

CLAIMS

1. A method of treating a Hepatitis B virus (HBV) infection in a subject, the method comprising administering to the subject a single dose of a pharmaceutical composition comprising an antibody, wherein the antibody comprises the heavy chain amino acid sequence of SEQ ID NO.:91 and the light chain amino acid sequence of SEQ ID NO.:93.
2. The method of claim 1, wherein the single dose of the pharmaceutical composition comprises the antibody in a range from 2 to 18 mg/kg (subject body weight).
3. The method of claim 1 or 2, wherein the single dose of the pharmaceutical composition comprises up to 6 mg, up to 18 mg, up to 75 mg, up to 90 mg, up to 300 mg, up to 900 mg, or up to 3000 mg of the antibody.
4. The method of any one of claims 1-3, wherein the single dose of the pharmaceutical composition comprises the antibody at a concentration in a range from 100 mg/mL to 200 mg/mL, such as 100 mg/mL, 110 mg/mL, 120 mg/mL, 130 mg/mL, 140 mg/mL, 150 mg/mL, 160 mg/mL, 170 mg/mL, 180 mg/mL, 190 mg/mL, or 200 mg/mL, preferably 150 mg/mL.
5. The method of any one of claims 1-4, wherein the single dose of the pharmaceutical composition comprises about 75 mg of the antibody.
6. The method of any one of claims 1-4, wherein the single dose of the pharmaceutical composition comprises about 90 mg of the antibody.
7. The method of any one of claims 1-4, wherein the single dose of the pharmaceutical composition comprises up to 300 mg of the antibody.
8. The method of any one of claims 1-4, wherein the single dose of the pharmaceutical composition comprises up to 900 mg of the antibody.
9. The method of any one of claims 1-4, wherein the single dose of the pharmaceutical composition comprises up to 3,000 mg of the antibody.

10. The method of any one of claims 1-9, wherein the method comprises administering the single dose by subcutaneous injection.
11. The method of any one of claims 1-9, wherein the method comprises administering the single dose by intravenous injection.
12. The method of any one of claims 1-11, wherein the pharmaceutical composition further comprises water, optionally USP water.
13. The method of any one of claims 1-12, wherein the pharmaceutical composition further comprises histidine, optionally at a concentration in a range from 10 mM to 40 mM, such as 20 mM, in the pharmaceutical composition.
14. The method of any one of claims 1-13, wherein the pharmaceutical composition further comprises a disaccharide, such as sucrose, optionally at 5%, 6%, 7%, 8%, or 9%, preferably about 7% (w/v).
15. The method of any one of claims 1-14, wherein the pharmaceutical composition further comprises a surfactant or a triblock copolymer, optionally a polysorbate or poloxamer-188, preferably polysorbate 80 (PS80), wherein, optionally, the polysorbate or poloxamer-188 is present in a range from 0.01% to 0.05% (w/v), preferably 0.02% (w/v).
16. The method of any one of claims 1-15, wherein the pharmaceutical composition has a pH in a range from 5.8 to 6.2, in a range from 5.9 to 6.1, or of 5.8, of 5.9, of 6.0, of 6.1, or of 6.2.
17. The method of claim 16, wherein the pharmaceutical composition comprises:
- (i) the antibody at 150 mg/mL;
 - (ii) USP water;
 - (iii) 20 mM histidine;
 - (iv) 7% sucrose; and
 - (v) 0.02% PS80,
- wherein the pharmaceutical composition comprises a pH of 6.
18. The method of any one of claims 1-17, wherein the subject is an adult.

19. The method of claim 18, wherein the subject is in a range from 18 years of age to 65 years of age.
20. The method of any one of claims 1-19, wherein the subject weighs from 40 kg to 125 kg.
21. The method of any one of claims 1-20, wherein the subject has a chronic HBV infection; *e.g.*, defined by positive serum HBsAg, HBV DNA, and/or HBeAg on 2 occasions, wherein the 2 occasions are at least 6 months apart.
22. The method of any one of claims 1-21, wherein the subject does not have cirrhosis.
23. The method of claim 22, wherein absence of cirrhosis is determined by:
Fibroscan evaluation (*e.g.*, within 6 months prior to administering the single dose of the pharmaceutical composition); or
liver biopsy (*e.g.*, within 12 months prior to administering the single dose of the pharmaceutical composition),
wherein, preferably the absence of cirrhosis is determined by the absence of Metavir F3 fibrosis or the absence of F4 cirrhosis.
24. The method of any one of claims 1-23, wherein the subject has received a nucleos(t)ide reverse transcriptase inhibitor (NRTI), optionally within 120 days, further optionally within 60 days, prior to the single dose being administered.
25. The method of claim 24, wherein the NRTI comprises one or more of: tenofovir; tenofovir disoproxil (*e.g.*, tenofovir disoproxil fumarate); tenofovir alafenamide; Entecavir; Lamivudine; Adefovir; and adefovir dipivoxil.
26. The method of any one of claims 1-25, wherein the subject has a serum HBV DNA concentration of less than 100 IU/mL no more than 28 days prior to the single dose being administered.
27. The method of any one of claims 1-26, wherein the subject has a serum HBsAg concentration of less than 1,000 IU/mL prior to the single dose being administered.

28. The method of any one of claims 1-26, wherein the subject has a serum HBsAg concentration of greater than or equal to 1,000 IU/mL no more than 28 days prior to the single dose being administered.

29. The method of any one of claims 1-28, wherein the subject was HB e-antigen (HBeAg)-negative no more than 28 days prior to the single dose being administered.

30. The method of any one of claims 1-29, wherein the subject was negative for anti-HB antibodies no more than 28 days prior to the single dose being administered.

31. The method of any one of claims 1-30, wherein the subject, prior to administration of the single dose:

- (i) does not have fibrosis and/or does not have cirrhosis; and/or
- (ii) has alanine aminotransferase (ALT) < 2 x Upper Limit of Normal (ULN).

32. The method of any one of claims 1-31, wherein at 56 days following administration of the single dose, the subject has a > 2-fold reduction in serum HBsAg (e.g., concentration of HBsAg in serum, e.g., as determined using an Abbott ARCHITECT assay) as compared to the subject's serum HBsAg at from 0 days to 28 days prior to administration of the single dose.

33. The method of any one of claims 1-32, wherein following administration of the single dose (e.g., at 56 days following administration of the single dose), the subject has:

- (i) has reduced or less severe intrahepatic spread of HBV as compared to a reference subject; and/or
- (ii) comprises an adaptive immune response against HBV.

34. The method of any one of claims 1-33, wherein the subject is male.

35. The method of any one of claims 1-33, wherein the subject is female.

36. A pharmaceutical composition comprising an antibody, wherein the antibody comprises the heavy chain amino acid sequence of SEQ ID NO.:91 and the light chain amino acid sequence of SEQ ID NO.:93, wherein the pharmaceutical composition comprises the antibody at a concentration ranging from 100 mg/mL to 200 mg/mL, such as 100 mg/mL, 110 mg/mL,

120 mg/mL, 130 mg/mL, 140 mg/mL, 150 mg/mL, 160 mg/mL, 170 mg/mL, 180 mg/mL, 190 mg/mL, or 200 mg/mL, preferably 150 mg/mL.

37. The pharmaceutical composition of claim 36, wherein the pharmaceutical composition comprises up to 6 mg, up to 18 mg, up to 75 mg, up to 90 mg, up to 300 mg, up to 900 mg, or up to 3000 mg of the antibody.

38. The pharmaceutical composition of claim 36 or 37, wherein the pharmaceutical composition comprises about 75 mg of the antibody.

39. The pharmaceutical composition of claim 36 or 37, wherein the pharmaceutical composition comprises about 90 mg of the antibody.

40. The pharmaceutical composition of claim 36 or 37, wherein the pharmaceutical composition comprises about 300 mg of the antibody.

41. The pharmaceutical composition of claim 36 or 37, wherein the pharmaceutical composition comprises about 900 mg of the antibody.

42. The pharmaceutical composition of claim 36 or 37, wherein the pharmaceutical composition comprises about 3,000 mg of the antibody.

43. The pharmaceutical composition of any one of claims 36-42, wherein the pharmaceutical composition further comprises water, optionally USP water.

44. The pharmaceutical composition of any one of claims 36-43, wherein the pharmaceutical composition further comprises histidine, optionally at a concentration from 10 mM to 40 mM, such as 20 mM, in the pharmaceutical composition.

45. The pharmaceutical composition of any one of claims 36-44, wherein the pharmaceutical composition further comprises a disaccharide, such as sucrose, optionally at 5%, 6%, 7%, 8%, or 9%, preferably about 7% (w/v).

46. The pharmaceutical composition of any one of claims 36-45, wherein the pharmaceutical composition further comprises a surfactant, optionally a polysorbate, preferably

polysorbate 80 (PS80), wherein, optionally, the polysorbate is present in a range from 0.01% to 0.05% (w/v), preferably 0.02% (w/v).

47. The pharmaceutical composition of any one of claims 36-46, wherein the pharmaceutical composition has a pH ranging from 5.8 to 6.2, ranging from 5.9 to 6.1, or of 5.8, of 5.9, of 6.0, of 6.1, or of 6.2.

48. The pharmaceutical composition of any one of claims 36-47, wherein the pharmaceutical composition comprises:

- (i) the antibody at 150 mg/mL;
- (ii) USP water;
- (iii) 20 mM histidine;
- (iv) 7% sucrose; and
- (v) 0.02% PS80,

wherein the pharmaceutical composition comprises a pH of 6.