What is claimed:

1. A method for treating metastatic castration-sensitive prostate cancer in a male human comprising administering a therapeutically effective amount of an anti-androgen 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,
4-(3-(4-cyano-3-(trifluoromethyl)phenyl)-5,5-dimethyl-4-oxo-2-thioxoimidazolidin-l-yl)-2-fluoro-N-methylbenzamide,
4-[7-[4-cyano-3-(trifluoromethyl)phenyl]-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide, or
N-{(2S)-1-[3-(3-chloro-4-cyanophenyl)-1H-pyrazol-1-yl]propan-2-yl}-5-(1-hydroxyethyl)-1H-pyrazole-3-carboxamide.

2. The method of claim 1, wherein administration of the anti-androgen provides an increase in overall survival of the male human relative to the overall survival rate of a population of male humans with the metastatic castration-sensitive prostate cancer, said population having been administered a placebo in combination with an androgen deprivation therapy.

3. The method of claim 1 or 2, wherein administration of the anti-androgen 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 the metastatic castration-sensitive prostate cancer, said population having been administered a placebo in combination with an androgen deprivation therapssy.

4. The method of any one of the preceding claims, 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.

5. The method of any one of claims 1 to 3, wherein the male human is treatment naïve.

6. The method of any one of the preceding claims, 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.

7. The method of 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 daily to the male human.

8. The method of 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.

9. The method of 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 on a continuous daily dosing schedule.

10. The method of 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 about 30 mg per day to about 480 mg per day.

11. The method of 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 about 180 mg per day to about 480 mg per day.

12. The method of 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) about 30 mg per day;
(b) about 60 mg per day;
(c) about 90 mg per day;
(d) about 120 mg per day; or
(d) about 240 mg per day.

13. The method of 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 about 240 mg per day.

14. The method of claim 13, 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.

15. The method of 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 in combination with androgen deprivation therapy.

16. The method of claim 15, 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.

17. The method of claim 16, 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.

18. The method of claim 15, 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.

19. The method of claim 6, 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 strong 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.

20. The method of claim 1, wherein the anti-androgen is 4-(3-(4-cyano-3-(trifluoromethyl)phenyl)-5,5-dimethyl-4-oxo-2- thioxoimidazolidin-l-yl)-2-fluoro-N-methylbenzamide.

21. The method of claim 20, wherein the 4-(3-(4-cyano-3-(trifluoromethyl)phenyl)-5,5-dimethyl-4-oxo-2- thioxoimidazolidin-l-yl)-2-fluoro-N-methylbenzamide is administered orally to the male human at a dose of about 160 mg per day.

22. The method of claim 1, wherein the anti-androgen is 4-[7-[4-cyano-3-(trifluoromethyl)phenyl]-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide.

23. The method of claim 1, wherein the anti-androgen is N-{(2S)-1-[3-(3-chloro-4-cyanophenyl)-1H-pyrazol-1 yl]propan-2-yl}-5-(1-hydroxyethyl)-1H-pyrazole-3-carboxamide.

24. A method for treating metastatic castration-sensitive prostate cancer in a male human consisting essentially of administering a therapeutically effective amount of an anti-androgen to a male human with metastatic castration-sensitive prostate cancer, wherein the anti-androgen is one or more 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,
4-(3-(4-cyano-3-(trifluoromethyl)phenyl)-5,5-dimethyl-4-oxo-2-thioxoimidazolidin-l-yl)-2-fluoro-N-methylbenzamide,
4-[7-[4-cyano-3-(trifluoromethyl)phenyl]-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide, or
N-{(2S)-1-[3-(3-chloro-4-cyanophenyl)-1H-pyrazol-1 yl]propan-2-yl}-5-(1-hydroxyethyl)-1H-pyrazole-3-carboxamide.

25. The method of claim 23, 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.

26. The method of claim 25, 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) about 30 mg per day;

(b) about 60 mg per day;

(c) about 90 mg per day;

(d) about 120 mg per day; or

(d) about 240 mg per day.

27. A method of treating metastatic castration-sensitive prostate cancer in a male human, comprising:

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

(b) administering an anti-androgen to a male human in a therapeutically effective amount to treat the 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,

4-(3-(4-cyano-3-(trifluoromethyl)phenyl)-5,5-dimethyl-4-oxo-2-thioxoimidazolidin-l-yl)-2-fluoro-N-methylbenzamide,

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

N-{(2S)-1-[3-(3-chloro-4-cyanophenyl)-1H-pyrazol-1 yl]propan-2-yl}-5-(1-hydroxyethyl)-1H-pyrazole-3-carboxamide.

28. A method of treating metastatic castration-sensitive prostate cancer comprising administering an approved drug product comprising apalutamide to a male human with metastatic castration-sensitive prostate cancer in an amount that is described in a drug product label for said drug product.

29. The method of claim 28, wherein the approved drug product comprising apalutamide is an ANDA drug product, a supplemental New Drug Application drug product or a 505(b)(2) drug product.

30. The method of any one of claims 27 to 29, wherein the method is clinically proven safe and/or effective.

31. A pharmaceutical product comprising a clinically proven safe and clinically proven effective amount of apalutamide, wherein the pharmaceutical product is packaged and wherein the package includes a label that

(a) identifies apalutamide as a regulatory approved chemical entity, and

(b) instructs use of apalutamide in the treatment of castration-sensitive prostate cancer.

32. A method of selling an approved drug product comprising apalutamide, said method comprising selling such drug product, wherein a drug product label for a reference listed drug for such drug product includes instructions for treating castration-sensitive prostate cancer.

33. A method of offering for sale an approved drug product comprising apalutamide, said method comprising offering for sale such drug product, wherein a drug product label for a reference listed drug for such drug product includes instructions for treating castration-sensitive prostate cancer.

34. The method of claim 32 or 33, wherein the drug product is an ANDA drug product, a supplemental New Drug Application drug product or a 505(b)(2) drug product.