

Claims

1. Use of a composition ~~that modulates~~comprising an inhibitor of IRAK1 in the
5 manufacture of a medicament for treating triple negative breast cancer in a patient who is
resistant to paclitaxel therapy, wherein the level of IRAK1 protein in a tumour test sample
from the patient has been determined to be elevated in comparison to a normal tissue control
sample and wherein the inhibitor is a ginsenoside.
- 10 ~~2. The use according to claim 1, wherein the composition modulates one or more of:~~
~~activity; phosphorylation; or level of expression.~~
- ~~3. The use according to any one of claim 1 or 2, wherein the breast cancer is triple~~
~~negative breast cancer.~~
- 15 ~~4. The use according to any one of the preceding claims, wherein the composition~~
~~comprises a ginsenoside.~~
- ~~52. The use according to any one of the preceding claim 1s, wherein the~~
20 ~~composition~~further comprises comprising a pharmaceutical composition and a
pharmaceutically acceptable carrier.
- ~~63. The use according to any one of claims 1 or 52, wherein the composition is suitable~~
~~for parenteral administration to a patient~~is administered a further anti-cancer agent or
25 treatment.
- ~~7. An inhibitor of IRAK1 activity for use in treating a breast cancer patient.~~
- ~~8. The inhibitor of IRAK1 according to claim 7, wherein the patient is administered a~~
30 ~~further anti-cancer agent or treatment.~~

9. ~~A method for aiding in categorising or determining prognosis in a patient with breast cancer, or in selecting a therapeutic strategy for a patient with breast cancer, the method comprising assessing the level of IRAK1 nucleic acid, protein or activity in a sample.~~
- 5 10. ~~The method of claim 9, further comprising the step of assessing the level of NF- κ B nucleic acid, protein or activity in the sample.~~
11. ~~The method of claim 9, further comprising the step of assessing the level of IL-6, IL-8 or CSCL1 nucleic acid, protein or activity in the sample.~~
- 10 12. ~~The method according to any one of claims 9 to 11, further comprising the step of selecting a treatment regime making use of the information on the level of IRAK1 nucleic acid, protein or activity in the sample.~~
- 15 13. ~~The method according to any one of claims 9 to 12, wherein the sample is obtained from the patient and the sample is a tissue sample in which breast cancer is suspected or in which breast cancer has been found, or contains cells from said tissue.~~
- 20 14. ~~The method according to any one of claims 9 to 13, wherein the breast cancer is triple negative breast cancer.~~
- 15 15. A method for ~~determining~~aiding in selecting a therapeutic strategy for a patient's cancer-free survival, the patient having been diagnosed with triple negative breast cancer and who is receiving paclitaxel therapy, or a patient who has previously received or is receiving paclitaxel therapy and has relapsed, the method comprising assessing the level of IRAK1 protein in a tumour sample obtained from the patient and comparing the level to an IRAK1 level in a normal tissue control sample, wherein a normal IRAK1 level is considered to indicate a >90% chance of 10 year breast cancer free survival with standard therapy, and an elevated level is considered to indicate a <85% chance of 10 year breast cancer free survival~~nucleic acid, protein or activity in a sample, and assessing the paclitaxel resistance status of the patient.~~
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16. — The method according to claim 15 wherein (a) if the level of IRAK1 nucleic acid, protein or activity in the sample is an elevated level; and (b) if the patient is assessed as having an elevated paclitaxel resistance status or being resistant to paclitaxel therapy, then the selected treatment regime comprises treating the patient with an inhibitor of IRAK1 activity.

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17. — The method according to claim 16, wherein the inhibitor is a ginsenoside.

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18. — A method for aiding in determining whether a patient with breast cancer has a relatively high or relatively low likelihood of disease free survival, the method comprising assessing the level of IRAK1 nucleic acid, protein or activity in a sample obtained from the patient.

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19. — A method for treating a patient with breast cancer, the method comprising administering an inhibitor of IRAK1 activity to the patient.

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20. — The method according to claim 19, wherein the inhibitor is a ginsenoside.

21. — Use of an inhibitor of IRAK1 activity in the manufacture of a medicament for treating a patient with breast cancer, wherein the level of IRAK1 nucleic acid or protein in a sample from the patient has been determined to be elevated.

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22. — The use according to claim 21, wherein the breast cancer is triple negative breast cancer.

23. — A kit of parts useful for assessing breast cancer comprising:

- (a) — an agent which is specifically capable of use in determining the level of IRAK1 protein in a sample; and
- (b) — means for separating breast cells from a sample, or identifying breast cells in a sample in order to carry out the IRAK1 assay.

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24. — The kit of claim 23, wherein the agent is a nucleic acid which selectively hybridises to IRAK1 nucleic acid, or is a molecule which selectively binds to IRAK1 protein.

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~~25. A screening method for identifying a compound likely to be useful in treating breast cancer, the method comprising:~~

~~(a) determining the effect of a test compound on IRAK1 nucleic acid, protein or activity level; and~~

~~(b) selecting a compound that reduces said level.~~

~~26. The method according to claim 25, wherein the effect of the test compound is determined in vitro, or in a breast cancer cell line.~~