Claims

1. A method for predicting an effect of an immunotherapy in a cancer patient, comprising
a) determining the level of at least one marker selected from the group consisting of Apolipoprotein A1 (ApoA1), CCL17/TARC, eosinophils, monocytes, CD95/Fas, aspartate aminotransferase/serum glutamic oxaloaceticacid transaminase (ASAT/SGOT), cancer antigen 19-9 (CA19-9), lactate dehydrogenase (LDH), threonine, immunoglobulin E (IgE), and matrix metalloproteinase 3 (MMP-3) in a sample from said cancer patient, wherein an increase or higher level compared to the median of a given cancer patient population is indicative for a beneficial effect of an immunotherapy for said patient,
and/or
b) determining the level of at least one marker selected from the group consisting of B-cell attracting chemokine (CXCL13/BCA-1), neutrophils, interleukin-6 (IL-6), and short-chain acylcarnitines in a sample from said cancer patient, wherein a decrease or lower level compared to the median of a given cancer patient population is indicative for a beneficial effect of an immunotherapy for said patient.

2. The method according to claim 1, wherein said marker is selected from ApoA1 and/or CCL17/TARC; CXCL13/BCA-1, neutrophils%, ApoA1, eosinophils%, eosinophils ABS (absolute), monocytes%, FAS, TARC; LDH, Thr, IL-6, albumin, IgE, MMP-3, CA19-9; monocytes ABS, ASAT, bilirubin, acylcarnitines (scAC); and IL-33.

3. The method according to claim 1 or 2, further comprising
c) determining at least one marker selected from the group consisting of albumin, and direct bilirubin in said sample from said cancer patient, wherein an increase or higher level compared to the median of a given cancer patient population is indicative for a beneficial effect of an immunotherapy for said patient,
and/or
d) determining the level of the marker interleukin-33 (IL-33) in said sample from said cancer patient, wherein an decrease or lower level compared to the median of a given cancer patient population is indicative for a beneficial effect of an immunotherapy for said patient.

4. The method according to any of claims 1 to 3, wherein said immunotherapy comprises a vaccination with an anti-cancer vaccine, optionally together with an adjuvant, preferably GM-CSF.

5. The method according to any of claims 1 to claim 4, wherein said patient is treated or has been pre-treated with therapies including surgery, radiotherapy and/or chemotherapy, and preferably therapies wherein said patient is treated or has been pre-treated with an anti-cancer agent selected from cytokines, and tyrosine kinase inhibitors (TKI), such as sorafenib and sunitinib, and cyclophosphamide.

6. The method according to any of claims 1 to 5, wherein said cancer is selected from renal cell carcinoma (RCC), colorectal cancer (CRC), gastric cancer (GC), melanoma, non-small-cell lung cancer (NSCLC), glioblastoma, and adenocarcinomas of any type.

7. The method according to any of claims 1 to 6, wherein said sample is selected from whole blood, peripheral blood, or fractions thereof, serum, buffy coat, tumor tissue, lymphatic fluid, urine, bone marrow, EDTA plasma, heparinized plasma, citrate plasma, heparinized whole blood, and frozen samples thereof, such as frozen heparinized whole blood.

8. The method according to any of claims 1 to 7, further comprising prognosing an effect of said immunotherapy in said patient.

9. The method according to any of claims 1 to 8, wherein said effect is selected from overall survival, occurrence of single and/or multiple T-cell responses against the immunotherapy, retardation of tumor growth, tumor shrinkage or progression-free survival.

10. The method according to any of claims 1 to 9, further comprising a monitoring of the effect of said cancer treatment in said patient, comprising repeating said determining step at least once.

11. The method according to any of claims 1 to 10, wherein said determining comprises at least one method selected from immunoassays, bead-based immunoassays, multiplex immunoassays, ELISA, microarray based assays, epigenetic assays, expression analysis, FACS analysis, established methods of hematology, proteomics, and mass spectrometry.

12. The method according to any of claims 4 to 11, wherein said anti-cancer vaccine is selected from an anti-cancer vaccine comprising at least one immunogenic peptides selected from the group of SEQ ID No. 1 to 37, for example comprising SEQ ID No. 1 to 10; SEQ ID No. 11 to 19 and 1, 5, 8, and 9; SEQ ID No. 20 to 29, and SEQ ID No. 30 to 37.

13. A diagnostic kit comprising materials for performing a method according to any of claims 1 to 12 in one or separate containers, preferably comprising at least one marker-specific antibody, optionally together with instructions for performing said method.

14. An improved method for treating cancer in a cancer patient in need thereof, comprising
a) performing a method according to any of claims 1 to 3 and 5 to 11, and
b) using the results for treatment decisions, particularly administering a suitable anti-cancer immunotherapy to said cancer patient based on the results as obtained in step a), and
c) optionally, repeating steps a) and b).

15. The method according to claim 14, wherein said cancer is selected from renal cell carcinoma (RCC), colorectal cancer (CRC), gastric cancer (GC), melanoma, non-small-cell lung cancer (NSCLC), glioblastoma, and adenocarcinoma of any type.

Claims

1. A method for predicting a beneficial effect of an immunotherapy in a cancer patient, comprising

determining the level of at least one marker selected from the group consisting of Apolipoprotein A1 (ApoA1) in a sample previously obtained from said cancer patient,

- wherein a level of said marker at least 10% higher as compared to a median level of said marker in a given cancer patient population is indicative of a beneficial effect of an immunotherapy for said cancer patient,
- wherein said cancer patient is experiencing a cancer selected from the group consisting of renal cell carcinoma (RCC), colorectal cancer (CRC), gastric cancer (GC), melanoma, non-small-cell lung cancer (NSCLC), glioblastoma, and adenocarcinomas of any type;
- wherein said sample is selected from the group consisting of whole blood, peripheral blood, or fractions thereof, serum, buffy coat, tumor tissue, lymphatic fluid, urine, bone marrow, EDTA plasma, heparinized plasma, citrate plasma, heparinized whole blood, and frozen samples thereof, including frozen heparinized whole blood;
- wherein said determining comprises at least one method selected from the group consisting of immunoassays, bead-based immunoassays, multiplex immunoassays, ELISA, microarray based assays, epigenetic assays, expression analysis, FACS analysis, established methods of hematology, proteomics, and mass spectrometry;
- wherein said immunotherapy comprises vaccination with an anti-cancer vaccine, wherein said vaccination is at least one vaccine comprising at least one immunogenic peptide selected from the group consisting the peptides according to SEQ ID NO: 1 to 37; and
- wherein said beneficial effect is selected from the group consisting of longer overall survival, occurrence of single and/or multiple T-cell responses induced by the immunotherapy, retardation of tumor growth, tumor shrinkage, and longer progression-free survival.

2. The method according to claim 1, further comprising the step of determining the level of at least one marker selected from the group consisting of B-cell attracting chemokine (CXCL13/BCA-1), neutrophils, interleukin-6 (IL-6), and short-chain acylcarnitines in a sample from said cancer patient, wherein a level of said marker at least 10% lower compared to a median level of said marker in a given cancer patient population is indicative of a

beneficial effect of an immunotherapy for said patient.

3. The method according to claim 1 or 2, wherein said vaccine comprises an adjuvant, such as, for example, GM-CSF.

4. The method according to any of claims 1 to 3, further comprising the step of determining a level of at least one marker selected from the group consisting of albumin, and direct bilirubin in said sample from said patient, wherein a level of said marker at least 10% higher compared to a median level of said marker in a given cancer patient population is indicative of a beneficial effect of the immunotherapy for said patient,
and, optionally, determining a level of a marker comprising interleukin-33 (IL-33) in said sample from said patient, wherein a level of said marker at least 10% lower compared to the median level of said marker in a given cancer patient population is indicative of a beneficial effect of the immunotherapy for said patient.

5. The method according to any of claims 1 to 4, wherein said patient is receiving treatment or has been pre-treated with therapies including surgery, radiotherapy and/or chemotherapy, such as, for example, therapies wherein said patient is treated or has been pre-treated with an anti-cancer agent selected from cytokines, and tyrosine kinase inhibitors (TKI), such as sorafenib and sunitinib, and cyclophosphamide.

6. The method according to any of claims 1 to 5, further comprising establishing a prognosis for the effect of said immunotherapy in said patient based on said method.

7. The method according to any of claims 1 to 6, further comprising a monitoring of the effect of said cancer treatment in said patient based on said method, comprising repeating said determining step at least once.

8. The method according to any of claims 1 to 7, wherein said at least one peptide is selected from the group consisting of SEQ ID NO: 1 to 10.

9. The method according to any of claims 1 to 7, wherein said at least one peptide is selected from the group consisting of SEQ ID NO: 1, 5, 8, 9, and 11 to 19.

10. The method according to any of claims 1 to 7, wherein said at least one peptide is selected from the group consisting of SEQ ID NO: 20 to 29.

11. The method according to any of claims 1 to 7, wherein said at least one peptide is selected from the group consisting of SEQ ID NO: 30 to 37.