Claims

1. A combination of neratinib and pharmaceutically acceptable salts thereof with capecitabine for use in a method of treating an Erb-2 positive metastatic breast cancer.

2. The combination for use according to claim 1, wherein the breast cancer is a locally advanced breast cancer.

3. The combination for use according to claim 1, wherein one or both of the active components is provided in a subtherapeutically effective amount.

4. The combination for use according to any one of claims 1-3, wherein the capecitabine is administered in an amount of about 1250 mg to about 3000 mg daily.

5. The combination for use according to any one of claims 1-4, wherein the capecitabine is administered at least once over a period of 21 days.

6. The combination for use according to claim 5, wherein the capecitabine regimen is continued for 3 to 6 cycles.

7. The combination for use according to claim 1, wherein the neratinib or pharmaceutically acceptable salt thereof is administered in an amount of at least about 40 mg.

8. The combination for use according to claim 7, wherein the neratinib or pharmaceutically acceptable salt thereof is administered in an amount of at least about 120 mg.

9. The combination for use according to claim 8, wherein the neratinib or pharmaceutically acceptable salt thereof is administered in an amount of at least about 240 mg.

10. The combination for use according to claim 1, wherein the neratinib or pharmaceutically acceptable salt thereof is administered daily.

11. The combination for use according to claim 1, wherein the neratinib or pharmaceutically acceptable salt thereof is administered for at least 2 continuous weeks.

12. A product containing capecitabine, neratinib or a pharmaceutically acceptable salt thereof, and at least one pharmaceutically acceptable carrier, for simultaneous, separate or sequential delivery in a combined regimen for use in a method of treating an Erb-2 positive metastatic breast cancer in a mammal.

13. A pharmaceutical pack for use in a method of treating an Erb-2 positive metastatic breast cancer in one individual mammal, said pharmaceutical pack comprising:
    (a) at least one unit dose of capecitabine; and
    (b) at least one unit dose of neratinib or a pharmaceutically acceptable salt thereof.