CLAIMS

1. Use of crystalline (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy)anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-butenamide maleate, monohydrate (Form II) in the manufacture of a medicament for the treatment, prevention or inhibition of cancer, wherein the medicament increases oral absorption of neratinib and/or reduces diarrhea associated with neratinib therapy, relative to neratinib in a free base formulation; wherein the crystalline (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy)anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-butenamide maleate, monohydrate (Form II) is characterized by a DSC-plot with two thermal events at 109.63°C and 203.81°C.

2. The use of claim 1, wherein the crystalline (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy)anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-butenamide maleate, monohydrate (Form II) produces at least a two-fold greater AUC (area under curve), relative to neratinib in a free base formulation.

3. The use of claim 1 or claim 2, wherein the crystalline (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy)anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-butenamide maleate, monohydrate (Form II), is prepared by steps comprising:

i) heating (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy)anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-butenamide free base and maleic acid to 50-60 °C in a water:n-propanol solution, and maintaining the mixture at 50-60 °C for a minimum of 15 min. until a solution is obtained;
ii) cooling said solution over at least one hour to 40 °C and maintaining the cooled solution at 40 °C for 12 hours;
iii) further cooling the cooled solution to room temperature of 25 °C over a minimum of 4 hours and maintaining the further cooled solution at room temperature 25 °C for at least 2 hours; and
iv) filtering the mixture obtained in step iii) to obtain the crystalline (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy)anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-butenamide maleate monohydrate (Form II).

4. The use of any one of claims 1-3, wherein the crystalline (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy)anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-

butenamide maleate, monohydrate (Form II) is characterized by X-ray diffraction peaks at the following angles (±0.20°) of 2Theta in its X-ray diffraction pattern: 6.53, 8.43, 10.16, 12.19, 12.47, 13.01, 15.17, 16.76, 17.95, 19.86, 21.11, 21.88, 23.22, 23.78, 25.69, 26.17, 27.06, 27.58, 28.26, 28.73, and 29.77.

5. The use of any one of claims 1-4, wherein the crystalline (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy)anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-butenamide maleate, monohydrate (Form II) has a water content of 2.5 to 2.7%, by weight.

6. The use of any one of claims 1-5, wherein the crystalline (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy)anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-butenamide maleate, monohydrate (Form II) has substantially the X-ray diffraction pattern as shown in Fig. 7.

7. The use of any one of claims 1-6, wherein the crystalline (E)-N-{4-[3-chloro-4-(2-pyridinylmethoxy)anilino]-3-cyano-7-ethoxy-6-quinolinyl}-4-(dimethylamino)-2-butenamide maleate, monohydrate (Form II) has substantially the X-ray diffraction pattern as shown in Fig. 1 (upper scan).

8. The use of any one of claims 1-7, wherein the cancer is selected from at least one of: breast cancer, ovarian cancer, epidermoid tumors, colon cancer, prostate cancer, kidney cancer, bladder cancer, larynx cancer, esophagus cancer, stomach cancer, and lung cancer.

9. The use of claim 8, wherein the cancer comprises breast cancer.

10. The use of claim 8, wherein the cancer comprises lung cancer.