

What is claimed is:

1. ~~A method of~~ Use of a programmed death 1 (PD-1) inhibitor in the manufacture of a medicament for treating or inhibiting the growth of a tumor, ~~comprising:~~
 - (a) ~~selecting in~~ a patient with cancer, wherein the patient has a tumor with a tumor mutation burden (TMB) of greater than or equal to 10 mutations/Mb, and wherein the patient does not exhibit downregulated major histocompatibility complex (MHC); ~~and~~
 - (b) ~~administering to the patient a therapeutically effective amount of programmed death 1 (PD-1) inhibitor.~~
2. The ~~method of~~ use according to claim 1, wherein the cancer is skin cancer selected from basal cell carcinoma (BCC), cutaneous squamous cell carcinoma (CSCC), Merkel cell carcinoma, and melanoma.
3. The ~~method of~~ use according to any one of claims 1-2, wherein the cancer is BCC.
4. The ~~method of~~ use according to any one of claims 1-3, wherein the cancer is metastatic BCC or unresectable locally advanced BCC.
5. The ~~method of~~ use according to any one of claims 1-4, wherein at least 35% of the tumor cells are positive for MHC expression.
6. The ~~method of~~ use according to any one of claims 1-5, wherein the MHC is MHC-I.
7. The ~~method of~~ use according to any one of claims 1-6, wherein the patient has experienced progression of disease on Hedgehog Inhibitor (HHI) therapy or was intolerant of prior HHI therapy.
8. The ~~method~~ use according to any one of claims 1-7, wherein the PD-1 inhibitor is to be administered as a monotherapy.
9. The ~~method~~ use according to any one of claims 1-8, wherein ~~the administration of~~ the PD-1 inhibitor promotes tumor regression, reduces tumor cell load, reduces tumor burden, and/or prevents tumor recurrence in the patient.
10. The ~~method~~ use according to any one of claims 1-9, wherein the PD-1 inhibitor is to be administered in combination with a second therapeutic agent or therapy selected from radiation,

surgery, a cancer vaccine, imiquimod, an anti-viral agent, photodynamic therapy, HHI therapy, a PD-L1 inhibitor, a LAG3 inhibitor, a cytotoxic CTLA-4 inhibitor, GITR agonist, a TIM3 inhibitor, a BTLA inhibitor, a TIGIT inhibitor, a CD38 inhibitor, a CD47 inhibitor, an IDO inhibitor, a CD28 activator, a VEGF antagonist, an Ang2 inhibitor, a TGF β inhibitor, an EGFR inhibitor, an antibody to a tumor-specific antigen, a vaccine, a GM-CSF, an oncolytic virus, a cytotoxin, a chemotherapeutic agent, an IL-6R inhibitor, an IL-4R inhibitor, an IL-10 inhibitor, a cytokine, an antibody drug conjugate, an anti-inflammatory drug, and a dietary supplement.

11. The [methoduse](#) according to any one of claims 1-10, wherein the PD-1 inhibitor is selected from an anti-PD-1 antibody or antigen-binding fragment thereof, an anti-PD-L1 antibody or antigen-binding fragment thereof, and an anti-PD-L2 antibody or antigen-binding fragment thereof.

12. The [methoduse](#) according to any one of claims 1-11, wherein the PD-1 inhibitor is selected from an anti-PD-1 antibody or antigen-binding fragment thereof.

13. The [methoduse](#) according to any one of claims 1-12, wherein the PD-1 inhibitor is an anti-PD-1 antibody or antigen-binding fragment thereof that comprises a heavy chain variable region (HCVR) comprising three heavy chain complementarity determining regions (CDRs) (HCDR1, HCDR2 and HCDR3) and a light chain variable region (LCVR) comprising three light chain CDRs (LCDR1, LCDR2 and LCDR3), wherein: HCDR1 has an amino acid sequence of SEQ ID NO: 3; HCDR2 has an amino acid sequence of SEQ ID NO: 4; HCDR3 has an amino acid sequence of SEQ ID NO: 5; LCDR1 has an amino acid sequence of SEQ ID NO: 6; LCDR2 has an amino acid sequence of SEQ ID NO: 7; and LCDR3 has an amino acid sequence of SEQ ID NO: 8.

14. The [methoduse](#) according to claim 13, wherein the HCVR comprises an amino acid sequence of SEQ ID NO: 1.

15. The [methoduse](#) according to claim 13, wherein the LCVR comprises an amino acid sequence of SEQ ID NO: 2.

16. The [methoduse](#) according to claim 13, wherein the anti-PD-1 antibody or antigen-binding fragment thereof comprises an HCVR/LCVR amino acid sequence pair of SEQ ID NOs: 1/2.

17. The [methoduse](#) according to any one of claims 13-16, wherein the anti-PD-1 antibody or antigen-binding fragment thereof comprises a heavy chain and a light chain, wherein the heavy chain has an amino acid sequence of SEQ ID NO: 9.
18. The [methoduse](#) according to any one of claims 13-16, wherein the anti-PD-1 antibody comprises a heavy chain and a light chain, wherein the light chain has an amino acid sequence of SEQ ID NO: 10.
19. The [methoduse](#) according to any one of claims 13-16, wherein the anti-PD-1 antibody comprises a heavy chain and a light chain, wherein the heavy chain has an amino acid sequence of SEQ ID NO: 9 and the light chain has an amino acid sequence of SEQ ID NO: 10.
20. The [methoduse](#) according to any one of claims 1-12, wherein the PD-1 inhibitor is an anti-PD-1 antibody or antigen-binding fragment thereof comprising a HCVR with 90% sequence identity to SEQ ID NO: 1.
21. The [methoduse](#) according to any one of claims 1-12, wherein the PD-1 inhibitor is an anti-PD-1 antibody or antigen-binding fragment thereof comprising a LCVR with 90% sequence identity to SEQ ID NO: 2.
22. The [methoduse](#) according to any one of claims 1-12, wherein the PD-1 inhibitor is an anti-PD-1 antibody or antigen-binding fragment thereof comprising a HCVR with 90% sequence identity to SEQ ID NO: 1, and a LCVR with 90% sequence identity to SEQ ID NO: 2.
23. The [methoduse](#) according to any one of claims 1-19, wherein the PD-1 inhibitor is cemiplimab or a bioequivalent thereof.
24. The [methoduse](#) according to any one of claims 1-12, wherein the PD-1 inhibitor is an anti-PD-1 antibody selected from the group consisting of cemiplimab, nivolumab, pembrolizumab, pidilizumab, MEDI0608, BI 754091, PF-06801591, spartalizumab, camrelizumab, JNJ-63723283, and MCLA-134.
25. The [methoduse](#) according to any one of claims 1-11, wherein the PD-1 inhibitor is an anti-PD-L1 antibody selected from the group consisting of REGN3504, avelumab, atezolizumab, durvalumab, MDX-1105, LY3300054, FAZ053, STI-1014, CX-072, KN035, and CK-301.

26. The ~~method of use according to~~ any one of claims 1-25, wherein the PD-1 inhibitor is to be administered at a dose of 5mg to 1500mg.
27. The ~~method of use according to~~ any one of claims 1-26, wherein the PD-1 inhibitor is to be administered at a dose of 200mg, 250mg, or 350mg.
28. The ~~method of use according to~~ any one of claims 1-25, wherein the PD-1 inhibitor is to be administered at a dose of 1 mg/kg to 20 mg/kg of the patient's body weight.
29. The ~~method of use according to~~ any one of claims 1-25, wherein the PD-1 inhibitor is to be administered at a dose of 1 mg/kg, 3 mg/kg or 10 mg/kg of the patient's body weight.
30. The ~~method of use according to~~ any one of claims 1-29, wherein the PD-1 inhibitor is to be administered as one or more doses, wherein each dose is to be administered two weeks, three weeks, four weeks, five weeks or six weeks after the immediately preceding dose.
31. The ~~method use~~ according to any one of claims 1-30, wherein the PD-1 inhibitor is to be administered intravenously, subcutaneously, or intraperitoneally.
32. A kit comprising a therapeutically effective amount of a programmed death 1 (PD-1) inhibitor in combination with written instructions for use ~~in of a therapeutically effective amount of the PD-1 inhibitor for~~ treating or inhibiting the growth of a tumor in a patient with cancer, wherein the patient has a tumor with a tumor mutation burden (TMB) of greater than or equal to 10 mutations/Mb, and wherein the patient does not exhibit downregulated major histocompatibility complex (MHC).
33. ~~A method of Use of a programmed death 1 (PD-1) inhibitor in the manufacture of a medicament for~~ treating or inhibiting the growth of a tumor in a patient with a basal cell carcinoma (BCC) tumor, wherein comprising:
- (a) ~~selecting a patient with a basal cell carcinoma (BCC) tumor, wherein~~ the patient has experienced progression of disease on Hedgehog Inhibitor (HHI) therapy or was intolerant of prior HHI therapy;
 - (b) ~~collecting~~ a biopsy of the tumor is collected;
 - (c) ~~measuring~~ the tumor mutation burden (TMB) of the tumor biopsy is measured;
 - (d) ~~measuring~~ the expression of major histocompatibility complex (MHC)-I in the tumor biopsy is measured; and

(e) ~~administering to the patient~~ a therapeutically effective amount of ~~the programmed death 1 (PD-1)~~ inhibitor is to be administered to the patient if the tumor biopsy exhibits a TMB of greater than or equal to 10 mutations/Mb, and if at least 35% of the tumor biopsy cells are positive for MHC-I expression.

34. A method of selecting a patient with a basal cell carcinoma (BCC) tumor for treatment with a programmed death 1 (PD-1) inhibitor, comprising:

- (a) collecting a biopsy of the BCC tumor;
- (b) measuring the tumor mutation burden (TMB) of the tumor biopsy;
- (c) measuring the expression of major histocompatibility complex (MHC)-I in the tumor biopsy; and
- (d) selecting the patient for treatment with a PD-1 inhibitor if the tumor biopsy has a TMB of greater than or equal to 10 mutations/Mb, and a positive MHC-I expression in at least 35% of tumor cells.