

CLAIMS

1. A method of identifying a tumor that is sensitive to treatment with axitinib, comprising:
(a) measuring CD68 polypeptide expression level in a tissue sample from a tumor
5 obtained from a human patient being considered for treatment with axitinib; and (b)
comparing the CD68 expression level in step (a) against a threshold CD68 expression
level determined by measuring CD68 polypeptide expression in tissue samples of
tumors obtained from human patients previously treated with axitinib and shown to be
resistant to axitinib and human patients previously treated with axitinib and shown to be
10 sensitive to axitinib, wherein a CD68 expression level above the threshold level
indicates that the tumor is sensitive to treatment with axitinib.
2. The method of claim 1, wherein the step of measuring CD68 polypeptide expression
is performed by immunohistochemistry.
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3. The method of claim 2, wherein the step of measuring CD68 polypeptide expression
by immunohistochemistry is carried out by image analysis from a whole slide scan,
where the percentage of CD68-positive cells in the sample is determined.
- 20 4. The method of claim 3, further comprising the step of determining the density of
CD68-positive cells in the sample.
5. The method of claim 1, wherein the tumor is selected from the group consisting of a
breast tumor, a lung tumor, a kidney tumor, a colorectal tumor, and a pancreatic tumor.
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6. Use of axitinib in the manufacture of a medicament for the treatment of an mRCC
tumor that is sensitive to axitinib according to claim 1.
7. Use of axitinib in the manufacture of a medicament for the treatment of cancer,
30 whereby if the percentage of CD68-positive cells in a tumor from a subject is initially
determined to be at least 5%, the medicament is to be administered.
8. Use of axitinib in the manufacture of a medicament for the treatment of cancer,

whereby if the cell density of CD68-positive cells in a tumor from a subject is initially determined to be at least 0.08 cells/mm², the medicament is to be administered.

5 9. Use of axitinib in the manufacture of a medicament for the treatment of cancer, whereby the medicament is to be administered to a subject with a tumor if at least 5% of the cells in said tumor are CD68-positive.

10 10. Use of axitinib in the manufacture of a medicament for the treatment of cancer, whereby the medicament is to be administered to a subject with a tumor if the cell density of CD68-positive cells in said tumor is at least 0.08 cells/mm².

15 11. Use of axitinib in the manufacture of a medicament for the treatment of cancer, whereby if the percentage of CD68-positive cells in a tumor from a subject and the cell density of CD68-positive cells in the tumor are initially determined to be at least 5% and at least 0.08 cells/mm² respectively, the medicament is to be administered.

20 12. Use of axitinib in the manufacture of a medicament for the treatment of cancer, whereby the medicament is to be administered to a subject with a tumor if at least 5% of the cells in said tumor are CD68-positive and the cell density of CD68-positive cells in said tumor is at least 0.08 cells/mm².

25 13. The use of any one of claims 7 - 12, wherein said tumor is selected from the group consisting of a breast tumor, a lung tumor, a kidney tumor, a colorectal tumor, and a pancreatic tumor.

14. The use of any one of claims 7, 8, or 11, wherein the step of measuring the percentage or cell density of CD68 positive cells is performed using immune-histochemistry.

30 15. The use of claim 14, wherein the step of measuring the percentage or cell density of CD68 positive cells is performed using immunohistochemistry and the use of image analysis from a whole slide scan.