Claims

1. Use of an effective amount of abiraterone acetate in the manufacture of a medicament for the treatment of metatatic high-risk castration-sensitive prostate cancer in a human male comprising adding whereby the administration of the medicament is to be in conjunction with a safe and effective amount of prednisone and non-surgical androgen deprivation therapy in the human.

2. The use of claim 1, whereby the medicament and the prednisone are to be administered to the human in the amounts of about 1000 mg/day of abiraterone acetate in the medicament and about 5 mg/day of prednisone.

3. The use of claim 1, wherein the androgen deprivation therapy comprises a hormonal ablation agent that is selected from the group consisting of histrelin acetate, leuprolide acetate, goserelin acetate, and triptorelin palmoate.

4. Use of a safe and effective amount of abiraterone acetate in the manufacture of a medicament for treating newly diagnosed metatatic high-risk castration-sensitive prostate cancer in a human male whereby the medicament is to be administered to the human in the form of a combination therapy demonstrated to a) increase overall survival of men with newly diagnosed metastatic castration-sensitive prostate cancer; or
b) increase radiographic progression-free survival ith newly diagnosed metastatic castration-sensitive prostate cancer; or
c) increase time to pain progression for men with newly diagnosed metastatic castration-sensitive prostate cancer; or
d) increase time to a next symptomatic skeletal event for men with newly diagnosed metastatic castration-sensitive prostate cancer; or
e) increase time to time to PSA progression for men with newly diagnosed metastatic castration-sensitive prostate cancer;

wherein the combination therapy comprises the administration of safe and effective amounts ofthe medicament, prednisone and non-surgical androgen deprivation therapy.

5. A method of selling a drug product comprising abiraterone acetate, said method comprising selling such drug product, wherein a drug product label for a reference listed drug for abiraterone acetate includes an indication for treating patients with metatatic high-risk castration-sensitive prostate cancer using abiraterone acetate in combination prednisone.

6. The method of claim 5, wherein the drug product is an ANDA drug product or a supplemental New Drug Application drug product.

7. A method of selling a drug product comprising abiraterone acetate, said method comprising selling such drug product, wherein a drug product label for a reference listed drug for abiraterone acetate includes data from LATITUDE: patients with metatatic high-risk castration-sensitive prostate cancer.

8. The method of claim 7, wherein the drug product is an ANDA drug product or a supplemental New Drug Application drug product.

9. A method of claim 8, wherein the drug product label comprises a hazard ratio of 0.621 for overall survival.

10. The method of claim 9, wherein the drug product is an ANDA drug product or a supplemental New Drug Application drug product.

11. The method of offering for sale a drug product comprising abiratererone acetate, said method comprising offering for sale such drug product, wherein the drug product label for a reference listed for abiraterone acetate includes an indication for the treatment of patients with metatatic high-risk castration-sensitive prostate cancer with abiraterone acetate in combination with prednisone

12. The method of claim 11, wherein the drug product is an ANDA drug product or a supplemental New Drug Application drug product.

13. A method of selling a drug product comprising abiraterone acetate, said method comprising selling such drug product, wherein a drug product label for a reference listed drug for abiraterone acetate includes data from LATITUDE: patients with metatatic high-risk castration-sensitive prostate cancer.

14. The method of claim 13, wherein the drug product is an ANDA drug product or a supplemental New Drug Application drug product.

15. A method of claim 13, wherein the drug product label comprises a hazard ratio of 0.621 for overall survival.

16. The method of claim 14, wherein the drug product is an ANDA drug product or a supplemental New Drug Application drug product.

17. The use of claim 1, wherein the overall survival after treatment is estimable with a 95% confidence interval.

18. The method of any one of claims 7 to 15, wherein the drug product label for a reference listed drug for such drug product includes an indication for patients with metatatic high-risk castration-sensitive prostate cancer using abiraterone acetate and prednisone.

19. A safe and effective amount of abiraterone acetate and a safe and effective amount of prednisone for use as a medicament in a combination therapy with non-surgical androgen deprivation therapy in a human.