## SUMMARY

**[0009]** In one aspect, the present invention refers to an isolated nucleic acid molecule selected from the group consisting of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:11, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, SEQ ID NO:21, SEQ ID NO:23, SEQ ID NO:25, SEQ ID NO:27 and SEQ ID NO:29. In another aspect, the present invention refers to An isolated nucleic acid molecule selected from the group consisting of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:12, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26, SEQ ID NO:28 and SEQ ID NO:30. In yet another aspect, the present invention refers to an isolated, double stranded, siRNA molecule selected from the group consisting of 1m (SEQ ID NO:1 and 2), 2m (SEQ ID NO:3 and 4), 3m (SEQ ID NO:5 and 6), 4m (SEQ ID NO:7 and 8), 5m (SEQ ID NO:9 and 10), 6m (SEQ ID NO:11 and 12), 7m (SEQ ID NO:13 and 14), 8m (SEQ ID NO:15 and 16), 9m (SEQ ID NO:17 and 18), 10m (SEQ ID NO:19 and 20), 11m (SEQ ID NO:21 and 22), 12m (SEQ ID NO:23 and 24), 13m (SEQ ID NO:25 and 26), 14m (SEQ ID NO:27 and 28) and 15m (SEQ ID NO:29 and 30). In a further aspect, the present invention refers to a composition comprising an isolated, double stranded siRNA molecule as described herein. In one aspect, the present invention refers to a nucleic acid-lipid particle comprising (a) one or more isolated, double stranded siRNA molecules selected from the isolated, double stranded siRNA molecules as described herein; (b) a cationic lipid; and (c) a non-cationic lipid. In another aspect, the present invention refers to a pharmaceutical composition comprising a nucleic acid-lipid particle as described herein and a pharmaceutically acceptable carrier. In yet another aspect, the present invention refers to use of a nucleic acid-lipid particle as described herein or a pharmaceutical composition as described herein in the manufacture of a medicament for treating a Hepatitis B virus infection by silencing expression of a Hepatitis B virus gene in a cell. In one example, there is disclosed use of a nucleic acid-lipid particle as described herein or a pharmaceutical composition as described herein in the manufacture of a medicament for silencing expression of a Hepatitis B virus gene in a cell. In one example, the present invention refers to a nucleic acid-lipid particle as disclosed herein or a pharmaceutical composition as disclosed herein for use in silencing expression of a Hepatitis B virus gene in a cell in a mammal. In another example, the present invention refers to use of a nucleic acid-lipid particle as disclosed herein or a pharmaceutical composition as disclosed herein in the manufacture of a medicament for ameliorating one or more symptoms associated with Hepatitis B virus and/or Hepatitis D virus infection in a mammal. In yet another example, the present invention refers to a nucleic acid-lipid particle as disclosed herein or a pharmaceutical composition as disclosed herein for use in ameliorating one or more symptoms associated with a Hepatitis B virus and/or Hepatitis D virus infection in a mammal. In another aspect, the present invention refers to Use of a nucleic acid-lipid particle as described herein or a pharmaceutical composition as described herein in the manufacture of a medicament for treating a Hepatitis B virus and/or Hepatitis D virus infection in a mammal. In yet another aspect, the present invention refers to a nucleic acid-lipid particle as disclosed herein or a

pharmaceutical composition as disclosed herein for use in treating a Hepatitis B virus and/or Hepatitis D virus infection in a mammal. In a further example, the present invention refers to a nucleic acid-lipid particle as disclosed herein or a pharmaceutical composition as disclosed herein for use in medical therapy. In yet another aspect, the present invention refers to use of a composition as disclosed herein in the manufacture of a medicament for treating a Hepatitis B infection by silencing expression of a Hepatitis B virus gene in a cell. In one example, there is disclosed use of a composition as disclosed herein in the manufacture of a medicament for silencing expression of a Hepatitis B virus gene in a cell. In one aspect, the present invention refers to a composition as described herein for use in silencing expression of a Hepatitis B virus gene in a cell in a mammal. In another aspect, the present invention refers to use of a composition as disclosed herein in the manufacture of a medicament for ameliorating one or more symptoms associated with Hepatitis B virus and/or Hepatitis D virus infection in a mammal. In a further aspect, the present invention refers to a composition as disclosed herein for use in ameliorating one or more symptoms associated with a Hepatitis B virus and/or Hepatitis D virus infection in a mammal. In yet another example, the present invention refers to use of a composition as disclosed herein in the manufacture of a medicament for treating a Hepatitis B virus and/or Hepatitis D virus infection in a mammal. In yet another aspect, the present invention refers to a composition as disclosed herein for use in treating a Hepatitis B virus and/or Hepatitis D virus infection in a mammal. In a further aspect, the present invention refers to a composition as disclosed herein for use in medical therapy. In another aspect, the present invention refers to use of a composition as disclosed herein, a nucleic acid-lipid particle as disclosed herein or a pharmaceutical composition as disclosed herein in the manufacture of a medicament for treating a Hepatitis D virus infection by inhibiting the replication of Hepatitis D virus and/or ameliorating one or more symptoms of Hepatitis D virus infection in a mammal. In one example, there is disclosed use of a composition as disclosed herein, a nucleic acid-lipid particle as disclosed herein or a pharmaceutical composition as disclosed herein in the manufacture of a medicament for inhibiting the replication of Hepatitis D virus and/or ameliorating one or more symptoms of Hepatitis D virus infection in a mammal. In a further aspect, the present invention refers to a composition as disclosed herein, a nucleic acid-lipid particle as disclosed herein or a pharmaceutical composition as disclosed herein for use in inhibiting the replication of Hepatitis D virus and/or ameliorating one or more symptoms of Hepatitis D virus infection in a mammal (e.g., a human), wherein the nucleic acid-lipid particle or composition inhibits the synthesis of Hepatitis B virus surface antigen. As described more fully herein, in one example there is disclosed isolated, double stranded, siRNA molecules, that each include a sense strand and an antisense strand that is hybridized to the sense strand. The siRNA of this example target one or more genes and/or transcripts of the HBV genome. Examples of siRNA molecules disclosed herein are the siRNA molecules set forth in Table A herein. The siRNA molecules are useful, for example, for the treatment of HBV infection and/or HDV infection when administered in a therapeutic amount to

NO:21 and 22), 12m (SEQ ID NO:23 and 24), 13m (SEQ ID NO:25 and 26), 14m (SEQ ID NO:27 and 28) and 15m (SEQ ID NO:29 and 30).

35. The nucleic acid-lipid particle of claim 34, wherein a combination of the three different double stranded siRNA molecules is selected from any one of the combinations described in Example 3.

36. A pharmaceutical composition comprising a nucleic acid-lipid particle of any one of claims 11-35 and a pharmaceutically acceptable carrier.

37. Use of a nucleic acid-lipid particle of any one of claims 11-35 or a pharmaceutical composition of claim 36 in the manufacture of a medicament for treating a Hepatitis B virus infection by silencing expression of a Hepatitis B virus gene in a cell.

38. The use of claim 37, wherein the cell is in a mammal.

39. The use of claim 38, wherein the cell is to be contacted to the particle, wherein the particle is to be administered to the mammal via a systemic route.

40. The use of claim 38 or 39, wherein the mammal is a human.

41. The use of claim 40, wherein the human has been diagnosed with liver disease caused by Hepatitis B virus infection or Hepatitis B virus/Hepatitis D virus infection.

42. The use of claim any one of claims 38-41, wherein silencing of the Hepatitis B virus gene expression reduces Hepatitis B virus and/or Hepatitis D virus particle load in the mammal by at least about 50% relative to Hepatitis B virus and/or Hepatitis D virus particle load in the absence of the nucleic acid-lipid particle.

43. A nucleic acid-lipid particle of any one of claims 11-35 or a pharmaceutical composition of claim 36 for use in silencing expression of a Hepatitis B virus gene in a cell in a mammal.

44. Use of a nucleic acid-lipid particle of any one of claims 11-35 or a pharmaceutical composition of claim 36 in the manufacture of a medicament for ameliorating one or more symptoms associated with Hepatitis B virus and/or Hepatitis D virus infection in a mammal.

45. The use of claim 44, wherein the particle is to be administered via a systemic route.

46. The use of any one of claims 44-45, wherein the siRNA of the nucleic acid-lipid particle inhibits expression of a Hepatitis B virus gene in the mammal.

47. The use of any one of claims 44-46, wherein the mammal is a human.

48. The use of claim 47, wherein the human has liver disease.

49. A nucleic acid-lipid particle of any one of claims 11-35 or a pharmaceutical composition of claim 36 for use in ameliorating one or more symptoms associated with a Hepatitis B virus and/or Hepatitis D virus infection in a mammal.

50. Use of a nucleic acid-lipid particle of any one of claims 11-35 or a pharmaceutical composition of claim 36 in the manufacture of a medicament for treating a Hepatitis B virus and/or Hepatitis D virus infection in a mammal.

51. A nucleic acid-lipid particle of any one of claims 11-35 or a pharmaceutical composition of claim 36 for use in treating a Hepatitis B virus and/or Hepatitis D virus infection in a mammal.

52. A nucleic acid-lipid particle of any one of claims 11-35 or a pharmaceutical composition of claim 36 for use in medical therapy.

53. Use of a composition of any one of claims 4-10 in the manufacture of a medicament for treating a Hepatitis B virus infection by silencing expression of a Hepatitis B virus gene in a cell.

54. The use of claim 53, wherein the cell is in a mammal.

55. The use of claim 54, wherein the cell is to be contacted to the composition, wherein the composition is to be administered to the mammal via a systemic route.

56. The use of claim 54 or 55, wherein the mammal is a human.

57. The use of claim 56, wherein the human has been diagnosed with liver disease caused by Hepatitis B virus infection or Hepatitis B virus/Hepatitis D virus infection.

58. The use of claim any one of claims 54-57, wherein silencing of the Hepatitis B virus gene expression reduces Hepatitis B virus and/or Hepatitis D virus particle load in the mammal by at least about 50% relative to Hepatitis B virus and/or Hepatitis D virus particle load in the absence of the nucleic acid-lipid particle.

59. A composition of any one of claims 4-10 for use in silencing expression of a Hepatitis B virus gene in a cell in a mammal.

60. Use of a composition of any one of claims 4-10 in the manufacture of a medicament for ameliorating one or more symptoms associated with Hepatitis B virus and/or Hepatitis D virus infection in a mammal.

61. The use of claim 60, wherein the composition is to be administered via a systemic route.

62. The use of any one of claims 60-61, wherein the siRNA of the composition inhibits expression of a Hepatitis B virus gene in the mammal.

63. The use of any one of claims 60-62, wherein the mammal is a human.

64. The use of claim 63, wherein the human has liver disease.

65. A composition of any one of claims 4-10 for use in ameliorating one or more symptoms associated with a Hepatitis B virus and/or Hepatitis D virus infection in a mammal (e.g., a human).

66. Use of a composition of any one of claims 4-10 in the manufacture of a medicament for treating a Hepatitis B virus and/or Hepatitis D virus infection in a mammal.

67. A composition of any one of claims 4-10 for use in treating a Hepatitis B virus and/or Hepatitis D virus infection in a mammal.

68. A composition of any one of claims 4-10 for use in medical therapy.

69. Use of a composition of any one of claims 4-10, a nucleic acid-lipid particle of any one of claims 11-35 or a pharmaceutical composition of claim 36 to the mammal in the manufacture of a medicament for treating a Hepatitis D virus infection by inhibiting the replication of Hepatitis D virus and/or ameliorating one or more symptoms of Hepatitis D virus infection in a mammal wherein the nucleic acid-lipid particle or composition inhibits the synthesis of Hepatitis B virus surface antigen.

70. A composition of any one of claims 4-10, a nucleic acid-lipid particle of any one of claims 11-35 or a pharmaceutical composition of claim 36 for use in inhibiting the replication of Hepatitis D virus and/or ameliorating one or more symptoms of Hepatitis D virus infection in