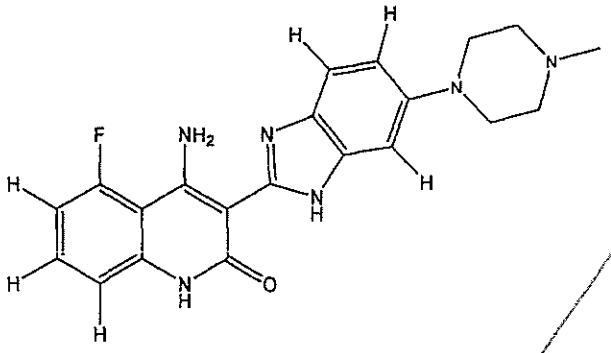
CLAIMS

1. A solid formulation of a lactic acid salt of the compound of formula I:



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for oral administration wherein said formulation comprises a non-hydrate crystalline form of said lactic acid salt of the compound of formula I.

2. The formulation of claim 1 wherein said non-hydrate crystalline form is Form A.

3. The formulation of claim 2 wherein said Form A is prepared by stirring the compound of formula I in a solution comprising water, organic solvent and lactic acid.

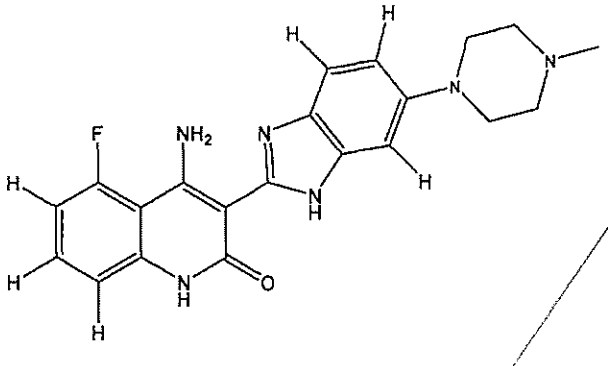
4. The formulation of claim 3 wherein said organic solvent is an alcohol.

5. The formulation of claim 4 wherein said alcohol is ethanol.

6. The formulation of claim 1 wherein said lactic acid salt of formula I is a mono-lactic acid salt.

7. The formulation of claim 1 in the form of a powder.

8. A solid formulation of a lactic acid salt of a compound of formula I:

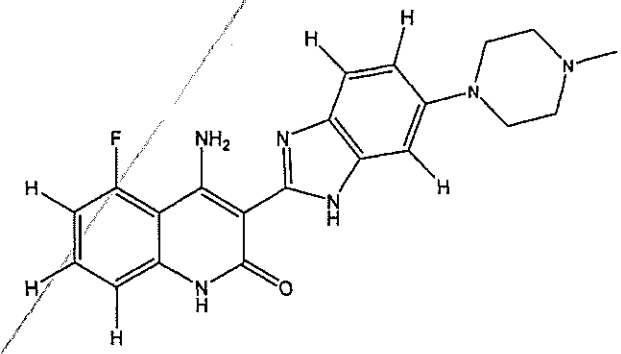


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wherein said formulation comprises a non-hydrate crystalline form of said lactic acid salt of the compound of formula I for use in therapy.

9. The use of claim 8 wherein said non-hydrate crystalline form is Form A.

10. The use of a solid formulation of a lactic acid salt of a compound of formula I:



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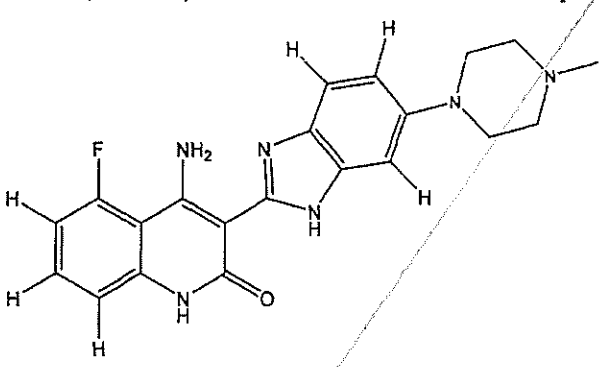
wherein said formulation comprises a non-hydrate crystalline form of said lactic acid salt of the compound of formula I in the manufacture of a medicament for the treatment of cancer.

11. The use of claim 10 wherein said non-hydrate crystalline form is Form A.

12. The use of claim 10 wherein said cancer is multiple myeloma (MM), acute myelogenous leukemia (AML), prostate cancer, breast cancer, colon cancer, or melanoma.

13. The formulation of claim 1 wherein said formulation is prepared in the form of a pill, tablet, capsule, or a caplet.

14. A crystalline form (Form A) of a lactic acid salt of the compound of formula I:



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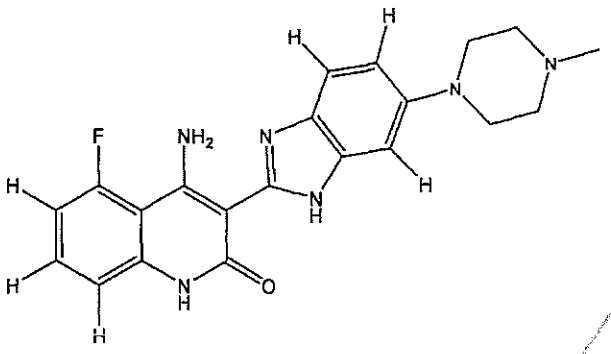
wherein said crystalline form has an X-ray powder diffraction pattern comprising characteristic peaks, in terms of 2θ, at about 5.7° and about 25.9°.

15. The crystalline form of claim 14 further having a characteristic peak, in terms of 2θ, at about 15.9°.

16. The crystalline form of claim 15 further having a characteristic peak, in terms of 2θ, at about 12.4°.

17. The crystalline form of claim 16 further having a characteristic peak, in terms of 2θ, at about 17.0°.

18. A crystalline form (Form A) of a lactic acid salt of the compound of formula I:



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wherein said crystalline form, has an X-ray powder diffraction pattern comprising at least 3 characteristic peaks, in terms of 2θ, selected from at about 5.7, about 11.3, about 12.4, about 15.3, about 15.9, about 17.0, about 19.1, about 19.7, about 20.5, about 20.9, about 22.8, about 23.4, about 23.7, about 24.7, about 25.0, about 25.9, about 26.9, and about 31.2 degrees.

19. The crystalline form of claim 14 having an X-ray powder diffraction pattern substantially as shown in Figure 1.

20. The crystalline form of claim 14 having a differential scanning calorimetry thermogram showing an endotherm at about 210 °C.

21. The crystalline form of claim 14 having a differential scanning calorimetry thermogram substantially as shown in Figure 2.

22. A composition comprising the crystalline form of claim 14.

23. The composition of claim 22 wherein at least about 50%, by weight of total lactic acid salt of the compound of formula I in said composition is present as said crystal form.

24. The composition of claim 22 wherein at least about 70% by weight of total lactic acid salt of the compound of formula I in said composition is present as said crystal form.

25. The composition of claim 22 wherein at least about 80% by weight of total lactic acid salt of the compound of formula I in said composition is present as said crystal form.

26. The composition of claim 22 wherein at least about 90% by weight of total lactic acid salt of the compound of formula I in said composition is present as said crystal form.

27. The composition of claim 22 wherein at least about 95% by weight of total lactic acid salt of the compound of formula I in said composition is present as said crystal form.

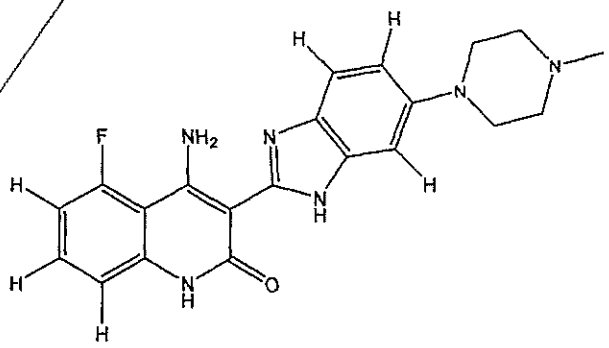
28. The composition of claim 22 wherein at least about 97% by weight of total lactic acid salt of the compound of formula I in said composition is present as said crystal form.

29. The composition of claim 22 wherein at least about 98% by weight of total lactic acid salt of the compound of formula I in said composition is present as said crystal form.

30. The composition of claim 22 wherein at least about 99% by weight of total lactic acid salt of the compound of formula I in said composition is present as said crystal form.

31. The composition of claim 22 further comprising a pharmaceutically acceptable carrier.

32. A composition consisting essentially of the lactic acid salt of the compound of formula I :




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wherein at least 95% by weight of said lactic acid salt of the compound of formula I is present in said composition as said crystal form of claim 14.

33. A composition consisting essentially of said lactic acid salt of the compound of formula I wherein at least 97% by weight of said lactic acid salt of the compound of formula I is present in said composition as said crystal form of claim 14.

34. A composition consisting essentially of said lactic acid salt of the compound of formula I wherein at least 98% by weight of said lactic acid salt of the compound of formula I is present in said composition as said crystal form of claim 14.

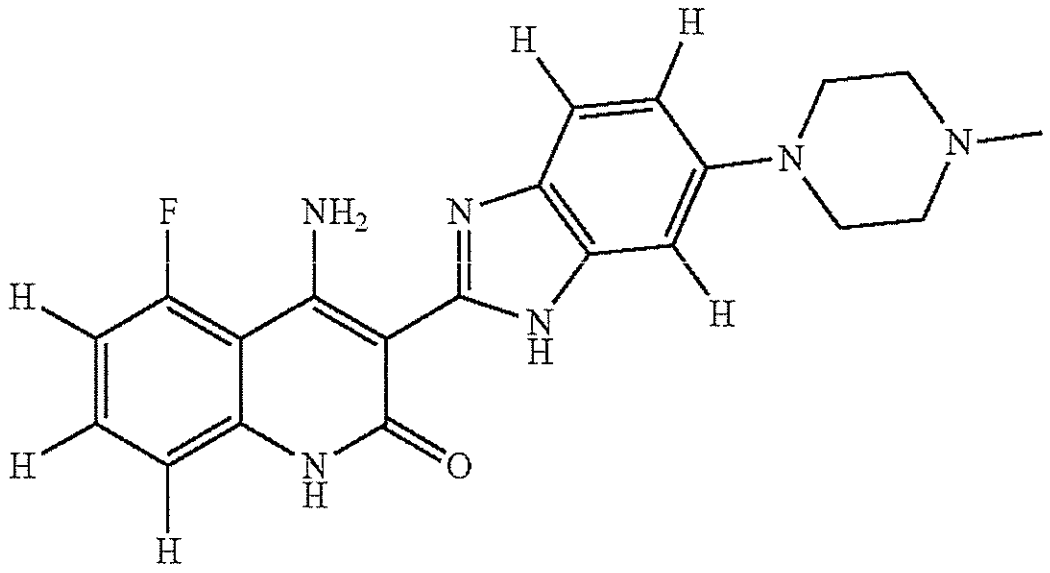
35. A composition consisting essentially of said lactic acid salt of the compound of formula I wherein at least 99% by weight of said lactic acid salt of the compound of formula I is present in said composition as said crystal form of claim 14.

36. A method of preparing the crystalline form of claim 14 comprising stirring the compound of formula I in a solution comprising water, organic solvent and lactic acid.

What is claimed is:

**1**. Crystalline hydrate Form B of a lactic acid salt of a compound of Formula I or a tautomer thereof:

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having

an X-ray powder diffraction pattern comprising characteristic peaks, in terms of 2θ at substantially 10.2, substantially 11.3, substantially 11.6, substantially 11.9, substantially 12.9, substantially 15.3, substantially 15.6, substantially 16.1, substantially 17.6, substantially 18.5, substantially 19.3, substantially 22.3, substantially 23.3, substantially 23.5, substantially 23.9, substantially 26.0, substantially 28.2, substantially 29.3, substantially 29.8, substantially 30.7, substantially 32.2, substantially 32.6, substantially 33.1 and substantially 34.3 degrees.

**2**. The crystalline form of claim **1**, which is a mono-lactic acid.

**3**. The crystalline form of claim **1**, having a differential scanning calorimetry thermogram comprising an endotherm at about 155° C.

**4**. A composition comprising the crystalline form of claim **1**.

**5**. A composition comprising at least 50% by weight of the crystalline form of claim **1**.

**6**. A composition comprising at least 70% by weight of the crystalline form of claim **1**.

**7**. A composition comprising at least 80% by weight of the crystalline form of claim **1**.

**8**. A composition comprising at least 90% by weight of the crystalline form of claim **1**.

**9**. A composition composing at least 95% by weight of the crystalline form of claim **1**.

**10**. A composition comprising at least 99% by weight of the crystalline form of claim **1**.

**11**. The composition of claim **4**, further comprising a pharmaceutically acceptable carrier.

**12**. A solid formulation for oral administration comprising the crystalline hydrate form of claim **1**.

**13**. The formulation of claim **12** in the form of a powder.

**14**. The formulation of claim **12** wherein said crystalline form remains substantially intact under ambient conditions for a period greater than about 38 hours.

**15**. The formulation of claim **12** wherein said crystalline hydrate form remains substantially intact under ambient conditions for a period greater than about 1 week.

**16**. The formation of claim **12** wherein said crystalline hydrate form remains substantially intact under ambient conditions for a period greater than about 1 month.

**17**. The formulation of claim **12** wherein said crystalline hydrate form remains substantially intact under ambient conditions for a period greater than about 6 months.

**18**. The formulation of claim **12** wherein said crystalline hydrate form remains substantially intact under ambient conditions for a period greater than about 1 year.

**19**. A dosage form comprising a formulation according to claim **12**.

**20**. The dosage form of claim **19**, wherein said dosage form is a powder, pill, tablet, capsule, caplet pellets, or granules.

**21**. A method for preparing the crystalline hydrate form of claim **1**, comprising suspending Form A in a solution comprising water and an organic solvent at a temperature of about 20° C. to about 60° C., wherein said water is present in said solution in an amount of about 5% to about 20% by volume, wherein Form A is a crystalline form of lactic acid salt of the compound of Formula I or a tautomer thereof, having an X-ray powder diffraction pattern comprising characteristic peaks, in terms of 2θ at about 5.7, about 11.3, about 12.4, about 15.3, about 15.9, about 17.0, about 19.1, about 19.7, about 20.5, about 20.9, about 22.8, about 23.4, about 23.7, about 24.7, about 25.0, about 25.9, about 26.9, and about 31.2 degrees.

**22**. The method of claim **21**, wherein said organic solvent comprises an alcohol, a ketone, an organic nitrile, or mixture thereof.

**23**. The method of claim **21**, wherein said organic solvent comprises one or more of ethanol, acetone, methyl ethyl ketone, acetonitrile.