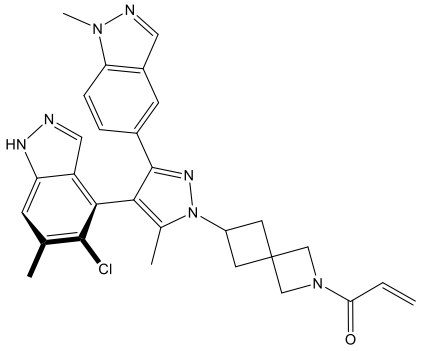
CLAIMS

1. A crystalline form of the compound, 1-{6-[(4*M*)-4-(5-chloro-6-methyl-1H-indazol-4-yl)-5-methyl-3-(1-methyl-1H-indazol-5-yl)-1H-pyrazol-1-yl]-2-azaspiro[3.3]heptan-2-yl}prop-2-en-1-one, of formula



(Compound A).

2. A crystalline form according to claim 1 which is selected from Hydrate HA, an alcohol solvate (e.g. an isopropyl alcohol solvate, an ethanol solvate, a methanol solvate, a propylene glycol solvate, a 1-butanol solvate, or an n-propanol solvate), Modification C, Hydrate HB, Hydrate C, and a lactic acid solvate form (e.g., Form G of the L-lactic acid solvate or Form F of L-lactic acid solvate).

3. A crystalline form according to claim 1, 2 or 3, which has an X-ray powder diffraction pattern substantially the same as the X-ray powder diffraction pattern shown in Figure 1, Figure 2, Figure 3, Figure 4, Figure 5, Figure 6, Figure 7, Figure 8, Figure 9, Figure 10, Figure 11, or Figure 12, when measured using CuKα radiation.

4. A crystalline form according to claim 1 or 2 or 3, which is in substantially pure form.

5. A crystalline form according to claim 1, 2, 3 or 4, which is Hydrate HA.

6. A crystalline form according to any one of claims 1 to 5, which has an X-ray powder diffraction pattern with at least one, two, three or four peaks having an angle of refraction 2θ values (CuKα λ=1.5418 Å) selected from the group consisting of 8.2°, 11.6°, 12.9° and 18.8°, measured at a temperature of about 25°C and an x-ray wavelength, λ, of 1.5418 Å.

7. A crystalline form according to claim 6, wherein the X-ray powder diffraction pattern further contains at least one, two, three, four or five peaks having an angle of refraction 2θ values (CuKα λ=1.5418 Å) selected from the group consisting of 12.1°, 14.6°, 16.2°, 20.4° and 24.1°, measured at a temperature of about 25°C and an x-ray wavelength, λ, of 1.5418 Å.

8. The crystalline Hydrate HA of the compound according to claim 1, 2 or 3, which has an X-ray powder diffraction pattern substantially the same as the X-ray powder diffraction pattern shown in Figure 1 when measured using CuKα radiation.

9. A process for the preparation of crystalline form Hydrate HA of Compound A comprising the steps:

(i) suspending Compound A in an alcohol to form the corresponding alcoholic solvate of Compound A in crystalline form;

(ii) separating at least a part of the crystals obtained from the mother liquor;

(iii) optionally washing the isolated crystals; and

(iv) drying the separated crystals (optionally drying under reduced pressure) in a humid atmosphere to form Hydrate HA crystalline form.

10. A process according to claim 9, wherein the alcoholic solvent is selected from methanol, ethanol, 2-propanol, propylene glycol, n-propanol and 1-bultanol, and combinations thereof.

11. A process according to claim 9 or 10, wherein drying is carried out at a relative humidity of below 90%.

12. The use of an alcoholic solvate of Compound A in a process for the preparation of Hydrate HA of Compound A.

13. A crystalline form according to claim 1, 2, 3 or 4, which is Modification C.

14. A crystalline form according to any one of claims 1 to 4, or claim 13, which has an X-ray powder diffraction pattern with at least one, two, three or four peaks having an angle of refraction 2θ values (CuKα λ=1.5418 Å) selected from the group consisting of 6.1°, 12.2°, 16.3°, and 19.4°, measured at a temperature of about 25°C and an x-ray wavelength, λ, of 1.5418 Å.

15. A crystalline form according to claim 14, wherein the X-ray powder diffraction pattern further contains at least one, two, three, four, five, six, seven or eight, or all peaks having an angle of refraction 2θ values (CuKα λ=1.5418 Å) selected from the group consisting of 7.3°, 8.8°, 14.7°, 15.4°, 18.2°, 20.8°, 21.8°, 25.4° and 29.4°, measured at a temperature of about 25°C and an x-ray wavelength, λ, of 1.5418 Å.

16. The crystalline Modification C of the compound according to claim 13, 14 or 15, which has an X-ray powder diffraction pattern substantially the same as the X-ray powder diffraction pattern shown in Figure 8 when measured using CuKα radiation.

17. A crystalline form according to claim 1 which is an alcoholic solvate, optionally wherein the solvate is an isopropyl alcohol solvate, an ethanol solvate, a methanol solvate, a propylene glycol solvate, a 1-butanol solvate, or an n-propanol solvate.

18. A crystalline form of claim 1 which is a lactic solvate form (e.g., an L-lactic acid solvate) of Compound A, optionally wherein the lactic acid solvate is Form G of the L-lactic acid solvate or Form F of L-lactic acid solvate.

19. A pharmaceutical composition comprising a crystalline form according to any one of claims 1 to 8, or any one of claims 13 to 18, and at least one pharmaceutically acceptable carrier or diluent.

20. A crystalline form according to any one of claims 1 to 8, or any one of claims 13 to 18, for use as a medicament.

21. A crystalline form according to any one of claims 1 to 8, or any one of claims 13 to 18, for use in the treatment of cancer, especially for KRAS G12C mutant cancer.

22. A crystalline form according to any one of claims 1 to 8, or any one of claims 13 to 18, wherein the cancer is a cancer or tumor which is selected from the group consisting of lung cancer (including lung adenocarcinoma, non-small cell lung cancer and squamous cell lung cancer), colorectal cancer (including colorectal adenocarcinoma), pancreatic cancer (including pancreatic adenocarcinoma), uterine cancer (including uterine endometrial cancer), rectal cancer (including rectal adenocarcinoma), appendiceal cancer, small-bowel cancer, esophageal cancer, hepatobiliary cancer (including liver cancer and bile duct carcinoma), bladder cancer, ovarian cancer and a solid tumor, particularly when the cancer or tumor harbors a KRAS G12C mutation.

23. Use of a compound according to any one of claims 1 to 8, or any one of claims 13 to 18, for the manufacture of a medicament for the treatment of cancer.

24. Use according to claim 23, wherein the cancer is a cancer or tumor which is selected from the group consisting of lung cancer (including lung adenocarcinoma, non-small cell lung cancer and squamous cell lung cancer), colorectal cancer (including colorectal adenocarcinoma), pancreatic cancer (including pancreatic adenocarcinoma), uterine cancer (including uterine

endometrial cancer), rectal cancer (including rectal adenocarcinoma), appendiceal cancer, small-bowel cancer, esophageal cancer, hepatobiliary cancer (including liver cancer and bile duct carcinoma), bladder cancer, ovarian cancer and a solid tumor, particularly when the cancer or tumor harbors a KRAS G12C mutation.