90%, about 10% to about 80%, about 20% to about 70%, about 30% to about 60% and about 40% to about 50% (weight/weight) based on the sum of the amount of Compound 1, or a pharmaceutically acceptable salt or prodrug thereof, and the amount of Compound 2, or a pharmaceutically acceptable salt or prodrug thereof, in the composition. As to Compound 2, in an embodiment, the composition can include an amount of Compound 2, or a pharmaceutically acceptable salt or prodrug thereof, in the range of about 1% to about 99% (weight/weight) based on the sum of the amount of Compound 1, or a pharmaceutically acceptable salt or prodrug thereof, and the amount of Compound 2, or a pharmaceutically acceptable salt or prodrug thereof, in the composition. Examples of additional embodiments, include, but are not limited to, an amount of Compound 2, or a pharmaceutically acceptable salt or prodrug thereof, in the range of about 5% to about 90%, about 10% to about 80%, about 20% to about 70%, about 30% to about 60% and about 40% to about 50% (weight/weight) based on the sum of the amount of Compound 1, or a pharmaceutically acceptable salt or prodrug thereof, and the amount of Compound 2, or a pharmaceutically acceptable salt or prodrug thereof, in the composition.

[0038] Additional therapeutic agents can also be included in a composition that includes Compounds 1 and 2, or pharmaceutically acceptable salts or prodrugs thereof. In some embodiments, the additional therapeutic agent can be an anti-viral agent. In an embodiment, the anti-viral agent can be a HCV anti-viral agent. A non-limiting list of examples of suitable therapeutic agents include nucleotides and nucleoside analogs (such as azidothymidine (AZT) (zidovudine), and analogs and derivatives thereof; 2',3'-dideoxyinosine (DDI) (didanosine), and analogs and derivatives thereof; 2',3'-dideoxycytidine (DDC) (dideoxycytidine), and analogs and derivatives thereof; 2',3'-didehydro-2',3'-dideoxythymidine (D4T) (stavudine), and analogs and derivatives thereof; combivir; abacavir; adefovir dipivoxil; cidofovir; ribavirin; ribavirin analogs; levovirin, viramidine, L-nucleoside, isatoribine and the like), pirfenidone or a pirfenidone analogs, NS5B RNA-dependent RNA polymerase inhibitors, tumor necrosis factor antagonists (such as etanercept, infliximab and adalimumab), thymosin-α (Zadaxin™), an interferon receptor agonist(s), α-glucosidase inhibitors, TNF-α antagonists, NS3 helicase inhibitors, NS5B polymerase inhibitors, NS3 protease inhibitors (for example, (VX-950) and (SCH 503034)), Ritonavir (10-hydroxy-2-methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)-4-thiazolyl]-3,6-dioxo-8,11-bis(phenylmethyl)-2,4,7,12-tetraazatridecan-13-oic acid, inosine monophosphate dehydrogenase inhibitor, 5-thiazolylmethyl ester [5*S*-(5*R**,8*R**,10*R**,11*R**)], available from Abbott

Type I interferon receptor agonists include interferons, including naturally-occurring interferons, modified interferons, synthetic interferons, pegylated interferons, fusion proteins comprising an interferon and a heterologous protein, shuffled interferons; antibody specific for an interferon receptor; non-peptide chemical agonists; and the like. As used herein, the term "Type II interferon receptor agonist" refers to any naturally occurring or non-naturally occurring ligand of human Type II interferon receptor that binds to and causes signal transduction via the receptor. Type II interferon receptor agonists include native human interferon-γ, recombinant IFN-γ species, glycosylated IFN-γ species, pegylated IFN-γ species, modified or variant IFN-γ species, IFN-γ fusion proteins, antibody agonists specific for the receptor, non-peptide agonists, and the like. As used herein, the term "a Type III interferon receptor agonist" refers to any naturally occurring or non-naturally occurring ligand of humanIL-28 receptor α ("IL-28R"), the amino acid sequence of which is described by Sheppard, et al., infra., that binds to and causes signal transduction via the receptor.

[0041] Suitable α-glucosidase inhibitors include any of the above-described imino-sugars, including long-alkyl chain derivatives of imino sugars as disclosed in U.S. Patent Publication No. 2004/0110795; inhibitors of endoplasmic reticulum-associated α-glucosidases; inhibitors of membrane bound α-glucosidase; miglitol (Glyset®), and active derivatives, and analogs thereof; and acarbose (Precose®), and active derivatives, and analogs thereof.

[0041a] When the additional therapeutic agent is thymosin-α, the thymosin-α can be in an amount in the range of from about 1.0 mg to about 1.6 mg. The thymosin-α can be for use or manufactured for use in an amount in the range of from about 1.0 mg to about 1.6 mg When the additional therapeutic agent is IFN-γ, the IFN-γ can be in an amount in the range of from about 10 μg to about 300 μg. The IFN-γ can be for use or manufactured for use in subcutaneous administration in an amount in the range of from about10 μg to about 300 μg.

[0042] The compositions described herein can be administered to a human patient *per se*, or in compositions where they are mixed with other active ingredients, as in combination therapy, or carriers, diluents, excipients or combinations thereof, and may be formulated into preparations in solid, semi-solid, liquid or gaseous forms, such as tablets, capsules, powders, granules, ointments, solutions, suppositories, injections, inhalants and aerosols. Proper formulation is dependent upon the route of administration chosen. Techniques for formulation and administration of the compositions described

herein are known to those skilled in the art. Pharmaceutically acceptable excipients are known to those skilled in the art, and are described in a variety of publications, including, for example, A. Gennaro (2000) "Remington: The Science and Practice of Pharmacy," 20th edition, Lippincott, Williams, & Wilkins; Pharmaceutical Dosage Forms and Drug Delivery Systems (1999) H.C. Ansel et al., eds., 7th ed., Lippincott, Williams, & Wilkins;

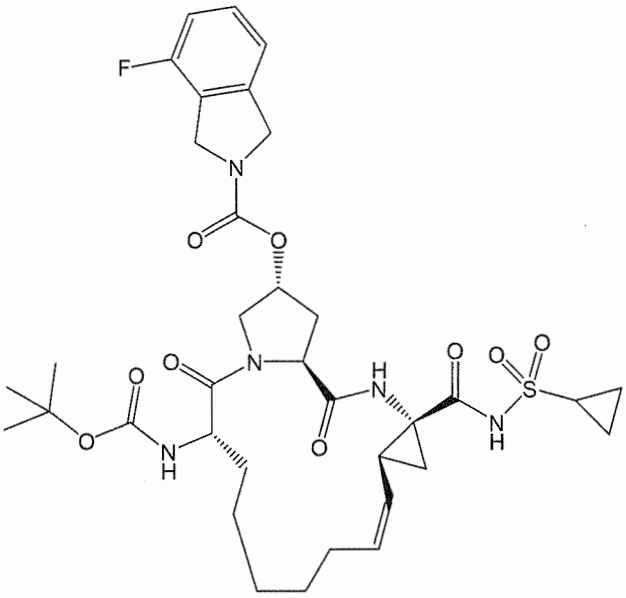
linear)-ylate consensus, INFERGEN consensus IFN-α, a 40 kD branched mono-methoxy PEG conjugate of interferon α-2b and a 12 kD mono-methoxy PEG conjugate of interferon α-2b. The monoPEG (30 kD, linear)-ylate consensus can be for use or manufactured for use at a dosing interval in the range of every 8 days to every 14 days. The monoPEG (30 kD, linear)-ylate consensus can be for use or manufactured for use at a dosing interval of once every 7 days. In an embodiment, the additional therapeutic agent can be ribavirin. In some embodiments, Compounds 1 and 2 can be administered without administering one or more additional therapeutic agents such as an interferon receptor agonist and/or ribavirin. In an embodiment, the interferon receptor agonist can be a Type 1 interferon receptor agonist, such as a pegylated Type 1 interferon receptor agonist.

[0061] One or more additional therapeutic agents can be administered after administration of Compound 1, or a pharmaceutically acceptable salt or prodrug thereof, and Compound 2, or a pharmaceutically acceptable salt or prodrug thereof. For example, one or more additional therapeutic agents can be administered after completion of a treatment regimen with Compound 1, or a pharmaceutically acceptable salt or prodrug thereof, and Compound 2, or a pharmaceutically acceptable salt or prodrug thereof. In some embodiments, the additional therapeutic agent can be an interferon receptor agonist such as a Type I interferon receptor agonist. In an embodiment, the Type I interferon receptor agonist can be a pegylated Type I interferon receptor agonist. In some embodiments, the additional therapeutic agent can be ribavirin.

[0062] Whether a subject method is effective in treating an HCV infection can be determined in various ways, for example, by a reduction in viral load, a reduction in time to seroconversion (virus undetectable in patient serum), an increase in the rate of sustained viral response to therapy, a reduction of morbidity or mortality in clinical outcomes, or other indicator of disease response. Thus, whether a subject method is effective in treating an HCV infection can be determined by measuring viral load, or by measuring a parameter associated with HCV infection, including, but not limited to, liver fibrosis, elevations in serum transaminase levels, and necroinflammatory activity in the liver.

[0063] In some embodiments, administration and/or use of Compounds 1 and 2, or pharmaceutically acceptable salts or prodrugs thereof, in combination can reduce the viral load more than the viral load reduction achieved by administration of Compound 1, or a pharmaceutically acceptable salt or prodrug thereof, alone at substantially the same amount. For example, the combination of Compounds 1 and 2, or pharmaceutically acceptable salts or prodrugs thereof, may reduce the viral load by at least about 10%, at least about 15%, at least about 20%, at least about 25%, at least about 30%, at least about

thereof, wherein the second compound is



3. The composition of Claim 1 ~~or 2~~, further comprising a pharmaceutically acceptable excipient, diluent or carrier.

4. The composition of any one of Claims 1 to 3, wherein the composition comprises an amount of the first compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 9000 mg to ~~about~~ 50 mg.

5. The composition of ~~any one of~~ Claim~~s 1 to 3~~ 4, wherein the composition comprises an amount of the first compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 5000 mg to ~~about~~ 150 mg.

6. The composition of ~~any one of~~ Claim~~s 1 to 3~~ 5, wherein the composition comprises an amount of the first compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 2000 mg to ~~about~~ 300 mg.

7. The composition of ~~any one of~~ Claims ~~1 to 3~~ 6, wherein the composition comprises an amount of the first compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 1000 mg to ~~about~~ 450 mg.

8. The composition of ~~any one of~~ Claims ~~1 to 3~~ 7, wherein the composition comprises an amount of the first compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 1000 mg to ~~about~~ 500 mg.

9. The composition of any one of Claims 1 to 8, wherein the composition comprises an amount of the second compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 2000 mg to ~~about~~ 2 mg.

10. The composition of ~~any one of~~ Claims ~~1 to 8~~ 9, wherein the composition comprises an amount of the second compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 1600 mg to ~~about~~ 25 mg.

11. The composition of ~~any one of~~ Claims ~~1 to 8~~ 10, wherein the composition comprises an amount of the second compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 500 mg to ~~about~~ 50 mg.

12. The composition of ~~any one of~~ Claims ~~1 to 8~~ 11, wherein the composition comprises an amount of the second compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 200 mg to ~~about~~ 100 mg.

13. The composition of any one of Claims 1 to 3, wherein the composition comprises a total amount of the first compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 1% to ~~about~~ 99% (weight/weight) based on the sum of the total amount of the first compound, or a pharmaceutically acceptable salt thereof, and the total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the composition.

14. The composition of ~~any one of~~ Claims ~~1 to 3~~ 13, wherein the composition comprises a total amount of the first compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 5% to ~~about~~ 90% (weight/weight) based on the sum of the total amount of the first compound, or a pharmaceutically acceptable salt thereof, and the total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the composition.

15. The composition of ~~any one of~~ Claims ~~1 to 3~~ 14, wherein the composition comprises a total amount of the first compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 10% to ~~about~~ 80% (weight/weight) based on the

sum of the total amount of the first compound, or a pharmaceutically acceptable salt thereof, and the total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the composition.

16. The composition ~~of any one of~~ Claim~~s 1 to 3~~ 15, wherein the composition comprises a total amount of the first compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 20% to ~~about~~ 70% (weight/weight) based on the sum of the total amount of the first compound, or a pharmaceutically acceptable salt thereof, and the total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the composition.

17. The composition of ~~any one of~~ Claim~~s 1 to 3~~ 16, wherein the composition comprises a total amount of the first compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 30% to ~~about~~ 60% (weight/weight) based on the sum of the total amount of the first compound, or a pharmaceutically acceptable salt thereof, and the total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the composition.

18. The composition of ~~any one of~~ Claim~~s 1 to 3~~ 17, wherein the composition comprises a total amount of the first compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 40% to ~~about~~ 50% (weight/weight) based on the sum of the total amount of the first compound, or a pharmaceutically acceptable salt thereof, and the total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the composition.

19. The composition of any one of Claims 13 to 18, wherein the composition comprises a total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 1% to ~~about~~ 99% (weight/weight) based on the sum of the total amount of the first compound, or a pharmaceutically acceptable salt thereof, and the total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the composition.

20. The composition of ~~any one of~~ Claim~~s 13 to 18~~ 19, wherein the composition comprises a total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 5% to ~~about~~ 90% (weight/weight) based on the sum of the total amount of the first compound, or a pharmaceutically acceptable salt thereof, and the total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the composition.

21. The composition of ~~any one of~~ Claims ~~13 to 18~~ 20, wherein the composition comprises a total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 10% to ~~about~~ 80% (weight/weight) based on the sum of the total amount of the first compound, or a pharmaceutically acceptable salt thereof, and the total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the composition.

22. The composition of ~~any one of~~ Claims ~~13 to 18~~ 21, wherein the composition comprises a total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 20% to ~~about~~ 70% (weight/weight) based on the sum of the total amount of the first compound, or a pharmaceutically acceptable salt thereof, and the total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the composition.

23. The composition of ~~any one of~~ Claims ~~13 to 18~~ 22, wherein the composition comprises a total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 30% to ~~about~~ 60% (weight/weight) based on the sum of the total amount of the first compound, or a pharmaceutically acceptable salt thereof, and the total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the composition.

24. The composition of ~~any one of~~ Claims ~~13 to 18~~ 23, wherein the composition comprises a total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the range of ~~about~~ 40% to ~~about~~ 50% (weight/weight) based on the sum of the total amount of the first compound, or a pharmaceutically acceptable salt thereof, and the total amount of the second compound, or a pharmaceutically acceptable salt thereof, in the composition.

25. The composition of Claim 1 or any one of its dependent Claims ~~1~~-3 to 24, wherein the composition further comprises one or more additional therapeutic agents.

26. The composition of Claim 25, wherein the one or more additional therapeutic agents are selected from the group consisting of pirfenidone, an NS5B RNA-dependent RNA polymerase inhibitor, a tumor necrosis factor antagonist, thymosin-α, interferon-gamma (IFN-γ), interferon-alpha (IFN-α), a nucleoside analog which is 3'-azidothymidine, 2',3'-dideoxyinosine, 2',3'-dideoxycytidine, 2-,3-didehydro-2',3'-dideoxythymidine, combivir, abacavir, adefovir dipivoxil, cidofovir, ribavirin, levovirin, viramidine, an L-nucleoside or isatoribine, ritonavir, an inosine monophosphate dehydrogenase inhibitor, an interferon, an additional NS3 protease inhibitor, an NS5B polymerase inhibitor, and an NS3 helicase inhibitor.

27. The composition of Claim 26, wherein the nucleoside analog is selected from the group consisting of ribavirin, levovirin, viramidine, an L-nucleoside, and isatoribine.

28. The composition of Claim 26, wherein the tumor necrosis factor antagonist is selected from the group consisting of etanercept, infliximab, and adalimumab.

29. The composition of Claim 26, wherein the thymosin-α is in an amount in the range of from ~~about~~ 1.0 mg to ~~about~~ 1.6 mg.

30. The composition of Claim 26, wherein the IFN-γ is in an amount in the range of from ~~about~~ 10 μg to ~~about~~ 300 μg.

31. The composition of Claim 26, wherein the IFN-α is monoPEG (30 kD, linear)-ylate consensus.

32.The composition of Claim 26, wherein the IFN-α is selected from the group consisting of a 40 kD branched mono-methoxy PEG conjugate of interferon α-2b and a 12 kD mono-methoxy PEG conjugate of interferon α-2b.

33. The composition of Claim 26, wherein the IFN-α is INFERGEN consensus IFN-α.

34. The composition of Claim 26, wherein the additional NS3 protease inhibitor is selected from

41. The ~~composition of Claim 38 or the~~ use of Claim 39 or Claim 40, wherein the first compound, or a pharmaceutically acceptable salt thereof, is to be administered before the second compound, or a pharmaceutically acceptable salt thereof.

42. The ~~composition of Claim 38 or the~~ use of Claim 39 or Claim40, wherein the first compound, or a pharmaceutically acceptable salt thereof, is to be administered after the second compound, or a pharmaceutically acceptable salt thereof.

43. The ~~composition of Claim 38 or the~~ use of Claim 39 or Claim 40, wherein the first compound, or a pharmaceutically acceptable salt thereof, is to be administered at approximately the same time as the second compound, or a pharmaceutically acceptable salt thereof.

44. The ~~composition of Claim 38 or the~~ use of Claim 39 or Claim 40, wherein the first compound, or a pharmaceutically acceptable salt thereof, and the second compound, or a pharmaceutically acceptable salt thereof, are together in one dosage form.

45. The ~~composition of any one of Claims 38 and 41 to 43 or the~~ use of any one of Claims 39 to 43, wherein the first compound, or a pharmaceutically acceptable salt thereof, and the second compound, or a pharmaceutically acceptable salt thereof, are in separate dosage forms.

46. The ~~composition of any one of Claims 38 and 41 to 45 or the~~ use of any one of Claims 39 to 45, wherein the disease condition is a hepatitis C viral infection.

47. The ~~composition of any one of Claims 38 and 41 to 46 or the~~ use of any one of Claims 39 to 46, wherein the first compound is for use or manufactured for use in combination with an effective amount of an additional nucleoside analog, wherein the nucleoside analog is selected from the group consisting of 3'-azidothymidine, 2',3'-dideoxyinosine,2',3'-dideoxycytidine, 2-,3-didehydro-2',3'-dideoxythymidine, combivir, abacavir, adefovir dipivoxil, cidofovir, ribavirin, levovirin, viramidine, an L-nucleoside and isatoribine.

48. The ~~composition of Claim 47 or the~~ use of Claim 47, wherein the additional nucleoside analog is selected from the group consisting of ribavirin, levovirin, viramidine, an L-nucleoside, and isatoribine.

49. The ~~composition of any one of Claims 38 and 41 to 48 or the~~ use of any one of Claims 39 to 48, wherein the first compound is for use or manufactured for use in combination with an effective amount of pirfenidone.

50. The ~~composition of any one of Claims 38 and 41 to 49 or the~~ use of any one of Claims 39 to 49, wherein the first compound is for use or manufactured for use in combination with an effective amount of an NS5B RNA-dependent RNA polymerase inhibitor.

51. The ~~composition of any one of Claims 38 and 41 to 50 or the~~ use of any one of Claims 39 to 50, wherein the first compound is for use or manufactured for use in combination with a tumor necrosis factor antagonist selected from the group consisting of etanercept, infliximab, and adalimumab.

52. The ~~composition of any one of Claims 38 and 41 to 51 or the~~ use of any one of Claims 39 to 51, wherein the first compound is for use or manufactured for use in combination with an effective amount of thymosin-α.

53. The ~~composition of Claim 52 or the~~ use of Claim 52, wherein the thymosin-α is for use or manufactured for use in an amount in the range of from ~~about~~ 1.0 mg to ~~about~~ 1.6 mg.

54. The ~~composition of any one of Claims 38 and 41 to 53 or the~~ use of any one of Claims 39 to 53, wherein the first compound is for use or manufactured for use in combination with an effective amount of interferon-gamma (IFN-γ).

55. The ~~composition of Claim 54 or the~~ use of Claim 54, wherein the IFN-γ is for use or manufactured for use in subcutaneous administration in an amount in the range of from ~~about~~ 10 μg to ~~about~~ 300 μg.

56. The ~~composition of any one of Claims 38 and 41 to 53 or the~~ use of any one of Claims 39 to 53, wherein the first compound is for use or manufactured for use in combination with an effective amount of interferon-alpha (IFN-α).

57. The ~~composition of Claim 56 or the~~ use of Claim 56, wherein the IFN-α is monoPEG (30 kD, linear)-ylate consensus for use or manufactured for use at a dosing interval in the range of every 8 days to every 14 days.

58. The ~~composition of Claim 56 or the~~ use of Claim 56, wherein the IFN-α is monoPEG (30 kD, linear)-ylated consensus IFN-α for use or manufactured for use at a dosing interval of once every 7 days.

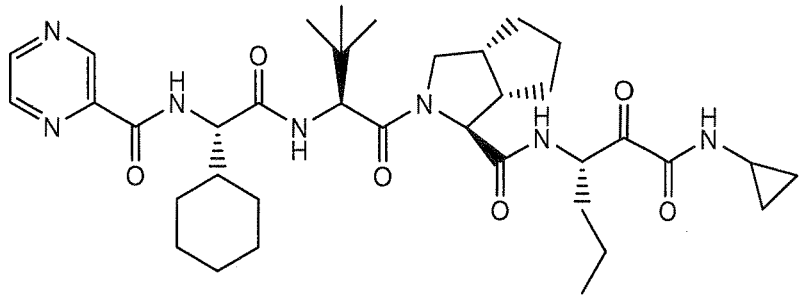
59. The ~~composition of Claim 56 or the~~ use of Claim 56, wherein the IFN-α is selected from the group consisting of a 40 kD branched mono-methoxy PEG conjugate of interferon α-2b and a 12 kD mono-methoxy PEG conjugate of interferon α-2b.

60. The ~~composition of Claim 56 or the~~ use of Claim 56, wherein the IFN-α is INFERGEN consensus IFN-α.

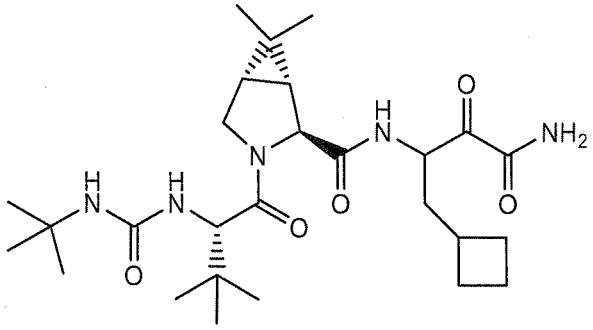
61. The ~~composition of any one of Claims 38 and 41 to 60 or the~~ use of any one of Claims 39 to 60, wherein the first compound is for use or manufactured for use in combination with an effective amount of an agent selected from 3'-azidothymidine,2',3'-dideoxyinosine,2',3'-dideoxycytidine,2-,3-didehydro-2',3'-dideoxythymidine, combivir, abacavir, adefovir dipivoxil, cidofovir, ritonavir, and an inosine monophosphate dehydrogenase inhibitor.

62. The ~~composition of any one of Claims 38 and 41 to 61 or the~~ use of any one of Claims 39 to 61, wherein the first compound is for use or manufactured for use in combination with an effective amount of an interferon, an additional NS3 protease inhibitor, an NS5B polymerase inhibitor, or an NS3 helicase inhibitor.

63. The ~~composition of Claim 62 or the~~ use of Claim 62, wherein the additional NS3 protease inhibitor is selected from



(VX-950) and



(SCH 503034).

64. The ~~composition of any one of Claims 38 and 41 to 63 or the~~ use of any one of Claims 39 to 63, wherein the first compound is for use or manufactured for use in combination with pegylated interferon that is for use or manufactured for use after administration of the first compound, or a pharmaceutically acceptable salt thereof, and the second compound, or a pharmaceutically acceptable salt thereof, is complete.

65. The ~~composition of any one of Claims 38 and 41 to 64 or the~~ use of any one of Claims 39 to 64, wherein the first compound is for use or manufactured for use in combination with ribavirin that for use or manufactured for use after administration of the first compound, or a pharmaceutically acceptable salt thereof, and the second compound, or a pharmaceutically acceptable salt thereof, is complete.

66. The ~~composition of any one of Claims 38 and 41 to 46 or the~~ use of any one of Claims 39 to 46, wherein the first compound is not for use and not manufactured for use in combination with an additional agent.

67. The ~~composition of Claim 66 or the~~ use of Claim 66, wherein the additional agent is ribavirin.

68. The ~~composition of Claim 66 or the~~ use of Claim 66, wherein the additional agent is an interferon.

69. The ~~composition of Claim 68 or the~~ use of Claim 68, wherein the interferon is a pegylated interferon.