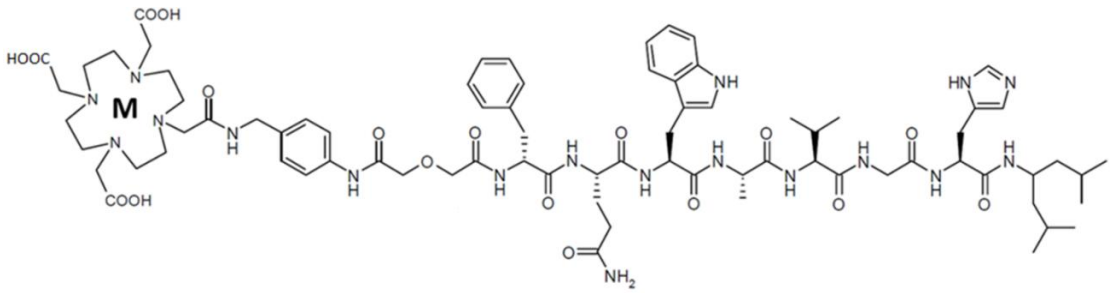
Claims

1. Use of a radiopharmaceutical compound in the manufacture of a medicament for treating breast cancer in a subject in need thereof, wherein a therapeutically effective amount of the radiopharmaceutical compound, in combination with ribociclib, and with fulvestrant are to be administered to the said subject, and wherein said radiopharmaceutical compound is a compound of formula (III), or pharmaceutically acceptable salts thereof:



(III),

and wherein M is ^{177}Lu.

2. The use of claim 1, wherein ribociclib is to be concomitantly administered with fulvestrant.

3. The use of any one of claims 1-2, wherein said radiopharmaceutical compound is to be administered 3 to 12 times, 4 to 10 times, 4 to 8 times, 6 times, or 10 times.

4. The use of claim 3, wherein said radiopharmaceutical compound comprises an administration interval of 2 weeks, 3 weeks, 4 weeks, 5 weeks, 6 weeks, 3 or 4 weeks, or 4 weeks.

5. The use of any one of Claims 1-4, wherein said radiopharmaceutical compound is to be administered at a dose ranging from 0.925 GBq (25mCi) to 29.6GBq (800 mCi), from 1.48 GBq (40 mCi) to 18.5 GBq (500mCi), from 1.85 GBq (50mCi) to 14.8 GBq (400mCi), from 3.7 GBq (100mCi) to 11.1 GBq(300mCi), about 3.7 GBq (100mCi), about 5.55 GBq (150mCi), about 7.4 GBq (200mCi), about 9.25GBq (250mCi), or about 11.1 GBq (300mCi).

6. The use of any one of claims 1-5, wherein ribociclib is to be administered orally at a daily dose of 400 to 800 mg, e.g. 600 mg, e.g. in cycles of a period of 15 to 28 days, each cycle including e.g. 21 days of daily administration followed by a period of 7 days off treatment, and is

to be administered for at least as long as the radiopharmaceutical is to be administered, and optionally administration of ribociclib continues until disease progression.

7. The use of claim 6, wherein said radiopharmaceutical compound is to be administered intravenously every 28 days, for 3 to 12 cycles, for example 6 cycles, at a dose ranging from 3.7 GBq (100mCi) to 11.1 GBq(300mCi), or from 3.7 GBq (100mCi) to 9.25 GBq(250mCi), e.g. 250 mCi, e.g. 150 mCi, in combination with ribociclib to be administered orally at a daily dose of 600 mg, for 15 to 21 days per cycle.

8. The use of any one of claims 1-7, wherein fulvestrant is to be administered via intramuscular administration, at a dose of 250 to 700 mg, for example using a long-acting formulation.

9. The use of any one of claims 1-8, wherein said subject has ER positive, HER-2 negative (ER+/HER2-) and GRPR-positive (GRPR+) breast cancer.

10. The use of any one of claims 1-9, wherein said subject has been selected from subjects experiencing early relapse after neoadjuvant or adjuvant prior endocrine treatment, or experiencing progression on prior endocrine treatment optionally in combination with a prior CDK4/6 inhibitor

11. The use of any one of claims 1-10, wherein said subject is a post-menopausal woman with advanced metastatic breast cancer.

12. The use of any one of claims 1-10, wherein said subject is a pre-menopausal or peri-menopausal woman with advanced metastatic breast cancer.

13. The use of any one of claims 1-12, wherein said subject has been selected from subjects experiencing early relapse after neoadjuvant or adjuvant prior endocrine treatment.

14. The use of any one of claims 1-12, wherein said subject has been selected from subjects experiencing progression on prior endocrine treatment optionally in combination with a prior CDK4/6 inhibitor.

15. The use of any one of claims 1-14, wherein administration of fulvestrant further comprises a synthetic analog of gonadotropin releasing hormone, for example goserelin, to be administered

concomitantly for example via subcutaneous administration, e.g. every 28 days at a dose of about 3.6mg.

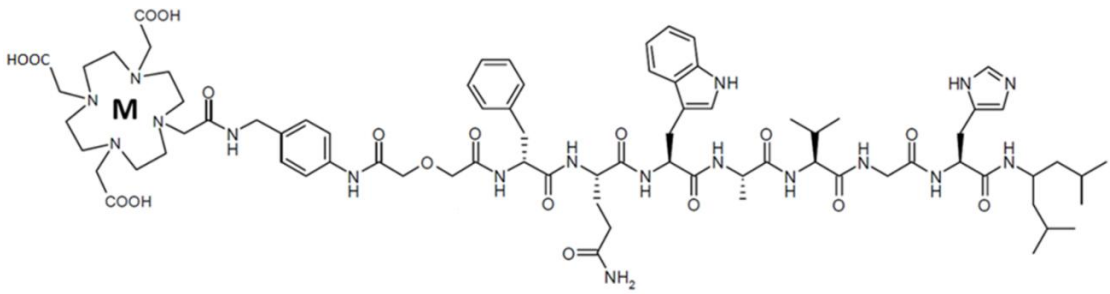
16. The use of any one of claims 1-15, wherein said subject has been selected by SPECT/CT or PET/CT or SPECT/MRI, PET/MRI imaging with the same radiopharmaceutical compound as defined for the treatment, but with an alternate radionuclide suitable for imaging, for example 68-Gallium, 67-Gallium or 64-Copper, e.g. 68-Gallium, based on detection of said radionuclide in the imaging scan at the tumor region, prior to any surgery, for example, two weeks prior to start of said treatment.

17. The use of any one of claims 1-16, wherein said subject has ER positive, HER-2 negative (ER+/HER2-) and GRPR-positive (GRPR+) breast cancer and is experiencing early relapse from neoadjuvant or adjuvant therapy, wherein said radiopharmaceutical compound is to be administered to said subject in combination with ribociclib and fulvestrant, wherein a first dose of said radiopharmaceutical compound is to be administered the same day as the first dose of ribociclib.

18. The use of claim 17, wherein ribociclib is to be administered orally at a daily dose of about 600 mg, for example in cycles of a period of 28 days, each cycle for example including 21 days of administration followed by a period of 7 days off treatment, wherein the radiopharmaceutical compound is to be administered for 4-10 cycles, and ribociclib is to be administered for at least as long as the radiopharmaceutical is to be administered, and optionally administration of said CDK4/6 inhibitor continues until disease progression.

19. The use of any one of claims 1-18, wherein said radiopharmaceutical compound is to be administered by intravenous infusion at a concentration of 370MBq/mL.

20. A radiopharmaceutical compound for use in therapy, wherein a therapeutically effective amount of the radiopharmaceutical compound, in combination with ribociclib, and with fulvestrant are to be administered to the said subject, and wherein said radiopharmaceutical compound is a compound of formula (III), or pharmaceutically acceptable salts thereof:



(III),

and wherein M is ^{177}Lu.