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 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 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.

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.

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 any one of claims 1 to 4, 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, and is preferably a metastatic renal cell cancer (mRCC) tumor.

6. Axitinib for use in the treatment of metastatic renal cell cancer (mRCC) by administration of axitinib to a patient determined to have a mRCC tumor that is sensitive to axitinib according to claim 5.

7. Axitinib for use in the treatment of cancer by (a) determination of the percentage of CD68-positive cells in a tumor from a subject; and (b) administration of axitinib to the subject if said percentage is at least 5%.

8. Axitinib for use in the treatment of cancer by (a) determination of the cell density of CD68-positive cells in a tumor from a subject; and (b) administration of axitinib to the subject if said cell density is at least 0.08 cells/mm^2.

9. Axitinib for use in the treatment of cancer by administration of axitinib to a subject with a tumor, wherein at least 2%, at least 3%, at least 4%, at least 4.5%, at least 4.6%, at least 4.7%, at least 4.8%, at least 4.9%, at least 5.0%, at least 5.1%, at least 5.2%, at least 5.3%, at least 5.4%, at least 5.5%, at least 5.6%, at least 5.7%, at least 5.8%, at least 5.9%, at least 6.0%, at least 6.5%, at least 7.0%, at least 8%, at least 9%, at least 10%, at least 15%, or at least 20% of the cells in said tumor are CD68-positive.

10. Axitinib for use in the treatment of cancer as claimed in claim 9 by administration of axitinib to a subject with a tumor, wherein at least 5% of the cells in said tumor are CD68-positive.

11. Axitinib for use in the treatment of cancer by administration of axitinib to a subject with a tumor, wherein the cell density of CD68-positive cells in said tumor is at least 0.05 cells/mm2, at least 0.06 cells/mm2, at least 0.07 cells/mm2, at least 0.08 cells/mm2, at least 0.09 cells/mm2, at least 1.0 cells/mm2, at least 1.1 cells/mm2, at least 1.2 cells/mm2, at least 1.3 cells/mm2, at least 1.4 cells/mm2, or at least 1.5 cells/mm2.

12. Axitinib for use in the treatment of cancer as claimed in claim 11 by administration of axitinib to a subject with a tumor, wherein the cell density of CD68-positive cells in said tumor is at least 0.08 cells/mm^2.

13. Axitinib for use in the treatment of cancer by (a) determination of the percentage of CD68-positive cells in a tumor from a subject; (b) determination of the cell density of CD68-positive cells in the tumor; and (c) administration of axitinib to the subject if said percentage is at least least 2%, at least 3%, at least 4%, at least 4.5%, at least 4.6%, at least 4.7%, at least 4.8%, at least 4.9%, at least 5.0%, at least 5.1%, at least 5.2%, at least 5.3%, at least 5.4%, at least 5.5%, at least 5.6%, at least 5.7%, at least 5.8%, at least 5.9%, at least 6.0%, at least 6.5%, at least 7.0%, at least 8%, at least 9%, at least 10%, at least 15%, or at least 20%; and said cell density is at least 0.05 cells/mm2, at least 0.06 cells/mm2, at least 0.07 cells/mm2, at least 0.08 cells/mm2, at least 0.09 cells/mm2, at least 1.0 cells/mm2, at least 1.1 cells/mm^2, at least 1.2 cells/mm2, at least 1.3 cells/mm2, at least 1.4 cells/mm2, or at least 1.5 cells/mm2.

14. Axitinib for use in the treatment of cancer as claimed in claim 13 by (a) determination of the percentage of CD68-positive cells in a tumor from a subject; (b) determination of the cell density of CD68-positive cells in the tumor; and (c) administration of axitinib to the subject if said percentage is at least 5% and said cell density is at least 0.08 cells/mm^2.

15. Axitinib for use in the treatment of cancer as claimed in any one of claims 7 to 14, 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, and is preferably a metastatic renal cell cancer (mRCC) tumor.

16. Axitinib for use in the treatment of cancer as claimed in claim 7, 8, 13 or 14, wherein the step of measuring the percentage or cell density of CD68 positive cells is performed using immunohistochemistry.

17. Axitinib for use in the treatment of cancer as claimed in claim 16, 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.

18. Use of a diagnostic test kit comprising certain components for performing methods of any one of claims 1 to 5, the components including, (a) for a quantitative reverse transcriptase polymerase chain reaction (qRT-PCR)-based kit, PCR primers for analyzing expression of the macrophage marker CD68 and optionally buffers, reagents and detailed instructions for measuring CD68 expression levels, using PCR technology; (b) for a DNA microarray-based kit, a