FORM 2

THE PATENTS ACT, 1970
(39 of 1970)
AND
THE PATENTS RULES, 2003

COMPLETE SPECIFICATION

(See Section 10; rule 13)

TITLE OF THE INVENTION

"PHARMACEUTICAL COMPOSITIONS OF 7-(6-(2-HYDROXYPROPAN-2-YL)PYRIDIN-3-YL)-1-((TRANS)-4-METHOXYCYCLOHEXYL)-3,4-DIHYDROPYRAZINO[2,3-B] PYRAZIN-2(1H)-ONE, A SOLID FORM THEREOF AND METHODS OF THEIR USE "

APPLICANT

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The following specification particularly describes
the invention and the manner in which
it is to be performed

CLAIMS

What is claimed is:

1. A pharmaceutical composition comprising an effective amount of 7-(6-(2-hydroxypropan-2-yl)pyridin-3-yl)-1-((*trans*)-4-methoxycyclohexyl)-3,4-dihydropyrazino[2,3-*b*]pyrazin-2(1*H*)-one, or a pharmaceutically acceptable salt, isotopologue, metabolite or solid form thereof, stearic acid and lactose monohydrate.

2. The pharmaceutical composition of claim 1, comprising about 0.1-5% by weight of stearic acid.

3. The pharmaceutical composition of claim 2, comprising about 0.4% by weight of stearic acid.

4. The pharmaceutical composition of claim 1, comprising about 40-60% by weight of lactose monohydrate.

5. The pharmaceutical composition of claim 4, comprising about 49.2% by weight of lactose monohydrate.

6. The pharmaceutical composition of claim 1, further comprising microcrystalline cellulose.

7. The pharmaceutical composition of claim 6, wherein the microcrystalline cellulose is AVICEL PH 102®.

8. The pharmaceutical composition of claim 7, comprising about 20-40% by weight of AVICEL PH 102®.

9. The pharmaceutical composition of claim 8, comprising about 31% by weight of AVICEL PH 102®.

10. The pharmaceutical composition of claim 1, further comprising a disintegrant.

11. The pharmaceutical composition of claim 10, wherein the disintegrant is croscarmellose sodium.

12. The pharmaceutical composition of claim 10, wherein the disintegrant is AC-DI-SOL®.

13. The pharmaceutical composition of claim 12, wherein the pharmaceutical composition comprises from about 1-5% by weight of AC-DI-SOL®.

14. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises about 40-60% by weight of 7-(6-(2-hydroxypropan-2-yl)pyridin-3-yl)-1-((*trans*)-4-methoxycyclohexyl)-3,4-dihydropyrazino[2,3-*b*]pyrazin-2(1*H*)-one, or a pharmaceutically acceptable salt, isotopologue, or solid form thereof.

15. The pharmaceutical composition of claim 14, wherein the pharmaceutical composition comprises about 15% by weight of 7-(6-(2-hydroxypropan-2-yl)pyridin-3-yl)-1-((*trans*)-4-methoxycyclohexyl)-3,4-dihydropyrazino[2,3-*b*]pyrazin-2(1*H*)-one or a pharmaceutically acceptable salt, isotopologue, or solid form thereof.

16. The pharmaceutical composition of claim 15, wherein the pharmaceutical composition comprises Form A of 7-(6-(2-hydroxypropan-2-yl)pyridin-3-yl)-1-((*trans*)-4-methoxycyclohexyl)-3,4-dihydropyrazino[2,3-*b*]pyrazin-2(1*H*)-one.

17. The pharmaceutical composition of claim 1, further comprising magnesium stearate.

18. The pharmaceutical composition of claim 17, wherein the pharmaceutical composition comprises from about 0.5-3% by weight of magnesium stearate.

19. The pharmaceutical composition of claim 18, wherein the pharmaceutical composition comprises from about 1% by weight of magnesium stearate.

20. The pharmaceutical composition of any claim 1, wherein the pharmaceutical composition is formulated as a tablet.

21. The pharmaceutical composition of claim 20, wherein the tablet is film coated.

22. The pharmaceutical composition of claim 21, wherein the film coating is about 4% by weight of the tablet.

23. A method for treating or preventing cancer, an inflammatory condition, an immunological condition, a neurodegenerative disease, diabete, obesity, a neurological disorder, an age-related disease, a cardiovascular condition, or a conditions treatable or preventable by inhibition of a kinase pathway, comprising administering an effective amount of a pharmaceutical composition of claim 1 to a subject in need thereof.

24. The method of claim 23, wherein the kinase pathway is the TOR kinase pathway.

25. A method for achieving a Response Evaluation Criteria in Solid Tumors (RECIST 1.1) of complete response, partial response or stable disease in a subject comprising

administering an effective amount of a pharmaceutical composition of claim 1 to a subject having a solid tumor.

26. A method for improving International Workshop Criteria (IWC) for NHL, International Uniform Response Criteria for Multiple Myeloma (IURC), Eastern Cooperative Oncology Group Performance Status (ECOG) or Response Assessment for Neuro-Oncology (RANO) Working Group for GBM, comprising administering an effective amount of a pharmaceutical composition of claim 1 to a subject in need thereof.

27. Solid Form A of 7-(6-(2-hydroxypropan-2-yl)pyridin-3-yl)-1-((trans)-4-methoxycyclohexyl)-3,4-dihydropyrazino[2,3-b]pyrazin-2(1H)-one.

28. The solid Form A of claim 27, having an X-ray powder diffraction pattern with one or more peaks expressed in two-theta at approximately 8.3, 13.2, 18.2 or 21.7 degrees.

29. The solid Form A of claim 28, having a DSC thermogram with an endotherm at a peak temperature of about 199 °C.

30. The solid Form A of claim 29, having less than about 0.1% weight loss between about 25 °C to about 100 °C in a thermogravimetric thermogram.

31. The solid Form A of claim 30, wherein Form A is anhydrous.

32. The solid Form A of claim 31, wherein Form A is substantially pure.

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