

We claim:

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 or improving overall survival of a ~~cervical cancer patient, comprising:~~

(a) ~~—selecting a patient with cervical cancer; and,~~

(b) ~~—administering to the patient a therapeutically effective amount of a programmed death 1 (PD-1) inhibitor.~~

2. The methoduse according to claim 1, wherein the cervical cancer is selected from the group consisting of squamous cell carcinoma, adenocarcinoma and adenosquamous carcinoma.

3. The methoduse according to claim 1 or 2, wherein the cervical cancer is advanced, recurrent, persistent and/or metastatic.

4. The methoduse according to any one of claims 1-3, wherein the cervical cancer is recurrent or metastatic.

5. The methoduse according to any one of claims 1-4, wherein the patient has received prior anti-cancer therapy, which was discontinued due to progression of disease and/or toxicity; or for whom the anti-cancer therapy was not appropriate.

6. The methoduse according to any one of claims 1-5, wherein the patient is resistant to, or the cervical cancer progressed after, prior treatment with an anti-cancer therapy.

7. The methoduse according to claim 5 or 6, wherein the prior anti-cancer therapy comprises one or more of chemotherapy, surgery, radiation therapy, and/or anti-VEGF therapy.

8. The methoduse according to any one of claims 5-7, wherein the prior anti-cancer therapy comprises platinum-based chemotherapy.

9. The methoduse according to any one of claims 5-8, wherein the prior anti-cancer therapy comprises platinum-based chemotherapy selected from pemetrexed, topotecan, irinotecan, gemcitabine, and vinorelbine.

10. The [methoduse](#) according to any one of claims 1-9, wherein the patient has received prior chemotherapy or prior anti-VEGF therapy.
11. The [methoduse](#) according to claim 10, wherein the prior anti-VEGF therapy comprises bevacizumab.
12. The [methoduse](#) according to any one of claims 1-11, wherein the patient has recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
13. The [methoduse](#) according to any one of claims 1-12, wherein the cervical cancer exhibits elevated expression of PD-L1.
14. The [methoduse](#) according to any one of claims 1-13, wherein the cervical cancer exhibits elevated expression of PD-L1 protein.
15. The [methoduse](#) according to any one of claims 1-14, wherein the cervical cancer exhibits elevated expression of PD-L1 mRNA.
16. The [methoduse](#) according to any one of claims 1-15, wherein the patient has tested positive for human papillomavirus (HPV).
17. The [methoduse](#) according to any one of claims 1-15, wherein the patient has tested negative for human papillomavirus (HPV).
18. The [methoduse](#) according to any one of claims 1-17, wherein the PD-1 inhibitor is [to be](#) administered as a monotherapy.
19. The [methoduse](#) according to any one of claims 1-18, 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.
20. The [methoduse](#) according to any one of claims 1-19, wherein ~~the~~ administration of the PD-1 inhibitor leads to at least one improvement selected from increase in overall survival, progression free survival, overall response rate, complete response, partial response, and stable disease, as compared to patients treated with chemotherapy.

21. The [methoduse](#) according to any one of claims 1-20, wherein ~~the~~ administration of the PD-1 inhibitor leads to increased overall survival as compared to patients treated with chemotherapy.
22. The [methoduse](#) according to any one of claims 1-21, wherein the PD-1 inhibitor is [to be](#) administered in combination with a second therapeutic agent or therapy.
23. The [methoduse](#) according to any one of claims 1-22, 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.
24. The [methoduse](#) according to any one of claims 1-23, wherein the PD-1 inhibitor is selected from an anti-PD-1 antibody or antigen-binding fragment thereof.
25. The [methoduse](#) according to any one of claims 1-24, 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.
26. The [methoduse](#) according to claim 25, wherein the HCVR comprises an amino acid sequence of SEQ ID NO: 1.
27. The [methoduse](#) according to claim 25, wherein the LCVR comprises an amino acid sequence of SEQ ID NO: 2.
28. The [methoduse](#) according to claim 25, 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.
29. The [methoduse](#) according to any one of claims 25-28, 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.

30. The [methoduse](#) according to any one of claims 25-28, 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.
31. The [methoduse](#) according to any one of claims 25-28, 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.
32. The [methoduse](#) according to any one of claims 1-24, wherein the PD-1 inhibitor is an anti-PD-1 antibody or antigen-binding fragment thereof comprising a HCVR with 90%, 95%, 97%, or 98% sequence identity to SEQ ID NO: 1.
33. The [methoduse](#) according to any one of claims 1-24, wherein the PD-1 inhibitor is an anti-PD-1 antibody or antigen-binding fragment thereof comprising a LCVR with 90%, 95%, 97%, or 98% sequence identity to SEQ ID NO: 2.
34. The [methoduse](#) according to any one of claims 1-24, wherein the PD-1 inhibitor is an anti-PD-1 antibody or antigen-binding fragment thereof comprising a HCVR with 90%, 95%, 97%, or 98% sequence identity to SEQ ID NO: 1, and a LCVR with 90%, 95%, 97%, or 98% sequence identity to SEQ ID NO: 2.
35. The [methoduse](#) according to any one of claims 1-31, wherein the PD-1 inhibitor is cemiplimab or a bioequivalent thereof.
36. The [methoduse](#) according to any one of claims 1-24, 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.
37. The [methoduse](#) according to any one of claims 1-23, 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.
38. The [methoduse](#) according to any one of claims 1-37, wherein the PD-1 inhibitor is [to be](#) administered at a dose of 5 mg to 1500 mg.

39. The ~~method~~use according to any one of claims 1-38, wherein the PD-1 inhibitor is to be administered at a dose of 200 mg, 250 mg, 350 mg, 400 mg, 500 mg, 600 mg, 700 mg, 750 mg, 800 mg, 1000 mg, 1050 mg, or 1200 mg.

40. The ~~method~~use according to any one of claims 1-37, 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.

41. The ~~method~~use according to any one of claims 1-37, 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.

42. The ~~method~~use according to any one of claims 38-41, wherein the PD-1 inhibitor is to be administered as one or more doses, wherein each dose is to be administered every week, two weeks, three weeks, four weeks, five weeks or six weeks.

43. The ~~method~~use according to any one of claims 1-42, wherein the PD-1 inhibitor is to be administered intravenously or subcutaneously.

44. A ~~programmed death 1 (PD-1) inhibitor for use in a method of treating or inhibiting the growth of a tumor or improving overall survival of a cervical cancer patient, the method comprising:~~
(a) ~~selecting a patient with cervical cancer; and~~
(b) ~~administering to the patient a kit comprising a~~ therapeutically effective amount of a PD-1 inhibitor.

45. ~~The PD-1 inhibitor of claim 44, wherein the cervical cancer is recurrent or metastatic cervical cancer with disease progression on or after chemotherapy or for whom chemotherapy is not appropriate.~~

46. ~~A kit comprising a~~ programmed death 1 (PD-1) inhibitor in combination with written instructions for use ~~of a therapeutically effective amount of the PD-1 inhibitor for~~in treating or inhibiting the growth of a tumor or improving overall survival of a patient with cervical cancer.