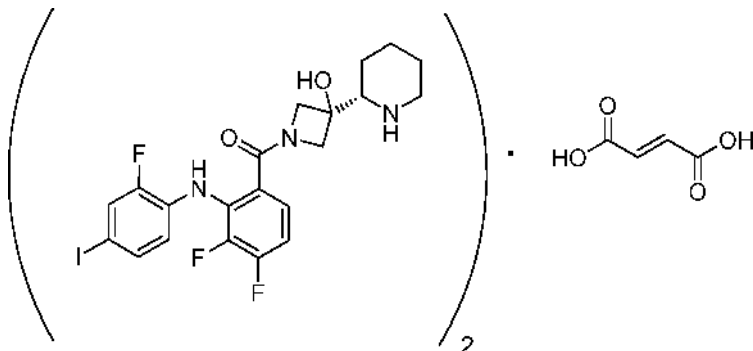


CLAIMS

What is claimed is:

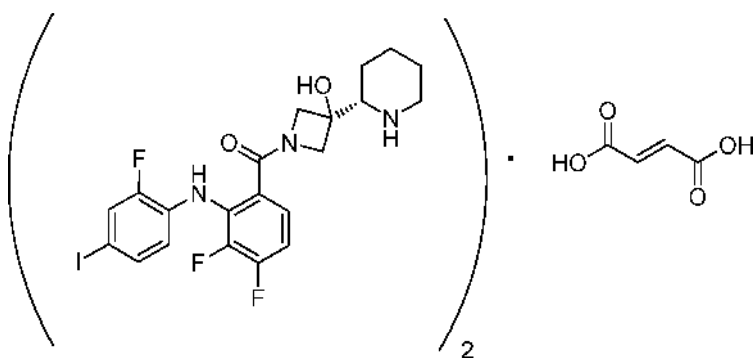
1. A crystalline fumarate salt of Compound I, wherein Compound I is (S)-[3,4-difluoro-2-(2-fluoro-4-iodophenylamino)phenyl] [3-hydroxy-3-(piperidin-2-yl) azetidin-1-yl]-methanone having the formula:



wherein the crystalline fumarate salt is designated as Form A, and

wherein said salt is characterized by a powder x-ray diffraction pattern (CuK α $\lambda=1.5418$ Å) comprising three or more 2θ values selected from 4.6, 12.1, 13.2, 13.6 and 14.5 ± 0.2 ° 2θ , wherein measurement of the crystalline form is at room temperature.

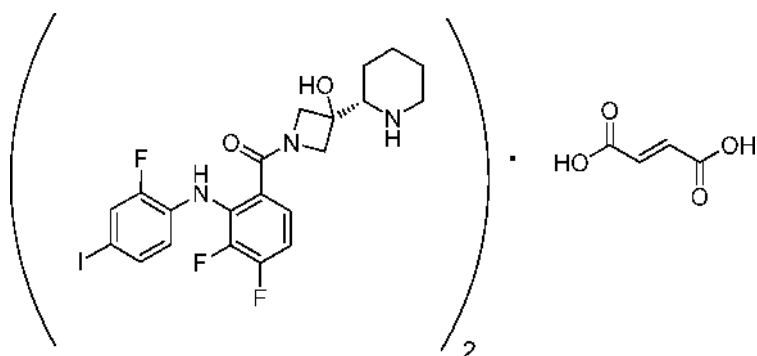
2. A crystalline fumarate salt of Compound I, wherein Compound I is (S)-[3,4-difluoro-2-(2-fluoro-4-iodophenylamino)phenyl] [3-hydroxy-3-(piperidin-2-yl) azetidin-1-yl]-methanone having the formula:



wherein the crystalline fumarate salt is designated as Form A, and

wherein said salt is characterized by a powder x-ray diffraction pattern substantially in accordance with the pattern shown in FIG. 10.

3. A crystalline fumarate salt of Compound I, wherein Compound I is (S)-[3,4-difluoro-2-(2-fluoro-4-iodophenylamino)phenyl] [3-hydroxy-3-(piperidin-2-yl) azetidin-1-yl]-methanone having the formula:



wherein the crystalline fumarate salt is designated as Form A, and

wherein said salt is characterized by a powder x-ray diffraction pattern ($\text{CuK}\alpha$ $\lambda=1.5418\text{\AA}$) comprising the 2θ values, $\pm 0.2^\circ 2\theta$, of the following table:

2-θ Values for Form A (± 0.20)
4.6
12.1
13.2
13.8
14.5
16.3
16.6
17.8
18.5
19.7
21.1
22.6
23.0
23.3
24.5

wherein measurement of the crystalline form is at room temperature.

4. The crystalline fumarate salt of Compound I of any one of claims 1-3, wherein said salt is at least 90 weight % Form A, based on weight of said salt.

5. A pharmaceutical composition comprising the crystalline fumarate salt of Compound I of any one of claims 1-4; and a pharmaceutically acceptable excipient.

6. Use of crystalline fumarate salt of Compound I of any one of claims 1-4, in the manufacture of a medicament for the treatment of cancer.

7. A crystalline fumarate salt of Compound I of any one of claims 1-4, for use in treating cancer.

8. The crystalline fumarate salt of Compound I for use of claim 7, wherein the cancer is selected from the group consisting of melanoma (including BRAF V600 mutant melanoma), breast cancer (including triple negative breast cancer), colorectal cancer (including KRAS mutant colorectal cancer), non-small cell lung cancer, acute myeloid leukemia, and pancreatic cancer.

9. The crystalline fumarate salt of Compound I for use of claim 7, wherein the cancer is melanoma.

10. The crystalline fumarate salt of Compound I for use of claim 9, wherein the cancer is BRAF V600 mutant melanoma.

11. The crystalline fumarate salt of Compound I for use of claim 9 or claim 10, wherein the crystalline fumarate salt of Compound I is administered in combination with vemurafenib.

12. The crystalline fumarate salt of Compound I for use of claim 11, wherein the crystalline fumarate salt of Compound I is administered prior or subsequent to, or concurrent with vemurafenib.

13. A process for preparing the crystalline fumarate salt of Compound I designated as Form A, as defined in any one of claims 1-4, comprising:

adding fumaric acid dissolved in a solvent to a mixture of Compound I dissolved in a solvent to form the crystalline fumarate salt of Compound I designated as Form A; and

collecting the resulting crystals of the crystalline fumarate salt of Compound I designated as Form A.