SUMMARY OF THE INVENTION

This invention addresses the need in the art by providing regimens, compositions and methods using a HKI-272 compound and a vinorelbine compound for the treatment of cancers, such as solid tumors and metastatic breast cancer.

In one ~~aspect~~example, regimens for treating a neoplasm in a subject are provided and include administering a vinorelbine compound and administering a HKI-272 compound. Desirably, the vinorelbine compound is vinorelbine and the HKI-272 compound is HKI-272. In one embodiment, the neoplasm is breast cancer.

In another ~~aspect~~example, a regimen for treating a solid tumor associated with overexpression or amplification of HER-2 in a subject is provided, wherein one cycle of the regimen includes 21 days. The regimen includes orally administering at least one unit dose of HKI-272 starting on day 1 of the cycle and intravenously administering at least one unit dose of vinorelbine on days 1 and 8 of the cycle.

In a further ~~aspect~~example, a regimen for treating a metastatic cancer associated with overexpression or amplification of HER-2 in a subject is provided. One cycle of the regimen includes 21 days and the regimen includes orally administering at least one unit dose of HKI-272 starting on day 2 of the cycle and intravenously administering at least one unit dose of vinorelbine on days 1 and 8 of the cycle.

In still another ~~aspect~~example, a product comprising a vinorelbine compound and HKI-272 compound is provided as a combined preparation for simultaneous, separate or sequential use in treating a neoplasm in a mammal.

In yet a further ~~aspect~~example, a pharmaceutical pack for treating a neoplasm in one individual mammal is provided and includes (a) at least one unit dose of vinorelbine; and (b) at least one unit dose of HKI-272.

In another ~~aspect~~example, a pharmaceutical composition is described and contains vinorelbine, HKI-272, and at least one pharmaceutically acceptable carrier.

In one aspect, there is provided the 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.

In another aspect, there is provided the 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.

In yet another aspect, there is provided the 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.

In still another ~~aspect~~example, a method of treating a neoplasm associated with overexpression or amplification of HER-2 in a mammal in need thereof is provided and includes administering a unit dose of a vinorelbine compound and administering a unit dose of a HKI-272 compound.

Other aspects and advantages of the invention will be readily apparent from the following detailed description of the invention.