CLAIMS

1. Use of abiraterone decanoate in its basic form and a pharmaceutically acceptable carrier in the preparation of a pharmaceutical compostion for treating prostate cancer in a human subject, wherein about 180 mg to about 1800 mg of abriraterone is to be administered to the human subject deconate once every 1-3 months.

2. The use of claim 1, wherein (i) the prostate cancer has metastasized to one or more lymph nodes, and the administering of the pharmaceutical composition is effective in inhibiting growth of the cancer in the one or more lymph nodes; (ii) the prostate cancer is characterized with a Gleason score of ≤ 6; (iii) the human subject has a measurable prostate specific antigen; (iv) the prostate cancer is a localized prostate cancer; or (v) the prostate cancer is a metastatic castration-sensitive prostate cancer, non-metastatic castration-sensitive prostate cancer, non-metastatic castration-resistant prostate cancer, or metastatic castration-resistant prostate cancer.

3. The use of claim 1 or 2, wherein the cancer is (i) a newly diagnosed high risk metastatic hormone sensitive prostate cancer; (ii) a metastatic CRPC (mCRPC), wherein the human subject is is asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated; (3) a metastatic CRPC (mCRPC), wherein the human subject's disease has progressed on or after a taxane-based chemotherapy regimen; or (4) a refractory prostate cancer.

4. The use of any one of claims 1-3, wherein (i) the human subject's disease has progressed on or after an androgen receptor antagonist based treatment; and/or (ii) the human subject has developed resistance to the treatment of abiraterone acetate in combination with prednisone.

5. The use of any one of claims 1-4, wherein the pharmaceutical composition comprises, for each milliliter, (a) abiraterone decanoate in its basic form, in an amount of about 100 mg to about 300 mg; (b) benzyl alcohol in an amount of about 50 mg to about 150 mg; (c)

benzyl benzoate in an amount of about 100 mg to about 300 mg ; and (d) corn oil, q.s. to 1 milliliter.

6. The use of any one of claims 1-5, wherein the pharmaceutical composition comprises, for each milliliter, (a) abiraterone decanoate in its basic form, in an amount of about 180 mg; (b) benzyl alcohol in an amount of about 50 mg to about 150 mg ; (c) benzyl benzoate in an amount of about 100 mg to about 300 mg ; and (d) corn oil, q.s. to 1 milliliter.

7. The use of claim 5 or 6, wherein the weight ratio of benzyl alcohol to benzyl benzoate in the pharmaceutical composition ranges from about 2:1 to about 1:5.

8. The use of any one of claims 1-7, wherein about 1260 mg of abiraterone decanoate is to be administered to the human subject once every three months.

9. The use of any one of claims 1-8, further wherein enzalutamide is to be administered to the human subject.

10. The use of any one of claims 1-9, further wherein one or more agents selected from hydrocortisone, prednisone, prednisolone, methylprednisolone, and dexamethasone is to be administered to the human subject.

11. The use of any one of claims 1-10, further wherein (1) a poly ADP ribose polymerase (PARP) inhibitor; (2) a chemotherapeutic agent; (3) an immunotherapy; (4) bispecific T-cell engager (BiTE) therapy; (5) a kinase inhibitor; (6) a bone protecting agent, wherein the human subject is characterized as having prostate cancer with bone metastasis; (8) an anti-IL23 targeting monoclonal antibody; (9) a selenium; (10) an EZH2 inhibitor; (11) a CDK4/6 inhibitor; (12) a bromodomain and extra-terminal domain (BET) inhibitor; (12) an anti-CD105 antibody; (13) niclosamide; (14) an A2A receptor antagonist; (15) a PI3K inhibitor; (16) a further non-steroidal CYP17A1 inhibitor; (17) an antiprogestogen; (18) navitoclax; (19) an HSP90 inhibitor; (20) an HSP27 inhibitor; (21) a 5-alpha-reductase

inhibitor; (22) metformin; (23) AMG-386; (24) dextromethorphan; (25) theophylline; (26) hydroxychloroquine; and/or (27) lenalidomide is to be administered to the human subject.

12. The use of any one of claims 1-11, wherein the human subject is (i) chemotherapy naïve or hormone therapy naïve prior to being administered the pharmaceutical composition, such as a chemotherapy naïve mCRPC patient; and/or (ii) wherein the human subject suffers from moderate to severe hepatic impairment (Child-Pugh Class B or C), prior to administration of the pharmaceutical composition.

13. The use of any one of claims 1-12, wherein (i) the use does not increase the level of progesterone in the human subject to a serum or plasma progesterone greater than 3 nM when measured at 4 weeks, 6 weeks, or 12 weeks after the first administration of the pharmaceutical composition; and/or (ii) the human subject is characterized as having a serum or plasma progesterone level of greater than 3 nM after three months of an abiraterone treatment, prior to the first administration of the pharmaceutical composition.

14. The use of any one of claims 1-13, wherein the human subject suffers from one or more side effects associated with inhibition of CYP17A1 hydroxylase activity or the human subject is susceptible to one or more side effects associated with inhibition of CYP17A1 hydroxylase activity.

15. The use of any one of claims 1-14, wherein the human subject is treated with a gonadotropin-releasing hormone agonist and/or antagonist.

16. The use of any one of claims 1-14, wherein the human subject is non-castrated.

17. The use of any of claims 1-16, wherein the pharmaceutical composition does not cause a mineralocorticoid toxicity in the human subject.

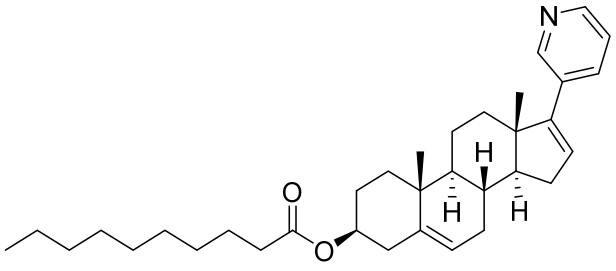
18. The use of any one claims 1-9 and 11-17, wherein the human subject is not treated with an agent effective for treating a mineralocorticoid toxicity.

19. The use of any of claims 1-17, wherein (i) about 1260 mg of abiraterone decanoate is to be administered intramuscularly once every three months; and (ii) one dose of about 0.5 mg dexamethasone is to be administered orally daily.

20. The use of any one of claims 19, wherein the pharmaceutical composition comprises an abiraterone decanoate solution, wherein each milliliter of the abiraterone decanoate solution comprises: (a) abiraterone decanoate in its basic form, in an amount of about 100 mg to about 300 mg; (b) benzyl alcohol in an amount of about 50 mg to about 150 mg; (c) benzyl benzoate in an amount of about 100 mg to about 300 mg; (d) 3-mercapto-1,2-propanediol in an amount of about 0.5 mg to about 20 mg; and (e) corn oil, q.s. to 1 milliliter.

21. The use of claim 20, wherein the pharmaceutical composition is in the form of a unit dosage form, wherein the unit dosage form comprises about 4 ml to about 10 ml of the abiraterone decanoate solution.

22. A pharmaceutical composition comprising an abiraterone decanoate solution, wherein each milliliter of the abiraterone decanoate solution comprises: (a) abiraterone decanoate in its basic form, in an amount of about 100 mg to about 300 mg; (b) benzyl alcohol in an amount of about 50 mg to about 150 mg; (c) benzyl benzoate in an amount of about 100 mg to about 300 mg ; (d) 3-mercapto-1,2-propanediol in an amount of about 0.5 mg to about 20 mg; and (e) corn oil, q.s. to 1 milliliter, wherein the abiraterone decanoate has the structure of:



abiraterone decanoate.

23. The pharmaceutical composition of claim 22, wherein each milliliter of the abiraterone decanoate solution comprises: (a) abiraterone decanoate in its basic form, in an amount of about 180 mg; (b) benzyl alcohol in an amount of about 50 mg to about 150 mg; (c) benzyl benzoate in an amount of about 100 mg to about 300 mg; (d) 3-mercapto-1,2-propanediol in an amount of about 0.5 mg to about 2 mg; and (e) corn oil, q.s. to 1 milliliter.

24. The pharmaceutical composition of claim 22 or23, wherein the weight ratio of benzyl alcohol to benzyl benzoate in the pharmaceutical composition ranges from about 2:1 to about 1:5 (e.g., about 1:1 to 1:3, such as about 1:2).

25. The pharmaceutical composition of any one of claims 22-24, wherein the pharmaceutical composition is in the form of a unit dosage form, wherein the unit dosage form comprises about 4 ml to about 10 ml of the abiraterone decanoate solution.