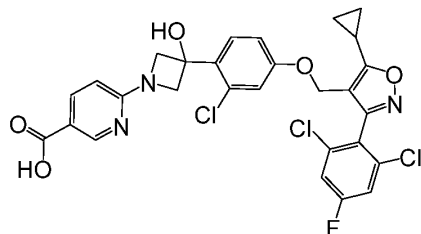


CLAIMS

1. A compound having the following Formula (I):



or a pharmaceutically acceptable salt thereof.

2. The compound according to claim 1 or pharmaceutically acceptable salt thereof for use in the treatment of a Farnesoid X Receptor (FXR) mediated condition.

3. The compound according to claim 2 or pharmaceutically acceptable salt thereof wherein the FXR mediated condition is a liver disease.

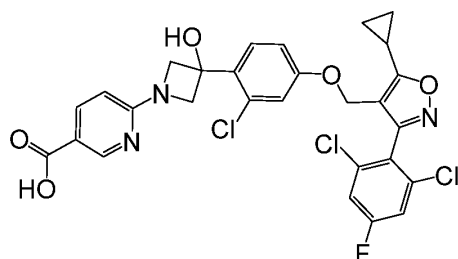
4. The compound according to any of claims 2 to 3 or pharmaceutically acceptable salt thereof, wherein the FXR mediated condition is Non-Alcoholic Steatohepatitis (NASH).

5. The compound according to any of claims 2 to 3 or pharmaceutically acceptable salt thereof, wherein the FXR mediated condition is Primary Sclerosing Cholangitis (PSC).

6. The compound according to any of claims 2 to 3 or pharmaceutically acceptable salt thereof, wherein the FXR mediated condition is Primary Biliary Cholangitis (PBC).

7. The compound according to any of claims 2 to 3 or pharmaceutically acceptable salt thereof, wherein the FXR mediated condition is liver fibrosis.

8. A pharmaceutical composition comprising a compound having the following Formula (I):



or a pharmaceutically acceptable salt thereof.

9. The pharmaceutical composition of claim 8, further comprising a pharmaceutically acceptable carrier.

10. A method of treating a patient having a Farnesoid X Receptor (FXR) mediated condition comprising administering a compound or pharmaceutically acceptable salt of claim 1 or a pharmaceutical composition of claim 8 to a patient in need thereof.

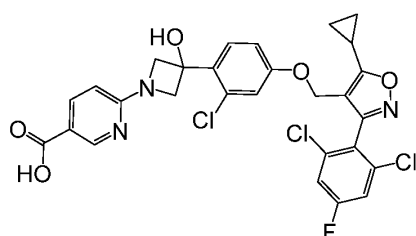
11. The method of claim 10, wherein the FXR mediated condition is selected from the group consisting of:

- a chronic intrahepatic or extrahepatic cholestatic condition;
- liver fibrosis;
- a chronic or obstructive inflammatory disorder of the liver;
- liver cirrhosis;
- liver steatosis or an associated syndrome;
- a cholestatic or fibrotic effect that is associated with alcohol-induced cirrhosis or with a viral-borne form of hepatitis;
- acute or chronic liver failure;
- liver ischemia after major liver resection;
- chemotherapy associated steatohepatitis (CASH);
- Primary Biliary Cirrhosis (PBC);
- Primary Sclerosing Cholangitis (PSC);
- a neoplastic disease of the gastrointestinal tract or liver; and
- an Inflammatory Bowel Disease (IBD);
- a lipid disorder or lipoprotein disorder;
- Type I Diabetes;
- Type II Diabetes;
- clinical complications of Type I and Type II Diabetes selected from the group consisting of diabetic nephropathy, diabetic neuropathy, diabetic retinopathy and other observed effects of clinically manifest long term Diabetes;
- Non-Alcoholic Fatty Liver Disease (NAFLD);
- Non-Alcoholic Steatohepatitis (NASH);
- obesity;
- a metabolic syndrome selected from the group consisting of combined conditions of dyslipidemia, diabetes and abnormally high body-mass index;

acute myocardial infarction;
acute stroke; and
thrombosis that occurs as an endpoint of chronic obstructive atherosclerosis;
a non-malignant hyperproliferative disorder;
a malignant hyperproliferative disorder selected from the group consisting of hepatocellular carcinoma, colon adenoma, and polyposis;
colon adenocarcinoma;
breast cancer;
pancreas adenocarcinoma; and
Barrett's esophagus.

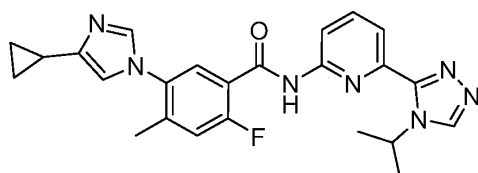
12. Use of a compound or pharmaceutically acceptable salt thereof of claim 1 for the manufacture of a medicament for the treatment of a Farnesoid X Receptor (FXR) mediated condition.

13. A method of treating and/or preventing a liver disease in a patient in need thereof, comprising administering to the patient a therapeutically effective amount of an Apoptosis Signal-Regulating Kinase 1 (ASK1) inhibitor in combination with a therapeutically effective amount of a Farnesoid X Receptor (FXR) agonist, wherein the FXR agonist is a compound of Formula (I):



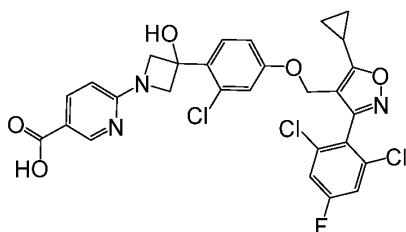
or a pharmaceutically acceptable salt thereof.

14. The method of claim 13, wherein the ASK1 inhibitor is a compound of Formula (II):



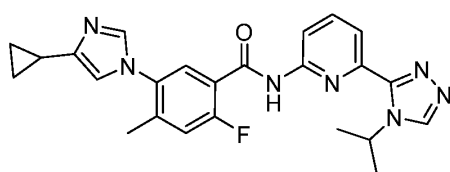
or a pharmaceutically acceptable salt, a stereoisomer, a mixture of stereoisomers, or a tautomer thereof.

15. The method of any one of claims 13 to 14, wherein FXR agonist and the ASK1 inhibitor are administered separately.
16. The method of any one of claims 13 to 15, wherein the liver disease is non-alcoholic steatohepatitis (NASH).
17. The method of any one of claims 13 to 15, wherein the liver disease is Primary Sclerosing Cholangitis (PSC).
18. The method of any one of claims 13 to 15, wherein the liver disease is Primary Biliary Cirrhosis (PBC).
19. A pharmaceutical composition comprising a therapeutically effective amount of an Apoptosis Signal-Regulating Kinase 1 (ASK1) inhibitor and a therapeutically effective amount of a Farnesoid X Receptor (FXR) agonist, wherein the FXR agonist is a compound of Formula (I):



or a pharmaceutically acceptable salt thereof.

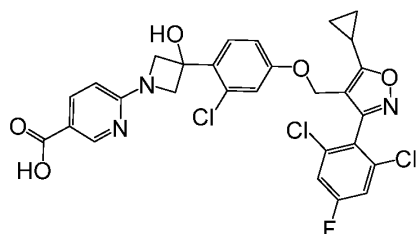
20. The pharmaceutical composition of claim 19, wherein the ASK1 inhibitor is a compound of Formula (II):



or a pharmaceutically acceptable salt, a stereoisomer, a mixture of stereoisomers, or a tautomer thereof.

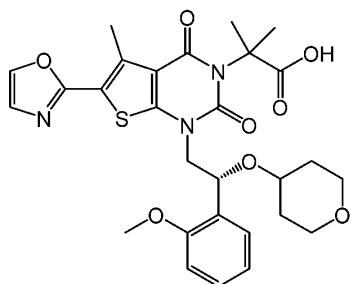
21. The pharmaceutical composition of any of claims 19 to 20, further comprising a pharmaceutically acceptable carrier.

22. A method of treating and/or preventing a liver disease in a patient in need thereof, comprising administering to the patient a therapeutically effective amount of an Acetyl CoA Carboxylase (ACC) inhibitor in combination with a therapeutically effective amount of a Farnesoid X Receptor (FXR) agonist, wherein the FXR agonist is a compound of Formula (I):



or a pharmaceutically acceptable salt thereof.

23. The method of claim 22, wherein the ACC inhibitor is a compound of Formula (III):



or a pharmaceutically acceptable salt, a stereoisomer, a mixture of stereoisomers, or a tautomer thereof.

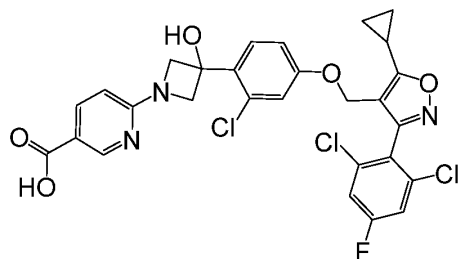
24. The method of any one of claims 22 to 23, wherein the ACC inhibitor and the FXR agonist are administered separately.

25. The method of any one of claims 22 to 24, wherein the liver disease is non-alcoholic steatohepatitis (NASH).

26. The method of any one of claims 22 to 24, wherein the liver disease is Primary Sclerosing Cholangitis (PSC).

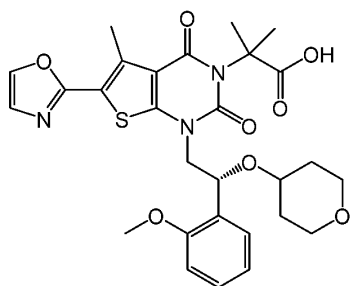
27. The method of any one of claims 22 to 24, wherein the liver disease is Primary Biliary Cirrhosis (PBC).

28. A pharmaceutical composition comprising a therapeutically effective amount of an Acetyl CoA Carboxylase (ACC) inhibitor and a therapeutically effective amount of a Farnesoid X Receptor (FXR) agonist, wherein the FXR agonist is a compound of Formula (I):



or a pharmaceutically acceptable salt thereof.

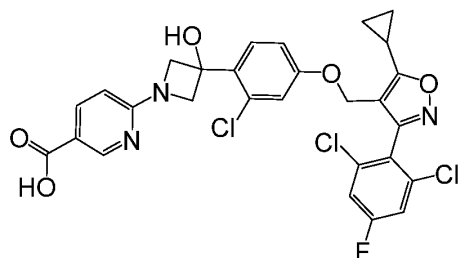
29. The pharmaceutical composition of claim 28, wherein the ACC inhibitor is a compound of Formula (III):



or a pharmaceutically acceptable salt, a stereoisomer, a mixture of stereoisomers, or a tautomer thereof.

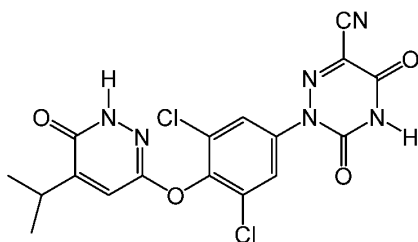
30. The pharmaceutical composition of any of claims 28 to 29, further comprising a pharmaceutically acceptable carrier.

31. A method of treating and/or preventing a liver disease in a patient in need thereof, comprising administering to the patient a therapeutically effective amount of a Thyroid Hormone Receptor (THR) β agonist in combination with a therapeutically effective amount of a Farnesoid X Receptor (FXR) agonist, wherein the FXR agonist is a compound of Formula (I):



or a pharmaceutically acceptable salt thereof.

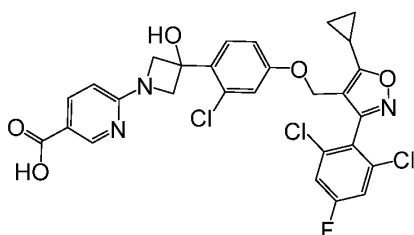
38. The pharmaceutical composition of claim 37, wherein the THR β agonist is a compound of Formula (IV):



or a pharmaceutically acceptable salt, a stereoisomer, a mixture of stereoisomers, or a tautomer thereof.

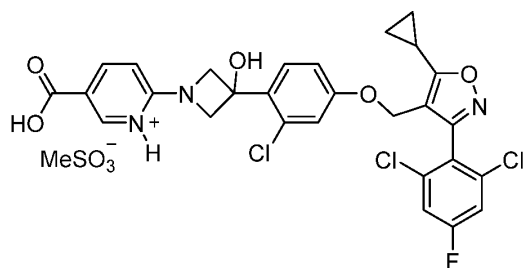
39. The pharmaceutical composition of any of claims 37 to 38, further comprising a pharmaceutically acceptable carrier.

40. A method of inhibiting UGT1A1 in a patient having a liver disease, comprising administering to the patient a therapeutically effective amount of a compound of Formula (I):



or a pharmaceutically acceptable salt thereof.

41. A crystalline form of a compound of the following formula:



42. The crystalline form of claim 41, wherein the crystalline form is Form I.

43. The crystalline form of claim 42, characterized by an X-ray diffraction pattern having 2 θ -reflections at 9.6, 19.3, and 22.6 degrees 2 θ , plus or minus 0.2 degrees 2 θ .

44. The crystalline form of any of claims 42-43, characterized by an X-ray diffraction pattern further comprising 2θ -reflections at 3.2, 6.4, and 12.8 degrees 2θ , plus or minus 0.2 degrees 2θ .

45. The crystalline form of any of claims 42-44, characterized by an X-ray diffraction pattern further comprising 2θ -reflections at 22.1, 25.8, 29.1 degrees 2θ , plus or minus 0.2 degrees 2θ .

46. The crystalline form of any of claims 42-45, having an X-ray diffraction pattern substantially as shown in Figure 4.

47. The crystalline form of any of claims 42-46, having a differential scanning calorimetry thermogram comprising an endothermic with onset at about 221 °C.

48. The crystalline form of any of claims 42-47, having a differential scanning calorimetry thermogram substantially as shown in Figure 5.

49. The crystalline form of any of claims 42-48, having a thermogravimetric analysis substantially as shown in Figure 6.