~~[Claims]~~

~~[Claim 1]~~

~~A combination for use in treatment, prevention, or prevention of recurrence of cancer or tumor, comprising:~~

~~a) an immune checkpoint inhibitor; and~~

~~b) a direct dendritic cell activating agent or means,~~

~~characterized in that a) and b) are administered at different times or at the same time.~~

~~[Claim 2]~~

~~A composition or medical device for use in treatment, prevention, or prevention of recurrence of cancer or tumor of a subject, comprising a direct dendritic cell activating agent or means, characterized in that the composition or medical device is administered or used in combination with an immune checkpoint inhibitor.~~

~~[Claim 3]~~

~~A composition for use in treatment, prevention, or prevention of recurrence of cancer or tumor of a subject, comprising an immune checkpoint inhibitor, characterized in that the composition is administered in combination with a direct dendritic cell activating agent or means.~~

~~[Claim 4]~~

~~The combination, composition, or medical device of any one of claims 1 to 3, wherein the direct dendritic cell activating agent or means comprises at least one selected from the group consisting of a radiation therapy providing means and an immunoadjuvant.~~

~~[Claim 5]~~

~~The combination, composition, or medical device of any one of claims 1 to 3, wherein the direct dendritic cell activating agent or means comprises a radiation therapy providing means and an immunoadjuvant.~~

~~[Claim 6]~~

~~The combination, composition, or medical device of any one of claims 1 to 5, 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.~~

~~[Claim 7]~~

~~The combination, composition, or medical device of any one of claims 1 to 5, wherein 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.~~

~~[Claim 8]~~

~~The combination, composition, or medical device of any one of claims 1 to 7, wherein the cancer or tumor expresses an immune checkpoint factor.~~

~~[Claim 9]~~

~~The combination, composition, or medical device of any one of claims 1 to 8, wherein the cancer expresses PD-L1.~~

~~[Claim 10]~~

~~The combination, composition, or medical device of any one of claims 1 to 9, wherein the immune checkpoint inhibitor comprises at least one selected from the group consisting of nivolumab, pembrolizumab, and atezolizumab.~~

~~[Claim 11]~~

~~The combination, composition, or medical device of any one of claims 1 to 10, wherein the cancer is lung cancer.~~

~~[Claim 12]~~

~~The combination, composition, or medical device of any one of claims 1 to 11, wherein the cancer or tumor has an EGFR gene mutation.~~

~~[Claim 13]~~

~~The combination, composition, or medical device of any one of claims 1 to 12, wherein the treatment, prevention, or prevention of recurrence is performed on a subject who has received therapy with a tyrosine kinase inhibitor.~~

~~[Claim 14]~~

~~The combination, composition, or medical device of any~~

~~one of claims 1 to 13, wherein the treatment, prevention, or prevention of recurrence is performed on a subject who has not received therapy with an immune checkpoint inhibitor.~~

~~[Claim 15]~~

~~The combination, composition, or medical device of any one of claims 1 to 14, wherein 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.~~

~~[Claim 16]~~

~~The combination, composition, or medical device of any one of claims 1 to 15, wherein 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).~~

~~[Claim 17]~~

~~The combination, composition, or medical device of any one of claims 1 to 15, wherein the treatment, prevention, or prevention of recurrence is performed on a subject who received therapy with a tyrosine kinase inhibitor and therapy with an immune checkpoint inhibitor which were effective, but subsequently experienced progressive disease (PD).~~

~~[Claim 18]~~

~~The combination, composition, or medical device of any one of claims 1 to 17, wherein the subject is CXCL10 positive in the subject's tumor.~~

~~[Claim 19]~~

~~The combination, composition, or medical device of any one of claims 1 to 18, wherein the subject is a $CD8^+$ T $cell^{low}$ subject.~~

~~[Claim 20]~~

~~A composition for use in directly activating a~~

~~dendritic cell, comprising an immunoadjuvant.~~

~~[Claim 21]~~

~~The composition of claim 20, wherein the immunoadjuvant comprises a human *Mycobacterium tuberculosis* hot water extract or a portion thereof.~~

~~[Claim 22]~~

~~The composition of claim 20 or 21, 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.~~

~~[Claim 23]~~

~~A combination for use in treatment, prevention, or prevention of recurrence of cancer or tumor, comprising:~~

~~a) an immune checkpoint inhibitor; and~~

~~b) an immunoadjuvant,~~

~~characterized in that a) and b) are administered at different times or at the same time.~~

~~[Claim 24]~~

~~A composition for use in treatment, prevention, or prevention of recurrence of cancer or tumor of a subject, comprising an immunoadjuvant, characterized in that the composition is administered in combination with an immune checkpoint inhibitor.~~

~~[Claim 25]~~

~~A composition for use in treatment, prevention, or prevention of recurrence of cancer or tumor of a subject, comprising an immune checkpoint inhibitor, characterized in that the composition is administered in combination with an immunoadjuvant.~~

~~[Claim 26]~~

~~The combination or composition of any one of claims 23 to 25, wherein the immunoadjuvant comprises a human *Mycobacterium tuberculosis* hot water extract or a portion thereof.~~

~~[Claim 27]~~

~~The composition of any one of claims 23 to 26, 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.~~

~~[Claim 28]~~

~~The combination or composition of any one of claims 23 to 27, wherein 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.~~

~~[Claim 29]~~

~~A combination, or a composition or medical device for use in activating a dendritic cell, comprising the composition of any one of claims 23 to 28 and a radiation therapy providing means.~~

~~[Claim 30]~~

~~The combination, composition, or medical device of claim 29, wherein 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.~~

~~[Claim 31]~~

~~The combination, composition, or medical device of claim 29 or 30, characterized in that the radiation therapy providing means is configured to provide palliative irradiation.~~

~~[Claim 32]~~

~~The combination, composition, or medical device of any one of claims 29 to 31, characterized in that the radiation therapy providing means is configured to irradiate to have an abscopal effect.~~

~~[Claim 33]~~

~~The combination, composition, or medical device of any one of claims 29 to 32, characterized in that the radiation therapy providing means is configured to irradiate a~~

~~measurable lesion that is present other than a lesion that is a target.~~

~~[Claim 34]~~

~~The combination, composition, or medical device of any one of claims 23 to 33, further comprising a regulatory T cell inhibitor.~~

~~[Claim 35]~~

~~The combination, composition, or medical device of claim 34, wherein the regulatory T cell inhibitor comprises a COX-2 inhibitor.~~

~~[Claim 36]~~

~~The combination, composition, or medical device of claim 35, wherein the COX-2 inhibitor is selected from the group consisting of celecoxib, etodolac, meloxicam, nabumetone, zaltoprofen, and lornoxicam.~~

~~[Claim 37]~~

~~A composition or medical device for use in activating a dendritic cell, comprising a radiation therapy providing means.~~

~~[Claim 38]~~

~~The composition or medical device of claim 37, wherein 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.~~

~~[Claim 39]~~

~~The composition or medical device of claim 37 or 38, 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.~~

~~[Claim 40]~~

~~The composition or medical device of any one of claims 37 to 39, characterized in that the radiation therapy providing means is configured to provide palliative irradiation.~~

~~[Claim 41]~~

~~The composition or medical device of any one of claims 37 to 40, characterized in that the radiation therapy providing means is configured to irradiate to have an abscopal effect.~~

~~[Claim 42]~~

~~The composition or medical device of any one of claims 37 to 41, characterized in that the radiation therapy providing means is configured to irradiate a measurable lesion that is present other than a lesion that is a target.~~

~~[Claim 43]~~

~~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.~~

~~[Claim 44]~~

~~The program of claim 43, 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.~~

~~[Claim 45]~~

~~A medicament for use in prevention or treatment of cancer in a patient,~~

~~the medicament comprising a combination of an immune checkpoint and a dendritic cell activating agent or means, 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 administered based on the identified dosage and administration.~~

~~[Claim 46]~~

~~A medicament or device for use in treatment, prevention, or prevention of recurrence of cancer, cancer, or tumor of a subject with a specific regimen,~~

~~the medicament comprising a combination of an immune checkpoint and a dendritic cell activating agent or means, wherein the regimen comprises:~~

~~a) a step of administering an immune checkpoint inhibitor; and~~

~~b) a step of administering a dendritic cell activating agent.~~

~~[Claim 47]~~

~~The medicament or device of claim 46, 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.~~

~~[Claim 48]~~

~~The medicament or device of any one of claim 46 or 47, wherein, in the specific regimen, the immune checkpoint inhibitor:~~

~~i) is nivolumab and administered at 240 mg every 2 weeks;~~

~~ii) is pembrolizumab and administered at 200 mg at an interval of 3 weeks or at 400 mg at an interval of 6 weeks; or~~

~~iii) is atezolizumab and administered at 1200 mg at an interval of 3 weeks.~~

~~[Claim 49]~~

~~The medicament or device of any one of claims 46 to 48, wherein the specific regimen further comprises:~~

~~c) a step of performing radiation therapy.~~

~~[Claim 50]~~

~~The medicament or device of claim 49, characterized in~~

~~that 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.~~
~~[Claim 51]~~

~~The medicament or device of any one of claims 46 to 50, wherein the dendritic cell activating agent or means comprises Extract Z that is administered by aspirating a liquid medicine into a 1 mL syringe and subcutaneously injecting 0.05 mL thereof twice a week.~~

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.

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.

3. The use of claim 1 or 2, wherein the direct dendritic cell activating agent or means comprises at least one selected from the group consisting of a radiation therapy providing means and an immunoadjuvant; wherein, preferably, the direct dendritic cell activating agent or means comprises a radiation therapy providing means and an immunoadjuvant; wherein, preferably,
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. Use of an immunoadjuvant in the manufacture of a medicament for directly activating a dendritic cell.

5. The use of claim 4, 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.

6. Use of an immunoadjuvant 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.

7. The use of any one of claims 4-6, wherein the immunoadjuvant comprises a human *Mycobacterium tuberculosis* hot water extract or a portion thereof; wherein, preferably, 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, a radiation therapy providing means is to be administered; 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; wherein, preferably,
the immunoadjuvant or immune checkpoint inhibitor further comprising a regulatory T cell inhibitor; wherein, preferably,
the regulatory T cell inhibitor comprises a COX-2 inhibitor; wherein, preferably,
the COX-2 inhibitor is selected from the group consisting of celecoxib, etodolac, meloxicam, nabumetone, zaltoprofen, and lornoxicam.

8. Use of a radiation therapy providing means in the manufacture of a medicament for activating a dendritic cell.

9. The use of claim 8, wherein 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; wherein, preferably,
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; wherein, preferably,
the radiation therapy providing means is characterized by being configured to provide palliative irradiation; wherein, preferably,
the radiation therapy providing means is characterized by being configured to irradiate to have an abscopal effect; wherein, preferably,
the radiation therapy providing means is characterized by being configured to irradiate a measurable lesion that is present other than a lesion that is a target.

10. 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.

11. The program of claim 10, 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.

12. 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.

13. 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.

14. 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.

15. 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.

16. The use of any one of claims 1-3, 12 and 14, 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 ~~and~~ 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; 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.