CLAIMS

1. Use of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate in the manufacture of a combined preparation for simultaneous, separate or sequential use with prednisone in treating prostate cancer, optionally wherein the prostate cancer is mCRPC, optionally wherein the mCRPC is first-line (L1) mCRPC, in a male human patient.
2. The use of claim 1, wherein the patient is positive for homologous recombination deficiency (HRD), or the patient is not positive for HRD.
3. The use of claim 2, wherein the HRD status is detected by monoallelic or biallelic alterations in one or more DNA repair genes, including without being limited to, BRCA1 (Breast Cancer gene 1), BRCA2 (Breast Cancer gene 2), ATM (ataxia-telangiectasia mutated), FANCA (Fanconi Anemia Complementation Group A gene), PALB2 (Partner and Localizer of BRCA2 gene), CHEK2 (Checkpoint Kinase 2 gene), BRIP1 (BRCA1 Interacting Protein C-terminal Helicase 1 gene), HDAC2 (Histone deacetylase 2), or CDK12 (Cyclin Dependent Kinase 12).
4. The use of any one of claims 1-3, wherein the patient had received gonadotropin releasing hormone agonists (GnRHa) therapy or had undergone bilateral orchiectomy, prior to the treatment with the pharmaceutical formulation plus prednisone.
5. The use of any one of claims 1-4, wherein the patient is to continue with GnRHa therapy during the treatment with the pharmaceutical formulation, plus prednisone, if not surgically castrated.
6. Use of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate in the manufacture of a combined preparation for simultaneous, separate or sequential use with prednisone, in treating mCRPC, with or without DNA-repair gene defects (DRD) or HRD, and optionally with cyclin dependent kinase 12 (CDK12) pathogenic alterations, in a male human patient.
7. The use of claim 6, wherein the patient is to continue with GnRHa therapy during the treatment with the pharmaceutical formulation plus prednisone, if not surgically castrated.
8. The use of claim 6, wherein the patient had been exposed to anti-androgens selected from nilutamide, flutamide, bicalutamide, enzalutamide, apalutamide, darolutamide, and abiraterone acetate; prior to the treatment with the pharmaceutical formulation plus prednisone.
9. The use of claim 8, wherein said anti-androgens are washed-out prior to the treatment with the pharmaceutical formulation plus prednisone.
10. Use of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate in the manufacture of a combined preparation for simultaneous, separate or sequential use with prednisone and leuprorelin acetate, in treating high risk and lymph node positive prostate cancer, prior to, during, and after radiotherapy, in a male human patient.

11. The use of claim 10, wherein said radiotherapy is stereotactic body radiotherapy (SBRT) or ultra-hypofractionated radiotherapy, with a total dose of about 37.5 to 40 Gy.
12. Use of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate in the manufacture of a combined preparation for simultaneous, separate or sequential use with prednisone, in treating castration-naïve prostate cancer, with or without metastases, in a male human patient.
13. The use of claim 12, wherein the patient is to continue with GnRHa therapy during the treatment with the pharmaceutical formulation plus prednisone, if not surgically castrated.
14. Use of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate in the manufacture of a combined preparation for simultaneous, separate or sequential use with prednisone, in treating biochemical recurrent prostate cancer, in a male human patient.
15. The use of claim 14, wherein said biochemical recurrent prostate cancer is detected by: i) a prostate-specific antigen (PSA) rise of $\geq$ 2.0 ng/mL above the nadir; or ii) next generation imaging (NGI) including prostate-specific membrane antigen positron emission tomography (PSMA-PET).
16. The use of claim 14 or 15, wherein the patients are HRD biomarker positive, high risk, and/or with oligometastatic disease.
17. The use of claim 16, wherein the HRD biomarker positive is one or more of, without being limited to, BRCA1, BRCA2, ATM, BRIP1, CDK12, CDK17, CHEK2, FANCA, HDAC2, PALB2, PPP2R2A, RAD51B, and RAD54L.
18. Use of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate in the manufacture of a combined preparation for simultaneous, separate or sequential use with prednisone, in treating locally advanced prostate cancer in a male human patient who is candidate for primary radiotherapy.
19. Use of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate in the manufacture of a combined preparation for simultaneous, separate or sequential use with prednisone, in treating mCRPC in a male human patient optionally having received prior chemotherapy comprising docetaxel or cabazitaxel.
20. Use of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate in the manufacture of a combined preparation for simultaneous, separate or sequential use with prednisone, in treating non-metastatic CRPC (nmCRPC) in a male human patient.
21. The use of claim 20, wherein the patients have a PSA doubling time equal to or less than 10 months and are HRD positive.
22. The use of claim 20, wherein the patients are HRD positive.
23. The use of claim 20, wherein the patients have high-risk BCR.

24. The use of any one of claims 1-23, wherein said pharmaceutical formulation comprises a free-dose combination (FrDC) of abiraterone acetate and niraparib tosylate monohydrate.
25. The use of any one of claims 1-23, wherein said pharmaceutical formulation comprises a fixed-dose combination (FDC) comprising abiraterone acetate and niraparib tosylate monohydrate.
26. The use of claim 24 or claim 25, wherein the FrDC or FDC comprise, each independently, about 50 mg eq. niraparib and about 500 mg abiraterone acetate; about 100 mg eq. niraparib and about 500 mg abiraterone acetate; about 50 mg eq. niraparib and about 375 mg abiraterone acetate; about 100 mg eq. niraparib and about 375 mg abiraterone acetate; about 50 mg eq. niraparib and about 250 mg abiraterone acetate; about 100 mg eq. niraparib and about 250 mg abiraterone acetate; about 33 mg eq. niraparib and about 333 mg abiraterone acetate; or about 67 mg eq. niraparib and about 333 mg abiraterone acetate.
27. The use of any one of claims 24-26, wherein the FrDC or FDC are oral dosage forms.
28. The use of claim 27, wherein the oral dosage form is a tablet, a capsule, or a sachet.
29. The use of any one of claims 1-23, wherein said pharmaceutical formulation comprises a fixed-dose combination (FDC) as defined in any one of Tables 1-12.