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 mCSPC, optionally wherein the mCSPC is deleterious germline or somatic homologous recombination repair (HRR) gene-mutated mCSPC, in a male human patient.
2. The pharmaceutical formulation for the use of claim 1, wherein the deleterious germline or somatic HRR gene mutation is in one or more genes, including without being limited to, BRCA1, BRCA2, BRIP1, CDK12, CHEK2, FANCA, PALB2, RAD51B, and RAD54L.
3. The pharmaceutical formulation for the use of claim 1 or 2, wherein the patient has undergone ADT prior to the treatment with the pharmaceutical formulation plus prednisone; optionally wherein said ADT is medical or surgical castration.
4. The pharmaceutical formulation for the use of claim 3, wherein said ADT started within 6 months, preferably at least 14 days, prior to the treatment with the pharmaceutical formulation plus prednisone.
5. The pharmaceutical formulation for the use of claim 3 or 4, wherein the patient undergoes ADT during the treatment with the pharmaceutical formulation plus prednisone.
6. The pharmaceutical formulation for the use of claim 1 or 2, wherein the patient has not undergone prior therapy with a next generation androgen signaling inhibitor therapy, said next generation androgen signaling inhibitor therapy optionally selected from abiraterone acetate, enzalutamide, apalutamide, darolutamide, nilutamide, flutamide, bicalutamide, and the like.
7. The pharmaceutical formulation for the use of claim 1 or 2, wherein the patient has received docetaxel or cabazitaxel prior to the treatment with the pharmaceutical formulation plus prednisone.
8. The pharmaceutical formulation for the use of claim 1 or 2, wherein the patient has received radiation or surgical intervention, prior to the treatment with the pharmaceutical formulation plus prednisone.
9. The pharmaceutical formulation for the use of claim 1 or 2, wherein the patient has received abiraterone acetate plus prednisone, prior to the treatment with the pharmaceutical formulation plus prednisone.
10. The pharmaceutical formulation for the use of claim 1 or 2, wherein the patient has received abiraterone acetate plus prednisone, during a month prior to the treatment with the pharmaceutical formulation plus prednisone.
11. The pharmaceutical formulation for the use of claim 1 or 2, wherein the patient has received treatments for localized prostate cancer, prior to the treatment with the pharmaceutical formulation plus prednisone.

12. The pharmaceutical formulation for the use of claim 11, wherein said treatments for localized prostate cancer have been completed at least 1 year prior to the treatment with the pharmaceutical formulation plus prednisone.
13. The pharmaceutical formulation for the use of claim 11 or 12, wherein said treatments for localized prostate cancer are up to 3 years of ADT including radiation therapy, prostatectomy, lymph node dissection, or systemic therapies.
14. The pharmaceutical formulation for the use of any one of claims 1-13, 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.
15. The pharmaceutical formulation for the use of any one of claims 1-13, 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.
16. The pharmaceutical formulation for the use of claim 14 or claim 15, 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.
17. The pharmaceutical formulation for the use of any one of claims 14-16, wherein the FrDC or FDC are oral dosage forms.
18. The pharmaceutical formulation for the use of claim 17, wherein the oral dosage form is a tablet, a capsule, or a sachet.
19. The pharmaceutical formulation for the use of any one of claims 1-13, wherein said pharmaceutical formulation comprises a fixed-dose combination (FDC) as defined in any one of Tables 1-12.
20. A method for the treatment of mCSPC, optionally wherein the mCSPC is deleterious germline or somatic homologous recombination repair (HRR) gene-mutated mCSPC, 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.
21. The method of claim 20, wherein the deleterious germline or somatic HRR gene mutation is in one or more genes, including without being limited to, BRCA1, BRCA2, BRIP1, CDK12, CHEK2, FANCA, PALB2, RAD51B, and RAD54L.

22. The method of claim 20 or 21, wherein the patient has undergone androgen deprivation therapy (ADT) prior to the treatment with the pharmaceutical formulation, plus prednisone; optionally wherein said ADT is a medical or surgical castration.
23. The method of claim 22, wherein said ADT started within 6 months, preferably at least 14 days, prior to the treatment with the pharmaceutical formulation, plus prednisone.
24. The method of claim 22, wherein said ADT started no more than 90 days prior to the treatment with the pharmaceutical formulation, plus prednisone; and wherein said ADT is abiraterone acetate.
25. The method of any one of claims 22-24, wherein the patient undergoes ADT during the treatment with the pharmaceutical formulation, plus prednisone.
26. The method of claim 20 or 21, wherein the patient has not undergone prior therapy with a next generation androgen signaling inhibitor therapy, said next generation androgen signaling inhibitor therapy optionally selected from abiraterone acetate, enzalutamide, apalutamide, darolutamide, nilutamide, flutamide, bicalutamide, and the like.
27. The method of claim 20 or 21, wherein the patient has received docetaxel or cabazitaxel prior to the treatment with the pharmaceutical formulation, plus prednisone.
28. The method of claim 20 or 21, wherein the patient has received radiation or surgical intervention, prior to the treatment with the pharmaceutical formulation, plus prednisone.
29. The method of claim 20 or 21, wherein the patient has received abiraterone acetate plus prednisone, prior to the treatment with the pharmaceutical formulation plus prednisone.
30. The method of claim 29, wherein the patient has received abiraterone acetate plus prednisone, during a month prior to the treatment with the pharmaceutical formulation plus prednisone.
31. The method of claim 20 or 21, wherein the patient has received treatments for localized prostate cancer, prior to the treatment with the pharmaceutical formulation plus prednisone.
32. The method of claim 31, wherein said treatments for localized prostate cancer have been completed at least 1 year prior to the treatment with the pharmaceutical formulation plus prednisone.
33. The method of claim 31 or 32, wherein said treatments for localized prostate cancer are up to 3 years of ADT including radiation therapy, prostatectomy, lymph node dissection, or systemic therapies.
34. The method of any one of claims 20-33, 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.
35. The method of any one of claims 20-33, 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.

36. The method of claim 34 or 35, 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.
37. The method of any one of claims 34-36, wherein the FrDC or FDC are oral dosage forms.
38. The method of claim 37, wherein the oral dosage form is a tablet, a capsule, or a sachet.
39. The method of any one of claims 20-33, wherein said pharmaceutical formulation is a fixed-dose combination (FDC) as defined in any one of Tables 1-12.