Claims

1. A combination comprising panobinostat, or a pharmaceutically acceptable salt thereof, and bortezomib for use in a method of treatment of multiple myeloma in a patient, where in the method when carried out comprises;

assaying a blood sample from the patient;

determining if the patient has no hepatic impairment or has mild, moderate or severe hepatic impairment; and

administering to the patient:

a starting dosage of 20 mg panobinostat if the patient has no or mild hepatic impairment;

a starting dosage of 10 mg of panobinostat if the patient has moderate hepatic impairment; and

not administering panobinostat if the patient has severe hepatic impairment;

wherein mild hepatic impairment is bilirubin ≤1x the upper limit of the normal range ("ULN") and aspartate aminotransferase ("AST") >1xULN, or bilirubin >1.0- ≤1.5x ULN and any amount of AST above ULN is present;

wherein moderate hepatic impairment is bilirubin >1.5x- ≤3.0x ULN and any amount of AST above ULN is present;

wherein severe hepatic impairment is bilirubin > 3.0x ULN and any amount of AST above ULN is present; and

wherein panobinostat, or a pharmaceutically acceptable salt thereof (e.g. the lactate or the anhydrous lactate salt thereof) is in the form of an oral dosage form.

2. Use of a combination comprising panobinostat, or a pharmaceutically acceptable salt thereof, and bortezomib in the manufacture of a medicament for the treatment of a human patient having multiple myeloma after assaying a blood sample from the patient; and determining if the patient has no hepatic impairment or has mild, moderate or severe hepatic impairment; and upon such an assessment, preparing:

a starting dosage of 20 mg of panobinostat which is to be administered if the patient has no hepatic impairment;

a starting dosage of 15 mg of panobinostat which is to be administered if the patient has mild hepatic impairment;

a starting dosage of 10 mg of panobinostat which is to be administered if the patient has moderate hepatic impairment; and

not administering panobinostat if the patient has severe hepatic impairment
wherein mild hepatic impairment is bilirubin ≤1x the upper limit of the normal range ("ULN") and aspartate aminotransferase ("AST") >1xULN, or bilirubin >1.0 to 1.5x ULN and any amount of AST above ULN is present);
wherein moderate hepatic impairment is bilirubin >1.5x to 3.0x ULN and any amount of AST above ULN is present;
wherein severe hepatic is bilirubin > 3.0x ULN and any amount of AST above ULN is present; and
wherein the term panobinostat is the molecule itself or a pharmaceutically acceptable salt thereof.

3. The use according to claim 2, wherein the use further comprises administering to the patient an effective dosage of dexamethasone once treatment begins.

4. The use according to claim 2 or 3, wherein the multiple myeloma is resistant or refractory to prior treatments.

5. The use according to any one of claims 2-4, wherein the dosage of bortezomib is 1.3 mg/m^2 is to be administered as an injection.

6. The use according to any one of claims 2-4, wherein the bortezomib is to be administered at a dosage of 0.7 mg/m^2 and wherein the patient has mild hepatic impairment.

7. The use according to any one of claims 2-6, wherein the prior treatments have been treatment with bortezomib or an immunomodulatory agent.

8. The use according to claim 7 wherein the prior treatments have included both bortezomib and an immunomodulatory agent.

9. The use according to claim 7, wherein the prior treatments were a chemotherapeutic agent.

10. Use of panobinostat in the manufacture of a medicament for the treatment of a human

patient having multiple myeloma after assaying a blood sample from the patient; and determining if the patient has no hepatic impairment or has mild, moderate or severe hepatic impairment; and upon such an assessment, preparing

a starting dosage of 20 mg of panobinostat which is to be administered if the patient has no hepatic impairment;

a starting dosage of 15 mg of panobinostat which is to be administered if the patient has mild hepatic impairment;

a starting dosage of 10 mg of panobinostat which is to be administered if the patient has moderate hepatic impairment; and

not administering panobinostat if the patient has severe hepatic impairment

wherein mild hepatic impairment is bilirubin ≤1x the upper limit of the normal range ("ULN") and aspartate aminotransferase ("AST") >1xULN, or bilirubin >1.0 to 1.5x ULN and any amount of AST above ULN is present);

wherein moderate hepatic impairment is bilirubin >1.5x to 3.0x ULN and any amount of AST above ULN is present;

wherein severe hepatic is bilirubin > 3.0x ULN and any amount of AST above ULN is present; and

wherein the term panobinostat is the molecule itself or a pharmaceutically acceptable salt thereof.

11. The use of claim 7, wherein the patient is also to be administered an effective dosage of dexamethasone.

12. The The use of claim 7, wherein the multiple myeloma is resistant or refractory to prior treatments.

13. The use of claim 10, wherein the prior treatments have been treatment with bortezomib or an immunomodulatory agent.

14. The use of claim 13., wherein the prior treatments have included both bortezomib and an immunomodulatory agent.

15. The use of claim 10, wherein the prior treatments included or consisted of treatment with a chemotherapeutic agent.

16. Panobinostat, for use in a method of treatment of multiple myeloma in a patient, where in the method when carried out comprises;

assaying a blood sample from the patient;

determining if the patient has no hepatic impairment or has mild, moderate or severe hepatic impairment; and

administering to the patient:

a starting dosage of 20 mg panobinostat if the patient has no or mild hepatic impairment;

a starting dosage of 10 mg of panobinostat if the patient has moderate hepatic impairment; and

not administering panobinostat if the patient has severe hepatic impairment;

wherein mild hepatic impairment is bilirubin ≤1x the upper limit of the normal range ("ULN") and aspartate aminotransferase ("AST") >1xULN, or bilirubin >1.0-≤1.5x ULN and any amount of AST above ULN is present;

wherein moderate hepatic impairment is bilirubin >1.5x- ≤3.0x ULN and any amount of AST above ULN is present;

wherein severe hepatic impairment is bilirubin > 3.0x ULN and any amount of AST above ULN is present; and

wherein the term panobinostat is the molecule itself or a pharmaceutically acceptable salt thereof.