Claims

1. A composition comprising 15 µg recombinant follicle stimulating hormone (rFSH) for daily use in the treatment of infertility in a patient of age ≥ 35 years, ~~wherein the composition is for administration at a (e.g. starting) dose of, or a (e.g. starting) dose equivalent to, 15 µg recombinant FSH per day.~~

~~2. A composition for use according to claim 1 wherein the composition is for administration at a (e.g. starting) dose of 15 µg recombinant FSH per day.~~

~~3. A composition for use according to claim 1, wherein the composition is for administration at a (e.g. starting) dose of 15 µg recombinant FSH per day, wherein the recombinant FSH is the sole active pharmaceutical ingredient in the composition.~~

~~4. A composition for use according to any preceding claim, wherein the composition is for administration at a starting dose of 15 µg recombinant FSH per day, wherein the starting dose is administered on at least day 1 of treatment (preferably on at least day 1 and day 2 of treatment, more preferably on each of days 1 to 4 of treatment), optionally wherein the dose is (i) increased by a first incremental dose increase of 3 µg recombinant FSH on any subsequent day of treatment; and/or (ii) decreased by a first incremental dose decrease of 3 µg recombinant FSH on any subsequent day of treatment.~~

~~5. A composition for use according to claim 4 wherein the dose is maintained at the starting dose for the duration of the treatment.~~

~~6. A composition for use according to claim 4 wherein the first incremental dose increase of 3 µg recombinant FSH is (a) followed by at least one further incremental dose increase of 3 µg recombinant FSH at least two days after the previous incremental change in dose; and/or (b) followed by at least one incremental dose decrease of 3 µg recombinant FSH at least one day after the previous incremental change in dose.~~

~~7. A composition for use according to claim 4 wherein the first incremental dose decrease of 3 µg recombinant FSH is (a) followed by at least one incremental dose increase of 3 µg recombinant FSH at least two days after the previous incremental dose change in dose; and/or (b) followed by at least one further incremental dose decrease of 3 µg recombinant FSH at least one day after the previous change in dose.~~

~~8. A composition for use according to claim 4, 6 or 7 wherein the dose is increased to a maximum daily dose of 24 µg or decreased to a minimum daily dose of 6 µg.~~

~~9. A composition comprising recombinant follicle stimulating hormone (FSH) for use in the treatment of infertility in a patient identified as being of age ≤ 34 years, wherein the composition is for administration at a (e.g. starting) dose of, or a (e.g. starting) dose equivalent to, 12 µg recombinant FSH per day.~~

~~10. A composition for use according to claim 9, wherein the composition is for administration at a starting dose of 12 µg recombinant FSH per day, wherein the starting dose is administered on at least day 1 of treatment (preferably on at least day 1 and day 2 of treatment, more preferably on each of days 1 to 4 of treatment), optionally wherein the dose is (i) increased by a first incremental dose increase of 3 µg recombinant FSH on any subsequent day of treatment; and/or~~
~~(ii) decreased by a first incremental dose decrease of 3 µg recombinant FSH on any subsequent day of treatment.~~

~~11. A composition for use according to any of claims 1 to 10 wherein the treatment of infertility comprises a step of determining the age of the patient, and a step of administering the defined dose of recombinant FSH to a patient having the defined age.~~

~~12. A composition for use according to any preceding claim~~ wherein the recombinant FSH includes α2,6-sialylation and α2,3-sialylation~~, optionally~~ wherein 1 % to 50% of the total sialylation is α2, 6-sialyation, and 50% to 99% of the total sialylation is α 2,3-sialyation.~~; and/or wherein the patient is over 30 years of age and/or has previously failed at least one cycle of infertility treatment; and/or wherein the treatment of infertility further comprises: retrieving (e.g. harvesting) oocyte(s); fertilizing (e.g. inseminating) the oocytes (s); and allowing the fertilized oocytes to develop to the blastocyst stage, optionally wherein the treatment of infertility further comprises assessing the quality of blastocysts obtained after fertilization of the harvested oocytes.~~

~~13. A composition for use according to any preceding claim wherein the treatment includes a step of monitoring the patient for over-response to treatment by identifying, during treatment, a patient with ≥ 20 follicles with a diameter of ≥ 12mm and/or a serum estradiol concentration ≥ 3,000 pg/mL; and optionally administering a dose of GnRH agonist (e.g. 4.0 mg) to the patient identified during treatment as having ≥ 20 follicles with a diameter of ≥ 12mm and/or a serum estradiol concentration ≥ 3,000 pg/mL.; and/or wherein the treatment of infertility is for development of multiple follicles and pregnancy after fresh and/or cryopreserved embryo transfer in ovulatory women undergoing assisted reproductive~~

technology (ART); and/or wherein the treatment of infertility is for optimising cumulative efficiency and/or reducing ovarian hyperstimulation syndrome (OHSS) risk.

14. A composition for use according to claim 1 or claim 9, wherein the treatment comprises:

determining the age of the patient;

if the patient is age ≥ 35 years, administering recombinant follicle stimulating hormone (rFSH) at a starting dose of 15 µg rFSH per day for at least 1-4 days;

if the patient is age ≤ 34 years, administering recombinant follicle stimulating hormone (rFSH) at a starting dose of 12 µg rFSH per day for at least 1-4 days;

optionally, on any subsequent day, (i) increasing the dose of rFSH by an incremental dose increase of 3 µg rFSH or (ii) decreasing the dose of rFSH by an incremental dose decrease of 3 µg rFSH,

wherein, throughout the treatment, the maximum daily dose of rFSH is 24 µg and the minimum daily dose is 6 µg.

15. A composition for use according to any preceding claim wherein the recombinant FSH is the sole active pharmaceutical ingredient in the composition; and/or a composition for use according to any preceding claim for use in the treatment of infertility in a patient who has not previously been treated for infertility by controlled ovarian stimulation; for use in the treatment of infertility in a patient who has not previously completed a treatment for infertility by controlled ovarian stimulation; or for use in the treatment of infertility in a patient who has not been treated for infertility by controlled ovarian stimulation in the previous six months.