

CLAIMS

1. An *in vitro* method for predicting the clinical response of a subject suffering from cancer to an anti-cancer treatment selected from the group consisting of:
 - a) a polypeptide comprising the sequence SEQ ID NO: 1 or a functionally equivalent variant thereof;
 - b) a conjugate comprising a polypeptide comprising the sequence SEQ ID NO: 1 or a functionally equivalent variant thereof and a chemical moiety that facilitates cellular uptake of the polypeptide or of the functionally equivalent variant thereof;
 - c) a polynucleotide encoding the polypeptide of a) or the conjugate of b);
 - d) a vector comprising the polynucleotide according to c); and
 - e) a cell capable of secreting into the medium the polypeptide according to a) or the conjugate according to b);
 said method comprising:
 - (i) determining the level of at least one biomarker selected from the group consisting of MIP-1 β , CD62E, IL-8, and GM-CSF in a sample from said subject; and
 - (ii) comparing the level of said at least one biomarker with a reference value, wherein:
 - a decreased level of said at least one biomarker with respect to the reference value is indicative of a good clinical response of the subject to the anti-cancer treatment, or
 - an equal or an increased level of said at least one biomarker with respect to the reference value is indicative of a poor clinical response of the subject to the anti-cancer treatment.
2. The method according to claim 1, wherein the good clinical response is stabilization of the disease and the poor clinical response is progression of the disease.
3. An *in vitro* method for selecting a customized therapy for a subject suffering from cancer comprising:

(i) determining the level of at least one biomarker selected from the group consisting of MIP-1 β , CD62E, IL-8, and GM-CSF in a sample from said subject; and

(ii) comparing the level of said at least one biomarker with a reference value,

5 wherein:

- a decreased level of said at least one biomarker with respect to the reference value is indicative that the therapy to be selected comprises an agent selected from the group consisting of:

10 a) a polypeptide comprising the sequence SEQ ID NO: 1 or a functionally equivalent variant thereof;

b) a conjugate comprising a polypeptide comprising the sequence SEQ ID NO: 1 or a functionally equivalent variant thereof and a chemical moiety that facilitates cellular uptake of the polypeptide or of the functionally equivalent variant thereof;

15 c) a polynucleotide encoding the polypeptide of a) or the conjugate of b);

d) a vector comprising the polynucleotide according to c); and

e) a cell capable of secreting into the medium the polypeptide according to a) or the conjugate according to b); or, alternatively,

20 - an equal or an increased level of said at least one biomarker with respect to the reference value is indicative that the therapy to be selected does not comprise an agent selected from the group consisting of:

a) a polypeptide comprising the sequence SEQ ID NO: 1 or a functionally equivalent variant thereof;

25 b) a conjugate comprising a polypeptide comprising the sequence SEQ ID NO: 1 or a functionally equivalent variant thereof and a chemical moiety that facilitates cellular uptake of the polypeptide or of the functionally equivalent variant thereof;

c) a polynucleotide encoding the polypeptide of a) or the conjugate of b);

d) a vector comprising the polynucleotide according to c); and

30 e) a cell capable of secreting into the medium the polypeptide according to a) or the conjugate according to b).

4. An *in vitro* method for selecting a subject suffering from cancer for a treatment comprising an agent selected from the group consisting of:

- a) a polypeptide comprising the sequence SEQ ID NO: 1 or a functionally equivalent variant thereof;
 - b) a conjugate comprising a polypeptide comprising the sequence SEQ ID NO: 1 or a functionally equivalent variant thereof and a chemical moiety that facilitates cellular uptake of the polypeptide or of the functionally equivalent variant thereof;
 - c) a polynucleotide encoding the polypeptide of a) or the conjugate of b);
 - d) a vector comprising the polynucleotide according to c); and
 - e) a cell capable of secreting into the medium the polypeptide according to a) or the conjugate according to b);
- 10 said method comprising:
- (i) determining the level of at least one biomarker selected from the group consisting of MIP-1 β , CD62E, IL-8, and GM-CSF in a sample from said subject; and
 - (ii) comparing the level of said at least one biomarker with a reference value,
- 15 wherein the patient is selected for said treatment if a decreased level of said at least one biomarker with respect to the reference value is detected.
5. The method according to any one of claims 1 to 4, wherein the sample is blood, serum or plasma.
- 20 6. The method according to any one of claims 1 to 5, wherein the levels of at least one biomarker that are determined are mRNA levels or protein levels.
7. The method according to claim 6, wherein the level of at least one biomarker protein
- 25 is determined by an immunoassay.
8. The method according to any one of claims 1 to 7, wherein the anti-cancer treatment comprises the use of a polypeptide consisting of SEQ ID NO: 4.
- 30 9. The method according to any one of claims 1 to 4, further comprising determining the level of at least one additional biomarker selected from the group consisting of MCP-1, ICAM-1, IFN-gamma, IL-1 β , IL-12, IL-1 α and combinations thereof.

10. Use of an agent selected from the group consisting of:

- a) a polypeptide comprising the sequence SEQ ID NO: 1 or a functionally equivalent variant thereof;
- b) a conjugate comprising a polypeptide comprising the sequence SEQ ID NO: 1 or a functionally equivalent variant thereof and a chemical moiety that facilitates cellular uptake of the polypeptide or of the functionally equivalent variant thereof;
- c) a polynucleotide encoding the polypeptide of a) or the conjugate of b);
- d) a vector comprising the polynucleotide according to c); and
- e) a cell capable of secreting into the medium the polypeptide according to a) or the conjugate according to b);

in the manufacture of a medicament for the treatment of cancer in a subject, wherein the subject has been identified as a good responder to said agent by a method as defined in any one of claims 1 or 2 or 6 to 9 or wherein the treatment has been selected by a method as defined in any one of claims 3 or 5 to 9.

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11. A kit comprising a reagent specific for determining the expression level of at least one biomarker selected from the group consisting of MIP-1 β , CD62E, IL-8, and GM-CSF.

12. The kit according to claim 11, further comprising reagents specific for determining the expression level of at least one additional biomarker selected from the group consisting of MCP-1, ICAM-1, IFN-gamma, IL-1 β , IL-12, IL-1 α and combinations thereof.

13. The kit according to any one of claims 11 or 12, wherein the reagent is an antibody capable of specifically recognizing at least one of the biomarkers.

14. The kit according to any one of claims 11 to 13, wherein the reagent specific for determining the expression level of at least one biomarker comprises at least 10% of the total amount of reagents forming the kit.

15. Use of a kit according to any one of claims 11 to 14 or of a reagent specific for determining the expression level of at least one biomarker selected from the group

consisting of MIP-1 β , CD62E, IL-8, GM-CSF, IL-1 α , MCP-1, ICAM-1, IFN-gamma, IL-1 β , and IL-12 in the method as defined in any one of claims 1 to 9.