

WHAT IS CLAIMED IS:

1. A composition comprising highly purified menotropin (HP-hMG) for use in the treatment of infertility, optionally by controlled ovarian stimulation, in a patient with polycystic ovary syndrome (PCOS), wherein the patient has a serum anti-Müllerian hormone (AMH) level $\geq 35.7 \pm 0.5$ pmol/L ($\geq 5.0 \pm 0.2$ ng/ml) prior to treatment/stimulation.

2. A composition comprising highly purified menotropin (HP-hMG) for use in the treatment of infertility, optionally by controlled ovarian stimulation, in a patient with oligoovulation caused by polycystic ovary syndrome (PCOS), wherein the patient has a serum anti-Müllerian hormone (AMH) level $\geq 35.7 \pm 0.5$ pmol/L ($\geq 5.0 \pm 0.2$ ng/ml) prior to treatment/stimulation.

3. A composition for use according to claim 1 or claim 2, comprising 75 to 450 IU HP-hMG.

4. A composition for use according to any preceding claim, wherein the treatment of infertility comprises administering a daily dose of HP-hMG to the patient of from 75-450 IU/day, preferably from 75-225 IU/day, more preferably 150 or 225 IU/day, most preferably 150 IU/day, optionally from day 1 of treatment to at least day 5 of treatment.

5. A composition for use according to any preceding claim, wherein the treatment of infertility comprises:

identifying (e.g., diagnosing) a patient who has (a) a serum anti-Müllerian hormone (AMH) level $\geq 35.7 \pm 0.5$ pmol/L ($\geq 5.0 \pm 0.2$ ng/ml) prior to treatment/stimulation and (b) a serum estradiol level of ≥ 145 pmol/L (e.g., a serum estradiol level of ≥ 150 pmol/L) prior to treatment/stimulation, and optionally also has one or both of (c) a serum testosterone level of ≥ 1.10 nmol/L (e.g., a serum testosterone level of ≥ 1.14 nmol/L) prior to treatment/stimulation, and (d) a serum luteinizing hormone (LH) level of ≥ 7 U/L (e.g., a serum luteinizing hormone of ≥ 7.55 U/L) prior to treatment/stimulation; and

administering a daily dose of HP-hMG to the patient of from 75-450 IU/day, preferably from 75-225 IU/day, more preferably 150 or 225 IU/day, most preferably 150 IU/day, optionally from day 1 of treatment to at least day 5 of treatment.

6. A composition comprising highly purified menotropin (HP-hMG) for use in the treatment of infertility, optionally by controlled ovarian stimulation, in a patient with polycystic ovary syndrome (PCOS) and a serum anti-Müllerian hormone (AMH) level $\geq 35.7 \pm 0.5$ pmol/L ($\geq 5.0 \pm 0.2$ ng/ml) prior to treatment/stimulation, the treatment comprising:

identifying (e.g., diagnosing) a patient with PCOS who has a serum anti-Müllerian hormone (AMH) level $\geq 35.7 \pm 0.5$ pmol/L ($\geq 5.0 \pm 0.2$ ng/ml) prior to treatment/stimulation; and

administering a daily dose of HP-hMG to the patient of from 75-450 IU/day, preferably from 75-225 IU/day, more preferably 150 or 225 IU/day, most preferably 150 IU/day, optionally from day 1 of treatment to at least day 5 of treatment.

7. A composition comprising highly purified menotropin (HP-hMG) for use in the treatment of infertility, optionally by controlled ovarian stimulation, in a patient with oligoovulation caused by polycystic ovary syndrome (PCOS) and a serum anti-Müllerian hormone (AMH) level $\geq 35.7 \pm 0.5$ pmol/L ($\geq 5.0 \pm 0.2$ ng/ml) prior to treatment/stimulation, the treatment comprising:

identifying (e.g., diagnosing) a patient with oligoovulation caused by PCOS who has a serum anti-Müllerian hormone (AMH) level $\geq 35.7 \pm 0.5$ pmol/L ($\geq 5.0 \pm 0.2$ ng/ml) prior to treatment/stimulation; and

administering a daily dose of HP-hMG to the patient of from 75-450 IU/day, preferably from 75-225 IU/day, more preferably 150 or 225 IU/day, most preferably 150 IU/day, optionally from day 1 of treatment to at least day 5 of treatment.

8. A composition for use according to claim 6 or 7, wherein the treatment of infertility comprises:

identifying (e.g., diagnosing) a patient who has (a) a serum anti-Müllerian hormone (AMH) level $\geq 35.7 \pm 0.5$ pmol/L ($\geq 5.0 \pm 0.2$ ng/ml) prior to treatment/stimulation and (b) a serum estradiol level of ≥ 145 pmol/L (e.g., a serum estradiol level of ≥ 150 pmol/L) prior to treatment/stimulation, and optionally also has one or both of (c) a serum testosterone level of ≥ 1.10 nmol/L (e.g., a serum testosterone level of ≥ 1.14 nmol/L) prior to treatment/stimulation, and (d) a serum luteinizing hormone (LH) level of ≥ 7 U/L (e.g., a serum luteinizing hormone of ≥ 7.55 U/L) prior to treatment/stimulation; and

administering a daily dose of HP-hMG to the patient of from 75-450 IU/day, preferably from 75-225 IU/day, more preferably 150 or 225 IU/day, most preferably 150 IU/day, optionally from day 1 of treatment to at least day 5 of treatment.

9. A composition for use according to any preceding claim, wherein the treatment of infertility increases ongoing pregnancy rate compared to treatment with recombinant follicle-stimulating hormone (rFSH).

10. A composition for use according to any preceding claim, wherein the treatment further comprises triggering final follicular maturation by administering hCG or a GnRH agonist, optionally supplemented with hCG.

11. A composition for use according to any preceding claim, wherein the treatment is a fresh transfer method further comprising retrieving oocyte(s), fertilizing the oocyte(s), allowing the fertilized oocyte(s) to develop to the blastocyst stage, optionally assessing the quality/morphology of the blastocyst(s), and implanting a fresh blastocyst (optionally selected based on, e.g., visual assessment of quality/morphology) in a uterus.

12. A composition for use according to any one of claims 1-10, wherein the treatment is a frozen transfer method further comprising retrieving oocyte(s), fertilizing the oocyte(s), allowing the fertilized oocyte(s) to develop to the blastocyst stage, optionally assessing the chromosomal quality of the blastocyst(s), freezing one or more or all blastocyst(s), and implanting a thawed frozen blastocyst (e.g., a euploid blastocyst selected based on chromosomal assessment) in a uterus.

13. A composition for use according to any one of claims 1-10, wherein the treatment further comprises:

retrieving oocyte(s), freezing unfertilized oocytes(s), subsequently thawing one or more oocyte(s), fertilizing one or more or all thawed oocyte(s), allowing fertilized oocyte(s) to develop to the blastocyst stage, optionally assessing the quality/morphology of the blastocyst(s), and implanting a blastocyst (optionally selected based on, e.g., visual assessment of quality/morphology) in a uterus; or

retrieving oocyte(s), freezing unfertilized oocytes(s), subsequently thawing one or

more frozen oocytes, fertilizing one or more or all thawed oocyte(s), allowing fertilized oocyte(s) to develop to the blastocyst stage, optionally assessing chromosomal quality of the blastocyst(s), freezing one or more or all blastocyst(s), and implanting a thawed-frozen blastocyst (e.g., a euploid blastocyst selected based on chromosomal assessment) in a uterus.

14. A composition for use according to any preceding claim, further comprising a step of administering a GnRH antagonist starting on day 6 of treatment.

15. A composition for use according to any preceding claim, wherein the patient is not anovulatory, is 21-35 years old, and has a BMI of 18-30 kg/m² at the start of treatment.

16. An assisted reproductive technology method for treating a woman diagnosed with one or both of oligoovulation and PCOS and predicted to have a high ovarian response to controlled ovarian stimulation, comprising:

identifying a woman as diagnosed with one or both of oligoovulation and PCOS and as having a serum anti-Müllerian hormone (AMH) level 35.7 ± 0.5 pmol/L ($\geq 5.0 \pm 0.2$ ng/ml) prior to treatment, and

conducting controlled ovarian stimulation by administering to the identified woman an amount of highly purified menotropin (HP-hMG) effective to stimulate follicle development.

17. The method of claim 16, further comprising identifying the woman as having one or more of (i) a serum luteinizing hormone (LH) level of greater than or equal to 7 U/L prior to treatment/stimulation, (ii) a serum testosterone level of greater than or equal to 1.10 nmol/L prior to treatment/stimulation, and (iii) a serum estradiol level of greater than or equal to 145 pmol/L prior to treatment/stimulation.

18. The method of any one claims 16-17, wherein the woman is identified as being diagnosed with oligoovulation.

19. The method of any one claims 16-18, wherein the HP-hMG is administered at a dose of 75 to 450 IU hMG per day.

20. The method of any one claims 16-18, wherein the HP-hMG is administered at a dose of 150 IU hMG per day from day 1 to at least day 5 of treatment.

21. The method any one of claims 16-20, wherein the method is effective to increase ongoing pregnancy rate after *in vitro* fertilization compared to controlled ovarian stimulation by administration of recombinant follicle-stimulating hormone (rFSH).

22. The method of any one of claims 16-21, further comprising administering a gonadotropin-releasing hormone antagonist (GnRH antagonist) starting on day 6 of treatment/stimulation.

23. The method of any one claims 16-22, further comprising triggering final follicular maturation by administering human chorionic gonadotropin (hCG) or a gonadotropin-releasing hormone agonist (GnRH agonist), optionally supplemented with hCG.

24. The method of any one claims 16-23, further comprising:

(a) retrieving oocyte(s), fertilizing the oocyte(s), allowing the fertilized oocyte(s) to develop to the blastocyst stage, optionally assessing the quality/morphology of the blastocyst(s), and implanting a fresh blastocyst (optionally selected based on, e.g., visual assessment of quality/morphology) in a uterus; or

(b) retrieving oocyte(s), fertilizing the oocyte(s), allowing the fertilized oocyte(s) to develop to the blastocyst stage, optionally assessing chromosomal quality of the blastocyst(s), freezing one or more or all blastocyst(s), and implanting a thawed-frozen blastocyst (e.g., a euploid blastocyst selected based on chromosomal assessment) in a uterus; or

(c) retrieving oocyte(s), freezing unfertilized oocytes(s), subsequently thawing one or more oocyte(s), fertilizing one or more or all thawed oocyte(s), allowing fertilized oocyte(s) to develop to the blastocyst stage, optionally assessing the quality/morphology of the blastocyst(s), and implanting a blastocyst (optionally selected based on, e.g., visual assessment of quality/morphology) in a uterus; or

(d) retrieving oocyte(s), freezing unfertilized oocytes(s), subsequently thawing one or more frozen oocytes, fertilizing one or more or all thawed oocyte(s), allowing fertilized oocyte(s) to develop to the blastocyst stage, optionally assessing chromosomal quality of the

blastocyst(s), freezing one or more or all blastocyst(s), and implanting a thawed-frozen blastocyst (e.g., a euploid blastocyst selected based on chromosomal assessment) in a uterus.

25. The method of any one claims 16-24, wherein the woman is not anovulatory, is 21-35 years old, and has a BMI of 18-30 kg/m² at the start of treatment.

26. Use of HP-hMG in the manufacture of a medicament for the treatment of infertility in a woman identified as being diagnosed with oligoovulation and/or PCOS who has a serum AMH level $\geq 35.7 \pm 0.5$ pmol/L ($\geq 5.0 \pm 0.2$ ng/ml) prior to treatment, wherein the treatment comprises administering to the identified woman an amount of highly purified menotropin (HP-hMG) effective to stimulate follicle development.

27. The use of claim 26, wherein the woman is identified prior to treatment as having a serum estradiol level of ≥ 145 pmol/L (e.g., a serum estradiol level of ≥ 150 pmol/L) prior to treatment/stimulation, and optionally also as having one or both of a serum testosterone level of ≥ 1.10 nmol/L (e.g., a serum testosterone level of ≥ 1.14 nmol/L) prior to treatment/stimulation, and a serum luteinizing hormone (LH) level of ≥ 7 U/L (e.g., a serum luteinizing hormone of ≥ 7.55 U/L) prior to treatment/stimulation.