

CLAIMS

1. Use of 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, in the manufacture of a pharmaceutical for treating a Hepatitis B virus (HBV) infection and/or a Hepatitis D virus (HDV) infection in a subject, wherein a single dose of the pharmaceutical comprises from 6 mg up to 900 mg of the antibody.
2. The use of claim 1, wherein the single dose of the pharmaceutical comprises up to 300 mg of the antibody.
3. The use of claim 1 or 2, wherein the single dose of the pharmaceutical comprises the antibody at a concentration in a range from 100 mg/mL to 200 mg/mL.
4. The use of any one of claims 1-3, wherein the single dose of the pharmaceutical comprises about 75 mg of the antibody.
5. The use of any one of claims 1-3, wherein the single dose of the pharmaceutical comprises about 90 mg of the antibody.
6. The use of any one of claims 1-5, wherein the single dose of the pharmaceutical is to be administered by subcutaneous injection.
7. The use of any one of claims 1-5, wherein the single dose of the pharmaceutical is to be administered by intravenous injection.
8. The use of any one of claims 1-7, wherein the pharmaceutical further comprises water, optionally USP water.
9. The use of any one of claims 1-8, wherein the pharmaceutical further comprises histidine, optionally at a concentration in a range from 10 mM to 40 mM, such as 20 mM, in the pharmaceutical.
10. The use of any one of claims 1-9, wherein the pharmaceutical further comprises a disaccharide, such as sucrose, optionally at 5%, 6%, 7%, 8%, or 9%, preferably about 7% (w/v).

11. The use of any one of claims 1-10, wherein the pharmaceutical 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).

12. The use of any one of claims 1-11, wherein the pharmaceutical 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.

13. The use of claim 12, wherein the pharmaceutical comprises:

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

and wherein the pharmaceutical comprises a pH of 6.

14. The use of any one of claims 1-13, wherein the subject is an adult.

15. The use of claim 14, wherein the subject is in a range from 18 years of age to 65 years of age.

16. The use of any one of claims 1-15, wherein the subject weighs from 40 kg to 125 kg.

17. The use of any one of claims 1-16, wherein the subject has a chronic HBV infection.

18. The use of claim 17, wherein the chronic HBV infection is defined by positive serum HBsAg, HBV DNA, and/or HBeAg on 2 occasions, wherein the 2 occasions are at least 6 months apart.

19. The use of any one of claims 1-18, wherein the subject does not have cirrhosis.

20. The use of claim 19, 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.

21. The use of any one of claims 1-20, 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.

22. The use of claim 21, wherein the NRTI comprises one or more of: tenofovir; tenofovir disoproxil (*e.g.*, tenofovir disoproxil fumarate); tenofovir alafenamide; Entecavir; Lamivudine; Adefovir; and adefovir dipivoxil.

23. The use of any one of claims 1-22, 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.

24. The use of any one of claims 1-23, wherein the subject has a serum HBsAg concentration of less than 1,000 IU/mL prior to the single dose being administered.

25. The use of any one of claims 1-23, 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.

26. The use of any one of claims 1-25, wherein the subject was HB e-antigen (HBeAg)-negative no more than 28 days prior to the single dose being administered.

27. The use of any one of claims 1-26, wherein the subject was negative for anti-HB antibodies no more than 28 days prior to the single dose being administered.

28. The use of any one of claims 1-27, 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).

29. The use of any one of claims 1-28, wherein the subject is male.
30. The use of any one of claims 1-28, wherein the subject is female.
31. 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.
32. The pharmaceutical composition of claim 31, 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.
33. The pharmaceutical composition of claim 31 or 32, wherein the pharmaceutical composition comprises about 75 mg of the antibody.
34. The pharmaceutical composition of claim 31 or 32, wherein the pharmaceutical composition comprises about 90 mg of the antibody.
35. The pharmaceutical composition of claim 31 or 32, wherein the pharmaceutical composition comprises about 300 mg of the antibody.
36. The pharmaceutical composition of claim 31 or 32, wherein the pharmaceutical composition comprises about 900 mg of the antibody.
37. The pharmaceutical composition of claim 31 or 32, wherein the pharmaceutical composition comprises about 3,000 mg of the antibody.
38. The pharmaceutical composition of any one of claims 31-37, wherein the pharmaceutical composition further comprises water, optionally USP water.

39. The pharmaceutical composition of any one of claims 31-38, 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.

40. The pharmaceutical composition of any one of claims 31-39, wherein the pharmaceutical composition further comprises a disaccharide, such as sucrose, optionally at 5%, 6%, 7%, 8%, or 9%, preferably about 7% (w/v).

41. The pharmaceutical composition of any one of claims 31-40, 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).

42. The pharmaceutical composition of any one of claims 31-41, 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.

43. The pharmaceutical composition of any one of claims 31-42, 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,

and wherein the pharmaceutical composition comprises a pH of 6.