

CLAIMS

1. A use of an anti-PD-1 antibody or a fragment antigen binding thereof in the manufacture of a medicament in the treatment of hepatocellular carcinoma (HCC),
wherein the anti-PD-1 antibody comprises CDR-H1, CDR-H2 and CDR-H3 (SEQ ID NOs: 11, 32, 13, respectively); and CDR-L1, CDR-L2 and CDR-L3 (SEQ ID NOs: 61, 15, 16, respectively), and
wherein the anti-PD1 antibody comprises an IgG4 heavy chain constant domain that minimizes FcγR binding on macrophages to abrogate antibody-dependent phagocytosis.
2. The use of Claim 1, wherein the anti-PD-1 antibody is an antibody which comprises a heavy chain variable region (Vh) (SEQ ID NO: 24) and a light chain variable region (Vk) (SEQ ID NO: 26).
3. The use of Claim 1, wherein the IgG4 heavy chain constant domain comprises SEQ ID NOs: 83-88 or 91-106.
4. The use of Claim 1, wherein the anti-PD-1 antibody comprises a heavy chain variable region (Vh) (SEQ ID NO: 24) and a light chain variable region (Vk) (SEQ ID NO: 26), and the IgG4 heavy chain constant domain comprises SEQ ID NO: 88.
5. The use according to Claims 1-4, wherein the HCC is an advanced HCC and/or a metastatic HCC.
6. The use of any one of Claims 1-4, wherein the HCC is a virus infection related HCC.
7. The use of Claim 6, wherein the virus infection related HCC is HBV-infected HCC, HCV-infected HCC, or HBV/HCV co-infected HCC.
8. The use of Claim 7, wherein the virus infection related HCC is an advanced HBV-infected HCC, metastatic HBV-infected HCC, HCV-infected HCC, or metastatic HCV-infected HCC.
9. The use of Claim 8, wherein the virus infection related HCC is an advanced HBV-infected HCC, or metastatic HBV-infected HCC.

- 10.** The use of any one of Claims 1-9, wherein the anti-PD-1 antibody is to be administered at a dose of 0.5-10 mg/kg QW, or Q2W, or Q3W, or Q4W.
- 11.** The use of any one of Claims 1-9, wherein the anti-PD-1 antibody is to be administered at a dose of 0.5-10 mg/kg QW or Q2W or Q3W.
- 12.** The use of any one of Claims 1-9, wherein the Anti-PD-1 antibody is to be administered at a dose of 0.5-10 mg/kg Q2W or Q3W.
- 13.** The use of any one of Claims 1-9, wherein the anti-PD-1 antibody is to be administered parenterally at a dose of 0.5-5 mg/kg Q2W, 5-10 mg/kg Q2W, or 2-5 mg/kg Q3W.
- 14.** The use of any one of Claims 1-9, wherein the anti-PD-1 antibody is to be administered parenterally at a dose of 0.5 mg/kg Q2W, 5 mg/kg Q2W, 10 mg/kg Q2W, 2 mg/kg Q3W or 5 mg/kg Q3W.
- 15.** The use of any one of Claims 1-9, wherein the anti-PD-1 antibody is to be administered parenterally at a dose of about 200 mg.
- 16.** The use of Claim 15, wherein the anti-PD-1 antibody is to be administered Q3W.
- 17.** The use of Claim 6, wherein the virus infection related HCC has a HBV viral load <200 IU/mL (~1000 cps/mL).
- 18.** The use of Claim 6, wherein the virus infection related HCC has active HBV infection need to be on anti-HBV suppression for ≥ 3 months during anti-PD-1 antibody treatment and for 6 months after cessation of during anti-PD-1 antibody treatment.