Claims

1. A pharmaceutical product comprising (A) a first component which comprises, as an active agent, propane-1-sulfonic acid {3-[5-(4-chloro-phenyl)-1H-pyrrolo [2,3-b] pyridine-3-carbonyl]-2,4-difluoro-phenyl}-amide (Compound I), or a pharmaceutically-acceptable salt thereof; and (B) a second component which comprises, as an active agent, an EGFR inhibitor; as a combined preparation for the simultaneous or sequential use in the treatment of ~~a proliferative disorder, in particular~~ cancer~~, more particularly colorectal cancer, melanoma, and thyroid cancer~~ comprising b-Raf having a V600 mutation, wherein the EGFR inhibitor is selected from erlotinib or a pharmaceutically acceptable salt thereof, or cetuximab.

2. The pharmaceutical product for use according to claim 1 for the treatment of colorectal cancer, melanoma and thyroid cancer, comprising b-Raf having the V600E mutation.

~~3. The pharmaceutical product according to claim 1 or 2, wherein said EGFR inhibitor is erlotinib, or a pharmaceutically acceptable salt thereof.~~

~~4. The pharmaceutical product according to claim 1 or 2, wherein said EGFR inhibitor is cetuximab.~~

~~5. The pharmaceutical product according to any one of claims 1 to 4, further comprising a third component (C), which comprises as an active agent a topoisomerase inhibitor, in particular an inhibitor of type I topoisomerase.~~

~~6~~3. The pharmaceutical product for use according to any one of claims ~~5~~1 and 2, further comprising a third component (C), which comprises as an active agent a topoisomerase inhibitor, wherein said topoisomerase inhibitor is irinotecan, or a pharmaceutically acceptable salt thereof.

~~7~~4. The pharmaceutical product for use according to any one of claims 1 to ~~6~~3 wherein propane-1-sulfonic acid {3-[5-(4-chloro-phenyl)-1H-pyrrolo [2,3-b] pyridine-3-carbonyl]-2,4-difluoro-phenyl}-amide, or a pharmaceutically-acceptable salt thereof, is in amorphous or substantially amorphous form.

~~8~~5. A kit comprising: (A) a first component which comprises, as an active agent, propane-1-sulfonic acid {3-[5-(4-chloro-phenyl)-1H-pyrrolo [2,3-b] pyridine-3-carbonyl]-2,4-difluoro-phenyl}-amide, or a pharmaceutically-acceptable salt thereof; and (B) a second component which comprises, as an active agent, an EGFR inhibitor wherein the EGFR inhibitor is selected from erlotinib or a pharmaceutically acceptable salt thereof, or cetuximab.

~~9~~6. A kit according to claim ~~8~~ 5 further comprising a third component which comprises, as an active agent, ~~a topoisomerase inhibitor, more particularly~~ irinotecan.

~~10~~7. A kit according to claims ~~8~~ 5 or ~~9~~6, for use in the treatment of ~~a proliferative disorder, in particular~~ cancer~~, more particularly colorectal cancer, melanoma and thyroid cancer~~ comprising b-Raf having the V600E mutation.

~~11~~8. The pharmaceutical product for use according to claim ~~3~~1, wherein said propane-1-sulfonic acid {3-[5-(4-chloro-phenyl)-1H-pyrrolo [2,3-b] pyridine-3-carbonyl]-2,4-difluoro-phenyl}-amide, or a pharmaceutically acceptable salt thereof, is administered twice daily in an amount of from about 850 mg to about 1050 mg; and said erlotinib, or a pharmaceutically acceptable salt thereof, is administered daily in an amount of from ~~from~~ about 100 mg to about 200 mg.

~~12~~9. The pharmaceutical product for use according to claim 41, wherein said propane-1-sulfonic acid {3-[5-(4-chloro-phenyl)-1H-pyrrolo [2,3-b] pyridine-3-carbonyl]-2,4-difluoro-phenyl}-amide, or a pharmaceutically acceptable salt thereof, is administered twice daily in an amount of from about 850 mg to about 1050 mg; and said cetuximab is administered weekly with the first administration being in an amount of from about 400 mg/m^2 to about 500 mg/m^2 and each subsequent administration being in an amount of from about 200 mg/m^2 to about 300 mg/m^2.

~~13~~10. The pharmaceutical product for use according to claims ~~11~~ 8 and ~~12~~9, further comprising irinotecan, or a pharmaceutically acceptable salt thereof.

~~14~~11. The pharmaceutical product for use according to claim ~~13~~10, wherein said irinotecan, or a pharmaceutically acceptable salt thereof, is administered weekly in an amount of from about 50 mg/m^2 to about 200 mg/m^2.

~~15~~12. The pharmaceutical product for use according to claim ~~13~~10, wherein irinotecan, or a pharmaceutically acceptable salt thereof, is administered in a six week cycle at about 75 to about 175 mg/m^2 weekly for the first four weeks.

~~16~~13. The pharmaceutical product for use according to claim ~~13~~10, wherein irinotecan, or a pharmaceutically acceptable salt thereof, is administered once every three weeks at about 300 to about 400 mg/m^2; or once every two weeks at about 130 to about 230 mg/m^2.

~~17~~14. A pharmaceutical product comprising (A) a first component which comprises, as an active agent, Compound I or a pharmaceutically-acceptable salt thereof; and (B) a second component which comprises, as an active agent, erlotinib or a pharmaceutically acceptable salt thereof, as a combined preparation for simultaneous or sequential use in the treatment of ~~a proliferative disorder, in particular~~ cancer~~, more particularly colorectal cancer, melanoma, and thyroid cancer~~ comprising b-Raf having the V600E mutation, wherein

(A) is administered in an amount of from about 200 mg/day to about 3000 mg/day, from about 1000 mg/day to about 2500 mg/day, from about 1700 mg/day to about 2100 mg/day or about 1920 mg/day, and

(B) is administered in an amount of from about 20 mg/day to about 500 mg/day, from about 100 mg/day to about 400 mg/day, or from about 100 mg/day to about 200 mg/day.

~~18~~15. A pharmaceutical product comprising (A) a first component which comprises, as an active agent, Compound I, or a pharmaceutically-acceptable salt thereof; and (B) a second component which comprises, as an active agent, cetuximab; as a combined preparation for simultaneous or sequential use in the treatment of ~~a proliferative disorder~~cancer comprising b-Raf having the V600E mutation, wherein

(A) is administered in an amount of from about 200 mg/day to about 3000 mg/day, from about 1000 mg/day to about 2500 mg/day, from about 1700 mg/day to about 2100 mg/day or about 1920 mg/day; and

(B) is administered in an amount of from about 50 mg/m^2/week to about 700 mg/m^2/week, from about 100 mg/m^2/week to about 600 mg/m^2/week, or from about 200 mg/m^2/week to about 500 mg/m^2/week.

~~19~~16. A pharmaceutical product comprising (A) a first component which comprises, as an active agent, Compound I or a pharmaceutically-acceptable salt thereof; (B) a second component which comprises, as an active agent, cetuximab; and (C) a third component which comprises, as an active agent, irinotecan or a pharmaceutically-acceptable salt thereof; as a combined preparation for simultaneous or sequential use in the treatment of ~~a proliferative disorder~~cancer comprising b-Raf having the V600E mutation, wherein

(A) is administered in an amount of from about 200 mg/day to about 3000 mg/day, from about 1000 mg/day to about 2500 mg/day, from about 1700 mg/day to about 2100 mg/day or about 1920 mg/day;

(B) is administered in an amount of from about 50 mg/m^2/week to about 700 mg/m^2/week, from about 100 mg/m^2/week to about 600 mg/m^2/week, or from about 200 mg/m^2/week to about 500 mg/m^2/week; and

(C) is administered in an amount of from about 1 to about 250 mg/m^2/week, about 50 to about 200 mg/m^2/week, or about 125 mg/m^2/week.

~~20~~17. The use of propane-1-sulfonic acid {3-[5-(4-chloro-phenyl)-1H-pyrrolo [2,3-b] pyridine-3-carbonyl]-2,4-difluoro-phenyl}-amide , or a pharmaceutically-acceptable salt thereof, and an EGFR inhibitor for the manufacture of medicaments for the treatment of ~~a proliferative disorder such as~~ cancer, ~~more particularly colorectal cancer, melanoma and thyroid cancer which all comprise~~ comprising b-Raf having a V600 mutation, ~~in particular the V600E mutation~~wherein the EGFR inhibitor is selected from erlotinib or a pharmaceutically acceptable salt thereof, or cetuximab.

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