mg/day of abiraterone acetate; or administering about 1000 mg/day of abiraterone acetate. In an example, the medical use or method of treatment comprises administering about 33 to about 300 mg/day of niraparib eq.; administering about 100 to about 200 mg/day of niraparib eq.; administering about 66 mg/day of niraparib eq.; administering about 100 mg/day of niraparib eq.; administering about 134 mg/day of niraparib eq.; or administering about 200 mg/day eq. of niraparib. In an example, the medical use or method of treatment comprises administering 1, 2, or 3 oral dosage forms per day. In an example, the medical use or method of treatment comprises administering the oral dosage form(s) once a day (q.d.) or two times a day (b.i.d.); preferably once a day at least 1 hour before a meal or at least two hours after a meal. In an example, the medical use or method of treatment comprises administering separately about 1 to about 60 mg/day of prednisone; about 5 to about 15 mg/day of prednisone; about 9 to about 11 mg/day of prednisone; about 10 mg/day of prednisone; about 5 mg/day of prednisone; or about 5 mg/day of prednisone.

The present disclosure also relates to a process for preparing certain of the granule compositions disclosed herein, comprising the steps of:

(a) preparing a binder solution comprising a wetting agent;

(b) blending the binder solution of step (a) with abiraterone acetate, niraparib, and a diluent, optionally in the presence of a disintegrant;

(c) wet granulating the blend obtained from step (b);

(d) drying the product obtained from step (c).

In an example, the binder solution comprises a binder, the wetting agent and a solvent. In an example, the inlet air temperature during the wet granulating of step (c), is from 25 °C to 65 °C. In an example, the spray rate during the wet granulating of step (c), is from 190 to 300 g/min. In an example, the inlet air flow during the wet granulating of step (c), is from 800 to 1300 m^3/h.

CLAIMS

1. A granule composition comprising abiraterone acetate, niraparib tosylate monohydrate, and a pharmaceutically acceptable carrier;

wherein the granules consist essentially of abiraterone acetate, niraparib tosylate monohydrate, and a pharmaceutically acceptable carrier;

wherein the pharmaceutically acceptable carrier of the granules comprises a wetting agent, a diluent, a disintegrant, optionally a glidant, optionally a lubricant, and optionally a binder;

wherein the wetting agent is sodium lauryl sulfate; and

wherein the disintegrant is crospovidone.

2. The granule composition of claim 1, wherein the granules have a particle size distribution with a d_{50} of 200 to 500 µm, or of 231 to 396 µm; a d_{10} of 50 to 250 µm, or of 93 to 192 µm; and/or a d_{90} of 500 to 900 µm, or of 616 to 723 µm.

3. The granule composition of claim 1 or 2, wherein the diluent is lactose, and wherein lactose is also used as a binder.

4. The granule composition of any one of claims 1-3, wherein the glidant is colloidal anhydrous silica.

5. The granule composition of any one of claims 1-4, wherein the lubricant is magnesium stearate.

6. The granule composition of any one of claims 1-5, wherein the binder is HPMC 2910 15 mPa.s.

7. An oral dosage form comprising the granule composition of any one of claims 1-6.

8. The oral dosage form of claim 7, wherein the oral dosage form comprises 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.

9. The oral dosage form of claims 7 or 8, wherein said oral dosage form is a tablet, wherein the pharmaceutically acceptable carrier comprises a wetting agent, a diluent, a disintegrant, a glidant, a lubricant, optionally a binder, and optionally a coating material.

10. The oral dosage form of claim 9, wherein the wetting agent is sodium lauryl sulfate (SLS) and is present in the dosage form in a percentage from 3 to 6 % (w/w).

11. The oral dosage form of claim 9 or 10, wherein the wetting agent is SLS and is present in the final dosage forms in a by weight ratio versus abiraterone acetate of 0.05:1 to 0.2:1 (SLS:abiraterone acetate), preferably 0.1:1, more preferably 0.11:1, 0.12:1, or 0.123:1.

12. The oral dosage form of any one of claims 9-11, wherein SLS is present both in the intragranular and extragranular phases of the tablet.

13. The oral dosage form of any one of claims 9-12, wherein the disintegrant is crospovidone and is present both in the intragranular and extragranular phases of the tablet.

14. The oral dosage form of any one of claims 9-13, wherein the diluent of the extragranular phase is silicified microcrystalline cellulose.

15. The oral dosage form of any one of claims 9-14, wherein the tablet has a hardness of 250 to 350 N.

16. The oral dosage form of any one of claims 9-15, wherein the tablet has a stratified content uniformity from 75 % to 125 %, or from 90 % to 110 %.

17. The oral dosage form of any one of claims 9-16, wherein the tablet has a blend uniformity with a relative standard deviation up to 3%.

18. Use of the oral dosage form of any one of claims 7-17 in the manufacture of a medicament for the treatment of prostate cancer in a patient.

19. The use according to claim 18, wherein the prostate cancer is first-line (L1) metastatic castration-resistant prostate cancer (mCRPC) and the patient is positive for homologous recombination repair (HRR) defects.

20. The use according to claim 18, wherein the prostate cancer is deleterious germline or somatic HRR gene-mutated metastatic castration sensitive prostate cancer (mCSPC).

21. The use according to any one of claims 18-20, wherein 1, 2, or 3 oral dosage forms is to be administered per day.

22. The use according to any one of claims 18-21, wherein the oral dosage form(s) is to be administered once a day (q.d.) or two times a day (b.i.d.); preferably once a day at least 1 hour before a meal or at least two hours after a meal.

23. The oral dosage form of any one of claims 7-17 for use in therapy.