Claims

1. An anti-androgen for use in the manufacture of a medicament for treating metastatic castration-sensitive prostate cancer in a male human, said treatment comprising or consisting essentially of administering a therapeutically effective amount of an anti-androgen in combination with androgen deprivation therapy to a male human with metastatic castration-sensitive prostate cancer, wherein the anti-androgen is

   4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N- methylbenzamide, and

   wherein administration of the anti-androgen in combination with androgen deprivation therapy provides an increase in overall survival of the male human, relative to the overall survival rate of a population of male humans with metastatic castration-sensitive prostate cancer, said population having been administered a placebo in combination with an androgen deprivation therapy, or administration of the anti-androgen in combination with androgen deprivation therapy provides an increase in progression-free survival of the male human, relative to the progression-free survival rate of a population of male humans with metastatic castration-sensitive prostate cancer, said population having been administered a placebo in combination with an androgen deprivation therapy.

2. The anti-androgen for use according to claim 1, wherein the male human received at least one prior therapy for the treatment of cancer, wherein the prior therapy for the treatment of cancer is radiation, surgical intervention or docetaxel therapy.

3. The anti-androgen for use according to claim 1, wherein the male human is treatment naïve.

4. The anti-androgen for use according to any one of the preceding claims, wherein 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide is administered daily to the male human.

5. The anti-androgen for use according to any one of the preceding claims, wherein 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide is administered orally to the male human, optionally on a continuous daily dosing schedule.

6. The anti-androgen for use according to claim 5, wherein 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide is administered orally to the male human at a dose of 30 mg per day to 480 mg per day, optionally at a dose of 180 mg per day to 480 mg per day.

7. The anti-androgen for use according to claim 6, wherein 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide is administered orally to the male human at a dose of:
(a) 30 mg per day;
(b) 60 mg per day;
(c) 90 mg per day;
(d) 120 mg per day; or
(d) 240 mg per day.

8. The anti-androgen for use according to claim 7, wherein 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide is administered orally to the male human at a dose of 240 mg per day.

9. The anti-androgen for use according to claim 8, wherein the dose of 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide is decreased to 180 mg per day or 120 mg per day if the male human experiences a greater than or equal to Grade 3 toxicity.

10. The anti-androgen for use according to any one of the preceding claims, wherein administration of the anti-androgen in combination with androgen deprivation therapy provides an increase in overall survival and a 33% reduction in risk of death or an increase in progression-free survival and a 52% reduction in risk of radiographic progression or death.

11. The anti-androgen for use according to any one of the preceding claims, wherein 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide is administered in combination with at least one gonadotropin-releasing hormone (GnRH) agonist or antagonist.

12. The anti-androgen for use according to claim 10, wherein the at least one GnRH agonist or antagonist is or comprises leuprolide, buserelin, naferelin, histrelin, goserelin, deslorelin, degarelix, ozarelix, ABT-620 (elagolix), TAK-385 (relugolix), EP-100, KLH-2109 or triptorelin.

13. The anti-androgen for use according to any one of claims 1 to 10, wherein 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide is used in combination with bilateral orchiectomy.

14. The anti-androgen for use according to any one of the preceding claims, wherein the 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide is not co-administered with:
(a) a medication that is a CYP2C8 or CYP3A4 inhibitor;
(b) a medication that is primarily metabolized by CYP3A4, CYP2C19, or CYP2C9;
(c) a medication that is a substrate of UDP-glucuronosyl transferase; or
(d) a medication that is a substrate of P-glycoprotein, breast cancer resistance protein or organic anion transporting polypeptide 1B1.

15. The anti-androgen for use according to any one of the preceding claims, wherein said treatment comprises:

(a) determining whether the male human has metastatic castration-sensitive prostate cancer; and

(b) administering the anti-androgen in combination with the androgen deprivation therapy to the male human in the therapeutically effective amount to treat the metastatic castration-sensitive prostate cancer.