                       |
| level                                   | 95 %                  |
| sides                                   | 2-sided               |
| lower limit                             | 1.81                  |
| upper limit                             | 2.2                   |

Notes:

[79] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                   |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[80]</sup>   |
| P-value                                 | < 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 1.94  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 1.75  |
| upper limit                             | 2.14  |

Notes:

[80] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

### **Secondary: Changes in serum hormone (testosterone) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval**

|                 |   |
|-----------------|---|
| End point title | Changes in serum hormone (testosterone) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval |
|-----------------|---|

End point description:

Blood samples for analysis of serum hormone levels were drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, end-of-stimulation, and at oocyte retrieval.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12 µg), Placebo

Stimulation day 6: n=101, n=98, n=97, n=105, n=103, n=102

Stimulation day 8: n=100, n=96, n=95, n=103, n=100, n=100

End-of-stimulation: n=101, n=98, n=99, n=104, n=103, n=100

Oocyte retrieval: n=101, n=98, n=98, n=106, n=103, n=100

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

End point timeframe:

Stimulation Day 1 (baseline), stimulation Day 6, stimulation Day 8, end-of-stimulation (up to 20

| End point values                     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed          | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: nmol/L                        |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Stimulation Day 6                    | 0.152 (± 0.201)                        | 0.190 (± 0.252)                        | 0.224 (± 0.226)                        | 0.319 (± 0.317)                        |
| Stimulation Day 8                    | 0.382 (± 0.299)                        | 0.414 (± 0.396)                        | 0.604 (± 0.467)                        | 0.824 (± 0.616)                        |
| End-of-stimulation visit             | 1.178 (± 0.736)                        | 1.252 (± 0.786)                        | 1.605 (± 1.097)                        | 2.296 (± 1.380)                        |
| Oocyte retrieval visit               | 2.088 (± 1.105)                        | 2.213 (± 1.198)                        | 2.691 (± 1.321)                        | 3.394 (± 1.780)                        |

| End point values                     | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|--------------------------------------|---|-------------------------------|--|--|
| Subject group type                   | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed          | 104                                     | 104                           |  |  |
| Units: nmol/L                        |   |                               |  |  |
| arithmetic mean (standard deviation) |   |                               |  |  |
| Stimulation Day 6                    | 0.371 (± 0.335)                         | 0.039 (± 0.187)               |  |  |
| Stimulation Day 8                    | 0.847 (± 0.575)                         | 0.195 (± 0.277)               |  |  |
| End-of-stimulation visit             | 2.106 (± 1.165)                         | 0.669 (± 0.472)               |  |  |
| Oocyte retrieval visit               | 3.136 (± 1.586)                         | 1.374 (± 0.798)               |  |  |

### Statistical analyses

|   |  |
|---|--|
| Statistical analysis title              | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[81]</sup>  |
| P-value                                 | = 0.001  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.18   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 1.07    |
| upper limit         | 1.31    |

Notes:

[81] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[82]</sup>  |
| P-value                                 | < 0.001  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.26   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.14   |
| upper limit                             | 1.39   |

Notes:

[82] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[83]</sup>  |
| P-value                                 | < 0.001  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.36   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.23   |
| upper limit                             | 1.5  |

Notes:

[83] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                 | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |



|   |                       |
|---|-----------------------|
| Number of subjects included in analysis | 211                   |
| Analysis specification                  | Pre-specified         |
| Analysis type                           | other <sup>[84]</sup> |
| P-value                                 | < 0.001               |
| Method                                  | ANCOVA                |
| Parameter estimate                      | Ratio vs Placebo      |
| Point estimate                          | 1.53                  |
| Confidence interval                     |                       |
| level                                   | 95 %                  |
| sides                                   | 2-sided               |
| lower limit                             | 1.39                  |
| upper limit                             | 1.69                  |

Notes:

[84] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[85]</sup>   |
| P-value                                 | < 0.001   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 1.62  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 1.46  |
| upper limit                             | 1.79  |

Notes:

[85] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[86]</sup>  |
| P-value                                 | < 0.001  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.28   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.14   |
| upper limit                             | 1.43   |

Notes:

[86] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[87]</sup>  |
| P-value                                 | < 0.001  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.3  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.16   |
| upper limit                             | 1.46   |

Notes:

[87] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[88]</sup>  |
| P-value                                 | < 0.001  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.59   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.42   |
| upper limit                             | 1.79   |

Notes:

[88] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[89]</sup>  |
| P-value                                 | < 0.001  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.91   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 1.71    |
| upper limit         | 2.14    |

Notes:

[89] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[90]</sup>   |
| P-value                                 | < 0.001   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 1.94  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 1.74  |
| upper limit                             | 2.17  |

Notes:

[90] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[91]</sup>  |
| P-value                                 | < 0.001  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.42   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.25   |
| upper limit                             | 1.6  |

Notes:

[91] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                 | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                       |
|---|-----------------------|
| Number of subjects included in analysis | 205                   |
| Analysis specification                  | Pre-specified         |
| Analysis type                           | other <sup>[92]</sup> |
| P-value                                 | < 0.001               |
| Method                                  | ANCOVA                |
| Parameter estimate                      | Ratio vs Placebo      |
| Point estimate                          | 1.48                  |
| Confidence interval                     |                       |
| level                                   | 95 %                  |
| sides                                   | 2-sided               |
| lower limit                             | 1.31                  |
| upper limit                             | 1.67                  |

Notes:

[92] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[93]</sup>  |
| P-value                                 | < 0.001  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.76   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.56   |
| upper limit                             | 1.99   |

Notes:

[93] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[94]</sup>  |
| P-value                                 | < 0.001  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 2.37   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 2.1  |
| upper limit                             | 2.68   |

Notes:

[94] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                 |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[95]</sup>   |
| P-value                                 | < 0.001   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 2.25  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 1.99  |
| upper limit                             | 2.54  |

Notes:

[95] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[96]</sup>  |
| P-value                                 | < 0.001  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.36   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.21   |
| upper limit                             | 1.52   |

Notes:

[96] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[97]</sup>  |
| P-value                                 | < 0.001  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.45   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 1.29    |
| upper limit         | 1.62    |

Notes:

[97] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[98]</sup>  |
| P-value                                 | < 0.001  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.71   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.53   |
| upper limit                             | 1.92   |

Notes:

[98] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[99]</sup>  |
| P-value                                 | < 0.001  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 2.09   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.87   |
| upper limit                             | 2.33   |

Notes:

[99] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | FE 999302, Placebo (Oocyte retrieval)                                   |
| Comparison groups                 | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                        |
|---|------------------------|
| Number of subjects included in analysis | 208                    |
| Analysis specification                  | Pre-specified          |
| Analysis type                           | other <sup>[100]</sup> |
| P-value                                 | < 0.001                |
| Method                                  | ANCOVA                 |
| Parameter estimate                      | Ratio vs Placebo       |
| Point estimate                          | 1.96                   |
| Confidence interval                     |                        |
| level                                   | 95 %                   |
| sides                                   | 2-sided                |
| lower limit                             | 1.75                   |
| upper limit                             | 2.19                   |

Notes:

[100] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

### Secondary: Changes in serum hormone (estradiol) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval

|                 |  |
|-----------------|--|
| End point title | Changes in serum hormone (estradiol) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval |
|-----------------|--|

End point description:

Blood samples for analysis of serum hormone levels were drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, end-of-stimulation, and at oocyte retrieval.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12 µg), Placebo

Stimulation day 6: n=101, n=96, n=96, n=101, n=101, n=101

Stimulation day 8: n=99, n=93, n=94, n=99, n=100, n=100

End-of-stimulation: n=102, n=93, n=97, n=99, n=100, n=101

Oocyte retrieval: n=100, n=94, n=94, n=98, n=98, n=99

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

End point timeframe:

Stimulation Day 1 (baseline), stimulation Day 6, stimulation Day 8, end-of-stimulation (up to 20 stimulation days), and oocyte retrieval

| End point values                     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed          | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: pmol/L                        |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Stimulation Day 6                    | 1183.4 (± 813.0)                       | 1413.4 (± 1028.7)                      | 1412.5 (± 1154.1)                      | 1612.9 (± 1098.4)                      |
| Stimulation Day 8                    | 2994.9 (± 1692.1)                      | 3526.3 (± 2186.1)                      | 3707.9 (± 3100.8)                      | 4204.8 (± 2478.1)                      |
| End-of-stimulation visit             | 9119.7 (± 4984.4)                      | 10006.3 (± 5322.4)                     | 10640.9 (± 6305.4)                     | 12705.8 (± 7412.0)                     |
| Oocyte retrieval visit               | 4410.7 (± 2308.4)                      | 4781.2 (± 2299.5)                      | 5925.5 (± 4389.5)                      | 7672.5 (± 10951.6)                     |

| <b>End point values</b>              | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|--------------------------------------|---|-------------------------------|--|--|
| Subject group type                   | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed          | 104                                     | 104                           |  |  |
| Units: pmol/L                        |   |                               |  |  |
| arithmetic mean (standard deviation) |   |                               |  |  |
| Stimulation Day 6                    | 1619.1 (± 1242.4)                       | 880.7 (± 959.2)               |  |  |
| Stimulation Day 8                    | 3969.7 (± 2364.1)                       | 2257.9 (± 1704.3)             |  |  |
| End-of-stimulation visit             | 11098.9 (± 5905.2)                      | 6864.6 (± 3706.8)             |  |  |
| Oocyte retrieval visit               | 6502.4 (± 2957.4)                       | 3273.2 (± 1729.9)             |  |  |

## Statistical analyses

| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
|---|--|
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[101]</sup>   |
| P-value                                 | = 0.0095   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.31   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.07   |
| upper limit                             | 1.61   |

Notes:

[101] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
|---|--|
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[102]</sup>   |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.57   |



|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 1.27    |
| upper limit         | 1.93    |

Notes:

[102] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[103]</sup>   |
| P-value                                 | = 0.0002   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.48   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.2  |
| upper limit                             | 1.82   |

Notes:

[103] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[104]</sup>   |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.85   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.51   |
| upper limit                             | 2.27   |

Notes:

[104] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | FE 999302, Placebo (Stimulation Day 6)                                  |
| Comparison groups                 | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                        |
|---|------------------------|
| Number of subjects included in analysis | 208                    |
| Analysis specification                  | Pre-specified          |
| Analysis type                           | other <sup>[105]</sup> |
| P-value                                 | < 0.0001               |
| Method                                  | ANCOVA                 |
| Parameter estimate                      | Ratio vs Placebo       |
| Point estimate                          | 1.69                   |
| Confidence interval                     |                        |
| level                                   | 95 %                   |
| sides                                   | 2-sided                |
| lower limit                             | 1.37                   |
| upper limit                             | 2.07                   |

Notes:

[105] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[106]</sup>   |
| P-value                                 | = 0.0016   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.37   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.13   |
| upper limit                             | 1.67   |

Notes:

[106] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[107]</sup>   |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.63   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.34   |
| upper limit                             | 1.99   |

Notes:

[107] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | Placebo and Follitropin Delta v FE 999302 (4 µg) and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[108]</sup>   |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.64   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.34   |
| upper limit                             | 2  |

Notes:

[108] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[109]</sup>   |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.93   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.59   |
| upper limit                             | 2.35   |

Notes:

[109] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[110]</sup>  |
| P-value                                 | < 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 1.8   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 1.48    |
| upper limit         | 2.18    |

Notes:

[110] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[111]</sup>   |
| P-value                                 | = 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.32   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.15   |
| upper limit                             | 1.52   |

Notes:

[111] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | Placebo and Follitropin Delta v FE 999302 (2 µg) and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[112]</sup>   |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.47   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.27   |
| upper limit                             | 1.7  |

Notes:

[112] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                 | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                        |
|---|------------------------|
| Number of subjects included in analysis | 203                    |
| Analysis specification                  | Pre-specified          |
| Analysis type                           | other <sup>[113]</sup> |
| P-value                                 | < 0.0001               |
| Method                                  | ANCOVA                 |
| Parameter estimate                      | Ratio vs Placebo       |
| Point estimate                          | 1.54                   |
| Confidence interval                     |                        |
| level                                   | 95 %                   |
| sides                                   | 2-sided                |
| lower limit                             | 1.34                   |
| upper limit                             | 1.78                   |

Notes:

[113] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | Placebo and Follitropin Delta v FE 999302 (8 µg) and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[114]</sup>   |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.87   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.62   |
| upper limit                             | 2.16   |

Notes:

[114] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                 |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[115]</sup>  |
| P-value                                 | < 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 1.64  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 1.42  |
| upper limit                             | 1.89  |

Notes:

[115] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[116]</sup>   |
| P-value                                 | = 0.0004   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.33   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.13   |
| upper limit                             | 1.55   |

Notes:

[116] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[117]</sup>   |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.47   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.25   |
| upper limit                             | 1.72   |

Notes:

[117] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[118]</sup>   |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.66   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 1.41    |
| upper limit         | 1.94    |

Notes:

[118] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                  |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[119]</sup>   |
| P-value                                 | < 0.0001   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 2.15   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 1.84   |
| upper limit                             | 2.52   |

Notes:

[119] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Oocyte retrieval)                                   |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[120]</sup>  |
| P-value                                 | < 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 2.02  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 1.73  |
| upper limit                             | 2.36  |

Notes:

[120] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

## Secondary: Changes in serum hormone (inhibin A) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation

|                 |  |
|-----------------|--|
| End point title | Changes in serum hormone (inhibin A) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation |
|-----------------|--|

End point description:

Blood samples for analysis serum hormone levels were drawn at stimulation Day 1, stimulation Day 6,

stimulation Day 8, and at end-of-stimulation.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12 µg), Placebo

Stimulation day 6: n=94, n=94, n=94, n=100, n=100, n=90

Stimulation day 8: n=94, n=94, n=93, n=97, n=93, n=89

End-of-stimulation: n=95, n=95, n=93, n=99, n=101, n=89

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

End point timeframe:

Stimulation Day 1 (baseline), Stimulation Day 6, stimulation Day 8, and end-of-stimulation (up to 20 stimulation days)

| End point values                     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed          | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: ng/L                          |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Stimulation Day 6                    | 57.0 (± 43.7)                          | 62.1 (± 42.8)                          | 56.9 (± 40.2)                          | 61.0 (± 45.9)                          |
| Stimulation Day 8                    | 145.7 (± 88.3)                         | 151.6 (± 88.4)                         | 140.7 (± 80.0)                         | 155.1 (± 101.1)                        |
| End-of-stimulation visit             | 380.1 (± 148.5)                        | 367.3 (± 158.1)                        | 356.4 (± 153.6)                        | 368.2 (± 179.5)                        |

| End point values                     | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|--------------------------------------|---|-------------------------------|--|--|
| Subject group type                   | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed          | 104                                     | 104                           |  |  |
| Units: ng/L                          |   |                               |  |  |
| arithmetic mean (standard deviation) |   |                               |  |  |
| Stimulation Day 6                    | 61.7 (± 47.2)                           | 58.1 (± 42.2)                 |  |  |
| Stimulation Day 8                    | 149.4 (± 92.8)                          | 148.2 (± 90.0)                |  |  |
| End-of-stimulation visit             | 319.1 (± 148.9)                         | 398.0 (± 165.7)               |  |  |

## Statistical analyses

|                            |  |
|----------------------------|--|
| Statistical analysis title | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups          | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |



|   |                        |
|---|------------------------|
| Number of subjects included in analysis | 208                    |
| Analysis specification                  | Pre-specified          |
| Analysis type                           | other <sup>[121]</sup> |
| P-value                                 | = 0.7029               |
| Method                                  | ANCOVA                 |
| Parameter estimate                      | Ratio vs Placebo       |
| Point estimate                          | 0.96                   |
| Confidence interval                     |                        |
| level                                   | 95 %                   |
| sides                                   | 2-sided                |
| lower limit                             | 0.78                   |
| upper limit                             | 1.18                   |

Notes:

[121] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[122]</sup>   |
| P-value                                 | = 0.4906   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.08   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.87   |
| upper limit                             | 1.33   |

Notes:

[122] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[123]</sup>   |
| P-value                                 | = 0.8638   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.02   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.82   |
| upper limit                             | 1.26   |

Notes:

[123] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[124]</sup>   |
| P-value                                 | = 0.4434   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.08   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.88   |
| upper limit                             | 1.33   |

Notes:

[124] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[125]</sup>  |
| P-value                                 | = 0.9426  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 0.99  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.81  |
| upper limit                             | 1.22  |

Notes:

[125] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[126]</sup>   |
| P-value                                 | = 0.5904   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.95   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.79    |
| upper limit         | 1.14    |

Notes:

[126] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[127]</sup>   |
| P-value                                 | = 0.5444   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.06   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.88   |
| upper limit                             | 1.27   |

Notes:

[127] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[128]</sup>   |
| P-value                                 | = 0.9847   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.83   |
| upper limit                             | 1.21   |

Notes:

[128] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                 | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                        |
|---|------------------------|
| Number of subjects included in analysis | 211                    |
| Analysis specification                  | Pre-specified          |
| Analysis type                           | other <sup>[129]</sup> |
| P-value                                 | = 0.4027               |
| Method                                  | ANCOVA                 |
| Parameter estimate                      | Ratio vs Placebo       |
| Point estimate                          | 1.08                   |
| Confidence interval                     |                        |
| level                                   | 95 %                   |
| sides                                   | 2-sided                |
| lower limit                             | 0.9                    |
| upper limit                             | 1.3                    |

Notes:

[129] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[130]</sup>  |
| P-value                                 | = 0.8388  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 0.98  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.81  |
| upper limit                             | 1.18  |

Notes:

[130] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[131]</sup>   |
| P-value                                 | = 0.3474   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.94   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.83   |
| upper limit                             | 1.07   |

Notes:

[131] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[132]</sup>   |
| P-value                                 | = 0.1652   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.92   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.81   |
| upper limit                             | 1.04   |

Notes:

[132] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[133]</sup>   |
| P-value                                 | = 0.1168   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.91   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.8  |
| upper limit                             | 1.03   |

Notes:

[133] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[134]</sup>   |
| P-value                                 | = 0.1567   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.92   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.81    |
| upper limit         | 1.03    |

Notes:

[134] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                 |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[135]</sup>  |
| P-value                                 | = 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 0.79  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.7   |
| upper limit                             | 0.89  |

Notes:

[135] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

### **Secondary: Changes in serum hormone (inhibin B) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation**

|                 |  |
|-----------------|--|
| End point title | Changes in serum hormone (inhibin B) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation |
|-----------------|--|

End point description:

Blood samples for analysis of serum hormone levels were drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, and at end-of-stimulation.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12 µg), Placebo

Stimulation day 6: n=99, n=97, n=95, n=103, n=103, n=96

Stimulation day 8: n=98, n=95, n=93, n=101, n=98, n=94

End-of-stimulation: n=97, n=94, n=94, n=102, n=103, n=94

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

End point timeframe:

Stimulation Day 1 (baseline), Stimulation Day 6, stimulation Day 8, and end-of-stimulation (up to 20 stimulation days)

| End point values                     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed          | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: ng/L                          |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Stimulation Day 6                    | 527.4 (± 256.8)                        | 538.2 (± 283.7)                        | 475.2 (± 258.1)                        | 505.3 (± 255.8)                        |
| Stimulation Day 8                    | 735.1 (± 271.2)                        | 684.9 (± 274.5)                        | 650.7 (± 256.8)                        | 652.5 (± 261.9)                        |
| End-of-stimulation visit             | 731.7 (± 285.8)                        | 668.7 (± 275.4)                        | 662.0 (± 268.5)                        | 620.5 (± 264.5)                        |

| End point values                     | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|--------------------------------------|---|-------------------------------|--|--|
| Subject group type                   | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed          | 104                                     | 104                           |  |  |
| Units: ng/L                          |   |                               |  |  |
| arithmetic mean (standard deviation) |   |                               |  |  |
| Stimulation Day 6                    | 456.0 (± 269.2)                         | 535.4 (± 275.8)               |  |  |
| Stimulation Day 8                    | 569.1 (± 261.6)                         | 717.7 (± 291.7)               |  |  |
| End-of-stimulation visit             | 531.5 (± 264.9)                         | 742.0 (± 287.2)               |  |  |

## Statistical analyses

|   |  |
|---|--|
| Statistical analysis title              | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[136]</sup>   |
| P-value                                 | = 0.8145   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.02   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.86   |
| upper limit                             | 1.21   |

Notes:

[136] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[137]</sup>   |
| P-value                                 | = 0.8796   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.01   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.86   |
| upper limit                             | 1.2  |

Notes:

[137] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[138]</sup>   |
| P-value                                 | = 0.1413   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.88   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.74   |
| upper limit                             | 1.04   |

Notes:

[138] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[139]</sup>   |
| P-value                                 | = 0.898  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.99   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.84   |
| upper limit                             | 1.17   |



Notes:

[139] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[140]</sup>  |
| P-value                                 | = 0.02  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 0.82  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.69  |
| upper limit                             | 0.97  |

Notes:

[140] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[141]</sup>   |
| P-value                                 | = 0.7899   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.02   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.89   |
| upper limit                             | 1.17   |

Notes:

[141] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[142]</sup>   |
| P-value                                 | = 0.4413   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.95   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.83    |
| upper limit         | 1.09    |

Notes:

[142] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[143]</sup>   |
| P-value                                 | = 0.1804   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.91   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.79   |
| upper limit                             | 1.04   |

Notes:

[143] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[144]</sup>   |
| P-value                                 | = 0.2936   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.93   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.81   |
| upper limit                             | 1.06   |

Notes:

[144] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | FE 999302, Placebo (Stimulation Day 8)                                  |
| Comparison groups                 | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                        |
|---|------------------------|
| Number of subjects included in analysis | 208                    |
| Analysis specification                  | Pre-specified          |
| Analysis type                           | other <sup>[145]</sup> |
| P-value                                 | = 0.0002               |
| Method                                  | ANCOVA                 |
| Parameter estimate                      | Ratio vs Placebo       |
| Point estimate                          | 0.77                   |
| Confidence interval                     |                        |
| level                                   | 95 %                   |
| sides                                   | 2-sided                |
| lower limit                             | 0.67                   |
| upper limit                             | 0.88                   |

Notes:

[145] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[146]</sup>   |
| P-value                                 | = 0.5204   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.96   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.84   |
| upper limit                             | 1.09   |

Notes:

[146] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[147]</sup>   |
| P-value                                 | = 0.0468   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.88   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.77   |
| upper limit                             | 1  |

Notes:

[147] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[148]</sup>   |
| P-value                                 | = 0.0417   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.87   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.77   |
| upper limit                             | 0.99   |

Notes:

[148] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[149]</sup>   |
| P-value                                 | = 0.0084   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.84   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.74   |
| upper limit                             | 0.96   |

Notes:

[149] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[150]</sup>  |
| P-value                                 | < 0.0001  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 0.69  |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.6     |
| upper limit         | 0.78    |

Notes:

[150] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

### Secondary: Changes in serum hormone (follicle stimulating hormone [FSH]) levels of from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation

|                 |  |
|-----------------|--|
| End point title | Changes in serum hormone (follicle stimulating hormone [FSH]) levels of from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation |
|-----------------|--|

End point description:

Blood samples for analysis of serum hormone levels were drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, at end-of-stimulation.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12 µg), Placebo

Stimulation day 6: n=103, n=101, n=94, n=104, n=104, n=101

Stimulation day 8: n=99, n=96, n=93, n=103, n=101, n=99

End-of-stimulation: n=102, n=99, n=97, n=103, n=102, n=101

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

End point timeframe:

Stimulation Day 1 (baseline), stimulation Day 6, stimulation Day 8, and end-of-stimulation (up to 20 stimulation days)

| End point values                     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed          | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: IU/L                          |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Stimulation Day 6                    | 10.77 (± 3.39)                         | 11.57 (± 3.51)                         | 11.44 (± 3.85)                         | 10.95 (± 3.20)                         |
| Stimulation Day 8                    | 11.16 (± 3.48)                         | 12.19 (± 4.02)                         | 12.12 (± 4.22)                         | 11.56 (± 3.58)                         |
| End-of-stimulation visit             | 11.11 (± 3.54)                         | 12.20 (± 4.31)                         | 11.87 (± 3.91)                         | 11.67 (± 3.73)                         |

| End point values                     | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|--------------------------------------|---|-------------------------------|--|--|
| Subject group type                   | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed          | 104                                     | 104                           |  |  |
| Units: IU/L                          |   |                               |  |  |
| arithmetic mean (standard deviation) |   |                               |  |  |

|                          |                |                |  |  |
|--------------------------|----------------|----------------|--|--|
| Stimulation Day 6        | 11.08 (± 3.72) | 11.03 (± 3.55) |  |  |
| Stimulation Day 8        | 11.93 (± 4.20) | 11.60 (± 3.50) |  |  |
| End-of-stimulation visit | 11.92 (± 4.41) | 11.73 (± 3.87) |  |  |

## Statistical analyses

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[151]</sup>   |
| P-value                                 | = 0.8378   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.99   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.94   |
| upper limit                             | 1.05   |

Notes:

[151] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[152]</sup>   |
| P-value                                 | = 0.2155   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.03   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.98   |
| upper limit                             | 1.09   |

Notes:

[152] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                 | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                        |
|---|------------------------|
| Number of subjects included in analysis | 203                    |
| Analysis specification                  | Pre-specified          |
| Analysis type                           | other <sup>[153]</sup> |
| P-value                                 | = 0.5823               |
| Method                                  | ANCOVA                 |
| Parameter estimate                      | Ratio vs Placebo       |
| Point estimate                          | 1.02                   |
| Confidence interval                     |                        |
| level                                   | 95 %                   |
| sides                                   | 2-sided                |
| lower limit                             | 0.96                   |
| upper limit                             | 1.07                   |

Notes:

[153] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[154]</sup>   |
| P-value                                 | = 0.9766   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.95   |
| upper limit                             | 1.05   |

Notes:

[154] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[155]</sup>  |
| P-value                                 | = 0.7826  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 1.01  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.96  |
| upper limit                             | 1.06  |

Notes:

[155] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[156]</sup>   |
| P-value                                 | = 0.5283   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.98   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.93   |
| upper limit                             | 1.04   |

Notes:

[156] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[157]</sup>   |
| P-value                                 | = 0.2565   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.03   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.98   |
| upper limit                             | 1.1  |

Notes:

[157] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[158]</sup>   |
| P-value                                 | = 0.671  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.01   |



|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.96    |
| upper limit         | 1.07    |

Notes:

[158] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[159]</sup>   |
| P-value                                 | = 0.9139   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.94   |
| upper limit                             | 1.06   |

Notes:

[159] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[160]</sup>  |
| P-value                                 | = 0.3999  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 1.02  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.97  |
| upper limit                             | 1.09  |

Notes:

[160] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                 | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                        |
|---|------------------------|
| Number of subjects included in analysis | 208                    |
| Analysis specification                  | Pre-specified          |
| Analysis type                           | other <sup>[161]</sup> |
| P-value                                 | = 0.4039               |
| Method                                  | ANCOVA                 |
| Parameter estimate                      | Ratio vs Placebo       |
| Point estimate                          | 0.98                   |
| Confidence interval                     |                        |
| level                                   | 95 %                   |
| sides                                   | 2-sided                |
| lower limit                             | 0.92                   |
| upper limit                             | 1.03                   |

Notes:

[161] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[162]</sup>   |
| P-value                                 | = 0.5442   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.02   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.96   |
| upper limit                             | 1.08   |

Notes:

[162] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[163]</sup>   |
| P-value                                 | = 0.7983   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.99   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.94   |
| upper limit                             | 1.05   |

Notes:

[163] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[164]</sup>   |
| P-value                                 | = 0.8476   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.99   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.94   |
| upper limit                             | 1.05   |

Notes:

[164] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                 |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[165]</sup>  |
| P-value                                 | = 0.6936  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 1.01  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.96  |
| upper limit                             | 1.07  |

Notes:

[165] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

### **Secondary: Changes in serum hormone (luteinising hormone [LH]) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation**

|                 |   |
|-----------------|---|
| End point title | Changes in serum hormone (luteinising hormone [LH]) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation |
|-----------------|---|

End point description:

Blood samples for analysis of hormone concentrations are drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, and at end-of-stimulation.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12

µg), Placebo

Stimulation day 6: n=103, n=101, n=97, n=104, n=104, n=102

Stimulation day 8: n=100, n=97, n=95, n=103, n=101, n=100

End-of-stimulation: n=103, n=99, n=99, n=103, n=102, n=101

|  |           |
|--|-----------|
| End point type   | Secondary |
| End point timeframe:   |           |
| Stimulation Day 1 (baseline), stimulation Day 6, stimulation Day 8, and end-of-stimulation (up to 20 stimulation days) |           |

| End point values                     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed          | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: IU/L                          |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Stimulation Day 6                    | -0.75 (± 0.72)                         | -0.79 (± 0.86)                         | -0.66 (± 0.75)                         | -0.76 (± 0.88)                         |
| Stimulation Day 8                    | -0.70 (± 0.83)                         | -0.78 (± 0.99)                         | -0.67 (± 0.93)                         | -0.64 (± 1.04)                         |
| End-of-stimulation visit             | -0.56 (± 0.96)                         | -0.68 (± 1.15)                         | -0.59 (± 1.00)                         | -0.60 (± 1.01)                         |

| End point values                     | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|--------------------------------------|---|-------------------------------|--|--|
| Subject group type                   | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed          | 104                                     | 104                           |  |  |
| Units: IU/L                          |   |                               |  |  |
| arithmetic mean (standard deviation) |   |                               |  |  |
| Stimulation Day 6                    | -0.80 (± 0.75)                          | -0.75 (± 0.75)                |  |  |
| Stimulation Day 8                    | -0.71 (± 0.94)                          | -0.83 (± 0.82)                |  |  |
| End-of-stimulation visit             | -0.80 (± 1.02)                          | -0.67 (± 0.86)                |  |  |

## Statistical analyses

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[166]</sup>   |
| P-value                                 | = 0.5027   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.96   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.85    |
| upper limit         | 1.08    |

Notes:

[166] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[167]</sup>   |
| P-value                                 | = 0.6268   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.03   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.92   |
| upper limit                             | 1.16   |

Notes:

[167] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[168]</sup>   |
| P-value                                 | = 0.2721   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.07   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.95   |
| upper limit                             | 1.2  |

Notes:

[168] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo (Stimulation Day 6)                                 |
| Comparison groups                 | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                        |
|---|------------------------|
| Number of subjects included in analysis | 211                    |
| Analysis specification                  | Pre-specified          |
| Analysis type                           | other <sup>[169]</sup> |
| P-value                                 | = 0.5182               |
| Method                                  | ANCOVA                 |
| Parameter estimate                      | Ratio vs Placebo       |
| Point estimate                          | 1.04                   |
| Confidence interval                     |                        |
| level                                   | 95 %                   |
| sides                                   | 2-sided                |
| lower limit                             | 0.92                   |
| upper limit                             | 1.17                   |

Notes:

[169] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 6)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[170]</sup>  |
| P-value                                 | = 0.892   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 0.99  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.88  |
| upper limit                             | 1.11  |

Notes:

[170] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[171]</sup>   |
| P-value                                 | = 0.5371   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.05   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.91   |
| upper limit                             | 1.2  |

Notes:

[171] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[172]</sup>   |
| P-value                                 | = 0.0608   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.15   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.99   |
| upper limit                             | 1.32   |

Notes:

[172] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[173]</sup>   |
| P-value                                 | = 0.101  |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.13   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.98   |
| upper limit                             | 1.3  |

Notes:

[173] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                 |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[174]</sup>   |
| P-value                                 | = 0.0118   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.2  |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 1.04    |
| upper limit         | 1.38    |

Notes:

[174] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (Stimulation Day 8)                                  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[175]</sup>  |
| P-value                                 | = 0.1043  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 1.12  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.98  |
| upper limit                             | 1.29  |

Notes:

[175] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[176]</sup>   |
| P-value                                 | = 0.3746   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.06   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.93   |
| upper limit                             | 1.21   |

Notes:

[176] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                 | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |



|   |                        |
|---|------------------------|
| Number of subjects included in analysis | 205                    |
| Analysis specification                  | Pre-specified          |
| Analysis type                           | other <sup>[177]</sup> |
| P-value                                 | = 0.3276               |
| Method                                  | ANCOVA                 |
| Parameter estimate                      | Ratio vs Placebo       |
| Point estimate                          | 1.07                   |
| Confidence interval                     |                        |
| level                                   | 95 %                   |
| sides                                   | 2-sided                |
| lower limit                             | 0.93                   |
| upper limit                             | 1.22                   |

Notes:

[177] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[178]</sup>   |
| P-value                                 | = 0.1474   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.1  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.97   |
| upper limit                             | 1.26   |

Notes:

[178] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                |
| Comparison groups                       | Placebo and Follitropin Delta v FE 999302 (8 µg) and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[179]</sup>   |
| P-value                                 | = 0.3032   |
| Method                                  | ANCOVA   |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 1.07   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.94   |
| upper limit                             | 1.23   |

Notes:

[179] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo (End-of-stimulation)                                 |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[180]</sup>  |
| P-value                                 | = 0.4131  |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 0.95  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.83  |
| upper limit                             | 1.08  |

Notes:

[180] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

### Secondary: Positive βhCG (positive serum βhCG test 13-15 days after transfer)

|                 |  |
|-----------------|--|
| End point title | Positive βhCG (positive serum βhCG test 13-15 days after transfer) |
|-----------------|--|

End point description:

Positive βhCG rate was defined as positive serum βhCG test 13-15 days after transfer.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

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

End point timeframe:

13-15 days after blastocyst transfer

| End point values                   | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|------------------------------------|--|--|--|--|
| Subject group type                 | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed        | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: Number of positive subjects |  |  |  |  |
| number (not applicable)            | 36                                     | 40                                     | 45                                     | 51                                     |

|                  |   |                               |  |  |
|------------------|---|-------------------------------|--|--|
| End point values | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|------------------|---|-------------------------------|--|--|

|                                    |                 |                 |  |  |
|------------------------------------|-----------------|-----------------|--|--|
| Subject group type                 | Reporting group | Reporting group |  |  |
| Number of subjects analysed        | 104             | 104             |  |  |
| Units: Number of positive subjects |                 |                 |  |  |
| number (not applicable)            | 43              | 52              |  |  |

## Statistical analyses

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | Placebo and Follitropin Delta v FE 999302 (1 µg) and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[181]</sup>   |
| P-value                                 | = 0.0264   |
| Method                                  | Logistic regression model  |
| Parameter estimate                      | Odds ratio (OR)  |
| Point estimate                          | 0.53   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.3  |
| upper limit                             | 0.93   |

Notes:

[181] - Logistic regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[182]</sup>   |
| P-value                                 | = 0.1293   |
| Method                                  | Logistic regression model  |
| Parameter estimate                      | Odds ratio (OR)  |
| Point estimate                          | 0.65   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.37   |
| upper limit                             | 1.13   |

Notes:

[182] - Logistic regression model with treatment, age strata, and AMH group as factors.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo   |
| Comparison groups                 | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                           |
|---|---------------------------|
| Number of subjects included in analysis | 203                       |
| Analysis specification                  | Pre-specified             |
| Analysis type                           | other <sup>[183]</sup>    |
| P-value                                 | = 0.5392                  |
| Method                                  | Logistic regression model |
| Parameter estimate                      | Odds ratio (OR)           |
| Point estimate                          | 0.84                      |
| Confidence interval                     |                           |
| level                                   | 95 %                      |
| sides                                   | 2-sided                   |
| lower limit                             | 0.48                      |
| upper limit                             | 1.47                      |

Notes:

[183] - Logistic regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[184]</sup>   |
| P-value                                 | = 0.7899   |
| Method                                  | Logistic regression model  |
| Parameter estimate                      | Odds ratio (OR)  |
| Point estimate                          | 0.93   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.54   |
| upper limit                             | 1.6  |

Notes:

[184] - Logistic regression model with treatment, age strata, and AMH group as factors.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[185]</sup>  |
| P-value                                 | = 0.2208  |
| Method                                  | Logistic regression model   |
| Parameter estimate                      | Odds ratio (OR)   |
| Point estimate                          | 0.71  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.41  |
| upper limit                             | 1.23  |

Notes:

[185] - Logistic regression model with treatment, age strata, and AMH group as factors.

**Secondary: Clinical pregnancy (at least one gestational sac 5-6 weeks after transfer)**

|                 |  |
|-----------------|--|
| End point title | Clinical pregnancy (at least one gestational sac 5-6 weeks after transfer) |
|-----------------|--|

End point description:

Clinical pregnancy was defined as at least one gestational sac 5-6 weeks after transfer.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

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

End point timeframe:

5-6 weeks after blastocyst transfer

| End point values                   | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|------------------------------------|--|--|--|--|
| Subject group type                 | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed        | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: Number of positive subjects |  |  |  |  |
| number (not applicable)            | 32                                     | 34                                     | 44                                     | 48                                     |

| End point values                   | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|------------------------------------|---|-------------------------------|--|--|
| Subject group type                 | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed        | 104                                     | 104                           |  |  |
| Units: Number of positive subjects |   |                               |  |  |
| number (not applicable)            | 40                                      | 51                            |  |  |

**Statistical analyses**

| Statistical analysis title              | FE 999302, Placebo   |
|---|--|
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[186]</sup>   |
| P-value                                 | = 0.0081   |
| Method                                  | Logistic regression model  |
| Parameter estimate                      | Odds ratio (OR)  |
| Point estimate                          | 0.46   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.26    |
| upper limit         | 0.82    |

Notes:

[186] - Logistic regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[187]</sup>   |
| P-value                                 | = 0.0242   |
| Method                                  | Logistic regression model  |
| Parameter estimate                      | Odds ratio (OR)  |
| Point estimate                          | 0.52   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.29   |
| upper limit                             | 0.92   |

Notes:

[187] - Logistic regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[188]</sup>   |
| P-value                                 | = 0.5407   |
| Method                                  | Logistic regression model  |
| Parameter estimate                      | Odds ratio (OR)  |
| Point estimate                          | 0.84   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.48   |
| upper limit                             | 1.47   |

Notes:

[188] - Logistic regression model with treatment, age strata, and AMH group as factors.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo   |
| Comparison groups                 | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                           |
|---|---------------------------|
| Number of subjects included in analysis | 211                       |
| Analysis specification                  | Pre-specified             |
| Analysis type                           | other <sup>[189]</sup>    |
| P-value                                 | = 0.5971                  |
| Method                                  | Logistic regression model |
| Parameter estimate                      | Odds ratio (OR)           |
| Point estimate                          | 0.86                      |
| Confidence interval                     |                           |
| level                                   | 95 %                      |
| sides                                   | 2-sided                   |
| lower limit                             | 0.5                       |
| upper limit                             | 1.49                      |

Notes:

[189] - Logistic regression model with treatment, age strata, and AMH group as factors.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[190]</sup>  |
| P-value                                 | = 0.1325  |
| Method                                  | Logistic regression model   |
| Parameter estimate                      | Odds ratio (OR)   |
| Point estimate                          | 0.65  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.37  |
| upper limit                             | 1.14  |

Notes:

[190] - Logistic regression model with treatment, age strata, and AMH group as factors.

### **Secondary: Vital pregnancy (at least one intrauterine gestational sac with fetal heart beat 5-6 weeks after transfer)**

|                 |  |
|-----------------|--|
| End point title | Vital pregnancy (at least one intrauterine gestational sac with fetal heart beat 5-6 weeks after transfer) |
|-----------------|--|

End point description:

Vital pregnancy was defined as at least one intrauterine gestational sac with fetal heart beat 5-6 weeks after transfer.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

|                                     |           |
|-------------------------------------|-----------|
| End point type                      | Secondary |
| End point timeframe:                |           |
| 5-6 weeks after blastocyst transfer |           |

| End point values                   | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|------------------------------------|--|--|--|--|
| Subject group type                 | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed        | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: Number of positive subjects |  |  |  |  |
| number (not applicable)            | 30                                     | 31                                     | 41                                     | 43                                     |

| End point values                   | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|------------------------------------|---|-------------------------------|--|--|
| Subject group type                 | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed        | 104                                     | 104                           |  |  |
| Units: Number of positive subjects |   |                               |  |  |
| number (not applicable)            | 37                                      | 45                            |  |  |

## Statistical analyses

| Statistical analysis title              | FE 999302, Placebo   |
|---|--|
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[191]</sup>   |
| P-value                                 | = 0.031  |
| Method                                  | Logistic regression model  |
| Parameter estimate                      | Odds ratio (OR)  |
| Point estimate                          | 0.53   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.3  |
| upper limit                             | 0.94   |

Notes:

[191] - Logistic regression model with treatment, age strata, and AMH group as factors.

| Statistical analysis title              | FE 999302, Placebo   |
|---|--|
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[192]</sup>   |
| P-value                                 | = 0.0589   |
| Method                                  | Logistic regression model  |
| Parameter estimate                      | Odds ratio (OR)  |
| Point estimate                          | 0.57   |



|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.32    |
| upper limit         | 1.02    |

Notes:

[192] - Logistic regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[193]</sup>   |
| P-value                                 | = 0.8116   |
| Method                                  | Logistic regression model  |
| Parameter estimate                      | Odds ratio (OR)  |
| Point estimate                          | 0.93   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.53   |
| upper limit                             | 1.64   |

Notes:

[193] - Logistic regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[194]</sup>   |
| P-value                                 | = 0.7012   |
| Method                                  | Logistic regression model  |
| Parameter estimate                      | Odds ratio (OR)  |
| Point estimate                          | 0.9  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.52   |
| upper limit                             | 1.56   |

Notes:

[194] - Logistic regression model with treatment, age strata, and AMH group as factors.

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | FE 999302, Placebo  |
| Comparison groups                 | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                           |
|---|---------------------------|
| Number of subjects included in analysis | 208                       |
| Analysis specification                  | Pre-specified             |
| Analysis type                           | other <sup>[195]</sup>    |
| P-value                                 | = 0.2665                  |
| Method                                  | Logistic regression model |
| Parameter estimate                      | Odds ratio (OR)           |
| Point estimate                          | 0.73                      |
| Confidence interval                     |                           |
| level                                   | 95 %                      |
| sides                                   | 2-sided                   |
| lower limit                             | 0.41                      |
| upper limit                             | 1.28                      |

Notes:

[195] - Logistic regression model with treatment, age strata, and AMH group as factors.

### Secondary: Ongoing pregnancy (at least one intrauterine viable fetus 10-11 weeks after transfer)

|                 |   |
|-----------------|---|
| End point title | Ongoing pregnancy (at least one intrauterine viable fetus 10-11 weeks after transfer) |
|-----------------|---|

End point description:

Ongoing pregnancy was defined as at least one intrauterine viable fetus 10-11 weeks after transfer.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

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

End point timeframe:

10-11 weeks after blastocyst transfer

| End point values                   | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|------------------------------------|--|--|--|--|
| Subject group type                 | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed        | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: Number of positive subjects |  |  |  |  |
| number (not applicable)            | 30                                     | 30                                     | 39                                     | 40                                     |

| End point values                   | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|------------------------------------|---|-------------------------------|--|--|
| Subject group type                 | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed        | 104                                     | 104                           |  |  |
| Units: Number of positive subjects |   |                               |  |  |
| number (not applicable)            | 32                                      | 45                            |  |  |

## Statistical analyses

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[196]</sup>   |
| P-value                                 | = 0.0307   |
| Method                                  | Logistic regression model  |
| Parameter estimate                      | Odds ratio (OR)  |
| Point estimate                          | 0.53   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.29   |
| upper limit                             | 0.94   |

Notes:

[196] - Logistic regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[197]</sup>   |
| P-value                                 | = 0.041  |
| Method                                  | Logistic regression model  |
| Parameter estimate                      | Odds ratio (OR)  |
| Point estimate                          | 0.54   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.3  |
| upper limit                             | 0.98   |

Notes:

[197] - Logistic regression model with treatment, age strata, and AMH group as factors.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo   |
| Comparison groups                 | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                           |
|---|---------------------------|
| Number of subjects included in analysis | 203                       |
| Analysis specification                  | Pre-specified             |
| Analysis type                           | other <sup>[198]</sup>    |
| P-value                                 | = 0.5934                  |
| Method                                  | Logistic regression model |
| Parameter estimate                      | Odds ratio (OR)           |
| Point estimate                          | 0.86                      |
| Confidence interval                     |                           |
| level                                   | 95 %                      |
| sides                                   | 2-sided                   |
| lower limit                             | 0.49                      |
| upper limit                             | 1.51                      |

Notes:

[198] - Logistic regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[199]</sup>   |
| P-value                                 | = 0.4221   |
| Method                                  | Logistic regression model  |
| Parameter estimate                      | Odds ratio (OR)  |
| Point estimate                          | 0.8  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.46   |
| upper limit                             | 1.39   |

Notes:

[199] - Logistic regression model with treatment, age strata, and AMH group as factors.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[200]</sup>  |
| P-value                                 | = 0.065   |
| Method                                  | Logistic regression model   |
| Parameter estimate                      | Odds ratio (OR)   |
| Point estimate                          | 0.58  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.33  |
| upper limit                             | 1.03  |

Notes:

[200] - Logistic regression model with treatment, age strata, and AMH group as factors.

**Secondary: Number of oocytes retrieved**

|   |                             |
|---|-----------------------------|
| End point title   | Number of oocytes retrieved |
| End point description:<br>The number of oocytes retrieved was recorded at the oocyte retrieval visit. |                             |
| End point type  | Secondary                   |
| End point timeframe:<br>Day of oocyte retrieval   |                             |

| End point values                     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed          | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: Number of oocytes retrieved   |  |  |  |  |
| arithmetic mean (standard deviation) | 10.9 (± 4.8)                           | 10.8 (± 5.6)                           | 10.8 (± 5.2)                           | 11.3 (± 4.9)                           |

| End point values                     | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|--------------------------------------|---|-------------------------------|--|--|
| Subject group type                   | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed          | 104                                     | 104                           |  |  |
| Units: Number of oocytes retrieved   |   |                               |  |  |
| arithmetic mean (standard deviation) | 9.8 (± 4.9)                             | 12.5 (± 6.4)                  |  |  |

**Statistical analyses**

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[201]</sup>   |
| P-value                                 | = 0.0075   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.84   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.75   |
| upper limit                             | 0.96   |

Notes:

[201] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[202]</sup>   |
| P-value                                 | = 0.013  |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.85   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.75   |
| upper limit                             | 0.97   |

Notes:

[202] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[203]</sup>   |
| P-value                                 | = 0.0081   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.84   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.74   |
| upper limit                             | 0.96   |

Notes:

[203] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[204]</sup>   |
| P-value                                 | = 0.091  |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.9  |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.8     |
| upper limit         | 1.02    |

Notes:

[204] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[205]</sup>  |
| P-value                                 | < 0.0001  |
| Method                                  | Negative binomial regression model                                      |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 0.78  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.69  |
| upper limit                             | 0.88  |

Notes:

[205] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

## Secondary: Number of metaphase II oocytes

|   |                                |
|---|--------------------------------|
| End point title   | Number of metaphase II oocytes |
| End point description:  |                                |
| Number of oocytes in metaphase II prior to intracytoplasmic sperm injection (ICSI) insemination.  |                                |
| The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received. |                                |
| End point type  | Secondary                      |
| End point timeframe:  |                                |
| Prior to insemination   |                                |

| End point values                     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed          | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: Number of oocytes             |  |  |  |  |
| arithmetic mean (standard deviation) | 8.5 (± 4.0)                            | 8.4 (± 4.9)                            | 8.2 (± 4.5)                            | 8.5 (± 4.3)                            |

|                                      |   |                               |  |  |
|--------------------------------------|---|-------------------------------|--|--|
| <b>End point values</b>              | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
| Subject group type                   | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed          | 104                                     | 104                           |  |  |
| Units: Number of oocytes             |   |                               |  |  |
| arithmetic mean (standard deviation) | 7.4 (± 4.2)                             | 9.7 (± 5.2)                   |  |  |

## Statistical analyses

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[206]</sup>   |
| P-value                                 | = 0.0203   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.85   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.74   |
| upper limit                             | 0.97   |

Notes:

[206] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[207]</sup>   |
| P-value                                 | = 0.0269   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.86   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.74   |
| upper limit                             | 0.98   |

Notes:

[207] - Treatment groups were compared using a Negative binomial regression model with treatment, age strata, and AMH group as factors.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo   |
| Comparison groups                 | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |



|   |                                    |
|---|------------------------------------|
| Number of subjects included in analysis | 203                                |
| Analysis specification                  | Pre-specified                      |
| Analysis type                           | other <sup>[208]</sup>             |
| P-value                                 | = 0.0078                           |
| Method                                  | Negative binomial regression model |
| Parameter estimate                      | Ratio vs Placebo                   |
| Point estimate                          | 0.83                               |
| Confidence interval                     |                                    |
| level                                   | 95 %                               |
| sides                                   | 2-sided                            |
| lower limit                             | 0.72                               |
| upper limit                             | 0.95                               |

Notes:

[208] - Treatment groups were compared using a Negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[209]</sup>   |
| P-value                                 | = 0.044  |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.87   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.76   |
| upper limit                             | 1  |

Notes:

[209] - Treatment groups were compared using a Negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[210]</sup>  |
| P-value                                 | < 0.0001  |
| Method                                  | Negative binomial regression model                                      |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 0.75  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.65  |
| upper limit                             | 0.86  |

Notes:

[210] - Treatment groups were compared using a Negative binomial regression model with treatment, age strata, and AMH group as factors.

**Secondary: Number of fertilised (2 pronuclei [PN]) oocytes**

|                 |   |
|-----------------|---|
| End point title | Number of fertilised (2 pronuclei [PN]) oocytes |
|-----------------|---|

End point description:

The number of pronuclei was counted on day 1 after insemination and recorded as 0, 1, 2, or >2. Fertilised oocytes with 2PN were regarded as correctly fertilised.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

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

End point timeframe:

On Day 1 after insemination

| End point values                     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed          | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: Number of oocytes             |  |  |  |  |
| arithmetic mean (standard deviation) | 6.2 (± 3.6)                            | 6.2 (± 3.9)                            | 5.7 (± 3.7)                            | 6.0 (± 3.6)                            |

| End point values                     | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|--------------------------------------|---|-------------------------------|--|--|
| Subject group type                   | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed          | 104                                     | 104                           |  |  |
| Units: Number of oocytes             |   |                               |  |  |
| arithmetic mean (standard deviation) | 5.2 (± 3.7)                             | 7.4 (± 4.2)                   |  |  |

**Statistical analyses**

|   |  |
|---|--|
| Statistical analysis title              | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[211]</sup>   |
| P-value                                 | = 0.0104   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.81   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.69    |
| upper limit         | 0.95    |

Notes:

[211] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 205  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[212]</sup>   |
| P-value                                 | = 0.0209   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.82   |

Confidence interval

|             |         |
|-------------|---------|
| level       | 95 %    |
| sides       | 2-sided |
| lower limit | 0.7     |
| upper limit | 0.97    |

Notes:

[212] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | FE 999302, Placebo   |
| Comparison groups                       | FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 203  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | other <sup>[213]</sup>   |
| P-value                                 | = 0.0006   |
| Method                                  | Negative binomial regression model                                     |
| Parameter estimate                      | Ratio vs Placebo   |
| Point estimate                          | 0.75   |

Confidence interval

|             |         |
|-------------|---------|
| level       | 95 %    |
| sides       | 2-sided |
| lower limit | 0.63    |
| upper limit | 0.88    |

Notes:

[213] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|                                   |  |
|-----------------------------------|--|
| <b>Statistical analysis title</b> | FE 999302, Placebo   |
| Comparison groups                 | FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta |

|   |                                    |
|---|------------------------------------|
| Number of subjects included in analysis | 211                                |
| Analysis specification                  | Pre-specified                      |
| Analysis type                           | other <sup>[214]</sup>             |
| P-value                                 | = 0.0069                           |
| Method                                  | Negative binomial regression model |
| Parameter estimate                      | Ratio vs Placebo                   |
| Point estimate                          | 0.8                                |
| Confidence interval                     |                                    |
| level                                   | 95 %                               |
| sides                                   | 2-sided                            |
| lower limit                             | 0.68                               |
| upper limit                             | 0.94                               |

Notes:

[214] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | FE 999302, Placebo  |
| Comparison groups                       | FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta |
| Number of subjects included in analysis | 208   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | other <sup>[215]</sup>  |
| P-value                                 | < 0.0001  |
| Method                                  | Negative binomial regression model                                      |
| Parameter estimate                      | Ratio vs Placebo  |
| Point estimate                          | 0.69  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.58  |
| upper limit                             | 0.82  |

Notes:

[215] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

### **Secondary: Incidence of ovarian hyperstimulation syndrome (OHSS) (early or late, any grade)**

|                 |  |
|-----------------|--|
| End point title | Incidence of ovarian hyperstimulation syndrome (OHSS) (early or late, any grade) |
|-----------------|--|

End point description:

Early OHSS was defined as OHSS with onset ≤9 days after triggering of final follicular maturation (including OHSS with onset before triggering and OHSS with onset during stimulation where triggering was not performed). Late OHSS was defined as OHSS with onset >9 days after triggering of final follicular maturation.

The safety analysis set was identical to the FAS (including allocation to treatment). The FAS consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

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

End point timeframe:

From stimulation Day 1 to end-of-trial

| End point values            | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|-----------------------------|--|--|--|--|
| Subject group type          | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: Number of subjects   |  |  |  |  |
| number (not applicable)     |  |  |  |  |
| All OHSS (Any grade)        | 6                                      | 2                                      | 6                                      | 11                                     |
| All early OHSS (Any grade)  | 3                                      | 2                                      | 4                                      | 7                                      |
| All late OHSS (Any grade)   | 3                                      | 0                                      | 2                                      | 4                                      |

| End point values            | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|-----------------------------|---|-------------------------------|--|--|
| Subject group type          | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed | 104                                     | 104                           |  |  |
| Units: Number of subjects   |   |                               |  |  |
| number (not applicable)     |   |                               |  |  |
| All OHSS (Any grade)        | 4                                       | 12                            |  |  |
| All early OHSS (Any grade)  | 3                                       | 6                             |  |  |
| All late OHSS (Any grade)   | 1                                       | 6                             |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Incidence and intensity of adverse events

|                 |   |
|-----------------|---|
| End point title | Incidence and intensity of adverse events |
|-----------------|---|

End point description:

The adverse events (AEs) occurring after start of IMP and before the end-of-trial visit, or a pre-treatment AE or pre-existing medical condition that worsens in intensity after start of FE 999302 or placebo treatment and before the end-of-trial visit were considered treatment-emergent AEs and are presented for this endpoint. Intensity of AEs was classified as mild, moderate or severe and is also presented for this endpoint.

The safety analysis set was identical to the FAS (including allocation to treatment). The FAS consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

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

End point timeframe:

From screening to end-of-trial (estimated maximum of 4 months from start of stimulation)

| <b>End point values</b>     | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta | FE 999302 (8 µg) and Follitropin Delta |
|-----------------------------|--|--|--|--|
| Subject group type          | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group                        |
| Number of subjects analysed | 104                                    | 101                                    | 99                                     | 107                                    |
| Units: Number of subjects   |  |  |  |  |
| number (not applicable)     |  |  |  |  |
| All AEs                     | 47                                     | 40                                     | 48                                     | 56                                     |
| Mild AEs                    | 40                                     | 33                                     | 37                                     | 45                                     |
| Moderate AEs                | 17                                     | 9                                      | 16                                     | 14                                     |
| Severe AEs                  | 0                                      | 5                                      | 1                                      | 3                                      |

| <b>End point values</b>     | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |  |  |
|-----------------------------|---|-------------------------------|--|--|
| Subject group type          | Reporting group                         | Reporting group               |  |  |
| Number of subjects analysed | 104                                     | 104                           |  |  |
| Units: Number of subjects   |   |                               |  |  |
| number (not applicable)     |   |                               |  |  |
| All AEs                     | 44                                      | 50                            |  |  |
| Mild AEs                    | 37                                      | 38                            |  |  |
| Moderate AEs                | 12                                      | 17                            |  |  |
| Severe AEs                  | 1                                       | 5                             |  |  |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

The AEs were recorded from From screening to end-of-trial

Adverse event reporting additional description:

Adverse events occurring after start of IMP and before the end-of-trial visit, or a pre-treatment AE or pre-existing medical condition that worsens in intensity after start of FE 999302 or placebo treatment and before the end-of-trial visit (treatment-emergent AEs) are presented for the safety analysis set.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 21.0 |
|--------------------|------|

### Reporting groups

|                       |  |
|-----------------------|--|
| Reporting group title | FE 999302 (1 µg) and Follitropin Delta |
|-----------------------|--|

Reporting group description:

Dose 1 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

|                       |  |
|-----------------------|--|
| Reporting group title | FE 999302 (2 µg) and Follitropin Delta |
|-----------------------|--|

Reporting group description:

Dose 2 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

|                       |  |
|-----------------------|--|
| Reporting group title | FE 999302 (4 µg) and Follitropin Delta |
|-----------------------|--|

Reporting group description:

Dose 4 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

|                       |  |
|-----------------------|--|
| Reporting group title | FE 999302 (8 µg) and Follitropin Delta |
|-----------------------|--|

Reporting group description:

Dose 8 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

|                       |   |
|-----------------------|---|
| Reporting group title | FE 999302 (12 µg) and Follitropin Delta |
|-----------------------|---|

Reporting group description:

Dose 12 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

|                       |                               |
|-----------------------|-------------------------------|
| Reporting group title | Placebo and Follitropin Delta |
|-----------------------|-------------------------------|

Reporting group description:

Placebo and individualised follitropin delta dose

| Serious adverse events                            | FE 999302 (1 µg) and Follitropin Delta | FE 999302 (2 µg) and Follitropin Delta | FE 999302 (4 µg) and Follitropin Delta |
|---|--|--|--|
| Total subjects affected by serious adverse events |  |  |  |
| subjects affected / exposed                       | 1 / 104 (0.96%)                        | 1 / 101 (0.99%)                        | 1 / 99 (1.01%)                         |
| number of deaths (all causes)                     | 0                                      | 0                                      | 0                                      |
| number of deaths resulting from adverse events    | 0                                      | 0                                      | 0                                      |
| Injury, poisoning and procedural complications    |  |  |  |
| Post procedural haemorrhage                       |  |  |  |
| subjects affected / exposed                       | 0 / 104 (0.00%)                        | 0 / 101 (0.00%)                        | 0 / 99 (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                                  |

|   |                 |                 |                |
|---|-----------------|-----------------|----------------|
| Pregnancy, puerperium and perinatal conditions  |                 |                 |                |
| Abortion spontaneous                            |                 |                 |                |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 101 (0.00%) | 0 / 99 (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          |
| Abortion threatened                             |                 |                 |                |
| subjects affected / exposed                     | 1 / 104 (0.96%) | 0 / 101 (0.00%) | 0 / 99 (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          |
| Vomiting in pregnancy                           |                 |                 |                |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 101 (0.00%) | 0 / 99 (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        |                 |                 |                |
| Ovarian hyperstimulation syndrome               |                 |                 |                |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 101 (0.00%) | 1 / 99 (1.01%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0          |
| Adnexal torsion                                 |                 |                 |                |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 101 (0.00%) | 0 / 99 (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          |
| Ovarian cyst                                    |                 |                 |                |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 1 / 101 (0.99%) | 0 / 99 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0          |

| <b>Serious adverse events</b>                     | FE 999302 (8 µg) and Follitropin Delta | FE 999302 (12 µg) and Follitropin Delta | Placebo and Follitropin Delta |
|---|--|---|-------------------------------|
| Total subjects affected by serious adverse events |  |   |                               |
| subjects affected / exposed                       | 3 / 107 (2.80%)                        | 2 / 104 (1.92%)                         | 3 / 104 (2.88%)               |
| number of deaths (all causes)                     | 0                                      | 0                                       | 0                             |
| number of deaths resulting from adverse events    | 0                                      | 0                                       | 0                             |
| Injury, poisoning and procedural complications    |  |   |                               |
| Post procedural haemorrhage                       |  |   |                               |



|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 1 / 107 (0.93%) | 0 / 104 (0.00%) | 0 / 104 (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           |
| Pregnancy, puerperium and perinatal conditions  |                 |                 |                 |
| Abortion spontaneous                            |                 |                 |                 |
| subjects affected / exposed                     | 0 / 107 (0.00%) | 1 / 104 (0.96%) | 0 / 104 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Abortion threatened                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 107 (0.00%) | 0 / 104 (0.00%) | 0 / 104 (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           |
| Vomiting in pregnancy                           |                 |                 |                 |
| subjects affected / exposed                     | 0 / 107 (0.00%) | 0 / 104 (0.00%) | 1 / 104 (0.96%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Reproductive system and breast disorders        |                 |                 |                 |
| Ovarian hyperstimulation syndrome               |                 |                 |                 |
| subjects affected / exposed                     | 1 / 107 (0.93%) | 1 / 104 (0.96%) | 2 / 104 (1.92%) |
| occurrences causally related to treatment / all | 1 / 1           | 1 / 1           | 1 / 2           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Adnexal torsion                                 |                 |                 |                 |
| subjects affected / exposed                     | 1 / 107 (0.93%) | 0 / 104 (0.00%) | 0 / 104 (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           |
| Ovarian cyst                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 107 (0.00%) | 0 / 104 (0.00%) | 0 / 104 (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           |

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

| <b>Non-serious adverse events</b>                     | FE 999302 (1 µg)<br>and Follitropin Delta | FE 999302 (2 µg)<br>and Follitropin Delta | FE 999302 (4 µg)<br>and Follitropin Delta |
|---|---|---|---|
| Total subjects affected by non-serious adverse events |   |   |   |
| subjects affected / exposed                           | 28 / 104 (26.92%)                         | 19 / 101 (18.81%)                         | 32 / 99 (32.32%)                          |
| Injury, poisoning and procedural complications        |   |   |   |
| Procedural pain                                       |   |   |   |
| subjects affected / exposed                           | 1 / 104 (0.96%)                           | 2 / 101 (1.98%)                           | 4 / 99 (4.04%)                            |
| occurrences (all)                                     | 1   | 2   | 4   |
| Nervous system disorders                              |   |   |   |
| Headache  |   |   |   |
| subjects affected / exposed                           | 11 / 104 (10.58%)                         | 8 / 101 (7.92%)                           | 13 / 99 (13.13%)                          |
| occurrences (all)                                     | 12  | 9   | 13  |
| Pregnancy, puerperium and perinatal conditions        |   |   |   |
| Abortion spontaneous                                  |   |   |   |
| subjects affected / exposed                           | 1 / 104 (0.96%)                           | 2 / 101 (1.98%)                           | 5 / 99 (5.05%)                            |
| occurrences (all)                                     | 1   | 2   | 5   |
| Biochemical pregnancy                                 |   |   |   |
| subjects affected / exposed                           | 4 / 104 (3.85%)                           | 6 / 101 (5.94%)                           | 1 / 99 (1.01%)                            |
| occurrences (all)                                     | 4   | 6   | 1   |
| Reproductive system and breast disorders              |   |   |   |
| Ovarian hyperstimulation syndrome                     |   |   |   |
| subjects affected / exposed                           | 6 / 104 (5.77%)                           | 2 / 101 (1.98%)                           | 5 / 99 (5.05%)                            |
| occurrences (all)                                     | 6   | 2   | 5   |
| Gastrointestinal disorders                            |   |   |   |
| Nausea  |   |   |   |
| subjects affected / exposed                           | 2 / 104 (1.92%)                           | 0 / 101 (0.00%)                           | 6 / 99 (6.06%)                            |
| occurrences (all)                                     | 3   | 0   | 6   |
| Infections and infestations                           |   |   |   |
| Nasopharyngitis                                       |   |   |   |
| subjects affected / exposed                           | 6 / 104 (5.77%)                           | 1 / 101 (0.99%)                           | 3 / 99 (3.03%)                            |
| occurrences (all)                                     | 6   | 1   | 3   |

| <b>Non-serious adverse events</b>                     | FE 999302 (8 µg)<br>and Follitropin Delta | FE 999302 (12 µg)<br>and Follitropin Delta | Placebo and<br>Follitropin Delta |
|---|---|--|----------------------------------|
| Total subjects affected by non-serious adverse events |   |  |                                  |
| subjects affected / exposed                           | 38 / 107 (35.51%)                         | 30 / 104 (28.85%)                          | 34 / 104 (32.69%)                |
| Injury, poisoning and procedural complications        |   |  |                                  |

|   |  |  |  |
|---|--|--|--|
| Procedural pain<br>subjects affected / exposed<br>occurrences (all)   | 4 / 107 (3.74%)<br>4                             | 2 / 104 (1.92%)<br>2                             | 7 / 104 (6.73%)<br>7                             |
| Nervous system disorders<br>Headache<br>subjects affected / exposed<br>occurrences (all)  | 18 / 107 (16.82%)<br>22                          | 15 / 104 (14.42%)<br>17                          | 11 / 104 (10.58%)<br>13                          |
| Pregnancy, puerperium and perinatal conditions<br>Abortion spontaneous<br>subjects affected / exposed<br>occurrences (all)<br><br>Biochemical pregnancy<br>subjects affected / exposed<br>occurrences (all) | 6 / 107 (5.61%)<br>6<br><br>3 / 107 (2.80%)<br>3 | 5 / 104 (4.81%)<br>5<br><br>3 / 104 (2.88%)<br>3 | 3 / 104 (2.88%)<br>3<br><br>5 / 104 (4.81%)<br>5 |
| Reproductive system and breast disorders<br>Ovarian hyperstimulation syndrome<br>subjects affected / exposed<br>occurrences (all)   | 10 / 107 (9.35%)<br>10                           | 3 / 104 (2.88%)<br>3                             | 10 / 104 (9.62%)<br>10                           |
| Gastrointestinal disorders<br>Nausea<br>subjects affected / exposed<br>occurrences (all)  | 7 / 107 (6.54%)<br>7                             | 3 / 104 (2.88%)<br>3                             | 2 / 104 (1.92%)<br>2                             |
| Infections and infestations<br>Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)  | 2 / 107 (1.87%)<br>3                             | 3 / 104 (2.88%)<br>3                             | 1 / 104 (0.96%)<br>1                             |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date          | Amendment  |
|---------------|--|
| 19 March 2020 | Amendment 04 (version 1.0, dated 19 March 2020) was a substantial amendment issued as urgent safety measures due to COVID-19 required to protect subjects against immediate hazard to their health and safety. The amendment included guidance for continued trial conduct and management of subjects included in the trial. |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported