Claims

1. A pharmaceutical composition comprising:
   (a) a complex formed by
      (ai) a radionuclide, and
      (aii) a gastrin-releasing peptide receptor peptide antagonist binding moiety linked to a chelating agent; and;
   (b) at least two stabilizers against radiolytic degradation, wherein said stabilizers comprise gentisic acid and ascorbic acid in a weight ratio between 1:16 and 1 :10, for example between 1 :15 and 1 :10; and
   (c) optionally a surfactant.

2. The pharmaceutical composition according to claim 1, wherein said radionuclide is selected from ^{111}In, ^{18}F, ^{211}At, ^{82}Rb, ^{123}I, ^{131}I, ^{133}mIn, ^{99}mTc, ^{94}mTc, ^{67}Ga, ^{66}Ga, ^{68}Ga, ^{52}Fe, ^{169}Er, ^{72}As, ^{97}Ru, ^{203}Pb, ^{212}Pb, ^{62}Cu, ^{64}Cu, ^{67}Cu, ^{186}Re, ^{188}Re, ^{86}Y, ^{90}Y, ^{51}Cr, ^{52}mMn, ^{157}Gd, ^{177}Lu, ^{161}Tb, ^{69}Yb, ^{175}Yb, ^{105}Rh, ^{166}Dy, ^{166}Ho, ^{153}Sm, ^{149}Pm, ^{151}Pm, ^{172}Tm, ^{121}Sn, ^{117}mSn, ^{213}Bi, ^{212}Bi, ^{142}Pr, ^{143}Pr, ^{198}Au, ^{199}Au, ^{89}Zr, ^{225}Ac, ^{43}Sc, ^{44}Sc and ^{47}Sc, preferably selected from ^{111}In, ^{177}Lu, ^{225}Ac and ^{68}Ga, more preferably is ^{177}Lu.

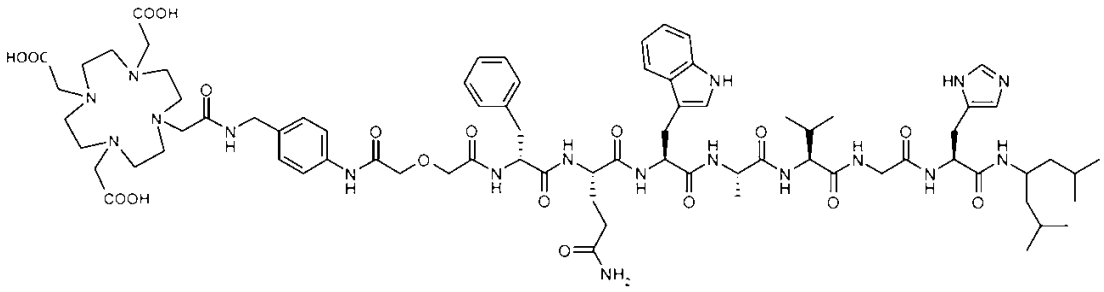
~~2.~~

3. The pharmaceutical composition according to claim 1, wherein said radionuclide is ^{177}Lu.

~~3.~~4. The pharmaceutical composition according to claim 1, wherein said radionuclide is present at a concentration that it provides a volumetric radioactivity of at least 370 MBq/mL (at End Of Processing) ± 37 MBq/mL (± 10%).

~~4.~~5. The pharmaceutical composition according to claim 1, wherein said chelating agent is selected from DOTA, DTPA, NTA, EDTA, DO3A, ~~NOC~~ and NOTA, preferably is DOTA.

~~5.~~6. The pharmaceutical composition according to claim 1, wherein said gastrin-releasing peptide receptor peptide antagonist binding moiety linked to a chelating agent is NeoB of formula (I):



(I)

~~6. The pharmaceutical composition according to claim 1, wherein said at least two stabilizer are selected from gentisic acid or salts thereof, ascorbic acid or salts thereof, methionine, histidine, melatonine, ethanol, and Se-methionine, preferably selected from gentisic acid or salts thereof and ascorbic acid or salts thereof.~~

~~7. The pharmaceutical composition according to claim 6, wherein said at least two stabilizer are gentisic acid or salts thereof and ascorbic acid or salts thereof.~~

7. The pharmaceutical composition according to claim 6, wherein said radionuclide is ^{177}Lu.

8. The pharmaceutical composition according to ~~claim 7~~any of claims 1 to 7, wherein the weight ratio between gentisic acid and ascorbic acid is ~~between 1:16 and 1 :10, typically~~ between 1 :15 and 1 :10 , for example between 1:12 and 1:11.

9. The pharmaceutical composition according to ~~claim 7 or 8~~any of claims 1 to 8, wherein said gentisic acid or salts thereof is present in a concentration of least 1000µg/mL, for example between 1000 µg/mL and 1500 µg/mL .

10. The pharmaceutical composition according to ~~claims 7 to 9~~any of claims 1 to 8, wherein said ascorbic acid or salts thereof is present in a concentration of at least 10000 µg/mL, preferably at least 12000 µg/mL, preferably at least 15000 µg/mL, for example between 12 000 and 18 000 µg/mL.

11. The pharmaceutical composition according to ~~claims 7 to 10~~any of claims 1 to 8, wherein said gentisic acid or salts thereof is present in a concentration of least 1000µg/mL, for example between 1000 µg/mL and 1500 µg/mL, and ascorbic acid or salts thereof is present in a concentration of between 12 000 and 18 000 µg/mL~~15000 µg/mL~~, for example ~~between 12 000 and 18 000 µg/mL~~ 15000 µg/mL.

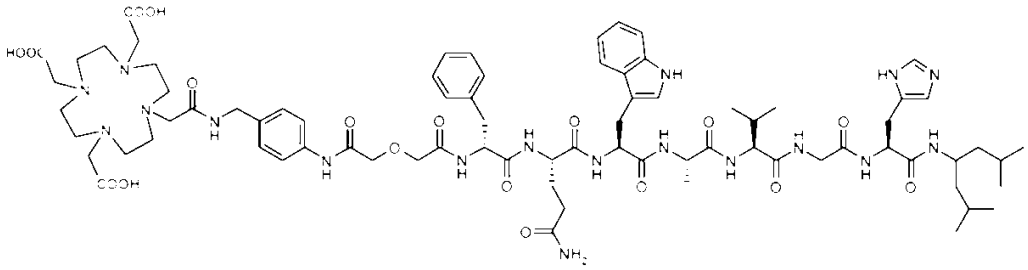
12. The pharmaceutical composition according to ~~claims 1 to 11~~any of claims 1 to 11, wherein said pharmaceutical formulation has a radiochemical purity higher than 95% up to 72hours, preferably higher than 98% up to 72h.

13. A pharmaceutical composition comprising:

(~~c~~a) a complex formed by

(ai) the radionuclide ^{177}Lutetium (Lu-177), and

(aii) NeoB of formula (I):



(I); and;

(b) gentisic acid or salts thereof and ascorbic acid or salts thereof, wherein gentisic acid and ascorbic acid are present in a weight ratio between 1:16 and 1:10, for example between 1:15 and 1:10;

(c) optionally, Macrogol 15 Hydroxystearate ,

(d) optionally, at least one other pharmaceutically acceptable excipient.

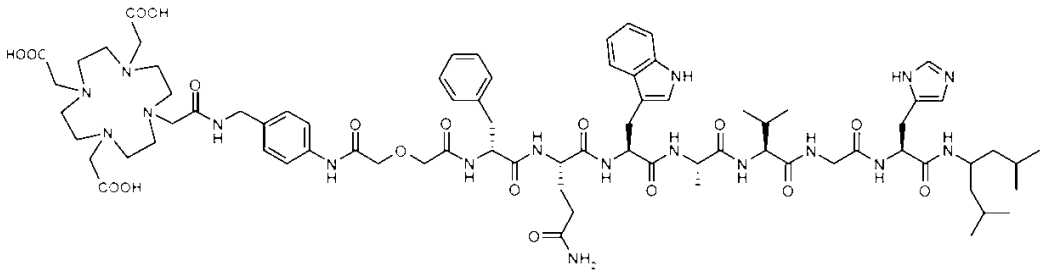
14. The pharmaceutical composition according to claim 13, wherein the at least one other pharmaceutically acceptable excipient is selected from buffer and/or solvent, and/or pH adjuster.

15. A pharmaceutical composition consisting of:

(a) a complex formed by

(ai) radionuclide ^{177}Lutetium (Lu-177), and

(aii) NeoB of formula (I):



(I); and;

(b) gentisic acid or salts thereof and ascorbic acid or salts thereof;

(c) Macrogol 15 Hydroxystearate ;

(d) acetate buffer;

(e) water for injection, and

(f) NaOH,

(g) DTPA.

16. The pharmaceutical composition according to claim 15, wherein gentisic acid and ascorbic acid are present in a weight ratio between 1:16 and 1:10, for example between 1:15 and 1:10.