

CLAIMS

1. Use of an antibody or antigen-binding fragment thereof that specifically binds PD-1 in the manufacture of a medicament for treating or inhibiting the growth of a tumor, wherein:

(a) a patient with cutaneous squamous cell carcinoma (CSCC) is to be selected; and
(b) a therapeutically effective amount of the antibody or antigen-binding fragment thereof that specifically binds PD-1 is to be administered to the patient in need thereof; wherein the anti-PD-1 antibody or antigen-binding fragment thereof comprises three heavy chain complementarity determining regions (HCDR1, HCDR2 and HCDR3) of a heavy chain variable region (HCVR) and three light chain complementarity determining regions (LCDR1, LCDR2 and LCDR3) of a light chain variable region (LCVR); wherein HCDR1 comprises the amino acid sequence of SEQ ID NO: 3; HCDR2 comprises the amino acid sequence of SEQ ID NO: 4; HCDR3 comprises the amino acid sequence of SEQ ID NO: 5; LCDR1 comprises the amino acid sequence of SEQ ID NO: 6; LCDR2 comprises the amino acid sequence of SEQ ID NO: 7; and LCDR3 comprises the amino acid sequence of SEQ ID NO: 8.

2. The use according to claim 1, wherein the CSCC is metastatic, unresectable and/or locally advanced.

3. The use according to claim 1 or 2, wherein:

the patient is intolerant to or progresses after prior treatment with an anti-cancer therapy, optionally (a) wherein said patient has been treated with at least one prior anti-cancer therapy selected from the group consisting of surgery, radiation, chemotherapy, and another anti-PD-1 antibody or (b) wherein said CSCC is metastatic or locally advanced, and wherein said patient is not amenable to curative surgery or curative radiation.

4. The use according to any one of claims 1-3, wherein said antibody or antigen-binding fragment thereof is to be administered as one or more doses, wherein each dose is to be administered 0.5 to 4 weeks after the immediately preceding dose, optionally (a) wherein each dose is to be administered 2 weeks after the immediately preceding dose, or (b) wherein each dose is to be administered 3 weeks after the immediately preceding dose.

5. The use according to claim 4, wherein:

(a) each dose comprises 1, 3 or 10 mg/kg of the patient's body weight, optionally wherein each dose comprises 3 mg/kg of the patient's body weight; or

(b) each dose comprises 50 - 600 mg of the anti-PD-1 antibody, optionally wherein each dose comprises 200, 250 or 350 mg of the anti-PD-1 antibody.

6. The use according to any one of claims 1-5, wherein the patient is resistant or inadequately responsive to, or relapsed after prior therapy.

7. The use according to any one of claims 1-6, wherein the anti-PD-1 antibody or antigen-binding fragment thereof to be administered leads to at least one effect selected from the group consisting of inhibition of tumor growth, tumor regression, reduction in the size of a tumor, reduction in tumor cell number, delay in tumor growth, abscopal effect, inhibition of tumor metastasis, reduction in metastatic lesions over time, reduced use of chemotherapeutic or cytotoxic agents, reduction in tumor burden, increase in progression-free survival, increase in overall survival, complete response, partial response, and stable disease.

8. The use according to any one of claims 1-7, wherein the anti-PD-1 antibody or antigen-binding fragment thereof is to be administered as a monotherapy.

9. The use according to any one of claims 1-8, wherein an additional therapeutic agent or therapy to be administered to the patient, wherein the additional therapeutic agent or therapy is selected from the group consisting of surgery, radiation, a chemotherapeutic agent, a cancer vaccine, a programmed death ligand 1 (PD-L1) inhibitor, a lymphocyte activation gene 3 (LAG3) inhibitor, a cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) inhibitor, a T-cell immunoglobulin and mucin-domain containing-3 (TIM3) inhibitor, a B- and T-lymphocyte attenuator (BTLA) inhibitor, a T cell immunoreceptor with Ig and ITIM domains (TIGIT) inhibitor, a CD47 inhibitor, an indoleamine-2,3-dioxygenase (IDO) inhibitor, a bispecific anti-CD3/anti-CD20 antibody, a vascular endothelial growth factor (VEGF) antagonist, an angiopoietin-2 (Ang2) inhibitor, a transforming growth factor beta (TGF β) inhibitor, a CD38 inhibitor, an epidermal growth factor receptor (EGFR) inhibitor, granulocyte-macrophage colony-stimulating factor (GM-CSF), cyclophosphamide, an antibody to a tumor-specific antigen, Bacillus Calmette-Guerin vaccine, a cytotoxin, an interleukin 6 receptor (IL-6R) inhibitor, an interleukin 4 receptor (IL-4R) inhibitor, an IL-10 inhibitor, IL-2, IL-7, IL-21, IL-15, an antibody-drug conjugate, an anti-inflammatory drug, and a dietary supplement.

10. The use according to any one of claims 1-9, wherein the anti-PD-1 antibody is to be administered intravenously, subcutaneously, or intraperitoneally.
11. The use according to any one of claims 1-10, wherein the anti-PD-1 antibody or antigen-binding fragment thereof comprises a HCVR with at least 90% sequence identity to SEQ ID NO: 1 and/or the anti-PD-1 antibody or antigen-binding fragment thereof comprises a LCVR with at least 90% sequence identity to SEQ ID NO: 2.
12. The use according to any one of claims 1-11, wherein the HCVR comprises the amino acid sequence of SEQ ID NO: 1 and the LCVR comprises the amino acid sequence of SEQ ID NO: 2.
13. The use according to any one of claims 1-11, wherein the anti-PD-1 antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 9 and a light chain comprising the amino acid sequence of SEQ ID NO: 10.
14. Use of an antibody that specifically binds PD-1 in the manufacture of a medicament for treating or inhibiting the growth of a tumor, wherein:
- (a) a patient with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC is to be selected, wherein the patient is not a candidate for curative surgery or curative radiation; and
 - (b) a therapeutically effective amount of the antibody that specifically binds PD-1 is to be administered to the patient in need thereof; wherein the anti-PD-1 antibody comprises three heavy chain complementarity determining regions (HCDR1, HCDR2 and HCDR3) of a heavy chain variable region (HCVR) and three light chain complementarity determining regions (LCDR1, LCDR2 and LCDR3) of a light chain variable region (LCVR);
- wherein HCDR1 comprises the amino acid sequence of SEQ ID NO: 3; HCDR2 comprises the amino acid sequence of SEQ ID NO: 4; HCDR3 comprises the amino acid sequence of SEQ ID NO: 5; LCDR1 comprises the amino acid sequence of SEQ ID NO: 6; LCDR2 comprises the amino acid sequence of SEQ ID NO: 7; and LCDR3 comprises the amino acid sequence of SEQ ID NO: 8; and
- wherein the antibody is to be administered intravenously every three weeks at a dose of 350 mg.

15. The use according to claim 14, wherein the anti-PD-1 antibody comprises a HCVR comprising the amino acid sequence of SEQ ID NO: 1 and a LCVR comprising the amino acid sequence of SEQ ID NO: 2.

16. The use according to any one of claims 14 or 15, wherein the anti-PD-1 antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 9 and a light chain comprising the amino acid sequence of SEQ ID NO: 10.