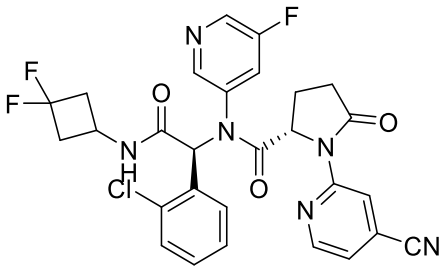


(I).

or a hydrate or solvate thereof. In one embodiment Form E is a solvated form. In another embodiment Form E is an isopropyl acetate solvate of a compound of Formula I.

[0013a] In one aspect, there is provided a solid state form E of a methyl isobutyl ketone (MIBK) solvate of a compound of formula (I), (ivosidenib) characterized by an x-ray powder diffraction pattern comprising five or more peaks chosen from 5.5 ± 0.2 °2θ, 6.1 ± 0.2 °2θ, 6.3 ± 0.2 °2θ, 7.6 ± 0.2 °2θ, 9.3 ± 0.2 °2θ, 9.4 ± 0.2 °2θ, 9.8 ± 0.2 °2θ, 11.2 ± 0.2 °2θ, 11.5 ± 0.2 °2θ, 11.6 ± 0.2 °2θ, 12.0 ± 0.2 °2θ, 13.2 ± 0.2 °2θ, 13.9 ± 0.2 °2θ, 14.3 ± 0.2 °2θ, 14.4 ± 0.2 °2θ, 15.0 ± 0.2 °2θ, 15.3 ± 0.2 °2θ, 15.7 ± 0.2 °2θ, 16.8 ± 0.2 °2θ, 17.1 ± 0.2 °2θ, 17.8 ± 0.2 °2θ, 17.9 ± 0.2 °2θ, 18.3 ± 0.2 °2θ, 18.8 ± 0.2 °2θ, 19.1 ± 0.2 °2θ, 19.3 ± 0.2 °2θ, 19.6 ± 0.2 °2θ, 19.9 ± 0.2 °2θ, 20.1 ± 0.2 °2θ, 20.2 ± 0.2 °2θ, 20.9 ± 0.2 °2θ, 21.0 ± 0.2 °2θ, 22.0 ± 0.2 °2θ, 22.5 ± 0.2 °2θ, 23.0 ± 0.2 °2θ, 23.6 ± 0.2 °2θ, 24.2 ± 0.2 °2θ, 24.5 ± 0.2 °2θ, 25.0 ± 0.2 °2θ, 25.3 ± 0.2 °2θ, 26.2 ± 0.2 °2θ, 27.6 ± 0.2 °2θ, 27.9 ± 0.2 °2θ, 28.3 ± 0.2 °2θ, 29.2 ± 0.2 °2θ, 29.8 ± 0.2 °2θ, 30.3 ± 0.2 °2θ, 30.8 ± 0.2 °2θ, 31.5 ± 0.2 °2θ, 32.5 ± 0.2 °2θ, 33.0 ± 0.2 °2θ, 34.1 ± 0.2 °2θ, 34.5 ± 0.2 °2θ and 34.8 ± 0.2 °2θ (Form E).

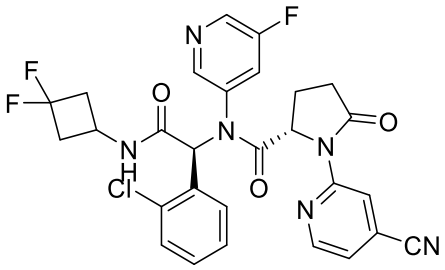
[0014] One embodiment of the present disclosure is Form G of a compound of formula (I):



(I).

or a hydrate or solvate thereof. In another embodiment Form G is a solvated or hydrated form of the compound of Formula I.

[0015] One embodiment of the present disclosure is Form M of a compound of formula (I):



(I).

or a hydrate or solvate thereof. In another embodiment Form M is an anhydrous form of the compound of Formula I.

[0015a] In another aspect, there is provided an anhydrous solid state form of a compound of formula (I) (ivosidenib) characterized by an x-ray powder diffraction pattern comprising five or more peaks chosen from 9.2 ± 0.2 °2θ, 10.1 ± 0.2 °2θ, 10.6 ± 0.2 °2θ, 11.4 ± 0.2 °2θ, 11.9 ± 0.2 °2θ, 12.5 ± 0.2 °2θ, 13.1 ± 0.2 °2θ, 13.4 ± 0.2 °2θ, 14.4 ± 0.2 °2θ, 15.3 ± 0.2 °2θ, 15.8 ± 0.2 °2θ, 17.2 ± 0.2 °2θ, 17.7 ± 0.2 °2θ, 17.8 ± 0.2 °2θ, 18.5 ± 0.2 °2θ, 19.5 ± 0.2 °2θ, 19.7 ± 0.2 °2θ, 19.9 ± 0.2 °2θ, 20.4 ± 0.2 °2θ, 20.9 ± 0.2 °2θ, 21.4 ± 0.2 °2θ, 22.0 ± 0.2 °2θ, 22.2 ± 0.2 °2θ, 22.9 ± 0.2 °2θ, 23.2 ± 0.2 °2θ, 24.6 ± 0.2 °2θ, 24.7 ± 0.2 °2θ, 25.0 ± 0.2 °2θ, 25.8 ± 0.2 °2θ, 26.2 ± 0.2 °2θ, 26.6 ± 0.2 °2θ, 27.0 ± 0.2 °2θ, 27.3 ± 0.2 °2θ, 27.8 ± 0.2 °2θ, 29.1 ± 0.2 °2θ, 29.7 ± 0.2 °2θ, 30.3 ± 0.2 °2θ, 31.3 ± 0.2 °2θ, 31.9 ± 0.2 °2θ, 33.1 ± 0.2 °2θ, 33.6 ± 0.2 °2θ, 33.8 ± 0.2 °2θ and 34.6 ± 0.2 °2θ (Form M).

[0016] One embodiment of the present disclosure is a Form N of a compound of formula (I)

embodiment, the partially crystalline form is at least 10%, 20%, 30%, 40%, 50%, 60%, 70%, 75%, 80%, 85%, 87%, 88%, 89%, 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99%, 99.5%, or 99.9% crystalline form I. In another embodiment, the partially crystalline form is at least 10%, 20%, 30%, 40%, 50%, 60%, 70%, 75%, 80%, 85%, 87%, 88%, 89%, 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99%, 99.5%, or 99.9% crystalline form K.

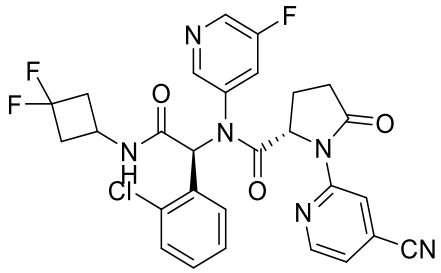
[0020] In another aspect, the present disclosure provides a process for making Form L of ivosidenib comprising making one or more meta-stable forms of ivosidenib in an anhydrous, hydrated, or solvated form, and allowing such one or more meta-stable form of ivosidenib to convert to Form L. One aspect provides a process where the one or more meta-stable form is selected from forms C, D, E, F, H, J, M, or N, each individually in an anhydrous, hydrated, or solvated form.

[0021] In another aspect, the present disclosure provides a pharmaceutical composition comprising ivosidenib in a mixture of two or more solid state forms chosen from Form L, Form B, Form A, Form C, Form D, Form E, Form F, Form G, Form H, Form I, Form J, Form K, Form M, and Form N, each individually in an anhydrous, hydrated, or solvated form. In one aspect, the pharmaceutical composition comprises no more than 0.15% (area% by HPLC) of a compound selected from: (i) 2-((2*S*)-2-((1-(2-chlorophenyl)-2-((3,3-difluorocyclobutyl)amino)-2-oxoethyl)(5-fluoropyridin-3-yl)carbamoyl)-5-oxopyrrolidin-1-yl)isonicotinamide; (ii) (*S*)-*N*-((S)-1-(2-chlorophenyl)-2-((3,3-difluorocyclobutyl)amino)-2-oxoethyl)-1-(4-cyanopyridin-2-yl)-5-oxo-*N*-(pyridin-3-yl)pyrrolidine-2-carboxamide; (iii) (*S*)-*N*-((*R*)-1-(2-Chlorophenyl)-2-((3,3-difluorocyclobutyl)amino)-2-oxoethyl)-1-(4-cyanopyridin-2-yl)-*N*-(5-fluoropyridin-3-yl)-5-oxopyrrolidine-2-carboxamide; (iv) (*R*)-*N*-((*S*)-1-(2-Chlorophenyl)-2-((3,3-difluorocyclobutyl)amino)-2-oxoethyl)-1-(4-cyanopyridin-2-yl)-*N*-(5-fluoropyridin-3-yl)-5-oxopyrrolidine-2-carboxamide; and (v) (*R*)-*N*-((*R*)-1-(2-Chlorophenyl)-2-((3,3-difluorocyclobutyl)amino)-2-oxoethyl)-1-(4-cyanopyridin-2-yl)-*N*-(5-fluoropyridin-3-yl)-5-oxopyrrolidine-2-carboxamide. In one aspect, the pharmaceutical composition comprises Form L together with one or more of Form B, Form A, Form C, Form D, Form E, Form F, Form G, Form H, Form I, Form J, Form K, Form M, and Form N, each individually in an anhydrous, hydrated, or solvated form. In another aspect, the pharmaceutical composition may optionally contain amorphous ivosidenib. In yet another aspect, the pharmaceutical composition comprises one or more forms of ivosidenib that are chosen from Form B, Form A, Form C, Form D, Form E, Form F, Form G, Form H, Form I, Form J, Form K, Form

CLAIMS

What is claimed is:

1. A solid state form E of a methyl isobutyl ketone (MIBK) solvate of a compound of formula (I):



(I).

(ivosidenib) characterized by an x-ray powder diffraction pattern comprising five or more peaks chosen from 5.5 ± 0.2 °2θ, 6.1 ± 0.2 °2θ, 6.3 ± 0.2 °2θ, 7.6 ± 0.2 °2θ, 9.3 ± 0.2 °2θ, 9.4 ± 0.2 °2θ, 9.8 ± 0.2 °2θ, 11.2 ± 0.2 °2θ, 11.5 ± 0.2 °2θ, 11.6 ± 0.2 °2θ, 12.0 ± 0.2 °2θ, 13.2 ± 0.2 °2θ, 13.9 ± 0.2 °2θ, 14.3 ± 0.2 °2θ, 14.4 ± 0.2 °2θ, 15.0 ± 0.2 °2θ, 15.3 ± 0.2 °2θ, 15.7 ± 0.2 °2θ, 16.8 ± 0.2 °2θ, 17.1 ± 0.2 °2θ, 17.8 ± 0.2 °2θ, 17.9 ± 0.2 °2θ, 18.3 ± 0.2 °2θ, 18.8 ± 0.2 °2θ, 19.1 ± 0.2 °2θ, 19.3 ± 0.2 °2θ, 19.6 ± 0.2 °2θ, 19.9 ± 0.2 °2θ, 20.1 ± 0.2 °2θ, 20.2 ± 0.2 °2θ, 20.9 ± 0.2 °2θ, 21.0 ± 0.2 °2θ, 22.0 ± 0.2 °2θ, 22.5 ± 0.2 °2θ, 23.0 ± 0.2 °2θ, 23.6 ± 0.2 °2θ, 24.2 ± 0.2 °2θ, 24.5 ± 0.2 °2θ, 25.0 ± 0.2 °2θ, 25.3 ± 0.2 °2θ, 26.2 ± 0.2 °2θ, 27.6 ± 0.2 °2θ, 27.9 ± 0.2 °2θ, 28.3 ± 0.2 °2θ, 29.2 ± 0.2 °2θ, 29.8 ± 0.2 °2θ, 30.3 ± 0.2 °2θ, 30.8 ± 0.2 °2θ, 31.5 ± 0.2 °2θ, 32.5 ± 0.2 °2θ, 33.0 ± 0.2 °2θ, 34.1 ± 0.2 °2θ, 34.5 ± 0.2 °2θ and 34.8 ± 0.2 °2θ (Form E).

2. The solid state form E of claim 1, wherein the solid state is characterized by an x-ray powder diffraction pattern comprising peaks at 6.3± 0.2 °2θ, 11.6± 0.2 °2θ, 12.0 ± 0.2 °2θ , 17.1 ± 0.2 °2θ, and 21.0 ± 0.2 °2θ.

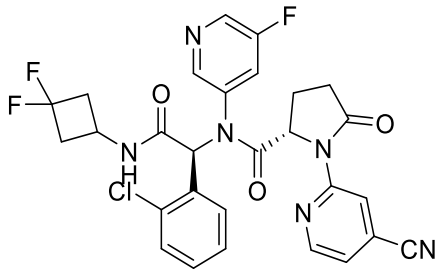
3. The solid state form E of claim 1, wherein the solid state is characterized by two or more of the following:

   (a) an x-ray powder diffraction pattern substantially corresponding to the pattern shown in Fig. 20;

   (b) a TGA and DSC profile substantially corresponding to those depicted in Fig. 21;

   (c) a ^{1}H NMR pattern substantially corresponding to the pattern shown in Fig. 22.

4. An anhydrous solid state form of a compound of formula (I):



(I).

(ivosidenib) characterized by an x-ray powder diffraction pattern comprising five or more peaks chosen from 9.2 ± 0.2 °2θ, 10.1 ± 0.2 °2θ, 10.6 ± 0.2 °2θ, 11.4 ± 0.2 °2θ, 11.9 ± 0.2 °2θ, 12.5 ± 0.2 °2θ, 13.1 ± 0.2 °2θ, 13.4 ± 0.2 °2θ, 14.4 ± 0.2 °2θ, 15.3 ± 0.2 °2θ, 15.8 ± 0.2 °2θ, 17.2 ± 0.2 °2θ, 17.7 ± 0.2 °2θ, 17.8 ± 0.2 °2θ, 18.5 ± 0.2 °2θ, 19.5 ± 0.2 °2θ, 19.7 ± 0.2 °2θ, 19.9 ± 0.2 °2θ, 20.4 ± 0.2 °2θ, 20.9 ± 0.2 °2θ, 21.4 ± 0.2 °2θ, 22.0 ± 0.2 °2θ, 22.2 ± 0.2 °2θ, 22.9 ± 0.2 °2θ, 23.2 ± 0.2 °2θ, 24.6 ± 0.2 °2θ, 24.7 ± 0.2 °2θ, 25.0 ± 0.2 °2θ, 25.8 ± 0.2 °2θ, 26.2 ± 0.2 °2θ, 26.6 ± 0.2 °2θ, 27.0 ± 0.2 °2θ, 27.3 ± 0.2 °2θ, 27.8 ± 0.2 °2θ, 29.1 ± 0.2 °2θ, 29.7 ± 0.2 °2θ, 30.3 ± 0.2 °2θ, 31.3 ± 0.2 °2θ, 31.9 ± 0.2 °2θ, 33.1 ± 0.2 °2θ, 33.6 ± 0.2 °2θ, 33.8 ± 0.2 °2θ and 34.6 ± 0.2 °2θ (Form M).

5. The solid state form M of claim 4, wherein the solid state is characterized by an x-ray powder diffraction pattern comprising peaks at 11.4 ± 0.2 °2θ, 17.7 ± 0.2 °2θ, 17.8 ± 0.2 °2θ, 19.7 ± 0.2 °2θ, and 21.4 ± 0.2 °2θ.

6. The solid state form M of claim 4, wherein the solid state is characterized by one or more of the following:

(a) an x-ray powder diffraction pattern substantially corresponding to the pattern shown in Fig. 1 for Form M;

(b) a TGA/DTA profile substantially corresponding to those depicted in Fig. 9;

(c) a DSC profile substantially corresponding to that shown in Fig. 10.