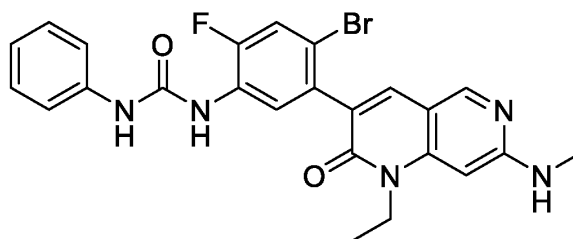


CLAIMS

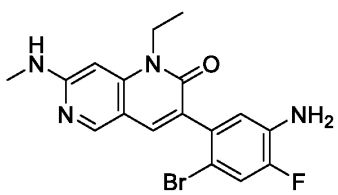
What is claimed is:

1. A pharmaceutical composition comprising:
 - a) a solid dispersion comprising: a compound represented by Formula (I) or



Formula (I)

- and a pharmaceutically acceptable polymer; and
 - b) one or more pharmaceutically acceptable carriers,
- wherein no single anilinic substance is present in an amount equal to or less than about 3.0% by weight.
2. The pharmaceutical composition of claim 1, wherein the anilinic substance is present in amount equal to or less than about 0.5% by weight based on the total weight of the compound of Formula (I) present in the composition.
 3. The pharmaceutical composition of claim 1 or 2, wherein the anilinic substance is present in an amount equal to or less than about 0.3% by weight based on the total weight of the compound of Formula (I) present in the composition.
 4. The pharmaceutical composition of any one of claims 1-3, wherein the anilinic substance is one of : the compound of Formula (II)

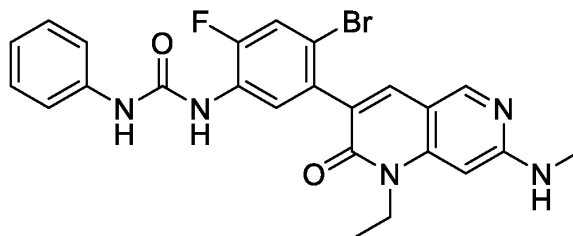


Formula (II)

aniline, or a combination thereof.

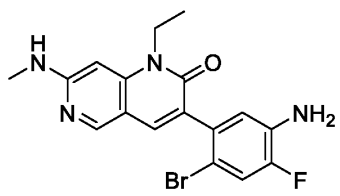
5. The pharmaceutical composition of any one of claims 1-4, wherein the compound is present in the solid dispersion as a free base in substantially amorphous form.

6. A pharmaceutical composition comprising:
 a) a solid dispersion comprising: an amorphous form of a compound represented by Formula (I)



5 **Formula (I)**

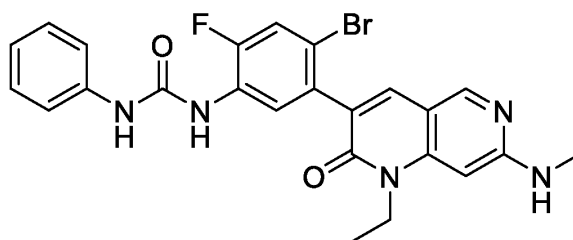
- and a pharmaceutically acceptable polymer; and
 b) one or more pharmaceutically acceptable carriers;
 wherein each of: a compound represented by Formula (II):



10 **Formula (II)**

aniline and diphenyl urea are present in amount equal to or less than about 1.5% by weight based on the total weight of the composition.

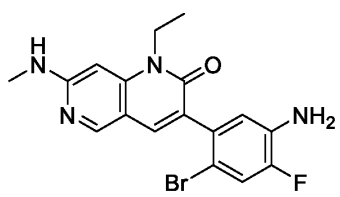
7. A pharmaceutical composition comprising:
 a) a solid dispersion comprising: an amorphous form of a compound represented by
 15 Formula (I)



Formula (I)

- and a pharmaceutically acceptable polymer; and
 b) one or more pharmaceutically acceptable carriers;
 20 wherein diphenyl urea is present in amount equal to or less than about 0.5% by weight based on the total weight of the composition.

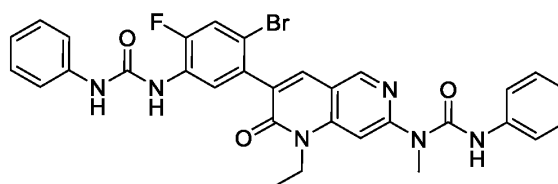
8. The pharmaceutical composition of any one of claims claim 1-6, wherein each of: a compound represented by Formula (II)



Formula (II)

5 aniline and diphenyl urea are present in amount equal to or less than about 0.5% by weight based on the total weight of the compound of Formula (I).

9. The pharmaceutically acceptable composition of any one of claims 1-8, further comprising less than about 10% by weight of a compound represented by Formula (III):

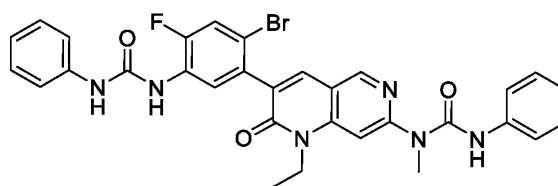


Formula (III)

10

based on the weight of the compound of Formula (I).

10. The pharmaceutically acceptable composition of any one of claims 1-9, further comprising less than about 3% by weight of a compound represented by Formula (III):

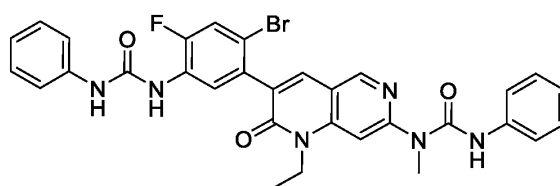


Formula (III)

15

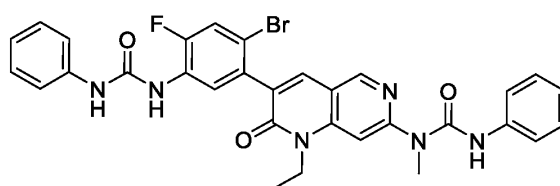
based on the weight of the compound of Formula (I).

11. The pharmaceutically acceptable composition of any one of claims 1-10, further comprising less than about 1% by weight of a compound represented by Formula (III):

**Formula (III)**

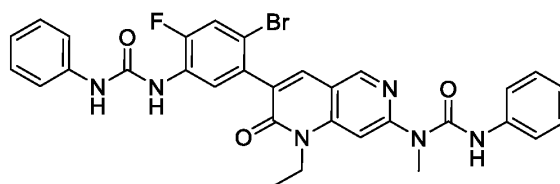
based on the weight of the compound of Formula (I).

12. The pharmaceutically acceptable composition of any one of claims 1-11, further
 5 comprising about 0.1 % by weight to about 0.5% by weight of a compound represented by
 Formula (III):

**Formula (III)**

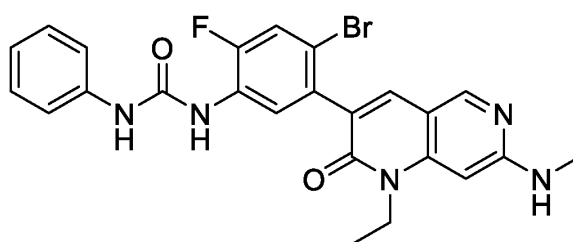
based on the weight of the compound of Formula (I).

- 10 13. The pharmaceutically acceptable composition of any one of claims 1-12, further
 comprising about 0.01 % by weight to about 0.1% by weight of a compound represented by
 Formula (III):

**Formula (III)**

- 15 based on the weight of the compound of Formula (I).

14. A pharmaceutical composition comprising the compound represented by Formula (I)



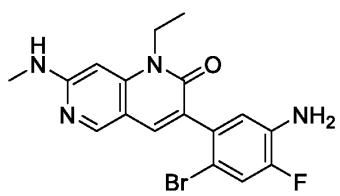
Formula (I)

and one or more pharmaceutically acceptable carriers, excipients or diluents, wherein the composition comprises one or more anilinic substances each in an amount equal to or less than about 3.0% by weight based on the weight of the compound of Formula (I).

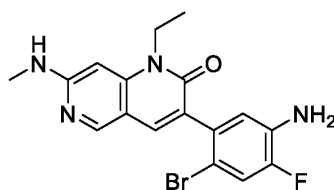
15 15. The composition of claim 14, wherein the composition has equal to or less than about 0.5% by weight one or more anilinic substances based on the weight of the compound of Formula (I).

16. The composition of claim 14 or 15, wherein the composition equal to or less than about 0.3% by weight anilinic substances based on the weight of the compound of Formula
10 (I).

17. The composition of any one of claims 1-16, wherein the one or more anilinic substances is selected from the group consisting of a compound represented by Formula (II):

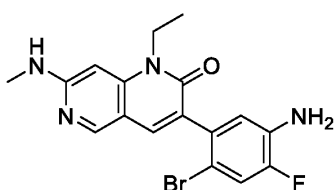
**Formula (II)**

15 aniline, and a combination thereof. 18. The pharmaceutically acceptable composition of any one of claims 1-17, wherein the one or more anilinic substances is a compound represented by Formula (II):

**Formula (II)**

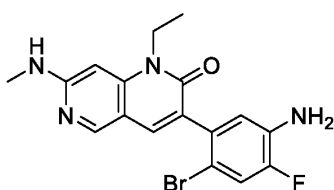
20 and is present in the composition in an amount of less than about 1 % by weight based on the weight of the compound of Formula (I).

19. The pharmaceutically acceptable composition of any one of claims 1-18, wherein the one or more anilinic substances is a compound represented by Formula (II):

**Formula (II)**

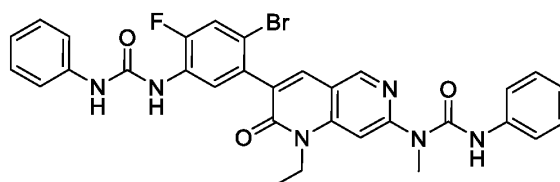
and is present in the composition in an amount of less than about 0.1 % by weight to about 0.5% by weight based on the weight of the compound of Formula (I).

- 5 20. The pharmaceutically acceptable composition of any one of claims 1-19, wherein the one or more anilinic substances is a compound represented by Formula (II):

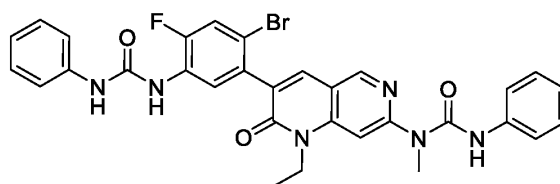
**Formula (II)**

- and is present in the composition in an amount of less than about 0.01 % by weight to about 0.1% by weight based on the weight of the compound of Formula (I).

21. The pharmaceutically acceptable composition of any one of claims 1-20, further comprising less than about 10% by weight of a compound represented by Formula (III):

**Formula (III)**

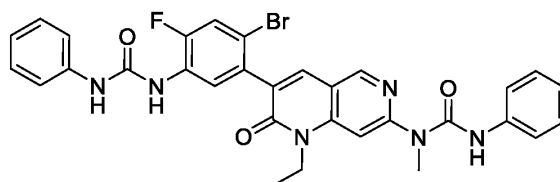
- 15 based on the weight of the compound of Formula (I).
22. The pharmaceutically acceptable composition of any one of claims 1-21, further comprising less than about 3% by weight of a compound represented by Formula (III):



Formula (III)

based on the weight of the compound of Formula (I).

23. The pharmaceutically acceptable composition of any one of claims 1-22, further comprising less than about 1% by weight of a compound represented by Formula (III):



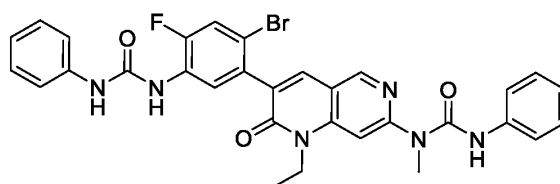
5

Formula (III)

based on the weight of the compound of Formula (I).

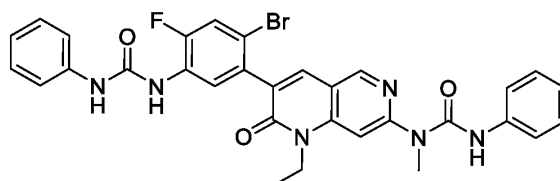
24. The pharmaceutically acceptable composition of any one of claims 1-23, further comprising about 0.1 % by weight to about 0.5% by weight of a compound represented by

10 Formula (III):

**Formula (III)**

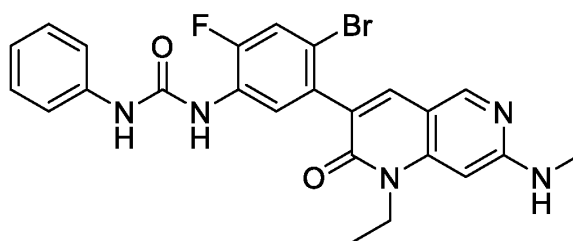
based on the weight of the compound of Formula (I).

25. The pharmaceutically acceptable composition of any one of claims 1-24, further comprising about 0.01 % by weight to about 0.1% by weight of a compound represented by
15 Formula (III):

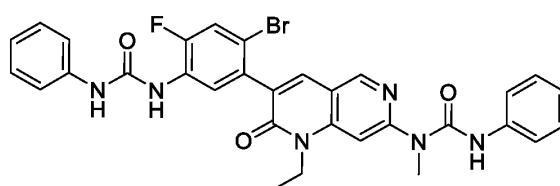
**Formula (III)**

based on the weight of the compound of Formula (I).

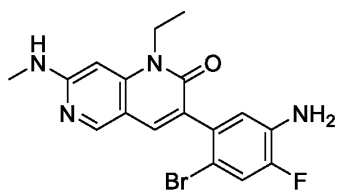
20 26. A pharmaceutical composition comprising the compound represented by Formula (I)

**Formula (I)**

- and one or more pharmaceutically acceptable carriers, excipients or diluents, wherein the pharmaceutical composition comprises one or more anilinic substances and a compound represented by Formula (III):

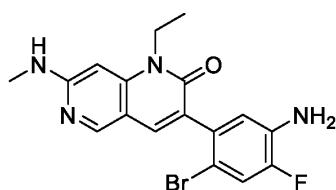
**Formula (III)**

- each in an amount equal to or less than 3.0% by weight based on the weight of the compound of Formula (I).
27. The composition of claim 26, wherein the composition has equal to or less than about 0.5% by weight one or more anilinic substances based on the weight of the compound of Formula (I).
28. The composition of claim 26 or 27, wherein the composition equal to or less than about 0.3% by weight anilinic substances based on the weight of the compound of Formula (I).
29. The composition of any one of claims 26-28, wherein the one or more anilinic substances is selected from the group consisting of a compound represented by Formula (II):

**Formula (II)**

- aniline, and a combination thereof.

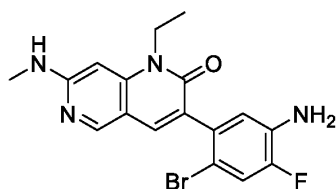
30. The pharmaceutically acceptable composition of any one of claims 26-29, wherein the one or more anilinic substances is a compound represented by Formula (II):



Formula (II)

5 and is present in the composition in an amount of less than about 1 % by weight based on the weight of the compound of Formula (I).

31. The pharmaceutically acceptable composition of any one of claims 26-30, wherein the one or more anilinic substances is a compound represented by Formula (II):

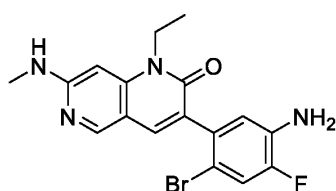


Formula (II)

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and is present in the composition in an amount of less than about 0.1 % by weight to about 0.5% by weight based on the weight of the compound of Formula (I).

32. The pharmaceutically acceptable composition of any one of claims 26-31, wherein the one or more anilinic substances is a compound represented by Formula (II):



15

Formula (II)

and is present in the composition in an amount of less than about 0.01 % by weight to about 0.1% by weight based on the weight of the compound of Formula (I).

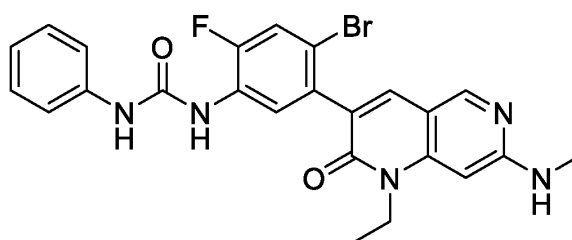
33. The pharmaceutically acceptable composition of any one of claims 26-32, wherein the compound of Formula (III) is present in the composition in an amount of less than about 1% by weight based on the weight of the compound of Formula (I).

20

34. The pharmaceutically acceptable composition of any one of claims 26-33, wherein the compound of Formula (III) is present in the composition in an amount of less than about 0.1 % by weight to about 0.5% by weight by weight based on the weight of the compound of Formula (I).

5 35. The pharmaceutically acceptable composition of any one of claims 26-34, wherein the compound of Formula (III) is present in the composition in an amount of less than about 0.01 % by weight to about 0.1 % by weight by weight based on the weight of the compound of Formula (I).

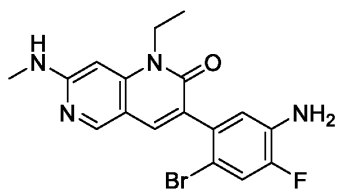
36. A pharmaceutical composition comprising a compound represented by Formula (I)



10

Formula (I)

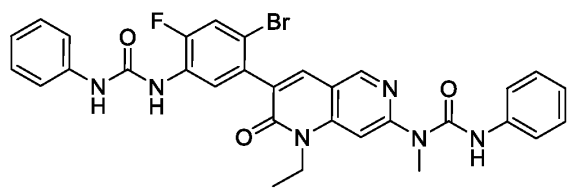
and a pharmaceutically acceptable carrier, wherein the composition has less than 3% w/w of each of: a compound represented by Formula (II):



15

Formula (II)

a compound represented by Formula (III):

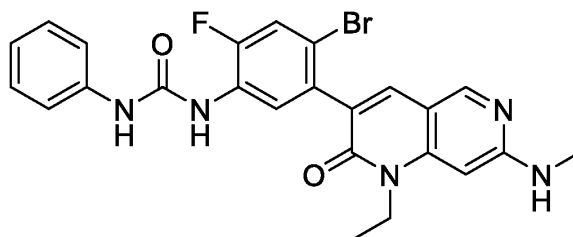


Formula (III)

aniline, and diphenyl urea.

20

37. A pharmaceutical composition comprising a compound represented by Formula (I):



Formula (I)

and a pharmaceutically acceptable carriers, wherein the composition has less than 3% w/w of each of: 3-(5-amino-2-bromo-4-fluorophenyl)-1-ethyl-7-(methylamino)-1,6-naphthyridin-2(1H)-one, aniline and diphenyl urea.

38. The composition of any one of claims 1-37, wherein the composition comprises about 10% to about 50% by weight of the compound based on the total weight of the composition.

39. The composition of any one of claims 1-38, wherein the composition comprises about 10% to about 30% by weight of the compound, based on the total weight of the composition

40. The composition of any one of claims 1-39, wherein the composition comprises about 20% to about 30% by weight of the compound based on the total weight of the composition.

41. The composition of any one of claims 1-40, wherein the composition comprises about 25% by weight of the compound based on the total weight of the composition.

42. The composition of any one of claims 1-41, wherein the compound has a purity of at least 98% as determined by HPLC.

43. The composition of any one of claims 1-42, wherein the compound is substantially in amorphous form.

44. The composition of any one of claims 1-43, wherein the pharmaceutically acceptable carrier is selected from the group consisting of polyvinyl pyrrolidone, polyethyleneoxide, polyethylene glycol, poly(vinyl pyrrolidone-co-vinyl acetate), polyoxyethylene-polyoxypropylene block copolymers, graft copolymers comprised of polyethylene glycol, polyvinyl caprolactam and polyvinyl acetate, polymethacrylates, polyoxyethylene alkyl ethers, polyoxyethylene castor oils, polycaprolactam, polylactic acid, polyglycolic acid, poly(lactic-glycolic)acid, lipids, cellulose, pullulan, dextran, maltodextrin, hyaluronic acid, polysialic acid, chondroitin sulfate, heparin, fucoidan, pentosan polysulfate, spirulan, hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose propionate

succinate, hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, methyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate, cellulose acetate terephthalate, cellulose acetate isophthalate, carboxymethyl ethylcellulose, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose acetate phthalate, hydroxypropyl methylcellulose propionate phthalate, hydroxypropyl methylcellulose acetate trimellitate, hydroxypropyl methylcellulose propionate trimellitate, cellulose acetate succinate, methyl cellulose acetate succinate, dextran, dextran acetate, dextran propionate, dextran succinate, dextran acetate propionate, dextran acetate succinate, dextran propionate succinate, dextran acetate propionate succinate, poly(methacrylic acid-co-methyl methacrylate) 1:1, poly(methacrylic acid-co-methyl methacrylate) 1:2, poly(methacrylic acid-co-ethyl acrylate) 1:1, hydroxyethyl cellulose, methyl cellulose and hydroxy propyl cellulose, poly methacrylic acid-ethyl acrylate, poly methacrylic acid-methyl methacrylate, poly methyl methacrylate-ethyl acrylate, poly trimethylammonioethyl methacrylate chloride-methyl methacrylate-ethyl acrylate and poly(butylmethacrylate-co-(2-dimethylaminoethyl)methacrylate-co-methyl methacrylate), and mixtures thereof.

45. The composition of any one of claims 1-44, wherein the pharmaceutically acceptable carrier is selected from the group consisting of polyvinyl pyrrolidone, polyethyleneoxide, polyethylene glycol, poly(vinyl pyrrolidone-co-vinyl acetate), polyoxyethylene-polyoxypropylene block copolymers, graft copolymers comprised of polyethylene glycol, polyvinyl caprolactam and polyvinyl acetate, polymethacrylates, polyoxyethylene alkyl ethers, polyoxyethylene castor oils, polycaprolactam, polylactic acid, polyglycolic acid, poly(lactic-glycolic)acid, lipids, cellulose, pullulan, dextran, maltodextrin, hyaluronic acid, polysialic acid, chondroitin sulfate, heparin, fucoidan, pentosan polysulfate, spirulan, hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose propionate succinate, hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, methyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate, cellulose acetate terephthalate, cellulose acetate isophthalate, carboxymethyl ethylcellulose, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose acetate phthalate, hydroxypropyl methylcellulose propionate phthalate, hydroxypropyl methylcellulose acetate trimellitate, hydroxypropyl methylcellulose propionate trimellitate, cellulose acetate succinate, methyl cellulose acetate succinate, dextran, dextran acetate, dextran propionate, dextran succinate, dextran acetate propionate, dextran acetate succinate, dextran propionate succinate, dextran acetate propionate succinate, poly(methacrylic acid-co-methyl methacrylate) 1:1, poly(methacrylic acid-co-methyl methacrylate) 1:2,

poly(methacrylic acid-co-ethyl acrylate) 1:1, and mixtures thereof.

46. The composition of any one of claims 1-45, wherein the pharmaceutically acceptable carrier is hydroxypropyl methyl cellulose acetate succinate.

47. The composition of any one of claims 1-46, wherein the ratio of the compound represented by Formula (I) and the one or more pharmaceutically acceptable carrier is from about 40:60 to about 10:90.

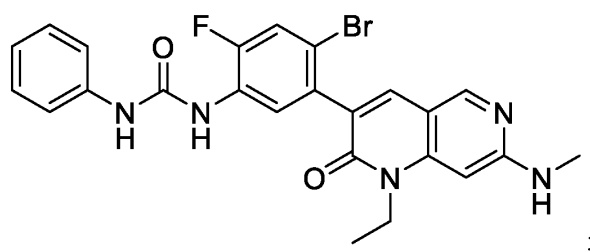
48. The composition of any one of claims 1-47, wherein the ratio of the compound represented by Formula (I) and one or more pharmaceutically acceptable carrier is from about 30:70 to about 20:80.

49. The composition of any one of claims 1-48, wherein the ratio of the compound represented by Formula (I) and one or more pharmaceutically acceptable carrier is about 25:75.

50. The composition of any one of claims 1-49, wherein the composition is a solid oral formulation.

38. The composition of claim 37, wherein the solid oral formulation is a tablet.

51. A pharmaceutically acceptable composition for a 50 mg single dosage unit of a compound represented by:



comprising:

20

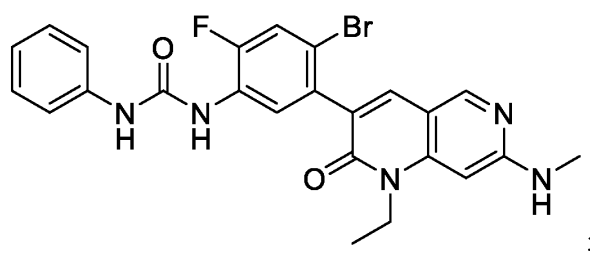
an intragranular blend, wherein the intragranular blend comprises:

a solid dispersion having 50 mg of the compound wherein the compound is present in amorphous form, hydroxypropyl methyl cellulose acetate succinate; a bulking agent and/or filler; and a lubricant and/or a glidant; and

25

an extragranular blend comprising a glidant and/or a lubricant; wherein diphenyl urea is present in amount equal to or less than about 0.5% by weight based on the total weight of the composition.

52. A pharmaceutically acceptable composition for orally delivering to a patient 50 mg of a compound represented by:



comprising:

5

a solid dispersion having:

50 mg of the compound wherein the compound is present in amorphous form;

hydroxypropyl methyl cellulose acetate succinate;

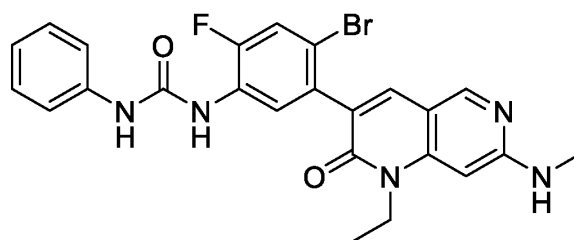
a bulking agent,

10

a filler, and

a lubricant and/or a glidant; wherein diphenyl urea is present in amount equal to or less than about 0.5% by weight based on the total weight of the composition.

53. A pharmaceutically acceptable composition for orally delivering 50 mg of a compound represented by:



15

comprising:

comprises:

a solid dispersion having 50 mg of the compound wherein the compound is present in amorphous form, and a polymer;

20

about 25-45% by weight of a bulking agent based on the total amount of the pharmaceutical composition;

about 25-45% by weight of a filler based on the total amount of the pharmaceutical composition; and

a glidant and/or a lubricant; wherein the composition has not more than about 1.5% (w/w) of 3-(5-amino-2-bromo-4-fluorophenyl)-1-ethyl-7-(methylamino)-1,6-naphthyridin-

25

2(1H)-one, when exposed to 60% relative humidity at 25 °C for 1 month, 3 months or 6 months.

54. The pharmaceutically acceptable composition of claim 53, wherein the polymer is hydroxypropyl methyl cellulose acetate succinate.

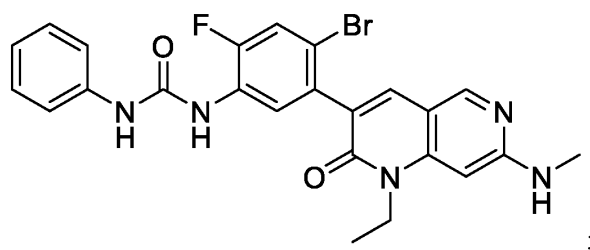
5

55. The pharmaceutically acceptable composition of claim 53 or 54, wherein the bulking agent is microcrystalline cellulose.

56. The pharmaceutically acceptable composition of any one of claims 53-55, wherein the filler is lactose or a hydrate thereof.

10 57. The pharmaceutically acceptable composition of any one of claims 53-57, wherein the composition is in the form of a tablet.

58. A pharmaceutically acceptable tablet having 50 mg of a compound represented by:



wherein the tablet comprises:

15 a solid dispersion having 50 mg of the compound wherein the compound is present in amorphous form, and hydroxypropyl methyl cellulose acetate succinate;

about 25-35% by weight microcrystalline cellulose based on the total weight of the tablet; and

20 about 25-35% by weight of lactose or a hydrate thereof based on the total amount of the pharmaceutical composition; wherein diphenyl urea is present in amount equal to or less than about 0.5% by weight based on the total weight of the composition.

59. The pharmaceutically acceptable tablet of claim 32, further comprising at least one of: magnesium stearate, crospovidone and silicon dioxide.

60. A method of treating a disease selected from the group consisting of gastrointestinal
25 stromal tumors (GIST), NF-1-deficient gastrointestinal stromal tumors, succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumors, KIT driven gastrointestinal stromal tumors, PDGFRA driven gastrointestinal stromal tumors, melanoma, acute myeloid leukemia, germ cell tumors of the seminoma or dysgerminoma, mastocytosis, mast cell leukemia, lung adenocarcinoma, squamous cell lung cancer, glioblastoma, glioma, pediatric

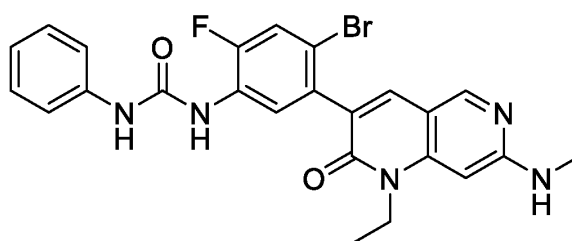
glioma, astrocytomas, sarcomas, malignant peripheral nerve sheath sarcoma, intimal sarcomas, hypereosinophilic syndrome, idiopathic hypereosinophilic syndrome, chronic eosinophilic leukemia, eosinophilia-associated acute myeloid leukemia, lymphoblastic T-cell lymphoma, and non-small cell lung cancer, comprising administering to a patient in need thereof a therapeutically effective amount of the composition of any one of claims 1-59.

61. The method of claim 60, wherein the disease is gastrointestinal stromal tumors (GIST).

62. The use of the composition of any one of claims 1-59 for the preparation of a medicament for the treatment of a disease selected from the group consisting of gastrointestinal stromal tumors (GIST), NF-1-deficient gastrointestinal stromal tumors, succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumors, KIT driven gastrointestinal stromal tumors, PDGFRA driven gastrointestinal stromal tumors, melanoma, acute myeloid leukemia, germ cell tumors of the seminoma or dysgerminoma, mastocytosis, mast cell leukemia, lung adenocarcinoma, squamous cell lung cancer, glioblastoma, glioma, pediatric glioma, astrocytomas, sarcomas, malignant peripheral nerve sheath sarcoma, intimal sarcomas, hypereosinophilic syndrome, idiopathic hypereosinophilic syndrome, chronic eosinophilic leukemia, eosinophilia-associated acute myeloid leukemia, lymphoblastic T-cell lymphoma, and non-small cell lung cancer.

63. The use of claim 62, wherein the disease is gastrointestinal stromal tumors (GIST).

64. A solid dispersion comprising the compound represented by Formula (I)



Formula (I)

and a pharmaceutically acceptable polymer, wherein the solid dispersion comprises one or more anilinic substances each in an amount equal to or less than about 3.0% by weight based on the weight of the compound of Formula (I).

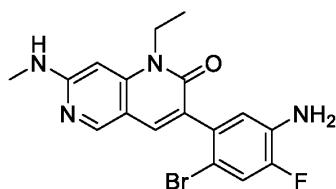
65. The solid dispersion of claim 65, wherein the pharmaceutically acceptable polymer is selected from the group consisting of polyvinyl pyrrolidone, polyethyleneoxide, polyethylene glycol, poly(vinyl pyrrolidone-co-vinyl acetate), polyoxyethylene-

polyoxypropylene block copolymers, graft copolymers comprised of polyethylene glycol, polyvinyl caprolactam and polyvinyl acetate, polymethacrylates, polyoxyethylene alkyl ethers, polyoxyethylene castor oils, polycaprolactam, polylactic acid, polyglycolic acid, poly(lactic-glycolic)acid, lipids, cellulose, pullulan, dextran, maltodextrin, hyaluronic acid, polysialic acid, chondroitin sulfate, heparin, fucoidan, pentosan polysulfate, spirulan, hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose propionate succinate, hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, methyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate, cellulose acetate terephthalate, cellulose acetate isophthalate, carboxymethyl ethylcellulose, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose acetate phthalate, hydroxypropyl methylcellulose propionate phthalate, hydroxypropyl methylcellulose acetate trimellitate, hydroxypropyl methylcellulose propionate trimellitate, cellulose acetate succinate, methyl cellulose acetate succinate, dextran, dextran acetate, dextran propionate, dextran succinate, dextran acetate propionate, dextran acetate succinate, dextran propionate succinate, dextran acetate propionate succinate, poly(methacrylic acid-co-methyl methacrylate) 1:1, poly(methacrylic acid-co-methyl methacrylate) 1:2, poly(methacrylic acid-co-ethyl acrylate) 1:1, hydroxyethyl cellulose, methyl cellulose and hydroxy propyl cellulose, poly methacrylic acid-ethyl acrylate, poly methacrylic acid-methyl methacrylate, poly methyl methacrylate-ethyl acrylate, poly trimethylammonioethyl methacrylate chloride-methyl methacrylate-ethyl acrylate and poly(butylmethacrylate-co-(2-dimethylaminoethyl)methacrylate-co-methyl methacrylate), and mixtures thereof.

66. The solid dispersion of claim 64 or 65, wherein the pharmaceutically acceptable polymer is selected from the group consisting of polyvinyl pyrrolidone, polyethyleneoxide, polyethylene glycol, poly(vinyl pyrrolidone-co-vinyl acetate), polyoxyethylene-polyoxypropylene block copolymers, graft copolymers comprised of polyethylene glycol, polyvinyl caprolactam and polyvinyl acetate, polymethacrylates, polyoxyethylene alkyl ethers, polyoxyethylene castor oils, polycaprolactam, polylactic acid, polyglycolic acid, poly(lactic-glycolic)acid, lipids, cellulose, pullulan, dextran, maltodextrin, hyaluronic acid, polysialic acid, chondroitin sulfate, heparin, fucoidan, pentosan polysulfate, spirulan, hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose propionate succinate, hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, methyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate, cellulose acetate terephthalate, cellulose acetate isophthalate, carboxymethyl ethylcellulose, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose acetate

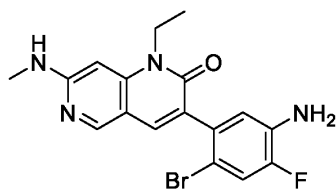
- phthalate, hydroxypropyl methylcellulose propionate phthalate, hydroxypropyl methylcellulose acetate trimellitate, hydroxypropyl methylcellulose propionate trimellitate, cellulose acetate succinate, methyl cellulose acetate succinate, dextran, dextran acetate, dextran propionate, dextran succinate, dextran acetate propionate, dextran acetate succinate, dextran propionate succinate, dextran acetate propionate succinate, poly(methacrylic acid-co-methyl methacrylate) 1:1, poly(methacrylic acid-co-methyl methacrylate) 1:2, poly(methacrylic acid-co-ethyl acrylate) 1:1, and mixtures thereof.

67. A pharmaceutical composition comprising the solid dispersion of any one of claims 43-45 and one or more pharmaceutically acceptable carriers, excipients or diluents.
68. The solid dispersion of any one of claims 64-66 or the pharmaceutically acceptable composition of claim 67, wherein the one or more anilinic substances is a compound represented by Formula (II):



Formula (II)

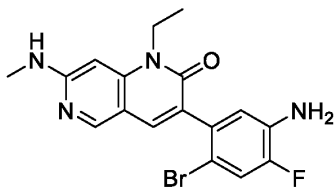
- and is present in the composition in an amount of less than about 1 % by weight based on the weight of the compound of Formula (I).
69. The solid dispersion of any one of claims 64-66 and 68 or the pharmaceutically acceptable composition of claim 67 or 68, wherein the one or more anilinic substances is a compound represented by Formula (II):



Formula (II)

and is present in the composition in an amount of less than about 0.1 % by weight to about 0.5% by weight based on the weight of the compound of Formula (I).

70. The solid dispersion of any one of claims 64-66 and 68-69 or the pharmaceutically acceptable composition of any one of claims 67-69, wherein the one or more anilinic substances is a compound represented by Formula (II):

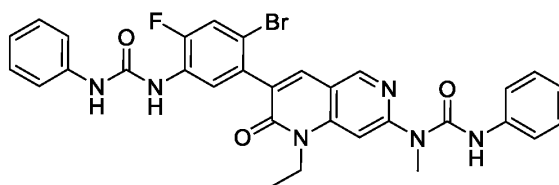


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Formula (II)

and is present in the composition in an amount of less than about 0.01 % by weight to about 0.1% by weight based on the weight of the compound of Formula (I).

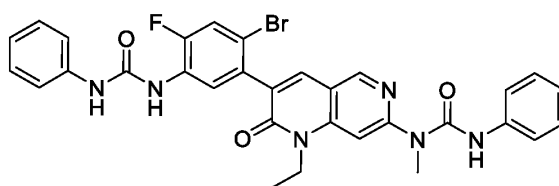
71. The solid dispersion of any one of claims 64-66 and 68-70 or the pharmaceutically acceptable composition of any one of claims 68-70, further comprising less than about 10% by weight of a compound represented by Formula (III):



Formula (III)

based on the weight of the compound of Formula (I).

72. The solid dispersion of any one of claims 64-66 and 68-71 or the pharmaceutically acceptable composition of any one of claims 68-71, further comprising less than about 3% by weight of a compound represented by Formula (III):

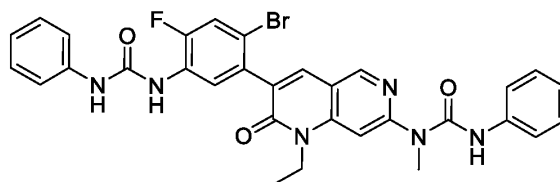


Formula (III)

based on the weight of the compound of Formula (I).

20

73. The solid dispersion of any one of claims 64-66 and 68-72 or the pharmaceutically acceptable composition of any one of claims 68-72, further comprising less than about 1% by weight of a compound represented by Formula (III):

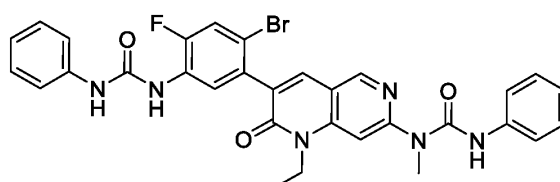


5

Formula (III)

based on the weight of the compound of Formula (I).

74. The solid dispersion of any one of claims 64-66 and 68-73 or the pharmaceutically acceptable composition of any one of claims 68-73, further comprising about 0.1 % by weight to about 0.5% by weight of a compound represented by Formula (III):

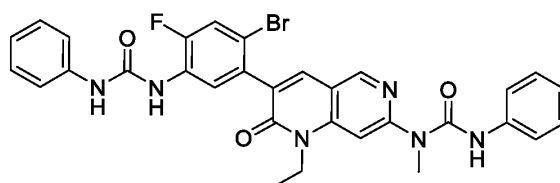


10

Formula (III)

based on the weight of the compound of Formula (I).

75. The solid dispersion of any one of claims 64-66 and 68-75 or the pharmaceutically acceptable composition of any one of claims 68-75, further comprising about 0.01 % by weight to about 0.1% by weight of a compound represented by Formula (III):



Formula (III)

based on the weight of the compound of Formula (I).

76. A method of treating a disease selected from the group consisting of gastrointestinal stromal tumors (GIST), NF-1-deficient gastrointestinal stromal tumors, succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumors, KIT driven gastrointestinal

stromal tumors, PDGFRA driven gastrointestinal stromal tumors, melanoma, acute myeloid leukemia, germ cell tumors of the seminoma or dysgerminoma, mastocytosis, mast cell leukemia, lung adenocarcinoma, squamous cell lung cancer, glioblastoma, glioma, pediatric glioma, astrocytomas, sarcomas, malignant peripheral nerve sheath sarcoma, intimal

5 sarcomas, hypereosinophilic syndrome, idiopathic hypereosinophilic syndrome, chronic eosinophilic leukemia, eosinophilia-associated acute myeloid leukemia, lymphoblastic T-cell lymphoma, and non-small cell lung cancer in a patient in need thereof, comprising administering to a patient a therapeutically effective amount of the composition of any one of claims 68-75.

10 77. The method of claim 76, wherein the disease is gastrointestinal stromal tumors (GIST).

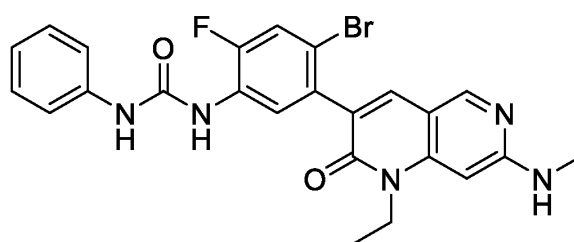
78. The use of the composition of any one of claims 68-75 for the preparation of a medicament for the treatment of a disease selected from the group consisting of

15 gastrointestinal stromal tumors (GIST), KIT driven gastrointestinal stromal tumors, PDGFRA driven gastrointestinal stromal tumors, melanoma, acute myeloid leukemia, germ cell tumors of the seminoma or dysgerminoma, mastocytosis, mast cell leukemia, lung adenocarcinoma, squamous cell lung cancer, glioblastoma, glioma, pediatric glioma, astrocytomas, sarcomas, malignant peripheral nerve sheath sarcoma, intimal sarcomas, hypereosinophilic syndrome, idiopathic hypereosinophilic syndrome, chronic eosinophilic leukemia, eosinophilia-

20 associated acute myeloid leukemia, lymphoblastic T-cell lymphoma, and non-small cell lung cancer.

79. The use of claim 77, wherein the disease is gastrointestinal stromal tumors (GIST).

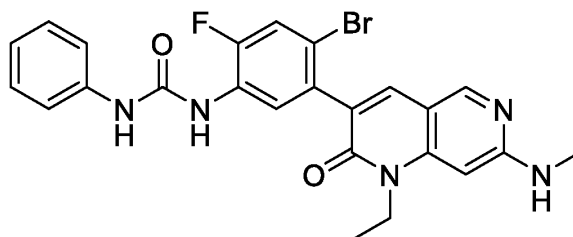
80. A pharmaceutical composition comprising a compound represented by Formula (I)



25 **Formula (I)**

and one or more pharmaceutically acceptable carriers, excipients or diluents, wherein the pharmaceutical composition has less than about 0.05% of diphenyl urea.

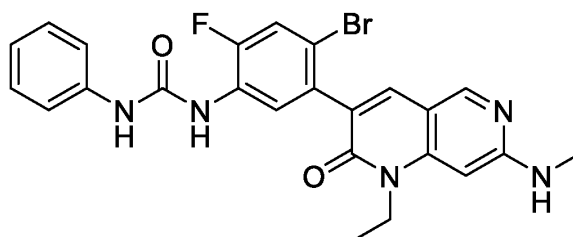
81. A pharmaceutical composition comprising a compound represented by Formula (I)



Formula (I)

and one or more pharmaceutically acceptable carriers, excipients or diluents, wherein the
 5 pharmaceutical composition has less than about 0.05% of diphenyl urea as detected by HPLC.

82. A solid dispersion comprising the compound represented by Formula (I)



Formula (I)

10 and a pharmaceutically acceptable polymer, wherein the compound has a purity by HPLC of greater than about 90%.

83. The solid dispersion of claim 82, having a purity by HPLC of greater than about 95%.

84. A pharmaceutical composition comprising the solid dispersion of claim 83 and one or more pharmaceutically acceptable carriers, excipients or diluents.

15 85. A pharmaceutical composition comprising the solid dispersion of claim 84 and one or more pharmaceutically acceptable carriers, excipients or diluents.

86. A method of treating a disease selected from the group consisting of gastrointestinal stromal tumors (GIST), NF-1-deficient gastrointestinal stromal tumors, succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumors, KIT driven gastrointestinal stromal tumors, PDGFRA driven gastrointestinal stromal tumors, melanoma, acute myeloid
 20 leukemia, germ cell tumors of the seminoma or dysgerminoma, mastocytosis, mast cell leukemia, lung adenocarcinoma, squamous cell lung cancer, glioblastoma, glioma, pediatric

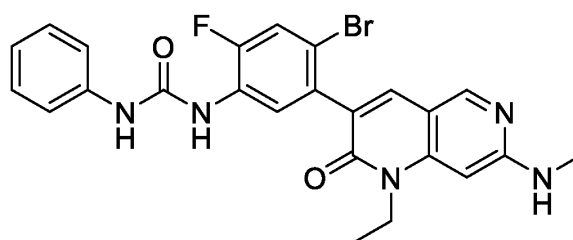
glioma, astrocytomas, sarcomas, malignant peripheral nerve sheath sarcoma, intimal sarcomas, hypereosinophilic syndrome, idiopathic hypereosinophilic syndrome, chronic eosinophilic leukemia, eosinophilia-associated acute myeloid leukemia, lymphoblastic T-cell lymphoma, and non-small cell lung cancer in a patient in need thereof, comprising
5 administering to the patient a therapeutically effective amount of the composition of claim 84 or 85.

87. The method of claim 86, wherein the disease is gastrointestinal stromal tumors (GIST).

88. The use of the composition of claim 84 or 85 for the preparation of a medicament for
10 the treatment of a disease selected from the group consisting of gastrointestinal stromal tumors (GIST), NF-1-deficient gastrointestinal stromal tumors, succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumors, KIT driven gastrointestinal stromal tumors, PDGFRA driven gastrointestinal stromal tumors, melanoma, acute myeloid leukemia, germ cell tumors of the seminoma or dysgerminoma, mastocytosis, mast cell leukemia, lung
15 adenocarcinoma, squamous cell lung cancer, glioblastoma, glioma, pediatric glioma, astrocytomas, sarcomas, malignant peripheral nerve sheath sarcoma, intimal sarcomas, hypereosinophilic syndrome, idiopathic hypereosinophilic syndrome, chronic eosinophilic leukemia, eosinophilia-associated acute myeloid leukemia, lymphoblastic T-cell lymphoma, and non-small cell lung cancer.

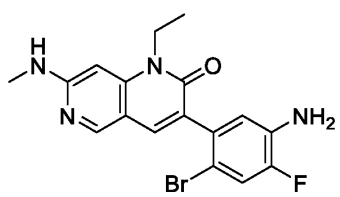
20 89. The use of claim 88, wherein the disease is gastrointestinal stromal tumors (GIST).

90. A substantially purified compound represented by Formula (I)



Formula (I)

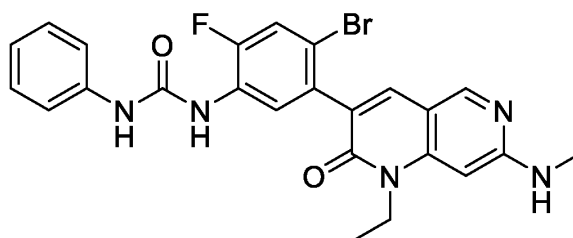
having less than about 3.0% by weight of an impurity selected from the group consisting of a
25 compound represented by Formula (II):

**Formula (II)**

aniline, and combinations thereof.

91. The compound of claim 90, wherein each of the impurities is in an amount equal to or less than about 0.5% by weight based on the weight of the compound of Formula (I).

92. A high purity compound represented by Formula (I)

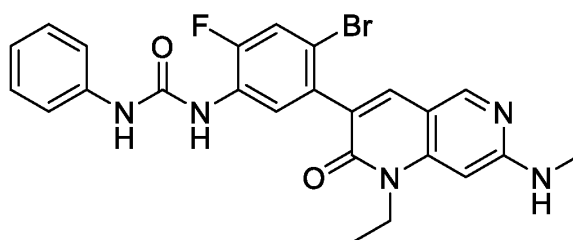
**Formula (I)**

having less than about 3.0% of anilinic substance impurities.

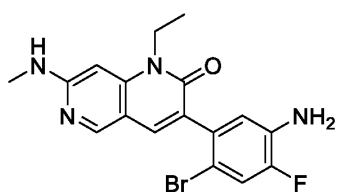
93. The compound of claim 92, wherein the compound comprises less than 0.5% of each of one or more anilinic substances.

94. The compound of claim 93, wherein each of the impurities is in an amount equal to or less than about 0.5% by weight based on the weight of the compound of Formula (I).

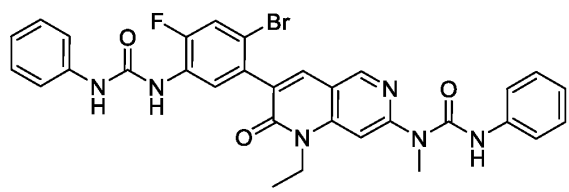
95. A substantially purified compound represented by Formula (I)

**Formula (I)**

having less than about 3.0% by weight of an impurity selected from the group consisting of a compound represented by Formula (II):

**Formula (II)**

a compound represented by Formula (III):

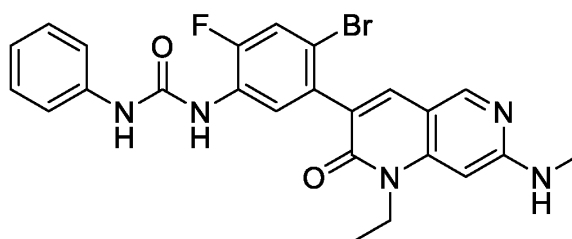
**Formula (III)**

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and combinations thereof.

96. The compound of claim 96, wherein the impurity is in an amount equal to or less than about 0.5% by weight based on the weight of the compound of Formula (I).

97. A high purity compound represented by Formula (I)

**Formula (I)**

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having less than about 0.05% of a diphenyl urea impurity.

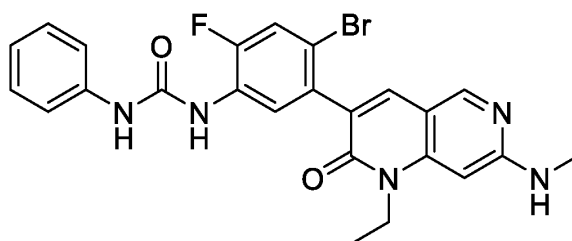
98. The compound of claim 98, wherein the compound comprises less than 0.5% of each of one or more anilinic substances.

15 99. A pharmaceutical composition comprising any one of the compounds of claims 90-98 and one or more pharmaceutically acceptable excipients, carriers or diluents.

100. A method of treating a disease selected from the group consisting of gastrointestinal stromal tumors (GIST), NF-1-deficient gastrointestinal stromal tumors, succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumors, KIT driven gastrointestinal

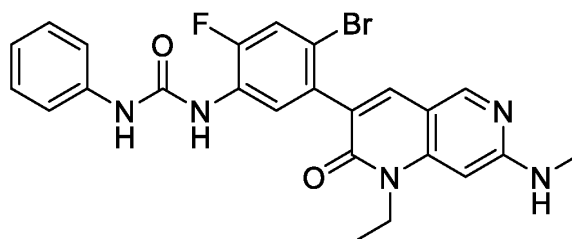
- stromal tumors, PDGFRA driven gastrointestinal stromal tumors, melanoma, acute myeloid leukemia, germ cell tumors of the seminoma or dysgerminoma, mastocytosis, mast cell leukemia, lung adenocarcinoma, squamous cell lung cancer, glioblastoma, glioma, pediatric glioma, astrocytomas, sarcomas, malignant peripheral nerve sheath sarcoma, intimal
- 5 sarcomas, hypereosinophilic syndrome, idiopathic hypereosinophilic syndrome, chronic eosinophilic leukemia, eosinophilia-associated acute myeloid leukemia, lymphoblastic T-cell lymphoma, and non-small cell lung cancer in a patient in need thereof, comprising administering to the patient a therapeutically effective amount of the composition of claim 99.
- 10 101. A method of treating a disease selected from the group consisting of gastrointestinal stromal tumors (GIST), NF-1-deficient gastrointestinal stromal tumors, succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumors, KIT driven gastrointestinal stromal tumors, PDGFRA driven gastrointestinal stromal tumors, lung cancer, glioblastoma, a glioma, malignant peripheral nerve sheath sarcoma, and hypereosinophilic syndrome in a
- 15 patient in need thereof, comprising administering to the patient a therapeutically effective amount of the composition of any one of claims 1-59, 67-75, 80-81, 84-85, and 99.
102. A method of treating a disease selected from the group consisting of KIT driven germ cell tumor, KIT driven skin cancer, or KIT driven renal cell carcinoma in a patient in need thereof, comprising administering to the patient a therapeutically effective amount of the
- 20 composition of any one of claims 1-59, 67-75, 80-81, 84-85, and 99.
103. A method of treating a disease selected from the group consisting of penile cancer, PDGFRA driven penile cancer, prostate cancer, PDGFRA driven prostate cancer, PDGFRA driven non-melanoma skin cancer, PDGFRA driven glioma, PDGFRA driven sarcoma, PDGFRA driven glioblastoma, or PDGFRA driven pancreatic cancer in a patient in need
- 25 thereof, comprising administering to the patient a therapeutically effective amount of the composition of any one of claims 1-59, 67-75, 80-81, 84-85, and 99.
104. A method of treating a disease selected from the group consisting of vaginal cancer, prostate cancer, penile cancer, non-melanoma skin cancer, melanoma, or breast sarcoma in a
- 30 patient in need thereof, comprising administering to the patient a therapeutically effective amount of the composition or one or more of the tablets of any one of claims 1-59, 67-75, 80-81, 84-85, and 99, wherein the disease comprises a PDGFRAB mutation.
105. The method of claim 104, wherein the disease is gastrointestinal stromal tumors (GIST).

106. A process for the preparation of the solid dispersion comprising a compound of Formula (I)



Formula (I)

- 5 according to any one of claims 64-66, 68-75, and 82-83, the process comprising:
- (a) mixing the compound of Formula (I), a solvent, the polymer and water to obtain a suspension;
 - (b) optionally agitating and/or mixing the suspension while maintaining a temperature of about 10 to about 25 °C;
 - 10 (c) heating the suspension to dissolve the suspended particles prior to introduction into a spray-dryer; and
 - (d) spray-drying the suspension to obtain a spray-dried dispersion;
 - (e) drying the spray-dried dispersion; thereby obtaining the solid dispersion.
107. The process of claim 106, wherein heating comprises passing the suspension through
- 15 an in-line heat exchanger.
108. A solid dispersion comprising a compound of Formula (I)



Formula (I)

produced by the process of claim 106 or 107.