Claims

1. A long-acting injectable depot pharmaceutical composition comprising:
    a. a helicase-primase inhibitor or a pharmaceutically acceptable salt thereof; and
    b. one or more pharmaceutically acceptable excipients;

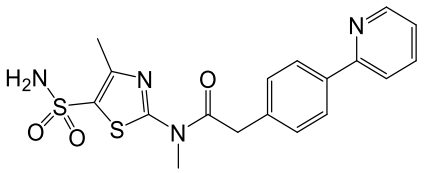
    wherein the helicase-primase inhibitor has a human biological terminal half-life of 10 hours or more.

2. A composition according to claim 1, wherein the composition is a subcutaneous or intramuscular long-acting injectable depot pharmaceutical composition.

3. A composition according to claim 2, wherein the composition is for administration twice a month, once a month, once every two months, once every three months, once every six months or once every year.

4. A composition according to any one of claims 1 to 3, wherein the helicase-primase inhibitor has an *in-vitro* EC_{50} value of less than 0.1 μM against HSV-1 and/or HSV-2.

5. A composition according to any one of claims 1 to 4, wherein the helicase-primase inhibitor is *N*-Methyl-*N*-(4-methyl-5-sulfamoyl-1,3-thiazol-2-yl)-2-[4-(pyridin-2-yl)phenyl]acetamide:



;

    or a pharmaceutically acceptable salt thereof.

6. A composition according to any one of claims 1 to 5, wherein the helicase-primase inhibitor is *N*-Methyl-*N*-(4-methyl-5-sulfamoyl-1,3-thiazol-2-yl)-2-[4-(pyridin-2-yl)phenyl]acetamide free base.

7. A composition according to claim 6, wherein the free base is present as a crystalline solid.

8. A composition according to claim 6, wherein the long-acting injectable depot pharmaceutical composition is an aqueous suspension and the free base is suspended as a crystalline solid.

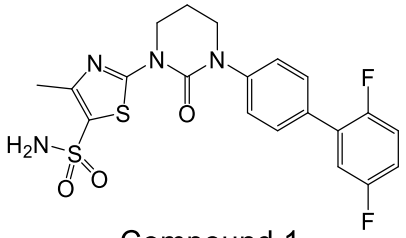
9. A composition according to claim 8, wherein the long-acting injectable depot pharmaceutical composition is an aqueous nanosuspension and the free base is suspended as a crystalline solid.

10. A composition according to any one of claims 1 to 6, wherein the long-acting injectable depot pharmaceutical composition comprises a solution in organic solvent based formulation.

11. A composition according to claim 10, wherein the organic solvent is selected from benzyl alcohol, benzyl benzoate, N-methyl-pyrrolidone (NMP), 2-pyrrolidone, ethanol, propylene glycol, acetone, methyl acetate, ethyl acetate, methyl ethyl ketone, dimethylacetamide (DMA), dimethylformamide, dimethyl sulfoxide (DMSO), tetrahydrofuran, caprolactam, oleic acid, l-dodecylazacycloheptan-2-one, and mixture thereof.

12. A composition according to claim 10, wherein the helicase-primase inhibitor is *N*-Methyl-*N*-(4-methyl-5-sulfamoyl-1,3-thiazol-2-yl)-2-[4-(pyridin-2-yl)phenyl]-acetamide and the organic solvent is selected from NMP, DMA and DMSO.

13. A composition according to any one of claims 1 to 4, wherein the helicase-primase inhibitor is 2-(3-(2',5'-difluoro-[1,1'-biphenyl]-4-yl)-2-oxotetrahydropyrimidin-1(2H)-yl)-4-methyl-thiazole-5-sulfonamide (Compound 1):



Compound 1 ;

or a pharmaceutically acceptable salt thereof.

14. A composition according to any one of claims 1 to 4, wherein the helicase-primase inhibitor is 2-(3-(2',5'-difluoro-[1,1'-biphenyl]-4-yl)-2-oxotetrahydropyrimidin-1(2H)-yl)-4-methylthiazole-5-sulfonamide free form.

15. A composition according to claim 14, wherein the free form is present as a crystalline solid.

16. A composition according to claim 14, wherein the long-acting injectable depot pharmaceutical composition is an aqueous suspension and the free form is suspended as a crystalline solid.

17. A composition according to claim 16, wherein the long-acting injectable depot pharmaceutical composition is an aqueous microsuspension or nanosuspension and the free form is suspended as a crystalline solid.

18. A composition according to claim 13 or 14, wherein the long-acting injectable depot pharmaceutical composition comprises a solution in organic solvent based formulation.

19. A composition according to claim 18, wherein the organic solvent is selected from N-methyl pyrrolidone (NMP), dimethylacetamide (DMA), dimethyl sulfoxide (DMSO), benzyl alcohol, benzyl benzoate and mixtures thereof.

20. A composition according to claim 19, wherein the organic solvent is selected from NMP, DMA and DMSO.

21. A composition according to any one of claims 1 to 20, wherein the long-acting injectable depot pharmaceutical composition comprises 2 wt % to 40 wt % of a helicase-primase inhibitor or a pharmaceutically acceptable salt thereof.

22. A composition according to any one of claims 1 to 21, wherein the long-acting injectable depot pharmaceutical composition comprises 100 mg to 1200 mg, 10 mg to 900 mg or 100 mg to 600 mg of a helicase-primase inhibitor or a pharmaceutically acceptable salt thereof.

23. A composition of any one of claims 1 to 22, wherein the long-acting injectable depot pharmaceutical composition comprises *N*-Methyl-*N*-(4-methyl-5-sulfamoyl-1,3-thiazol-2-yl)-2-[4-(pyridin-2-yl)phenyl]acetamide free base as the helicase-primase inhibitor and the composition produces a plasma concentration of *N*-Methyl-*N*-(4-methyl-5-sulfamoyl-1,3-thiazol-2-yl)-2-[4-(pyridin-2-yl)phenyl]acetamide in the subject after administration of at least 25 ng/mL for at least 80% of the dosing interval, wherein the dosing interval is at least 10 days.

24. A composition of any one of claims 1 to 22, wherein the long-acting injectable depot pharmaceutical composition comprises 2-(3-(2',5'-difluoro-[1,1'-biphenyl]-4-yl)-2-oxotetrahydropyrimidin-1(2H)-yl)-4-methylthiazole-5-sulfonamide free form as the helicase-primase inhibitor and the composition produces a plasma concentration of 2-(3-(2',5'-difluoro-[1,1'-biphenyl]-4-yl)-2-oxotetrahydropyrimidin-1(2H)-yl)-4-

methylthiazole-5-sulfonamide in the subject after administration of at least 25 ng/mL for at least 80% of the dosing interval, wherein the dosing interval is at least 10 days.

25. A composition according to any one of claims 1 to 24, wherein the composition is stable for at least four weeks.

26. A composition according to any one of claims 1 to 25, for use as a medicament.

27. A composition according to any one of claims 1 to 25, for use in the treatment of a herpes virus (such as HSV) infection in a subject in need thereof.

28. The composition according to claim 27, wherein the composition is to be administered twice a month, once a month, once every two months, once every three months, once every six months, or once every year.

29. The composition according to claim 27, wherein the composition is to be administered once a month, or once every three months.

30. Use of the composition according to any one of claims 1 to 25, in the manufacture of a medicament for use in the treatment of a herpes virus (such as HSV) infection in a subject in need thereof.

31. The use of claim 30, wherein the medicament is to be administered twice a month, once a month, once every two months, once every three months, once every six months, or once every year.

32. The use of claim 30, wherein the medicament is to be administered once a month, or once every three months.