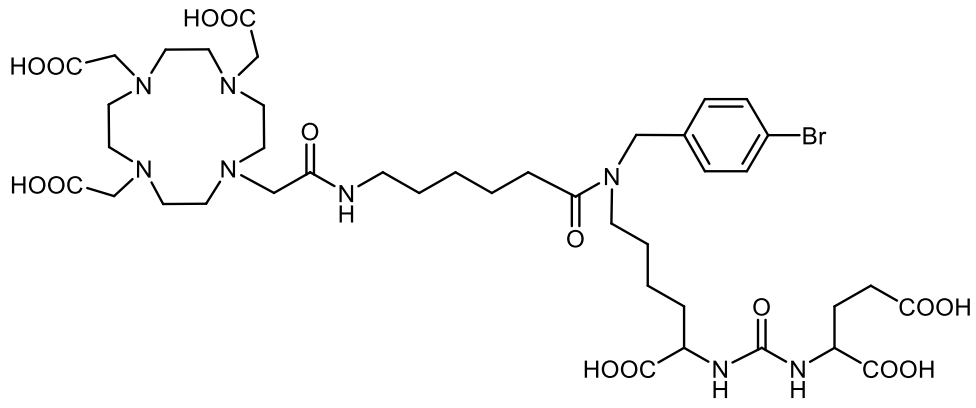
CLAIMS

1. A method for labeling a PSMA binding ligand of formula (II)



(II),

with a radioactive isotope, wherein the radioactive isotope is ^{68}Ga, ^{67}Ga or ^{64}Cu, said method comprising the steps of:

i. providing a first vial comprising said PSMA binding ligand, and the bulking agent mannitol, in dried form,

ii. adding a solution of said radioactive isotope into said first vial, thereby obtaining a solution of said PSMA binding ligand with said radioactive isotope,

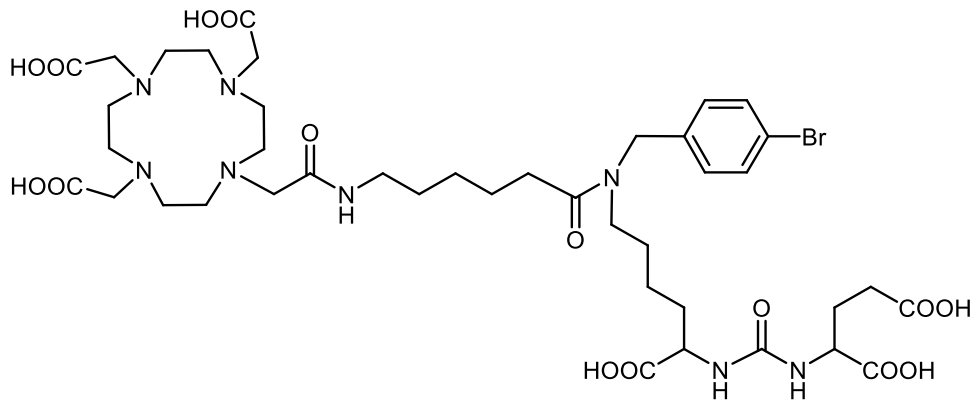
iii. mixing the solution obtained in ii. with a buffering agent comprising formic acid and sodium hydroxide and incubating it for a sufficient period of time and at a sufficiently elevated temperature for obtaining said PSMA binding ligand labeled with said radioactive isotope, and

iv. adjusting the pH of the solution.

2. The method of Claim 1, wherein the incubating step is performed at a temperature comprised between 50°C and 100°C.

3. The method of Claim 1 or Claim 2, wherein the incubating step is performed for a period of time comprised between 2 and 25 minutes.

4. A solution comprising a PSMA binding ligand of formula (II):

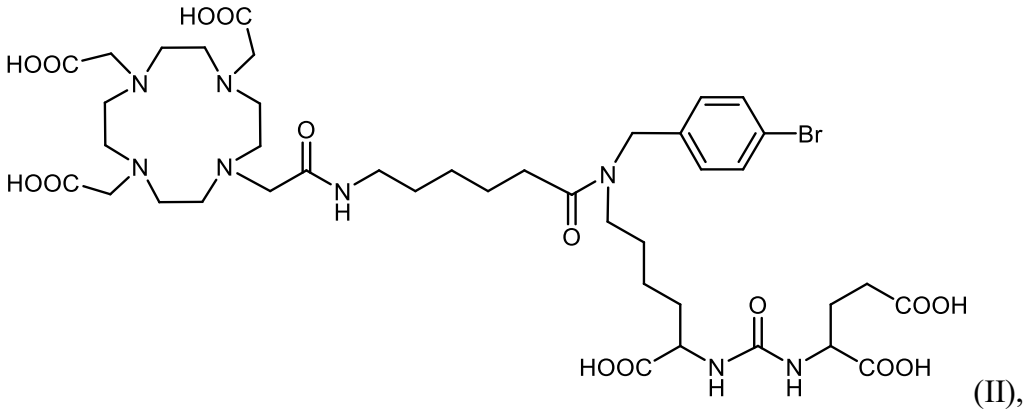


(II),

for use as an injectable solution for in vivo detection of PSMA-expressing tumors, by imaging in a subject in need thereof, wherein said PSMA binding ligand is labeled with ^{68}Ga, ^{67}Ga or ^{64}Cu.

5. A powder for a solution for injection comprising the following components:

i. a PSMA binding ligand of formula (II) in an amount between 10 and 100 μg,



(II),

and

ii. mannitol in an amount between 5 and 50 mg.

6. The powder for a solution for injection of Claim 5, wherein said powder does not contain an antioxidant.

7. The powder for a solution for injection of Claim 6, wherein the powder does not contain gentisic acid.

8. The powder for a solution for injection of Claim 5, wherein the powder comprises the PSMA binding ligand of formula (II) in an amount between 15 and 60 μg.

9. The powder for a solution for injection of Claim 5, wherein the powder comprises the PSMA binding ligand of formula (II) in an amount of about 30 μg.

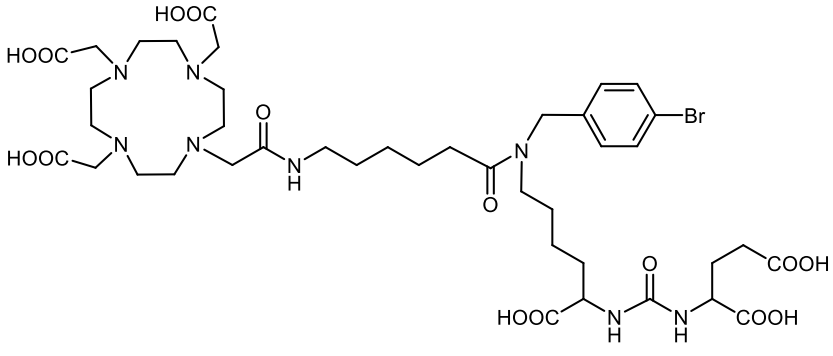
10. The powder for a solution for injection of Claim 5, wherein the powder comprises mannitol in an amount between 10 and 30 mg.

11. The powder for a solution for injection of Claim 5, wherein the powder comprises mannitol in an amount of about 20 mg.

12. A kit for carrying out the method of Claim 1, comprising:

i. a first vial with the following components:

i. a PSMA binding ligand of formula (II):



(II),

and

ii. the bulking agent mannitol, and

ii. a second vial comprising a buffering agent comprising formic acid and sodium hydroxide, and

iii. an accessory cartridge for eluting a radioactive isotope generated by a radioactive isotope generator or a cyclotron.

13. The kit of Claim 12, wherein the components of the first vial are in dried form.

14. The kit of Claim 12, wherein the buffering agent comprising formic acid and sodium hydroxide is in dried form.

15. The kit of Claim 12, wherein the first vial comprises the following components:

i. the PSMA binding ligand of formula (II) in an amount between 10 and 100 μg, and

ii. mannitol in an amount between 5 and 50 mg.

16. The kit of Claim 12, wherein the first vial comprises the PSMA binding ligand of formula (II) in an amount between 15 and 60 μg.

17. The kit of Claim 12, wherein the first vial comprises the PSMA binding ligand of formula (II) in an amount of about 30 μg.

18. The kit of Claim 12, wherein the first vial comprises mannitol in an amount between 10 and 30 mg.

19. The kit of Claim 12, wherein the first vial comprises mannitol in an amount of about 20 mg.

20. The kit of any one of Clams 12-19, wherein the second vial comprises formic acid and sodium hydroxide as buffering agents for maintaining a pH between 2.5 and 4.0.

21. The kit of Claim 20, wherein the buffering agents are for maintaining the pH between 2.8 and 4.0.

22. The kit of Claim 20, wherein the buffering agents are for maintaining the pH between 3.0 and 4.0.

23. The kit of Claim 20, wherein the buffering agents are for maintaining the pH between 3.2 and 3.8.

24. The kit of any one of Claims 12-19, wherein the kit does not contain an antioxidant, and said second vial comprises formic acid and sodium hydroxide as buffering agents for maintaining a pH between 2.5 and 4.0.

25. The kit of Claim 24, wherein the kit does not contain gentisic acid.

26. The kit of Claim 24, wherein the buffering agents are for maintaining the pH between 2.8 and 4.0.

27. The kit of Claim 24, wherein the buffering agents are for maintaining the pH between 3.0 and 4.0.

28. The kit of Claim 24, wherein the buffering agents are for maintaining the pH between 3.2 and 3.8.