CLAIMS

1. A pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, as 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 pharmaceutical formulation for 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 pharmaceutical formulation for 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 pharmaceutical formulation for the use of any one of claims 1-3, wherein the patient has received gonadotropin releasing hormone agonists (GnRHa) therapy or has undergone bilateral orchiectomy, prior to the treatment with the pharmaceutical formulation plus prednisone.
5. The pharmaceutical formulation for the use of any one of claims 1-4, wherein the patient continues with GnRHa therapy during the treatment with the pharmaceutical formulation, plus prednisone, if not surgically castrated.
6. A pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, as 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 pharmaceutical formulation for the use of claim 6, wherein the patient continues with GnRHa therapy during the treatment with the pharmaceutical formulation plus prednisone, if not surgically castrated.
8. The pharmaceutical formulation for the use of claim 6, wherein the patient has 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 pharmaceutical formulation for the use of claim 8, wherein said anti-androgens are washed-out prior to the treatment with the pharmaceutical formulation plus prednisone.
10. A pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, as 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 pharmaceutical formulation for 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. A pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, as 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 pharmaceutical formulation for the use of claim 12, wherein the patient continues with GnRHa therapy during the treatment with the pharmaceutical formulation plus prednisone, if not surgically castrated.
14. A pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, as a combined preparation for simultaneous, separate or sequential use with prednisone, in treating biochemical recurrent prostate cancer, in a male human patient.
15. The pharmaceutical formulation for 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 pharmaceutical formulation for the use of claim 14 or 15, wherein the patients are HRD biomarker positive, high risk, and/or with oligometastatic disease.
17. The pharmaceutical formulation for 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. A pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, as 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. A pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, as 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. A pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, as a combined preparation for simultaneous, separate or sequential use with prednisone, in treating non-metastatic CRPC (nmCRPC) in a male human patient.
21. The pharmaceutical formulation for 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 pharmaceutical formulation for the use of claim 20, wherein the patients are HRD positive.
23. The pharmaceutical formulation for the use of claim 20, wherein the patients have high-risk BCR.
24. The pharmaceutical formulation for the use of any one of claims 1-23, wherein said pharmaceutical formulation comprises a free-dose combination (FrDC) of abiraterone acetate and niraparib; or a FrDC of abiraterone acetate and niraparib tosylate monohydrate.
25. The pharmaceutical formulation for the use of any one of claims 1-23, wherein said pharmaceutical formulation comprises a fixed-dose combination (FDC) comprising abiraterone acetate and niraparib; or a FDC comprising abiraterone acetate and niraparib tosylate monohydrate.
26. The pharmaceutical formulation for 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 pharmaceutical formulation for the use of any one of claims 24-26, wherein the FrDC or FDC are oral dosage forms.
28. The pharmaceutical formulation for the use of claim 27, wherein the oral dosage form is a tablet, a capsule, or a sachet.
29. The pharmaceutical formulation for 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.
30. A method for the treatment of prostate cancer, optionally wherein the prostate cancer is mCRPC, optionally wherein the mCRPC is first-line (L1) mCRPC, in a male human patient, said method comprising administering to the patient an effective amount of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, plus prednisone.
31. The method of claim 30, wherein the patient is positive for homologous recombination deficiency (HRD), or the patient is not positive for HRD.
32. The method of claim 31, 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),.

33. The method of any one of claims 30-32, wherein the patient has received gonadotropin releasing hormone agonists (GnRHa) therapy or has undergone bilateral orchiectomy, prior to the treatment with the pharmaceutical formulation, plus prednisone.
34. The method of any one of claims 30-33, wherein the patient continues with GnRHa therapy during the treatment with the pharmaceutical formulation, plus prednisone, if not surgically castrated.
35. A method for the treatment of 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, said method comprising administering to the patient an effective amount of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, plus prednisone.
36. The method of claim 35, wherein the patient continues with GnRHa therapy during the treatment with the pharmaceutical formulation plus prednisone, if not surgically castrated.
37. The method of claim 35, wherein the patient has 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.
38. The method of claim 37, wherein said anti-androgens are washed-out prior to the treatment with the pharmaceutical formulation plus prednisone.
39. A method for the treatment of high risk and lymph node positive prostate cancer, in a male human patient, said method comprising administering to the patient an effective amount of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, plus prednisone and leuprorelin acetate, prior to, during, and after radiotherapy.
40. The method of claim 39, wherein said radiotherapy is stereotactic body radiotherapy (SBRT) or ultra-hypofractionated radiotherapy, with a total dose of about 37.5 to 40 Gy.
41. A method for the treatment of castration-naïve prostate cancer, with or without metastases, in a male human patient, said method comprising administering to the patient an effective amount of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, plus prednisone.
42. The method of claim 41, wherein the patient continues with GnRHa therapy during the treatment with the pharmaceutical formulation plus prednisone, if not surgically castrated.
43. A method for the treatment of biochemical recurrent prostate cancer, in a male human patient, said method comprising administering to the patient an effective amount of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, plus prednisone.

44. The method of claim 43, wherein said biochemical recurrent prostate cancer is detected by: i) a prostate-specific antigen (PSA) rise of ≥ 2.0 ng/mL above the nadir; or ii) next generation imaging (NGI) including prostate-specific membrane antigen positron emission tomography (PSMA-PET).
45. The method of claim 43 or 44, wherein the patient is HRD biomarker positive, high risk, and/or with oligometastatic disease.
46. The method of claim 45, 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.
47. A method for the treatment of locally advanced prostate cancer, in a male human patient who is a candidate for primary radiotherapy, said method comprising administering to the patient an effective amount of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, plus prednisone.
48. A method for the treatment of mCRPC, in a male human patient optionally having received prior chemotherapy comprising docetaxel or cabazitaxel, said method comprising administering to the patient an effective amount of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, plus prednisone.
49. A method for the treatment of nmCRPC, in a male human patient, said method comprising administering to the patient an effective amount of a pharmaceutical formulation comprising abiraterone acetate and niraparib tosylate monohydrate, plus prednisone.
50. The method of claim 49, wherein the patient has a PSA doubling time equal to or less than 10 months and is HRD positive.
51. The method of claim 49, wherein the patient is HRD positive.
52. The method of claim 49, wherein the patient has high-risk BCR.
53. The method of any one of claims 1-52, wherein said pharmaceutical formulation is a free-dose combination (FrDC) of abiraterone acetate and niraparib; or a FrDC of abiraterone acetate and niraparib tosylate monohydrate.
54. The method of any one of claims 1-52, wherein said pharmaceutical formulation is a fixed-dose combination (FDC) comprising abiraterone acetate and niraparib; or a FDC comprising abiraterone acetate and niraparib tosylate monohydrate.
55. The method of claim 53 or 54, wherein the FrDC or FDC comprise, each independently, about 50 mg niraparib eq. and about 500 mg abiraterone acetate; about 100 mg niraparib eq. and about 500 mg abiraterone acetate; about 50 mg niraparib eq. and about 375 mg abiraterone acetate; about 100 mg niraparib eq. and about 375 mg abiraterone acetate; about 50 mg niraparib eq. and about 250 mg abiraterone acetate; about 100 mg niraparib eq. and about 250 mg abiraterone acetate; about 33 mg niraparib eq. and about 333 mg abiraterone acetate; or about 67 mg niraparib eq. and about 333 mg abiraterone acetate.
56. The method of any one of claims 53-55, wherein the FrDC or FDC are oral dosage forms.

57. The method of claim 56, wherein the oral dosage form is a tablet, a capsule, or a sachet.
58. The method of any one of claims 30-52, wherein said pharmaceutical formulation is a fixed-dose combination (FDC) as defined in any one of Tables 1-12.