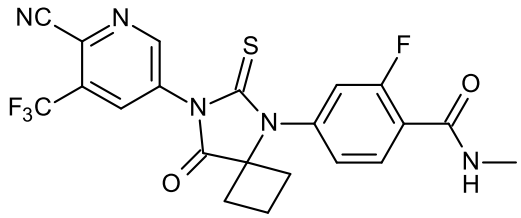
SUMMARY

In one aspect, there is provided a pharmaceutical formulation comprising a pharmaceutically acceptable carrier, abiraterone acetate and a solid dispersion, said solid dispersion comprising  (ARN-509) and a polymer selected from hydroxypropyl methylcellulose acetate succinate (HPMCAS), a poly(meth)acrylate copolymer, and mixtures thereof.

In another aspect, there is provided a process for preparing a pharmaceutical formulation as defined herein comprising the steps of: a) preparing a solid dispersion of ARN-509 and a polymer selected from HPMCAS, a poly(meth)acrylate copolymer, and mixtures thereof; b) preparing a granulate comprising abiraterone acetate; c) mixing the solid dispersion of a) and the granulate of b) and a pharmaceutically acceptable carrier.

In another aspect, there is provided use of the pharmaceutical formulation as defined herein for the preparation of a medicament for the treatment of prostate cancer.

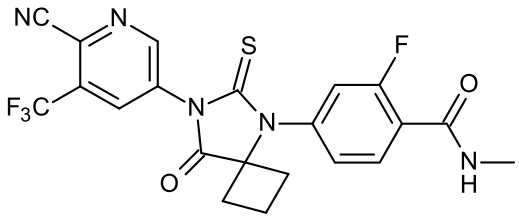
In another aspect, there is provided a combination of a pharmaceutical formulation as defined herein and a glucocorticoid selected from the group consisting of prednisone, prednisolone, methylprednisolone, dexamethasone and pharmaceutically acceptable salts and acetates thereof.

FIGURES

Fig. 1 : XRD pattern of ARN-509 Form B.

Claims

1. A pharmaceutical formulation comprising a pharmaceutically acceptable carrier, abiraterone acetate and a solid dispersion, said solid dispersion comprising



(ARN-509) and a polymer selected from hydroxypropyl methylcellulose acetate succinate (HPMCAS), a poly(meth)acrylate copolymer, and mixtures thereof.

2. The pharmaceutical formulation according to claim 1 wherein the solid dispersion comprises ARN-509 and HPMCAS.

3. The pharmaceutical formulation according to claim 2 wherein the dispersion consists of ARN-509 and HPMCAS.

4. The pharmaceutical formulation according to claim 2 or 3 wherein the weight-by-weight ratio of ARN-509 : HPMCAS in the solid dispersion is in the range from 1 : 1 to 1 : 5.

5. The pharmaceutical formulation according to claim 4 wherein the weight-by-weight ratio of ARN-509 : HPMCAS in the solid dispersion is 1:3.

6. The pharmaceutical formulation according to claim 4 wherein the weight-by-weight ratio of ARN-509 : HPMCAS in the solid dispersion is 1:2.

7. The pharmaceutical formulation according to claim 4 wherein the weight-by-weight ratio of ARN-509 : HPMCAS in the solid dispersion is 1:1.

8. The pharmaceutical formulation according to any one of the preceding claims wherein ARN-509 is present in amorphous form.

9. The pharmaceutical formulation according to any one of the preceding claims wherein the dispersion is a solid solution.

10. The pharmaceutical formulation according to any one of the preceding claims wherein the HPMCAS is HPMCAS granular grade.

11. The pharmaceutical formulation according to any one of the preceding claims comprising 250 mg of abiraterone acetate.

12. The pharmaceutical formulation according to any one of the preceding claims comprising 60 mg of ARN-509.

13. The pharmaceutical formulation according to any one of the preceding claims comprising a granulate of abiraterone acetate.

14. The pharmaceutical composition according to claim 13 wherein the granulate comprises a binder and a wetting agent.

15. The pharmaceutical composition according to claim 14 wherein the wetting agent is sodium lauryl sulfate.

16. The pharmaceutical formulation according to any one of the preceding claims wherein the formulation is a tablet.

17. The pharmaceutical formulation according to claim 16 which is suitable for oral administration.

18. A process for preparing a pharmaceutical formulation according to claim 1 comprising the steps of :
a) preparing a solid dispersion of ARN-509 and a polymer selected from HPMCAS, a poly(meth)acrylate copolymer, and mixtures thereof;
b) preparing a granulate comprising abiraterone acetate;
c) mixing the solid dispersion of a) and the granulate of b) and a pharmaceutically acceptable carrier.

19. The process according to claim 18 wherein the solid dispersion of ARN-509 and the polymer is prepared by mixing ARN-509 and the polymer in a suitable solvent and spray drying said mixture.

20. The process according to claim 19 wherein the suitable solvent is a mixture of dichloromethane and methanol.

21. The process according to claim 20 wherein the weight:weight ratio of dichloromethane to methanol in the mixture is 4 : 6.

22. The process according to any one of claims 18 to 21 wherein the polymer is HPMCAS.

23. Use of the pharmaceutical formulation according to any one of claims 1 to 17 for the preparation of a medicament for the treatment of prostate cancer.

24. Use according to claim 23 wherein the medicament is for oral administration.

25. A combination of a pharmaceutical formulation according to any one of claims 1 to 17 and a glucocorticoid selected from the group consisting of prednisone, prednisolone, methylprednisolone, dexamethasone and pharmaceutically acceptable salts and acetates thereof.

26. The combination according to claim 25 wherein the glucocorticoid is prednisone.

27. The combination according to claim 25 wherein the glucocorticoid is prednisolone.