CLAIMS

1. Use of neratinib and pharmaceutically acceptable salts thereof with capecitabine in the manufacture of a medicament for treating an Erb-2 positive metastatic breast cancer; wherein the medicament consists of neratinib and capecitabine as active ingredients; and wherein the medicament is manufactured for administration of neratinib or pharmaceutically acceptable salt thereof in an amount of at least about 40 mg per day and for administration of capecitabine in an amount from about 1250 mg to about 3000 mg per day.

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

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

4. The use according to any one of claims 1-3, wherein the capecitabine is administered at least once over a period of 21 days.

5. The use according to claim 4, wherein the capecitabine regimen is continued for 3 to 6 cycles.

6. The use according to claim 1, wherein the neratinib or pharmaceutically acceptable salt thereof is administered in an amount of at least about 120 mg.

7. The use according to claim 6, wherein the neratinib or pharmaceutically acceptable salt thereof is administered in an amount of at least about 240 mg.

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

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

10. A product consisting of capecitabine in an amount from at least about 1250 mg to about 3000 mg per day, neratinib in an amount of at least about 40 mg per day or a pharmaceutically acceptable salt thereof, and at least one pharmaceutically acceptable carrier, for simultaneous, separate or sequential delivery in a combined regimen for treating an Erb-2 positive metastatic breast cancer in a mammal; wherein the product consists of neratinib and capecitabine as active ingredients.

11. A pharmaceutical pack for treating an Erb-2 positive metastatic breast cancer in one individual mammal, said pharmaceutical pack consisting of:

(a) at least one unit dose of capecitabine;, wherein one unit dose of capecitabine comprises from at least about 1250 mg to about 3000 mg per day of capecitabine; and

(b) at least one unit dose of neratinib or a pharmaceutically acceptable salt thereof, wherein one unit dose of neratinib comprises at least about 40 mg per day of neratinib or a pharmaceutically acceptable salt thereof.