CLAIMS

1. A composition for treating and/or preventing Hepatitis B virus infection in a human or non-human primate, comprising polyriboinosinic acid-polyribocytidylic acid (PIC), at least one antibiotic or polyamide compound selected from a group including spermidine sault, spermidine, N-(3-aminopropyl), N-(3-aminopropyl)-1,4-butandiamine, spermine BR, spermine, OS-dimethylphosphoramidothioate, polylysine, and aminoglycoside, at least one positive ion selected from a group including spermidine sault, spermidine, N-(3-aminopropyl), N-(3-aminopropyl)-1,4-butandiamine, spermine BR, spermine, OS-dimethylphosphoramidothioate, polylysine, and aminoglycoside, and HBsAg, wherein the concentration of PIC in the composition ranges from 250 μg/unit dose to 6000 μg/unit dose and the concentration of the HBsAg in the composition ranges from 10 μg/unit dose to 100 μg/unit dose.

2. A composition of claim 1, further comprising HBcAg.

3. A composition of claim 1 or 2, wherein the HBsAg is produced by Hansenula polymorpha, CHO cells, insect expression system, Saccharomyces cerevisiae, or Pichia pastoris.

4. A composition of claim 2, wherein the HBcAg is produced by Escherichia coli, Hansenula polymorpha, insect expression system, Saccharomyces cerevisiae, or Pichia pastoris.

5. A composition of claim 1 or 2, wherein the composition is for administration to a Hepatitis B virus uninfected subject, a chronic Hepatitis B virus subject, or an acute Hepatitis B virus subject.

6. A composition of claim 1 or 2, wherein the composition is for administration to a subject by one way selected from a group including intramuscular injection, intraperitoneal injection, intravenous injection, subcutaneous injection, transdermal delivery, intradermal delivery, nasal delivery, opthamalical delivery, oral delivery, sublingual delivery, peritumoral delivery, and intratumor delivery.

7. A composition of claim 1 or 2, wherein the antibiotic is selected from a group including tobramycin, anthracycline, butyrosin sulfate, gentamicin, hygromycin, amikacin, dibekacin, nebramycin, beta-lactam, neomycin, puromycin, streptomycin, streptozotocin, and kanamycin.

8. A composition of claim 2, wherein the ratio of the HBcAg to PIC ranges from 1:50 to 1:5.

9. A composition of claim 10, wherein the ratio of the HBcAg to PIC is 1:50, 1:40, 1:30, 1:25, 1:20, 3:50, 1:15, 1:10, or 1:5.

10. A composition of any one of the preceding claims, wherein the concentration of PIC in the composition is 500 μg/unit dose, 1000 μg/unit dose, 1250 μg/unit dose, 1500 μg/unit dose, 2000 μg/unit dose, or 3000 μg/unit dose.

11. A composition of any one of the preceding claims, wherein the concentration of the HBsAg in the composition is 10 μg/unit dose, 20 μg/unit dose, 30 μg/unit dose, 40 μg/unit dose, 50 μg/unit dose, 60 μg/unit dose, 70 μg/unit dose, 80 μg/unit dose, 90 μg/unit dose, or 100 μg/unit dose.

12. A composition of claim 2, wherein the concentration of the HBcAg in the

composition ranges from 10 μg/unit dose to 100 μg/unit dose.

13. A composition of claim 12, wherein the concentration of the HBcAg in the composition is 10 μg/unit dose, 20 μg/unit dose, 30 μg/unit dose, 40 μg/unit dose, 50 μg/unit dose, 60 μg/unit dose, 70 μg/unit dose, 80 μg/unit dose, 90 μg/unit dose, or 100 μg/unit dose.

14. A composition of any of the preceding claims, wherein one unit dose ranges from 0.1 ml to 250.0 ml.

15. A composition of claim 14, wherein said unit dose is 0.1 ml, 0.15 ml, 0.2 ml, 0.5 ml, 1.0 ml, 1.5 ml, 2.0 ml, 2.5 ml, 3.0 ml, 4.0 ml, 5.0 ml, 10.0 ml, 20.0 ml, 30.0 ml, 40.0 ml, 50.0 ml, 60.0 ml, 70.0 ml, 80.0 ml, 90.0 ml, 100.0 ml, 150.0 ml, 200.0 ml, or 250.0 ml.

16. A composition of claim 1 or 2, wherein the composition further comprises at least one substance selected from a group including gelatin, saccharose, granulated sugar, lactose, maltose, trehalose, glucose, low molecular dextran, sorbitol, polysorbate 20, mannitol PEG, human blood albumin, recombinant human serum albumin, sodium caprylate, urea, aluminum hydroxide, phenol red, magnesium chloride, potassium chloride, sodium chloride, sodium thiosulphate, potassium dihydrogen, ascorbic acid, trichloromethane, phenol, and thiomersal.

17. A composition of claim 1 or 2, the composition further comprising at least one physiologically acceptable buffer, wherein the physiological acceptable buffer is selected from a group including acetate buffer, trisamine buffer, bicarbonate buffer, carbonate buffer, and phosphate buffered saline.

18. A composition of claim 1 or 2, wherein the pH of said composition ranges from 6.0 to 8.0.

19. A composition of claim 1 or 2, wherein the composition is in a liquid or solid form, wherein said liquid form is selected from a group including parenteral solution, suspension, ointment, emulsion, drop, syrup, and gel; wherein said solid form is selected from a group including dry powder, freeze-dried powder, tablet, capsule, suppository, granule, and sugar-coated tablet.

20. The composition of any one of claims 1 to 23, for use in medicine.

21. Use of PIC, at least one antibiotic or polyamide compound, at least one positive ion, and HBsAg, in the preparation of a pharmaceutical composition treating and/or prevention Hepatitis B virus infection in a human or non-human primate,wherein the concentration of PIC in the composition ranges from 250 μg/unit dose to 6000 μg/unit dose and the concentration of the HBsAg in the composition ranges from 10 μg/unit dose to 100 μg/unit dose.

22. The use of claim 21, wherein the composition further comprises HBcAg.

23. The use of claim 21 or 22, wherein the composition is to be administered to a subject once every two months, twice every two months, three times every two months, four times every two months, five times every two months, once every month, twice every month, once every three weeks, twice every three weeks, twice every two weeks, once every two weeks, or once every week.

24. The use of any one of claims 20-23, wherein said subject is a HBV uninfected subject, a chronic HBV subject, or an acute HBV subject.