

of the GPC3-targeting drug therapy is determined or the continuation of the GPC3-targeting drug therapy is determined. The present inventors have also created a GPC3-targeting drug or a preparation which is to be administered to a patient for which the efficacy of the GPC3-targeting drug therapy has been determined or the continuation of the GPC3-targeting drug therapy has been determined.

[0015]

More specifically, in one aspect, there is provided a method for determining the efficacy of anti-GPC3 antibody therapy for GPC3-expressing cancer in a patient or determining the continuation of anti-GPC3 antibody therapy for a patient, comprising measuring the number of an immunocyte or an expression level of a molecule expressed on the immunocyte in a peripheral blood isolated from the patient before the start of anti-GPC3 antibody therapy and/or the patient treated with the anti-GPC3 antibody therapy at arbitrary points in time between the start and completion of the therapy, wherein the anti-GPC3 antibody has cytotoxic activity, and wherein when the number of an immunocyte or the expression level of a molecule expressed on the immunocyte is above a predetermined value, the efficacy of the anti-GPC3 antibody therapy is

determined or the continuation of the anti-GPC3 antibody therapy is determined, and wherein

(i) when the immunocyte is a leukocyte, the predetermined value is selected from the range from 5,000 to 8,000 cells/ μ L;

(ii) when the immunocyte is a monocyte, the predetermined number is selected from the range from 500 to 1,000 cells/ μ L;

(iii) when the immunocyte is a lymphocyte, the predetermined number is selected from the range from 1,000 to 3,000 cells/ μ L; or

(iv) when the molecule expressed on the immunocyte is CD16, the predetermined value of CD16 expression is selected from a range from 200,000 mesf (molecules of equivalent soluble fluorescence intensity) to 700,000 mesf calculated from flow cytometry measurement value of fluorescence intensity of CD16. In another aspect, there is provided use of an anti-GPC3 antibody having cytotoxic activity in the manufacture of a medicament for treating GPC3-expressing cancer, wherein the anti-GPC3 antibody is to be administered to a GPC3-expressing cancer patient, wherein the GPC3-expressing cancer patient has been determined to have (i) a number of an immunocyte which is above a predetermined value, wherein

(a) when the immunocyte is a leukocyte, the predetermined value is selected from the range from 5,000 to 8,000 cells/ μ L;

(b) when the immunocyte is a monocyte, the predetermined number is selected from the range from 500 to 1,000 cells/ μ L; or

(c) when the immunocyte is a lymphocyte, the predetermined number is selected from the range from 1,000 to 3,000 cells/ μ L;

or (ii) an expression level of a molecule expressed on the immunocyte which is above a predetermined value, wherein, when the molecule expressed on the immunocyte is CD16, the predetermined value of CD16 expression is selected from a range from 200,000 mesf (molecules of equivalent soluble fluorescence intensity) to 700,000 mesf calculated from flow cytometry measurement value of fluorescence intensity of CD16; in a peripheral blood isolated from the GPC3-expressing cancer patient before or after start of administration of the anti-GPC3 antibody. Furthermore, the present disclosure describes [1] a method for determining the efficacy of GPC3-targeting drug therapy for cancer in a patient or determining the continuation of GPC3-targeting drug therapy for a patient, comprising measuring the number of an immunocyte or an expression level of a molecule

Claims

1. A method for determining the efficacy of anti-GPC3 antibody therapy for GPC3-expressing cancer in a patient or determining the continuation of anti-GPC3 antibody therapy for a patient, comprising measuring the number of an immunocyte or an expression level of a molecule expressed on the immunocyte in a peripheral blood isolated from the patient before the start of anti-GPC3 antibody therapy and/or the patient treated with the anti-GPC3 antibody therapy at arbitrary points in time between the start and completion of the therapy,

wherein the anti-GPC3 antibody has cytotoxic activity, and

wherein when the number of an immunocyte or the expression level of a molecule expressed on the immunocyte is above a predetermined value, the efficacy of the anti-GPC3 antibody therapy is determined or the continuation of the anti-GPC3 antibody therapy is determined,

and wherein

- (i) when the immunocyte is a leukocyte, the predetermined value is selected from the range from 5,000 to 8,000 cells/ μ L;
- (ii) when the immunocyte is a monocyte, the predetermined number is selected from the range from 500 to 1,000 cells/ μ L;

- (iii) when the immunocyte is a lymphocyte, the predetermined number is selected from the range from 1,000 to 3,000 cells/ μ L; or
- (iv) when the molecule expressed on the immunocyte is CD16, the predetermined value of CD16 expression is selected from a range from 200,000 mesf (molecules of equivalent soluble fluorescence intensity) to 700,000 mesf calculated from flow cytometry measurement value of fluorescence intensity of CD16.

2. The method according to claim 1, wherein the immunocyte is at least one lymphocyte cell selected from a CD45⁺ lymphocyte, a CD3⁺ T cell, a CD4⁺ T cell, and a CD8⁺ T cell; or at least one lymphocyte cell selected from a CD16⁺ NK cell, an NKp46⁺ NK cell, and a CD56⁺/CD16⁺ NK cell, wherein

- (i) when the immunocyte is a CD45⁺ lymphocyte, the predetermined value is selected from the range from 450 to 3,500 cells/ μ L;
- (ii) when the immunocyte is a CD3⁺ T cell, the predetermined value is selected from the range from 300 to 2,500 cells/ μ L;
- (iii) when the immunocyte is a CD4⁺ T cell, the predetermined value is selected from the range from 200 to 1,500 cells/ μ L;

(iv) when the immunocyte is a $CD8^+$ T cell, the predetermined value is selected from the range from 150 to 300 cells/ μ L;

or

(v) when the immunocyte is a $CD56^-/CD16^+$ NK cell, the predetermined value number is selected from the range from 2 to 30 cells/ μ L.

8. The method according to claim 5, wherein the anti-GPC3 antibody is conjugated with a cytotoxic substance.

9. Use of an anti-GPC3 antibody having cytotoxic activity in the manufacture of a medicament for treating GPC3-expressing cancer, wherein the anti-GPC3 antibody is to be administered to a GPC3-expressing cancer patient,

wherein the GPC3-expressing cancer patient has been determined to have

(i) a number of an immunocyte which is above a predetermined value, wherein

(a) when the immunocyte is a leukocyte, the predetermined value is selected from the range from 5,000 to 8,000 cells/ μ L;

(b) when the immunocyte is a monocyte, the predetermined number is selected from the range from 500 to 1,000 cells/ μ L; or

(c) when the immunocyte is a lymphocyte, the predetermined number is selected from the range from 1,000 to 3,000 cells/ μ L;

or

(ii) an expression level of a molecule expressed on the immunocyte which is above a predetermined value, wherein, when the molecule expressed on the immunocyte is CD16, the predetermined value of CD16 expression is selected from a range from 200,000 mesf (molecules of equivalent soluble fluorescence intensity) to 700,000 mesf

calculated from flow cytometry measurement value of fluorescence intensity of CD16;
in a peripheral blood isolated from the GPC3-expressing cancer patient before or after start of administration of the anti-GPC3 antibody.

10. The use according to claim 9, wherein the lymphocyte comprises at least one lymphocyte cell selected from a CD45+ lymphocyte, a CD3+ T cell, a CD4+ T cell, and a CD8+ T cell; or at least one lymphocyte cell selected from a CD16+ NK cell, an NKp46+ NK cell, and a CD56-/CD16+ NK cell.