

[Claims]

[Claim 1]

An in vitro method of using (i) a value of an amount of CD4⁺CD62L^{low} T-cells of a subject (X) or (ii) a relative value of an amount of X to an amount of CD4⁺Foxp3⁺CD25⁺ T-cells (Y) as an indicator for predicting a response to cancer immunotherapy of the subject, the method comprising: measuring the X; and

optionally measuring the Y; wherein a comparison of (i) X with an ineffective group threshold value or (ii) a relative value of X to Y with an ineffective group threshold value is used as an indicator for predicting that the subject is not a part of an ineffective group to the cancer immunotherapy,

wherein the cancer immunotherapy is to be administered to the subject, and wherein the cancer immunotherapy comprises an immune checkpoint inhibitor.

[Claim 2]

The method of claim 1, wherein the method uses a comparison of a relative value of X to Y with an ineffective group threshold value as an indicator for predicting that the subject is not a part of an ineffective group to the cancer immunotherapy.

[Claim 3]

The method of claim 2, wherein the relative value is X/Y or X²/Y.

[Claim 4]

The method of any one of claims 1-3, further using a ratio of a Foxp3⁺CD25⁺ T-cell subpopulation in CD4⁺ T-cells, a ratio of an ICOS⁺CD62L^{low}CD4⁺ T cell subpopulation in CD62L^{low}CD4⁺ T-cells,

a ratio of LAG-3⁺CD62L^{low}CD4⁺ T cell subpopulation in CD62L^{low}CD4⁺ T-cells, or

a ratio of PD-1⁺CD62L^{low}CD4⁺ T cell subpopulation in CD62L^{low}CD4⁺ T-cells,

in a subject who is shown to be not a part of the ineffective group as an indicator of a response to cancer immunotherapy of the subject, wherein

the ratio of the Foxp3⁺CD25⁺ T-cell subpopulation in the CD4⁺ T-cells,

the ratio of the ICOS⁺CD62L^{low}CD4⁺ T cell subpopulation in the CD62L^{low}CD4⁺ T-cells,

the ratio of LAG-3⁺CD62L^{low}CD4⁺ T cell subpopulation in CD62L^{low}CD4⁺ T-cells, or

the ratio of PD-1⁺CD62L^{low}CD4⁺ T cell subpopulation in

CD62L^{low}CD4⁺ T-cells,
higher than a response group threshold value indicates that
the subject is a part of a response group.

[Claim 5]

The method of any one of claims 1 to 4, wherein the
ineffective group threshold value is determined so that
sensitivity for the detection of an ineffective group
exceeds about 90%, or wherein the ineffective group
threshold value is determined so that specificity for the
detection of an ineffective group exceeds about 90%.

[Claim 6]

The method of any one of claims 1 to 5, wherein the amount
of the cell population is measured using a peripheral blood
sample.

[Claim 7]

The method of any one of claims 1-6, wherein the immune
checkpoint inhibitor is selected from the group consisting
of a PD-1 inhibitor and a PD-L1 inhibitor.

[Claim 8]

The method of claim 7, wherein the PD-1 inhibitor or PD-L1
inhibitor comprises nivolumab, pembrolizumab, durvalumab,
atezolizumab, or avelumab.

[Claim 9]

The method of any one of claims 1 to 8,
(a) wherein the X is an amount of a CD62L^{low}CD4⁺ T-cell
subpopulation and the Y is an amount of a Foxp3⁺CD25⁺CD4⁺ T-
cell subpopulation, and
the relative value higher than the ineffective group
threshold value indicating that the subject is not a part
of an ineffective group to the cancer immunotherapy; or
(b) wherein the X is a ratio of a CD62L^{low}CD4⁺ T-cell
subpopulation in CD4⁺ T-cells, the Y is a ratio of a
Foxp3⁺CD25⁺CD4⁺ T-cell subpopulation in CD4⁺ T-cells.

[Claim 10]

Use of a kit in the method according to any one of claims 1
to 9, wherein the kit comprises a detection agent for CD4,
a detection agent for CD62L, a detection agent for CD25,
and a detection agent for Foxp3.

[Claim 11]

The use of claim 10, wherein the detection agent is an antibody.

[Claim 12]

An immune checkpoint inhibitor for use in treating cancer in a subject, characterized in that the subject is predicted not to be a part of an ineffective group to the immune checkpoint inhibitor by the method of claim 1, wherein the immune checkpoint inhibitor is selected from the group consisting of a PD-1 inhibitor and a PD-L1 inhibitor.

[Claim 13]

An immune checkpoint inhibitor for use in treating cancer in a subject, characterized in that the subject is predicted to be a part of a response group to the immune checkpoint inhibitor by the method of claim 4, wherein the immune checkpoint inhibitor is selected from the group consisting of a PD-1 inhibitor and a PD-L1 inhibitor.

[Claim 14]

The immune checkpoint inhibitor for use of claim 12 or 13, wherein the PD-1 inhibitor or PD-L1 inhibitor is nivolumab, pembrolizumab, durvalumab, atezolizumab, or avelumab.