

Claims

1. A combination of AZD5305, or a pharmaceutically acceptable salt thereof, and darolutamide for use in the treatment of metastatic prostate cancer, hormone sensitive prostate cancer (HSPC) or castrate resistant prostate cancer (CRPC) in a subject, wherein
5 said treatment comprises the separate, sequential or simultaneous administration of i) said AZD5305, or a pharmaceutically acceptable salt thereof, and ii) darolutamide, or a pharmaceutically acceptable salt thereof, to said subject.
2. The combination for use according to claim 1, wherein the metastatic prostate cancer
10 is metastatic hormone sensitive prostate cancer (mHSPC) or metastatic castrate resistant prostate cancer (mCRPC).
3. Use of AZD5305, or a pharmaceutically acceptable salt thereof, in the manufacture of
15 a medicament for the treatment of metastatic prostate cancer, hormone sensitive prostate cancer (HSPC) or castrate resistant prostate cancer (CRPC) in a subject, wherein said treatment comprises the separate, sequential or simultaneous administration of i) said AZD5305, or a pharmaceutically acceptable salt thereof, and ii) darolutamide, or a pharmaceutically acceptable salt thereof, to said subject.
- 20 4. The use according to claim 3, wherein the metastatic prostate cancer is metastatic hormone sensitive prostate cancer (mHSPC) or metastatic castrate resistant prostate cancer (mCRPC).
5. Use of darolutamide, or a pharmaceutically acceptable salt thereof, in the
25 manufacture of a medicament for the treatment of metastatic prostate cancer, hormone sensitive prostate cancer (HSPC) or castrate resistant prostate cancer (CRPC) in a subject, wherein said treatment comprises the separate, sequential or simultaneous administration of i) said darolutamide, or a pharmaceutically acceptable salt thereof, and ii) AZD5305, or a pharmaceutically acceptable salt thereof, to said subject.
30
6. The use according to claim 5, wherein the metastatic prostate cancer is metastatic hormone sensitive prostate cancer (mHSPC) or metastatic castrate resistant prostate cancer (mCRPC).
- 35 7. The combination for use according to claim 1 or 2, or the use according to any one of claims 3 to 6, wherein AZD5305 is to be administered once daily.

8. The combination for use or the use according to claim 7, wherein AZD5305 is to be administered in a dose of up to 60 mg per day.

5 9. The combination for use or the use according to claim 8, wherein AZD5305 is to be administered in a dose of 60 mg per day.

10. The combination for use according to any one of claims 1, 2 and 7 to 9, or the use according to any one of claims 3 to 9, wherein darolutamide or a pharmaceutically acceptable salt thereof is to be administered twice daily.

11. The combination for use or the use according to claim 10, wherein darolutamide or a pharmaceutically acceptable salt thereof is to be administered in a dose of 600 mg twice daily.

15

12. The combination for use according to any one of claims 1, 2 and 7 to 11, or the use according to any one of claims 3 to 11, wherein AZD5305 and darolutamide are to be taken separately, where a dose of AZD5305 is to be taken on an empty stomach, with no food two hours before, and a dose of darolutamide is to be taken at least one hour after AZD5305 with food.

20

13. A pharmaceutical product comprising i) AZD5305 or a pharmaceutically acceptable salt thereof, and ii) darolutamide or a pharmaceutically acceptable salt thereof.

25 14. A kit comprising: a first pharmaceutical composition comprising AZD5305, or a pharmaceutically acceptable salt thereof; a second pharmaceutical composition comprising darolutamide, or a pharmaceutically acceptable salt thereof; and instructions for using the first and second pharmaceutical compositions in combination.

30