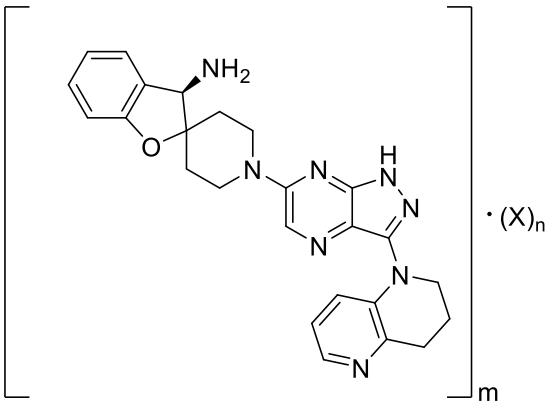
[0005b] In another aspect of the present disclosure, there is provided a compound of Formula (I)



(I),

or a solvatethereof;

wherein,

m is 1-9;

n is 1-3; and

X is selected from a group consisting of hydrochloric acid, hydrobromic acid, sulfuric acid, methane sulfonic acid, phosphoric acid, *p*-toluene sulfonic acid, benzene sulfonic acid, oxalic acid, L-aspartic acid, maleic acid, malonic acid, L-tartaric acid, fumaric acid, citric acid, succinic acid, and glutaric acid.

[0005c] In a further aspect of the present disclosure, there is provided a pharmaceutical composition comprising a solid form disclosed herein and a pharmaceutically acceptable carrier.

[0005d] In a further aspect of the present disclosure, there is provided a composition comprising the solid form disclosed herein, a composition comprising the compound

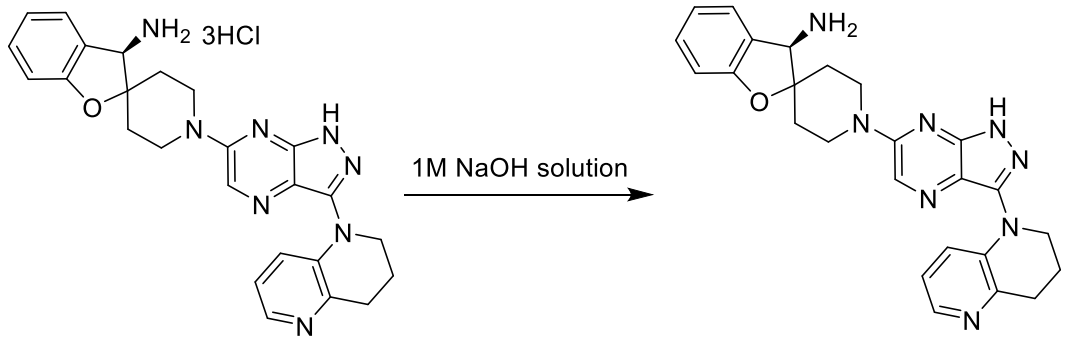
disclosed herein, or the pharmaceutical composition disclosed herein, for use in treating a disorder in a subject in need thereof.

[0005e] In another aspect of the present disclosure, there is provided a use of a composition comprising the solid form disclosed herein, a composition comprising the compound disclosed herein, or the pharmaceutical composition disclosed herein, in the manufacture of a medicament for treating a disorder in a subject in need thereof, wherein the disorder is Noonan syndrome, neutropenia, diabetes, neuroblastoma,
melanoma, acute myeloid leukemia, juvenile leukemia, juvenile myelomonocytic leukemia, breast cancer, lung cancer, or colorectal cancer.

[0005f] In a further aspect of the present disclosure, there is provided a kit comprising the solid form disclosed herein or a compound disclosed herein.

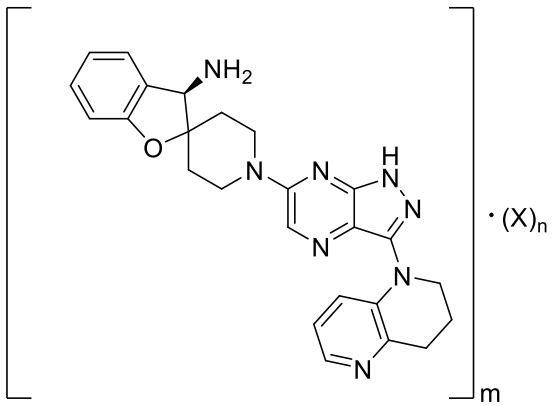
[0005g] In another aspect of the present disclosure, there is provided a process for preparing the crystalline form disclosed herein, comprising: a) preparing a solution of compound I-1 in a solvent comprising at least one of EtOH, ACN, MEK, EtOAc, IPAc, THF, MtBE, Toluene, 1,4 dioxane, and water; b) heating the solution to completely dissolve the compound I-1; c) adjusting the temperature so that solid precipitates out of the solution; and d) isolating the crystalline form of compound I-1.

[0005h] In a further aspect of the present disclosure, there is provided a process for preparing a compound of Formula I-1, the process comprising the step of neutralizing a compound of Formula I-3 with NaOH, thereby forming the compound of Formula I-1:



I-3 **I-1**

[0006] For example, provided herein is a compound of Formula (I)



(I),

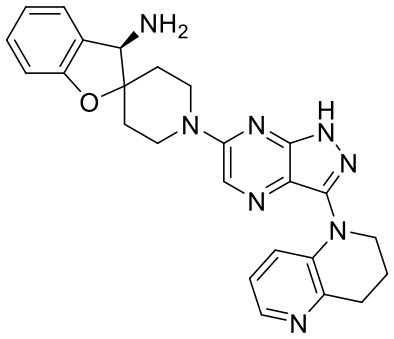
or a solvate thereof;

wherein,

CLAIMS

What is claimed:

1. A solid form of Compound I-1:



I-1,

or a solvate thereof.

2. The solid form of claim 1, wherein the solid form is amorphous.

3. The solid form of claim 1, wherein the solid form is crystalline.

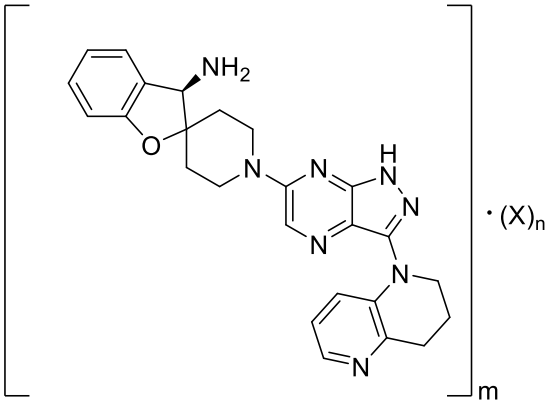
4. The solid form of claim 3, characterized by a powder X-ray diffraction pattern having at least two characteristic peaks, in degrees 2θ, each selected from the group consisting of 24.6 ± 0.5, 19.9 ± 0.5, and 16.0 ± 0.5 2θ.

5. The solid form of claim 3, characterized by a powder X-ray diffraction pattern with at least two characteristic peaks, in degrees 2θ, each selected from the group consisting of 24.6 ± 0.5 2θ, 19.9 ± 0.5 2θ, 16.0 ± 0.5 2θ, 6.7 ± 0.5 2θ, 12.8 ± 0.5 2θ, 13.4 ± 0.5 2θ, and 20.7 ± 0.5 2θ.

6. The solid form of claim 3, wherein the solid form is characterized by an XRPD pattern substantially similar to that depicted in FIG. 1A, or characterized by a X-ray powder diffraction pattern having peaks, in degrees 2θ, at 24.6 ± 0.5, 19.9 ± 0.5, 16.0 ± 0.5, 6.7 ± 0.5, 12.8 ± 0.5, 13.4 ± 0.5 and 20.7 ± 0.5.

7. The solid form of any one of claims 3-6, characterized by a differential scanning calorimetry (DSC) profile showing an endotherm with an onset of about 196 °C, and a peak of about 197 °C.

8. A compound of Formula (I)



(I),

or a solvate thereof;

wherein,

m is 1-9;

n is 1-3; and

X is selected from a group consisting of hydrochloric acid, hydrobromic acid, sulfuric acid, methane sulfonic acid, phosphoric acid, *p*-toluene sulfonic acid, benzene sulfonic acid, oxalic acid, L-aspartic acid, maleic acid, malonic acid, L-tartaric acid, fumaric acid, citric acid, succinic acid, and glutaric acid.

9. The compound of claim 8, wherein the compound is selected from the group consisting of a mono-hydrobromide salt of Formula (I), a bis-hydrobromide salt of Formula (I), a tris-hydrobromide salt of Formula (I), a mono-hydrochloride salt of Formula (I), a bis-hydrochloride salt of Formula (I), a tris- hydrochloride salt of Formula (I), a sulfuric acid salt of Formula (I), methane sulfonic acid salt of Formula (I), phosphoric acid salt of Formula (I), p-toluene sulfonic acid salt of Formula (I), benzene sulfonic acid salt of Formula (I), oxalic acid salt of Formula (I), L-aspartic acid salt of Formula (I), maleic acid salt of Formula (I), malonic acid salt of Formula (I), L-tartaric acid salt of Formula (I), fumaric acid salt of Formula (I) , citric acid salt of Formula (I), succinic acid salt of Formula (I), and glutaric acid salt of Formula (I).

10. The compound of claim 8 or 9, wherein the compound is in solid form.

11. The compound of claim 8 or 9, wherein the compound is amorphous.

12. The compound of claim 8 or 9, wherein the compound is crystalline.

13. The compound of claim 12, wherein X is hydrochloric acid, m is 1 and n is 1-3.

14. The compound of claim 12, wherein X is sulfuric acid.

15. The compound of claim 12, wherein X is benzene sulfonic acid.

16. The compound of claim 12, wherein X is malonic acid.

17. The compound of claim 12, wherein X is glutaric acid.

18. A pharmaceutical composition comprising a solid form of any of claims 1-7 or a compound of any of claims 8-17 and a pharmaceutically acceptable carrier.

19. A composition comprising the solid form of any of claims 1-7, a composition comprising the compound of any of claims 8-17, or the pharmaceutical composition of claim 18, for use in treating a disorder in a subject in need thereof.

20. Use of a composition comprising the solid form of any of claims 1-7, a composition comprising the compound of any of claims 8-17, or the pharmaceutical composition of claim 18, in the manufacture of a medicament for treating a disorder in a subject in need thereof, wherein the disorder is Noonan syndrome, neutropenia, diabetes, neuroblastoma, melanoma, acute myeloid leukemia, juvenile leukemia, juvenile myelomonocytic leukemia, breast cancer, lung cancer, or colorectal cancer.

21. The composition for use of claim 19 or use of claim 20, wherein the composition is to be administered in combination with an antibody, an antibody-drug conjugate, an immunomodulator, or a histone deacetylase inhibitor.

22. A kit comprising the solid form of claim 1 or a compound of any of claims 1-7.

23. The kit of claim 22, further comprising written instructions describing preparation of a pharmaceutical composition suitable for administration to a patient from the solid form or compound.

24. The kit of claim 23, further comprising written instructions describing how to administer the resulting composition to the patient.

25. The kit of claim 22, further comprising a pharmaceutically acceptable excipient.

26. A process for preparing the crystalline form of claim 3, comprising: a) preparing a solution of compound I-1 in a solvent comprising at least one of EtOH, ACN, MEK, EtOAc, IPAc, THF, MtBE, Toluene, 1,4 dioxane and water; b) heating the solution to completely dissolve the compound I-1; c) adjusting the temperature so that solid precipitates out of the solution; and d) isolating the crystalline form of compound I-1.

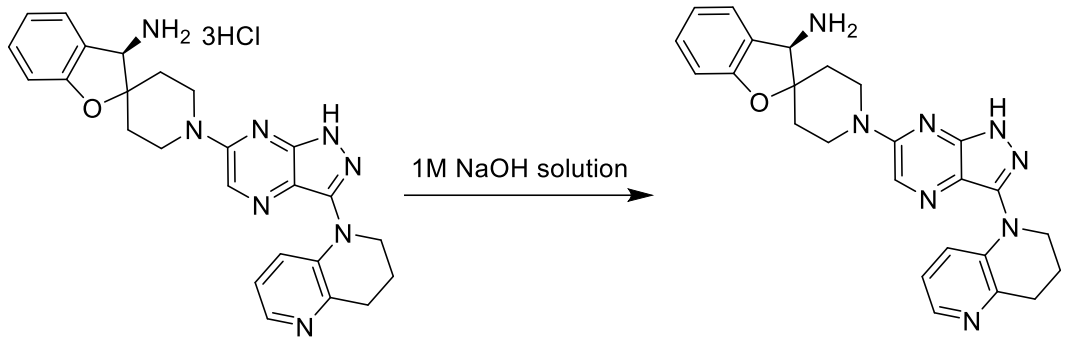
27. The process of claim 26, wherein the solvent is EtOH, ACN, EtOAc, IPAc, THF, MtBE, toluene, or 1,4 dioxane.

28. The process of claim 26, wherein the solvent comprises EtOH and water (9v/1v).

29. The process of claim 26, wherein heating the solution comprises heating the solution to about 50 ^{o}C.

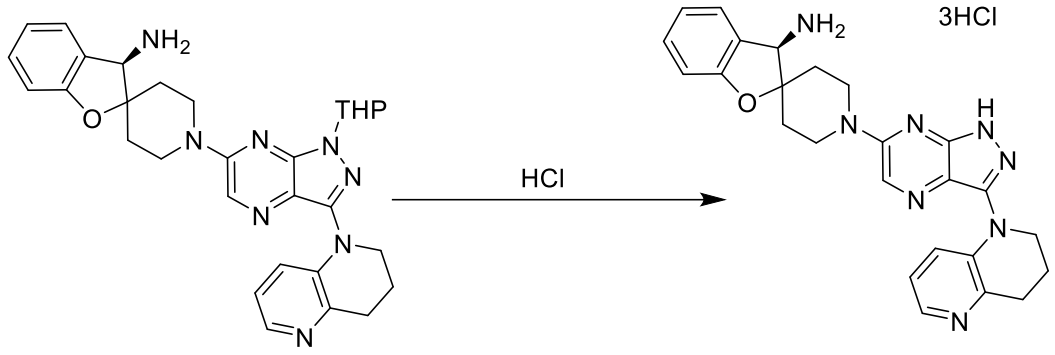
30. The process of claim 26, wherein adjusting the temperature comprises cooling the solution to about 5 ^{o}C.

31. A process for preparing a compound of Formula I-1, the process comprising the step of neutralizing a compound of Formula I-3 with NaOH, thereby forming the compound of Formula I-1:



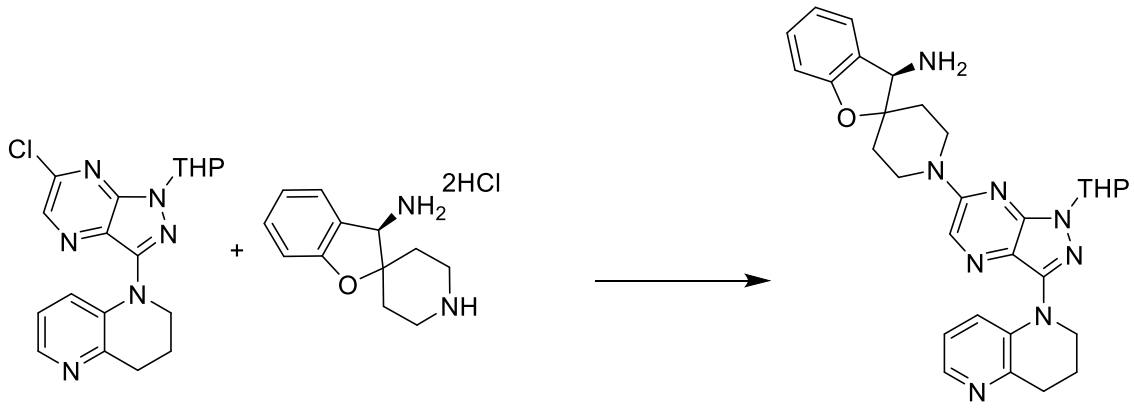
I-3 **I-1**

32. The process of claim 31, further comprising the step of reacting a compound of Formula 18 with HCl, thereby forming the compound of Formula I-3:



18 **I-3**

33. The process of claim 31 or 32, further comprising the step of coupling a compound of Formula 17 with compound of Formula 9, thereby forming the compound of Formula 18:



17 **9** **18**