WHAT IS CLAIMED IS:

1. Use of vinorelbine, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for treating a neoplasm associated with overexpression or amplification of HER-2 in a subject, said medicament is to be administered with HKI-272, or a pharmaceutically acceptable salt thereof.

2. The use according to claim 1, wherein the vinorelbine and HKI-272 are to be administered concurrently, sequentially, simultaneously, in a specified order, or according to a specific temporal relationship.

3. The use according to claim 1, wherein said vinorelbine is to be administered in a unit dose.

4. The use according to claim 1, wherein said HKI-272 is to be administered in a unit dose.

5. The use according to claim 1, wherein one or both of said vinorelbine and said HKI-272 are to be delivered intravenously to said subject.

6. The use according to claim 1, wherein one or both of said vinorelbine and said HKI-272 are to be delivered orally to said subject.

7. The use according to claim 1, wherein said neoplasm is metastatic.

8. The use according to claim 1, wherein said neoplasm is selected from the group consisting of a lung cancer, breast cancer, myeloma, prostate cancer, head and neck cancer, transitional cell carcinoma, small cell neuroendocrine carcinoma of the uterine cervix, and large cell neuroendocrine carcinoma of the uterine cervix.

9. The use according to claim 11, wherein said neoplasm is a breast cancer.

10. The use according to claim 12, wherein said breast cancer is a metastatic, HER-2 - positive breast cancer.

11. The use according to claim 1, wherein said neoplasm is an advanced solid tumor.

12. The use according to claim 1, wherein said vinorelbine is to be administered in an amount of at least about 20 mg/L.

13. The use according to claim 12, wherein said vinorelbine is to be administered in an amount of about 20 to about 25 mg/L.

14. The use according to claim 13, wherein said vinorelbine is to be administered in an amount of about 25 mg/L.

15. The use according to claim 1, wherein said HKI-272 is to be administered in an amount of at least about 120 mg.

16. The use according to claim 15, wherein said HKI-272 is to be administered in an amount of at least about 160 mg.

17. The use according to claim 16, wherein said HKI-272 is to be administered in an amount of at least about 240 mg.

18. The use according to claim 4, wherein said unit dose is a tablet.

19. The use according to claim 1, wherein said HKI- 272 is to be administered daily.

20. The use according to claim 1, wherein said HKI-272 is to be administered at least once daily.

21. The use according to claim 1, wherein said HKI-272 is to be administered on day 1 of a dosing regimen.

22. The use according to claim 1, wherein said HKI-272 is to be administered on day 2 of a dosing regimen.

23. The use according to claim 1, wherein said HKI-272is to be administered for at least 2 continuous weeks.

24. The use according to claim 1, wherein the medicament is a pharmaceutical composition further comprising at least one pharmaceutically acceptable carrier.

25. The use according to claim 1, further comprising radiation.

26. Use of a product in the manufacture of a medicament for treating a cancer or neoplasm associated with overexpression or amplification of HER-2 in a mammal, said product comprises a first compound and a second compound provided as a combined preparation for simultaneous, separate or sequential use, wherein the first compound is selected from (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy)anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-butenamide, or pharmaceutically acceptable salt thereof, and wherein the second compound is selected from vinorelbine or a pharmaceutically acceptable salt thereof.

27. The use according to claim 26 wherein said second compound is vinorelbine.

28. The use according to claim 26 or 27 wherein said first compound is (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy)anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-butenamide.

29. The use according to any one of claims 26 to 28, wherein the medicament is to be provided as a regimen and wherein a cycle of the regimen includes 21 days and the regimen includes oral administration of at least one unit dose of (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy)anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-butenamide starting on day 1 of the cycle, and intravenous administration of at least one unit dose of vinorelbine on days 1 and 8 of the cycle.

30. The use according to any one of claims 26 to 29, wherein the medicament is to be provided as a regimen and wherein a cycle of the regimen includes 21 days and the regimen includes oral administration of at least one unit dose of (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy) anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-butenamide starting on day 2 of the cycle, and intravenous administration of at least one unit dose of vinorelbine on days 1 and 8 of the cycle.

31. The use according to any one of claims 26 to 30, wherein said neoplasm is metastatic.

32. The use according to claim 31, wherein said neoplasm is selected from the group consisting of a lung cancer, breast cancer, myeloma, prostate cancer, head and neck cancer, transitional cell carcinoma, small cell neuroendocrine carcinoma of the uterine cervix, and large cell neuroendocrine carcinoma of the uterine cervix.

33. The use according to claim 32, wherein said neoplasm is a breast cancer.

34. The use according to claim 33, wherein said breast cancer is a metastatic or HER-2 - positive breast cancer.

35. The use according to any one of claims 26 to 30, wherein said neoplasm is an advanced solid tumor.

36. Use of a pharmaceutical pack in the manufacture of a medicament for treating a neoplasm associated with overexpression or amplification of HER-2 in a subject, said pharmaceutical pack comprising a first compound selected from (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy)anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-butenamide, or pharmaceutically acceptable salt thereof and a second compound selected from vinorelbine or a pharmaceutically acceptable salt thereof, wherein said first compound is in a unit dose and wherein the unit dose contains 50 to 300 mg of said first compound.

37. The use according to claim 36, wherein the unit dose contains 200 to 300 mg, 240 to 300 mg or at least 240 mg of the first compound.

38. The use according to claim 36 or 37, wherein the unit dose is a tablet.

39. The use according to any one of claims 36 to 38, wherein the second compound is in a unit dose and the unit dose contains 5 to 500 mg, 10 to 250 mg, or at least 240 mg of the second compound.

40. The use according to any one of claims 36 to 39, wherein the first compound and the second compound is to be administered concurrently, sequentially, simultaneously, in a specified order, or according to a specific temporal relationship.

41. The use according to any one of claims 36 to 40, wherein said first compound is (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy)anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-butenamide and/or wherein said second compound is vinorelbine.

42. The use according to any one of claims 36 to 41, wherein said neoplasm is selected from the group consisting of a lung cancer, breast cancer, myeloma, prostate cancer, head and neck cancer, transitional cell carcinoma, small cell neuroendocrine carcinoma of the uterine cervix, and large cell neuroendocrine carcinoma of the uterine cervix.

43. The use according to claim 42, wherein said neoplasm is a breast cancer.

44. The use according to claim 42 or 43, wherein said neoplasm is an advanced solid tumor.

45. The use according to any one of claims 42 to 44, wherein said neoplasm is metastatic.

46. The use according to any one of claims 36 to 45, wherein said first compound is to be administered daily or at least once daily.

47. The use according to any one of claims 36 to 46, wherein said first compound is to be administered on day 1 or 2 of a regimen.

48. The use according to any one of claims 36 to 47, wherein

(a) said first compound is to be administered for at least 2 continuous weeks;

(b) the neoplasm or tumor is a solid tumor associated with overexpression or amplification of HER-2 in a subject, wherein the use is to be provided as a regimen and wherein a cycle of the regimen includes 21 days and the regimen includes oral administration of at least one unit dose of the first compound starting on day 1 of the cycle, and intravenous administration of at least one unit dose of the second compound on days 1 and 8 of the cycle; or

(c) wherein the neoplasm or tumor is a metastatic cancer associated with overexpression or amplification of HER-2 in a subject, wherein the use is to be provided as a regimen and wherein a cycle of the regimen includes 21 days and the regimen includes oral administration of at least one unit dose of the first compound starting on day

2 of the cycle, and intravenous administration of at least one unit dose of the second compound on days 1 and 8 of the cycle.

49. The use according to any one of claims 36 to 48, wherein said subject has previously been administered lapatinib.

WHAT IS CLAIMED IS:

1. Use of a vinorelbine compound in the manufacture of a medicament for treating a neoplasm in a subject, said treatment further comprising administration ofa HKI-272 compound.

2. The use according to claim 1, wherein the administration steps occur concurrently, sequentially, simultaneously, in a specified order, or according to a specific temporal relationship.

3. The use according to claim 1, wherein said vinorelbine compound is administered in a unit dose.

4. The use according to claim 1, wherein said HKI-272 compound is administered in a unit dose.

5. The use according to claim 1, wherein said vinorelbine compound is vinorelbine.

6. The use according to claim 1, wherein said HKI-272 compound is HKI-272.

7. The use according to claim 1, wherein one or both of said vinorelbine compound and said HKI-272 compound are to be delivered intravenously to said subject.

8. The use according to claim 1, wherein one or both of said vinorelbine compound and said HKI-272 compound are to be delivered orally to said subject.

9. The use according to claim 1, wherein said neoplasm is associated with overexpression or amplification of HER-2.

~~10. The use according to claim 1, wherein said neoplasm is metastatic.~~

11. The use according to claim 1, wherein said neoplasm is selected from the group consisting of a lung cancer, breast cancer, myeloma, prostate cancer, head and neck cancer, transitional cell carcinoma, small cell neuroendocrine carcinoma of the uterine cervix, and large cell neuroendocrine carcinoma of the uterine cervix.

12. The use according to claim 11, wherein said neoplasm is a breast cancer.

13. The use according to claim 12, wherein said breast cancer is a metastatic, HER-2 - positive breast cancer.

14. The use according to claim 1, wherein said neoplasm is an advanced solid tumor.

15. The use according to claim 1, wherein said vinorelbine compound is to be administered in an amount of at least about 20 mg/L.

16. The use according to claim 15, wherein said vinorelbine compound is to be administered in an amount of about 20 to about 25 mg/L.

17. The use according to claim 16, wherein said vinorelbine compound is to be administered in an amount of about 25 mg/L.

18. The use according to claim 1, wherein said HKI-272 compound is to be administered in an amount of at least about 120 mg.

19. The use according to claim 18, wherein said HKI-272 compound is to be administered in an amount of at least about 160 mg.

20. The use according to claim 19, wherein said HKI-272 compound is to be administered in an amount of at least about 240 mg.

21. The use according to claim 4, wherein said unit dose is a tablet.

22. The use according to claim 1, wherein said HKI- 272 compound is to be administered daily.

23. The use according to claim 1, wherein said HKI-272 compound is to be administered at least once daily.

24. The use according to claim 1, wherein said HKI-272 compound is to be administered on day 1 of said regimen.

25. The use according to claim 10, wherein said HKI-272 compound is to be administered on day 2 of said regimen.

26. The use according to claim 1, wherein said HKI-272 compound is to be administered for at least 2 continuous weeks.

27. A pharmaceutical composition according to claim 1, further comprising at least one pharmaceutically acceptable carrier.

28. The use according to claim 1, further comprising radiation.