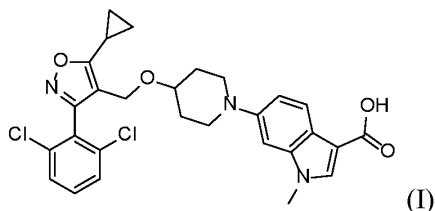


CLAIMS

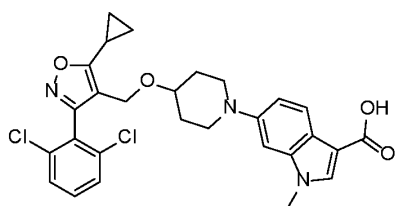
What is claimed is:

1. A method of treating a liver disorder in a patient in need thereof comprising administering a therapeutically effective amount of a compound of Formula (I)



or a pharmaceutically acceptable salt thereof, wherein the liver disorder is selected from liver inflammation, liver fibrosis, alcohol induced fibrosis, steatosis, alcoholic steatosis, primary sclerosing cholangitis (PSC), primary biliary cirrhosis (PBC), non-alcoholic fatty liver disease (NAFLD), and non-alcoholic steatohepatitis (NASH).

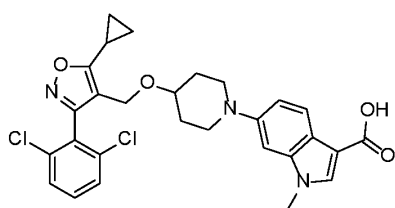
2. A method of treating a liver disorder in a patient in need thereof with a Farnesoid X Receptor (FXR) agonist, comprising administering a therapeutically effective amount of the FXR agonist, wherein the FXR agonist is a compound of Formula (I)



(I), or a pharmaceutically acceptable salt thereof, and

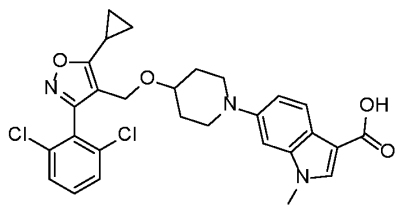
wherein the patient has discontinued one or more prior therapies with another FXR agonist other than a compound of Formula (I) or a pharmaceutically acceptable salt thereof, wherein the liver disorder is selected from liver inflammation, liver fibrosis, alcohol induced fibrosis, steatosis, alcoholic steatosis, primary sclerosing cholangitis (PSC), primary biliary cirrhosis (PBC), non-alcoholic fatty liver disease (NAFLD), and non-alcoholic steatohepatitis (NASH).

3. The method of claims 2, wherein the patient suffered from pruritus during the one or more prior therapies.
4. A method of impeding or slowing the progression of non- alcoholic fatty liver disease (NAFLD) to non-alcoholic steatohepatitis (NASH) in a patient in need thereof comprising administering a therapeutically effective amount of a compound of Formula (I)



(I), or a pharmaceutically acceptable salt thereof.

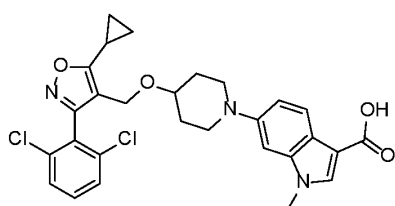
5. A method of impeding or slowing the progression of NASH in a patient in need thereof comprising administering a therapeutically effective amount of a compound of



Formula (I)

(I), or a pharmaceutically acceptable salt thereof.

6. A method of treating a liver disorder in a patient in need thereof with a Farnesoid X Receptor (FXR) agonist that preferentially concentrates in liver tissue over one or more of kidney, lung, heart, and skin tissues, the method comprising administering a therapeutically effective amount of the FXR agonist, wherein the FXR agonist is a compound of Formula (I)



(I), or a pharmaceutically acceptable salt thereof, wherein

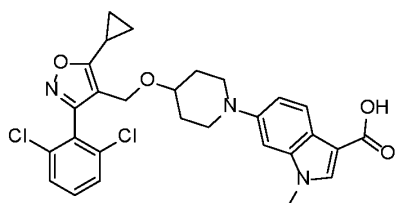
the liver disorder is selected from liver inflammation, liver fibrosis, alcohol induced fibrosis, steatosis, alcoholic steatosis, primary sclerosing cholangitis (PSC), primary biliary cirrhosis (PBC), non-alcoholic fatty liver disease (NAFLD), and non-alcoholic steatohepatitis (NASH).

7. The method of any one of claims 1-6, wherein the administration does not result in pruritus in the patient greater than Grade 2 in severity.

8. The method of any one of claims 1-7, wherein the administration does not result in pruritus in the patient greater than Grade 1 in severity.

9. The method of any one of claims 1-8, wherein the administration does not result in pruritus in the patient.

10. A method of treating a liver disorder with an FXR agonist that does not result in detectable pruritus in a patient in need thereof, the method comprising administering a therapeutically effective amount of the FXR agonist, wherein the FXR agonist is a compound of Formula (I)



(I), or a pharmaceutically acceptable salt thereof, wherein

the liver disorder is selected from liver inflammation, liver fibrosis, alcohol induced fibrosis, steatosis, alcoholic steatosis, primary sclerosing cholangitis (PSC), primary biliary cirrhosis (PBC), non-alcoholic fatty liver disease (NAFLD), and non-alcoholic steatohepatitis (NASH).

11. The method of any one of claims 1-3, or 6-10, wherein the liver disorder is NAFLD.
12. The method of any one of claims 1-3, or 6-10, wherein the liver disorder is NASH.
13. The method of any one of claims 1-3, or 6-10, wherein the liver disorder is PSC.
14. The method of any one of claims 1-3, or 6-10, wherein the liver disorder is PBC.
15. The method of any one of claims 1-14, wherein the administration results in a liver concentration to plasma concentration ratio of the compound of Formula (I) of 10 or greater.
16. The method of any one of claims 1-15, wherein the therapeutically effective amount is 0.5 µg/day – 600 mg/day.
17. The method of any one of claims 1-16, wherein the therapeutically effective amount is 0.5 µg/day – 20 mg/day.
18. The method of any one of claims 1-17, wherein the therapeutically effective amount is 0.5 µg/day – 4 mg/day.
19. The method of any one of claims 1-18, wherein the administration comprises administering the compound of Formula (I), or a pharmaceutically acceptable salt thereof, daily for a treatment period of one or more weeks.
20. The method of claim 19, wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is administered once daily or twice daily.

21. The method of claim 19 or 20, wherein the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, administered on day 1 of the treatment period is greater than or equal to the amount administered on all subsequent days of the treatment period.
22. The method of any one of claims 19-21, wherein the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, administered on day 1 of the treatment period is equal to the amount administered on all subsequent days of the treatment period.
23. The method of any one of claims 1-22, wherein the treatment period is one or more months.
24. The method of any one of claims 1-23, wherein the treatment period is the remaining lifespan of the patient.
25. The method of any one of claims 1-24, wherein the patient is obese.
26. The method of any one of claims 1-24, wherein the patient is not obese.
27. The method of any one of claims 1-26, wherein the patient also has diabetes mellitus and/or a cardiovascular disorder.
28. The method of any one of claims 1-27, wherein the patient is at risk for developing an adverse effect affecting one or more of the kidney, lung, heart, and skin.
29. The method of any one of claims 1-28, wherein the patient is 2-17 years old.
30. The method of any one of claims 1-28, wherein the patient is 18-54 years old.
31. The method of any one of claims 1-28, wherein the patient is 65 or more years old.
32. The method of any one of claims 1-31, wherein the patient has had a liver transplant.
33. The method of any one of claims 1-32, wherein the patient's alkaline phosphatase, gamma-glutamyl transferase (GGT), alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) levels are elevated.
34. The method of any one of claims 1-33, wherein the method does not comprise administering an antihistamine, an immunosuppressant, a steroid, rifampicin, an opioid antagonists, or a selective serotonin reuptake inhibitor (SSRI).

35. The method of any one of claims 1-34, wherein the NAS score of the patient is decreased.
36. The method of any one of claims 1-35, wherein TGR5 signaling is not activated.
37. The method of any one of claims 1-36, wherein the expression level of a marker of fibrosis is decreased.
38. The method of any one of claims 1-37, wherein the expression level of Ccr2, Col1a1, Col1a2, Col1a3, Cxcr3, Dcn, Hgf, Il1a, Inhbe, Lox, Loxl1, Loxl2, Loxl3, Mmp2, Pdgfb, Plau, Serpine1, Perpinh1, Snai, Tgfb1, Tgfb3, Thbs1, Thbs2, Timp2, and/or Timp3 is reduced.
39. The method of any one of claims 1-38, wherein the expression level of a marker of liver inflammation is decreased.
40. The method of any one of claims 1-39, wherein the level of Adgre1, Ccr2, Ccr5, Il1A, and/or Tlr4 is reduced.