CLAIMS:

1. Use of neratinib or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for treating a HER-2-positive solid tumor, wherein the medicament further comprises capecitabine.

2. The use according to claim 1, wherein the solid tumor is non-small cell lung cancer, prostate, colorectal, breast or ovarian cancer.

3. The use according to claim 2, wherein the breast cancer is HER-2 overexpressed metastatic or locally advanced breast cancer.

4. The use according to claim 1, wherein one or both of the active components of the medicament is provided in a sub-therapeutically effective amount.

5. The use according to any one of claims 1-4, wherein the capecitabine is formulated for administration in an amount of about 1250 mg to about 3000 mg, about 750 mg to about 2000 mg, about 900 mg to about 1800 mg, or 1250 mg to about 1450 mg daily.

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

7. The use according to claim 6, wherein the capecitabine is formulated for continued administration for 3 to 6 cycles.

8. The use according to any one of claims 1-4, wherein the neratinib or pharmaceutically acceptable salt thereof is formulated for administration at a dose range of about 20 to about 240 mg daily.

9. The use according to claim 8, wherein the neratinib or pharmaceutically acceptable salt thereof is formulated for administration in an amount of at least about 40 mg.

10. The use according to claim 9, wherein the neratinib or pharmaceutically acceptable salt thereof is formulated for administration in an amount of at least about 120 mg.

11. The use according to claim 10, wherein the neratinib or pharmaceutically acceptable salt thereof is formulated for administration in an amount of at least about 240 mg.

12. The use according to claim 1, wherein the neratinib or pharmaceutically acceptable salt thereof is formulated for daily administration.

13. The use according to claim 1, wherein the neratinib or pharmaceutically acceptable salt thereof is formulated for at least once daily administration.

14. The use according to claim 1, wherein the neratinib or pharmaceutically acceptable salt thereof is formulated for at least two continuous weeks administration.

15. The use according to claim 1, wherein the solid tumor is breast cancer and wherein one cycle of the treatment comprises 21 days and the treatment comprises:

(a) oral administration of at least one unit dose of the neratinib or pharmaceutically acceptable salt thereof daily starting on day 1 of said cycle; and

(b) oral administration of at least one unit dose of capecitabine on days 1 to 14 of said cycle.

16. The use according to claim 1, wherein the pharmaceutically acceptable salt of neratinib is maleate.

17. Use of capecitabine; neratinib or a pharmaceutically acceptable salt thereof; and at least one pharmaceutically acceptable carrier, in the manufacture of a pharmaceutical composition for simultaneous, separate or sequential delivery for treating an HER-2-positive solid tumor.

18. Use of a pharmaceutical pack for treating an HER-2-positive solid tumor, said pharmaceutical pack consisting of:

(a) at least one unit dose of capecitabine; and

(b) at least one unit dose of neratinib or a pharmaceutically acceptable salt thereof.