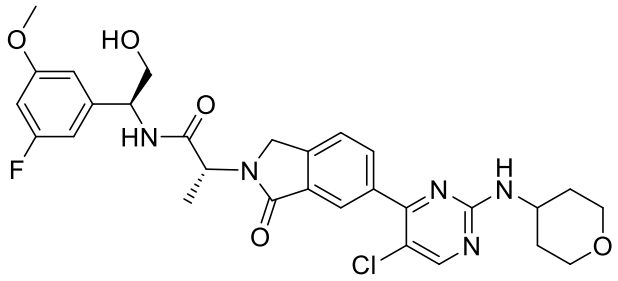
CLAIMS

1. A pharmaceutical composition comprising Compound I, having the formula:

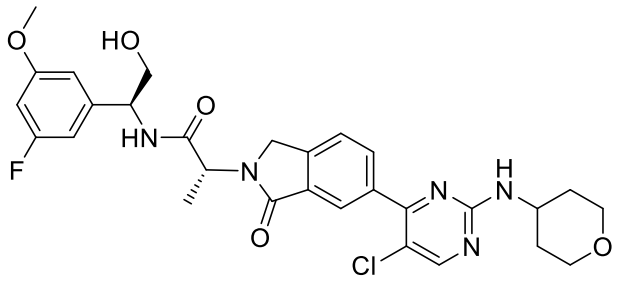


I,

or a pharmaceutically acceptable salt or solvate thereof, and a water soluble polymer.

2 The pharmaceutical composition of claim 1, wherein the water soluble polymer is polyvinylpyrrolidone/vinyl acetate (PVPVA), hydroxypropylmethyl cellulose (HPMC), or hydroxypropylmethyl cellulose acetate succinate (HPMCAS).

3. A solid dispersion comprising Compound I, having the formula:



I,

or a pharmaceutically acceptable salt or solvate thereof,

wherein Compound I, or a pharmaceutically acceptable salt or solvate thereof, is molecularly dispersed within a polymer matrix comprising hydroxypropylmethyl cellulose acetate succinate (HPMCAS).

4. The solid dispersion of claim 3, wherein Compound I, or a pharmaceutically acceptable salt or solvate thereof, is present in the solid dispersion in an amount of about 20% to about 50% (for example in an amount of about 20% to about 40%, or about 20% to about 30%) by weight of the solid dispersion.

5. The solid dispersion of any one of claims 3-4, wherein HPMCAS is present in an amount greater than about 50% (for example about 60% to about 80%) by weight of the solid dispersion.

6. A pharmaceutical composition comprising the solid dispersion of any one of claims 3-5.

7. The pharmaceutical composition of claim 6, wherein the composition is formulated as a tablet.

8. The pharmaceutical composition of claim 7, wherein the tablet comprises an intra-granular layer and an extra-granular layer.

9. The pharmaceutical composition of any one of claims 6-8, wherein the solid dispersion comprises about 40% – 70% (for example about 60%) by weight of the tablet.

10. The pharmaceutical composition of any one of claims 6-9, wherein the pharmaceutical composition is formulated as a tablet comprising an intra-granular layer and an extra-granular layer and wherein:

the intra-granular layer of the tablet further comprises:

about 8 – 18% by weight of microcrystalline cellulose;

about 8 – 18% by weight of lactose monohydrate;

about 2 – 8% by weight of croscarmellose sodium;

about 0.5 – 2% by weight of non-fumed silica; and

about 0.1 – 0.5% by weight of magnesium stearate;

11. The pharmaceutical composition of any one of claims 6-10, wherein the pharmaceutical composition is formulated as a tablet comprising an intra-granular layer and an extra-granular layer and wherein: about 0 –14% by weight of microcrystalline cellulose;

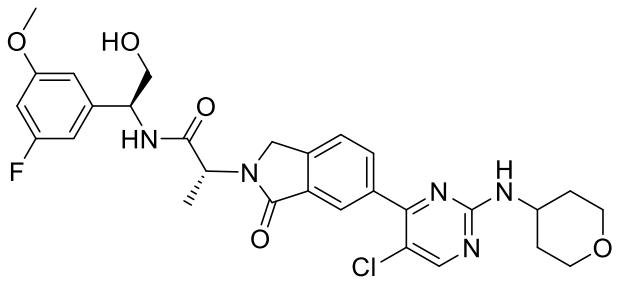
about 0 – 14% by weight of lactose monohydrate;

about 2 – 8% by weight of croscarmellose sodium;

about 0.5 – 2% by weight of non-fumed silica; and

about 0.1 – 0.5% by weight of magnesium stearate.

12. A tablet comprising a solid dispersion, wherein the solid dispersion comprises Compound I, having the formula:



I,

or a pharmaceutically acceptable salt or solvate thereof,

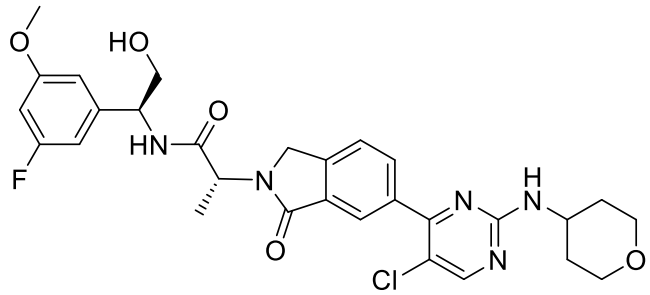
wherein Compound I, or a pharmaceutically acceptable salt or solvate thereof, is molecularly dispersed within a polymer matrix comprising hydroxypropylmethyl cellulose acetate succinate (HPMCAS); and the ratio of an amount by weight of Compound I, or a pharmaceutically acceptable salt or solvate thereof, in the solid dispersion to an amount by weight of HPMCAS in the solid dispersion is from about 1:1 to about 1:5.

13. The pharmaceutical composition of any one of claims 6-11, the solid dispersion of any one of claims 3 to 5 or the tablet of claim 12, wherein the ratio of an amount by weight of Compound I, or a pharmaceutically acceptable salt or solvate thereof, in the solid dispersion to an amount by weight of

HPMCAS in the solid dispersion is from about 1:1 to about 1:5, for example from about 1:2 to about 1:4 (such as about 1:3).

14. The pharmaceutical composition of any one of claims 6-11, the solid dispersion of any one of claims 3 to 5 or the tablet of claim 12, wherein Compound I, or a pharmaceutically acceptable salt or solvate thereof, is substantially amorphous, preferably wherein at least 98% of Compound I, or a pharmaceutically acceptable salt or solvate thereof, is in an amorphous form.

15. A tablet composition of Compound I having the formula:



I,

or a pharmaceutically acceptable salt or solvate thereof,

comprising:

an intra-granular portion comprising:

about 60% by weight of a solid dispersion of Compound I, or a pharmaceutically acceptable salt or solvate thereof, and HPMCAS, wherein Compound I, or a pharmaceutically acceptable salt or solvate thereof, is substantially amorphous and molecularly dispersed within a polymer matrix comprising hydroxypropylmethyl cellulose acetate succinate (HPMCAS), and the ratio of an amount by weight of Compound I, or a pharmaceutically acceptable salt or solvate thereof, in the solid dispersion to an amount by weight of HPMCAS in the solid dispersion is about 1:3;

about 14% by weight of microcrystalline cellulose;

about 13.5% by weight of lactose monohydrate;

about 6% by weight of croscarmellose sodium;

about 1% by weight of non-fumed silica; and

about 0.25% by weight of magnesium stearate;

and

an extra-granular portion comprising:

about 4% by weight of croscarmellose sodium;

about 1% by weight of non-fumed silica; and

about 0.25% by weight of magnesium stearate.

16. The tablet composition of claim 15, wherein the HPMCAS has an acetyl content in a range of about 7 to about 11 percent by weight, and succinoyl content in a range of about 10 to about 14 percent by weight of the HPMCAS.

17. The use of a pharmaceutical composition of any one of claims 1, 2 or 6-11, the solid dispersion of any one of claims 3 to 5 or the tablet of claims 12 or 15 for the manufacture of a medicament for treating cancer.

18. A process for preparing a solid dispersion of claim 3 comprising spray drying a solution of Compound I, or a pharmaceutically acceptable salt or solvate thereof, and HPMCAS in a solvent (such as methanol or acetone), wherein the solution has a solids loading of up to about 25% by weight, for example wherein the solid dispersion is prepared by spray drying a solution of Compound I, or a pharmaceutically acceptable salt or solvate thereof, and HPMCAS in acetone, wherein the acetone solution has a solids loading of up to about 10% by weight.

19. The pharmaceutical composition of any one of claims 1, 2 or 6-11, the solid dispersion of any one of claims 3 to 5, the tablet of claim 12 or 15 or the process of claim 18, wherein Compound I is in the form of a free base or a solvate thereof.

20. The pharmaceutical composition of any one of claims 1, 2 or 6-11, the solid dispersion of any one of claims 3 to 5, the tablet of claim 12 or 15 or the process of claim 18, wherein Compound I is in the form of a free base hydrate (for example, a free base monohydrate).