Claims

1. Use of a) an immune checkpoint inhibitor and b) a direct dendritic cell activating agent or means in the manufacture of a medicament for the treatment, prevention, or prevention of recurrence of cancer or tumor, wherein the direct dendritic cell activating agent comprises a radiation therapy providing means and an immunoadjuvant,

wherein the immunoadjuvant comprises a human *Mycobacterium tuberculosis* hot water extract or a portion thereof.

2. Use of a direct dendritic cell activating agent or means in the manufacture of a medicament that is to be used in combination with an immune checkpoint inhibitor for the treatment, prevention, or prevention of recurrence of cancer or tumor of a subject, wherein the direct dendritic cell activating agent or means comprises a radiation therapy providing means and an immunoadjuvant.

3. The use of claim 1 or 2, wherein,

the immune checkpoint inhibitor comprises an inhibitor against at least one factor selected from the group consisting of PD-1, PD-L1, and CTLA-4; or

the immune checkpoint inhibitor comprises at least one agent selected from the group consisting of a PD-1 inhibitor, a PD-L1 inhibitor, and a CTLA-4 inhibitor; wherein, preferably,

the cancer or tumor expresses an immune checkpoint factor; wherein, more preferably,

the cancer expresses PD-L1; wherein, preferably,

the immune checkpoint inhibitor comprises at least one selected from the group consisting of nivolumab, pembrolizumab, and atezolizumab; wherein, preferably,

the cancer is lung cancer; wherein, preferably, the cancer or tumor has an EGFR gene mutation; wherein, preferably,

the treatment, prevention, or prevention of recurrence is performed on a subject who has received therapy with a tyrosine kinase inhibitor; or

the treatment, prevention, or prevention of recurrence is performed on a subject who has not received therapy with an immune checkpoint inhibitor; or

the treatment, prevention, or prevention of recurrence is performed on a subject for whom therapy with an immune checkpoint inhibitor was determined to be ineffective; or

the treatment, prevention, or prevention of recurrence is performed on a subject who received therapy with an immune checkpoint inhibitor which was effective, but subsequently experienced progressive disease (PD); or

the treatment, prevention, or prevention of recurrence is performed on a subject who received therapy with a tyrosine kinase inhibitor and treatment with an immune checkpoint inhibitor which were effective, but subsequently experienced progressive disease (PD); wherein, preferably,

the subject is CXCL10 positive in the subject's tumor; or the subject is a CD8+ T cell^{low} subject.

4. The use of claim 2, wherein the immunoadjuvant comprises a human *Mycobacterium tuberculosis* hot water extract or a portion thereof; wherein,
the activation is determined by measuring an increase in an amount of expression of CD80/86 on a surface of a dendritic cell in the presence of the immunoadjuvant compared to in the absence of the immunoadjuvant.

5. The use of any one of claims 1-3, wherein, preferably, the radiation therapy providing means comprises at least one selected from the group consisting of a radiosensitizer, a radiation irradiating device, and a radioactive substance; or

the radiation therapy providing means is configured to provide palliative irradiation; or
the radiation therapy providing means is configured to irradiate to have an abscopal effect; or
the radiation therapy providing means is configured to irradiate a measurable lesion that is present other than a lesion that is a target.

6. The use of any one of claims 1-5, comprising a program utilized for cancer treatment or prevention of a patient, characterized by causing a computer to execute:

a step of performing either one or both of first therapy with an immune checkpoint inhibitor and/or a dendritic cell activating agent or means on the patient; and

a step of identifying an optimal therapy program based on a reaction of the patient.

7. The program of claim 6, characterized in that the reaction of the patient is a predetermined change in a medical image of the patient and a measurement value of a tumor marker in the patient.

8. Use of an immune checkpoint inhibitor in the manufacture of a medicament that is to be used in combination with a dendritic cell activating agent or means for the prevention or treatment of cancer in a patient, wherein the medicament is characterized in that dosage and administration are identified based on information on an optimization identifying marker of the combination obtained from the patient, and a therapeutically or prophylactically effective combination of the immune checkpoint and the dendritic cell activating agent or means is to be administered based on the identified dosage and administration.

9. Use of a dendritic cell activating agent or means in the manufacture of a medicament that is to be used in combination with an immune checkpoint inhibitor for the prevention or treatment of cancer in a patient, wherein the medicament is characterized in that dosage and administration are identified based on information on an optimization identifying marker of the combination obtained from the patient, and a therapeutically or prophylactically effective combination of the immune checkpoint and the dendritic cell activating agent or means is to be administered based on the identified dosage and administration.

10. Use of an immune checkpoint inhibitor and a dendritic cell activating agent in the manufacture of a medicament for the treatment, prevention, or prevention of recurrence of cancer or tumor of a subject with a specific regimen.

11. Use of a dendritic cell activating agent and an immune checkpoint inhibitor in the manufacture of a medicament for the treatment, prevention, or prevention of recurrence of cancer or tumor of a subject with a specific regimen.

12. The use of any one of claims 1-3, 8 and 10, wherein the subject is a subject who has not received therapy with an immune checkpoint inhibitor or a subject for whom therapy with an immune checkpoint inhibitor alone is ineffective; wherein, preferably, in the specific regimen, the immune checkpoint inhibitor:

i) is nivolumab which is to be administered at 240 mg every 2 weeks;

ii) is pembrolizumab which is to be administered at 200 mg at an interval of 3 weeks or at 400 mg at an interval of 6 weeks; or

iii) is atezolizumab which is to be administered at 1200 mg at an interval of 3 weeks; wherein, preferably, the specific regimen further comprises:

c) a step of performing radiation therapy; wherein, preferably

the radiation therapy is palliative irradiation other than brain metastasis, and irradiation is performed 10 fractions at 3 Gy or 20 to 25 fractions at 2 Gy.

13. The use of any one of claims 1-3, 8, 10 and 12, wherein, preferably, the dendritic cell activating agent or means comprises Extract Z that is to be administered by aspirating a liquid medicine into a 1 mL syringe and subcutaneously injecting 0.05 mL thereof twice a week.