CLAIMS

We Claim:

1. A crystalline form of 4-((4-(1-(*tert*-butyl)-1*H*-pyrazol-4-yl)pyridin-2-yl)((4-(4-methoxy-3-methylphenyl)bicyclo[2.2.2]octan-1-yl)methyl)carbamoyl)cyclohexyl 3-hydroxyazetidine-*trans*-1-carboxylate, or a pharmaceutically acceptable salt or solvate thereof.
2. The crystalline form of claim 1, wherein the 4-((4-(1-(*tert*-butyl)-1*H*-pyrazol-4-yl)pyridin-2-yl)((4-(4-methoxy-3-methylphenyl)bicyclo[2.2.2]octan-1-yl)methyl)carbamoyl)cyclohexyl 3-hydroxyazetidine-*trans*-1-carboxylate is a free base.
3. The crystalline form of claim 2, wherein the crystalline form of 4-((4-(1-(*tert*-butyl)-1*H*-pyrazol-4-yl)pyridin-2-yl)((4-(4-methoxy-3-methylphenyl)bicyclo[2.2.2]octan-1-yl)methyl)carbamoyl)cyclohexyl 3-hydroxyazetidine-*trans*-1-carboxylate is Form 1 having at least one of the following properties:
   (a) an X-ray powder diffraction (XRPD) pattern substantially the same as shown in **Figure 1**;
   (b) an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 7.4° 2-Theta, 8.4° 2-Theta, 14.6° 2-Theta, 15.4° 2-Theta, 16.8° 2-Theta, 17.0° 2-Theta, 17.3° 2-Theta, 17.6° 2-Theta, 18.9° 2-Theta, and 19.3° 2-Theta;
   (c) a thermo-gravimetric analysis (TGA) substantially similar to the one set forth in **Figure 2**;
   (d) a DSC thermogram substantially similar to the one set forth in **Figure 3**;
   (e) a DSC thermogram with an endotherm having an onset at about 213 °C; or
   (f) combinations thereof.
4. The crystalline form of claim 3, wherein the crystalline form has an X-ray powder diffraction (XRPD) pattern substantially the same as shown in **Figure 1**.
5. The crystalline form of claim 3, wherein the crystalline form has an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 7.4° 2-Theta, 8.4° 2-Theta, 14.6° 2-Theta, 15.4° 2-Theta, 16.8° 2-Theta, 17.0° 2-Theta, 17.3° 2-Theta, 17.6° 2-Theta, 18.9° 2-Theta, and 19.3° 2-Theta.
6. The crystalline form of claim 3, wherein the crystalline form has a thermo-gravimetric analysis (TGA) substantially similar to the one set forth in **Figure 2**.
7. The crystalline form of claim 3, wherein the crystalline form has a DSC thermogram substantially similar to the one set forth in **Figure 3**.
8. The crystalline form of claim 3, wherein the crystalline form has a DSC thermogram with an endotherm having an onset at about 213 °C.

9. The crystalline form of claim 3, wherein the crystalline form is characterized as having properties (a), (b), (c), (d), and (e).
10. The crystalline form of any one of claims 3-9, wherein the crystalline form is obtained from acetonitrile, ethanol, methanol, 2-propanol, ethyl acetate, ethanol/heptane (1:1 v/v), acetone, or acetonitrile/water (1:2 v/v).
11. The crystalline form of any one of claims 3-10, wherein the crystalline form is unsolvated.
12. The crystalline form of any one of claims 3-11, wherein the crystalline form is anhydrous.
13. The crystalline form of claim 2, wherein the crystalline form of 4-((4-(1-(*tert*-butyl)-1*H*-pyrazol-4-yl)pyridin-2-yl)((4-(4-methoxy-3-methylphenyl)bicyclo[2.2.2]octan-1-yl)methyl)carbamoyl)cyclohexyl 3-hydroxyazetidine-*trans*-1-carboxylate is Form 2 having at least one of the following properties:
    (a) an X-ray powder diffraction (XRPD) pattern substantially the same as shown in **Figure 4**;
    (b) an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 8.5° 2-Theta, 12.8° 2-Theta, 13.4° 2-Theta, 16.2° 2-Theta, 17.0° 2-Theta, 18.8° 2-Theta, 19.5° 2-Theta, and 20.5° 2-Theta;
    (c) a thermo-gravimetric analysis (TGA) substantially similar to the one set forth in **Figure 5**;
    (d) a DSC thermogram substantially similar to the one set forth in **Figure 6**;
    (e) a DSC thermogram with an endotherm having an onset at about 212 °C; or
    (f) combinations thereof.
14. The crystalline form of claim 13, wherein the crystalline form has an X-ray powder diffraction (XRPD) pattern substantially the same as shown in **Figure 4**.
15. The crystalline form of claim 13, wherein the crystalline form has an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 8.5° 2-Theta, 12.8° 2-Theta, 13.4° 2-Theta, 16.2° 2-Theta, 17.0° 2-Theta, 18.8° 2-Theta, 19.5° 2-Theta, and 20.5° 2-Theta.
16. The crystalline form of claim 13, wherein the crystalline form has a thermo-gravimetric analysis (TGA) substantially similar to the one set forth in **Figure 5**.
17. The crystalline form of claim 13, wherein the crystalline form has a DSC thermogram substantially similar to the one set forth in **Figure 6**.
18. The crystalline form of claim 13, wherein the crystalline form has a DSC thermogram with an endotherm having an onset at about 212 °C.
19. The crystalline form of claim 13, wherein the crystalline form is characterized as having properties (a), (b), (c), (d), and (e).

20. The crystalline form of any one of claims 13-19, wherein the crystalline form is obtained from ethyl acetate/water (97:3 v/v).
21. The crystalline form of any one of claims 13-19, wherein the crystalline form is obtained from acetonitrile.
22. The crystalline form of any one of claims 13-19, wherein the crystalline form is obtained from acetone.
23. The crystalline form of any one of claims 13-22, wherein the crystalline form is unsolvated.
24. The crystalline form of any one of claims 13-23, wherein the crystalline form is anhydrous.
25. The crystalline form of claim 2, wherein the crystalline form of 4-((4-(1-(*tert*-butyl)-1*H*-pyrazol-4-yl)pyridin-2-yl)((4-(4-methoxy-3-methylphenyl)bicyclo[2.2.2]octan-1-yl)methyl)carbamoyl)cyclohexyl 3-hydroxyazetidine-*trans*-1-carboxylate is Form 3 having at least one of the following properties:
    (a) an X-ray powder diffraction (XRPD) pattern substantially the same as shown in **Figure 7**;
    (b) an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 7.5° 2-Theta, 15.1° 2-Theta, 16.6° 2-Theta, 16.9° 2-Theta, 17.2° 2-Theta, 17.5° 2-Theta, and 18.7° 2-Theta;
    (c) a thermo-gravimetric analysis (TGA) substantially similar to the one set forth in **Figure 8**;
    (d) a DSC thermogram substantially similar to the one set forth in **Figure 9**;
    (e) a DSC thermogram with an endotherm having an onset at about 214 °C; or
    (f) combinations thereof.
26. The crystalline form of claim 25, wherein the crystalline form has an X-ray powder diffraction (XRPD) pattern substantially the same as shown in **Figure 7**.
27. The crystalline form of claim 25, wherein the crystalline form has an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 7.5° 2-Theta, 15.1° 2-Theta, 16.6° 2-Theta, 16.9° 2-Theta, 17.2° 2-Theta, 17.5° 2-Theta, and 18.7° 2-Theta.
28. The crystalline form of claim 25, wherein the crystalline form has a thermo-gravimetric analysis (TGA) substantially similar to the one set forth in **Figure 8**.
29. The crystalline form of claim 25, wherein the crystalline form has a DSC thermogram substantially similar to the one set forth in **Figure 9**.
30. The crystalline form of claim 25, wherein the crystalline form has a DSC thermogram with an endotherm having an onset at about 214 °C.
31. The crystalline form of claim 25, wherein the crystalline form is characterized as having properties (a), (b), (c), (d), and (e).

32. The crystalline form of any one of claims 25-31, wherein the crystalline form is obtained from methyl t-butyl ether (TBME).
33. The crystalline form of any one of claims 25-32, wherein the crystalline form is unsolvated.
34. The crystalline form of any one of claims 25-33, wherein the crystalline form is anhydrous.
35. The crystalline form of claim 2, wherein the crystalline form of 4-((4-(1-(*tert*-butyl)-1*H*-pyrazol-4-yl)pyridin-2-yl)((4-(4-methoxy-3-methylphenyl)bicyclo[2.2.2]octan-1-yl)methyl)carbamoyl)cyclohexyl 3-hydroxyazetidine-*trans*-1-carboxylate is Form 4 having at least one of the following properties:
    (a) an X-ray powder diffraction (XRPD) pattern substantially the same as shown in **Figure 10**;
    (b) an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 5.4° 2-Theta, 8.9° 2-Theta, 9.9° 2-Theta, 14.8° 2-Theta, 15.9° 2-Theta, 16.2° 2-Theta, 16.8° 2-Theta, 17.5° 2-Theta, 18.5° 2-Theta, and 20.1° 2-Theta;
    (c) a thermo-gravimetric analysis (TGA) substantially similar to the one set forth in **Figure 11**;
    (d) a DSC thermogram substantially similar to the one set forth in **Figure 12**;
    (e) a DSC thermogram with a first endotherm having an onset at about 164 °C and a second endotherm having an onset at about 209 °C; or
    (f) combinations thereof.
36. The crystalline form of claim 35, wherein the crystalline form has an X-ray powder diffraction (XRPD) pattern substantially the same as shown in **Figure 10**.
37. The crystalline form of claim 35, wherein the crystalline form has an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 5.4° 2-Theta, 8.9° 2-Theta, 9.9° 2-Theta, 14.8° 2-Theta, 15.9° 2-Theta, 16.2° 2-Theta, 16.8° 2-Theta, 17.5° 2-Theta, 18.5° 2-Theta, and 20.1° 2-Theta.
38. The crystalline form of claim 35, wherein the crystalline form has a thermo-gravimetric analysis (TGA) substantially similar to the one set forth in **Figure 11**.
39. The crystalline form of claim 35, wherein the crystalline form has a DSC thermogram substantially similar to the one set forth in **Figure 12**.
40. The crystalline form of claim 35, wherein the crystalline form has a DSC thermogram a first endotherm having an onset at about 164 °C and a second endotherm having an onset at about 209 °C.
41. The crystalline form of claim 35, wherein the crystalline form is characterized as having properties (a), (b), (c), (d), and (e).
42. The crystalline form of any one of claims 35-41, wherein the crystalline form is unsolvated.

43. The crystalline form of any one of claims 35-42, wherein the crystalline form is anhydrous.
44. A pharmaceutical composition comprising the crystalline form of any one of claims 1-43, or a pharmaceutically acceptable salt, or solvate thereof, and at least one inactive ingredient selected from pharmaceutically acceptable carriers, diluents, and excipients.
45. The crystalline form of any one of any one of claims 1-43 for use in medicine.
46. A method of treating or preventing a liver disease or condition in a mammal, comprising administering to the mammal a crystalline form of any one of claims 1-43.
47. The method of claim 46, wherein the liver disease or condition is an alcoholic or non-alcoholic liver disease or condition.
48. The method of claim 46, wherein the liver disease or condition is primary biliary cirrhosis, primary sclerosing cholangitis, cholestasis, nonalcoholic steatohepatitis (NASH), or nonalcoholic fatty liver disease (NAFLD).
49. The method of claim 47, wherein the alcoholic liver disease or condition is fatty liver (steatosis), cirrhosis, or alcoholic hepatitis.
50. The method of claim 47, wherein the non-alcoholic liver disease or condition is nonalcoholic steatohepatitis (NASH), or nonalcoholic fatty liver disease (NAFLD).
51. The method of claim 47, wherein the non-alcoholic liver disease or condition is nonalcoholic steatohepatitis (NASH).
52. The method of claim 47, wherein the non-alcoholic liver disease or condition is nonalcoholic steatohepatitis (NASH) and is accompanied by liver fibrosis.
53. The method of claim 47, wherein the non-alcoholic liver disease or condition is nonalcoholic steatohepatitis (NASH) without liver fibrosis.
54. The method of claim 47, wherein the non-alcoholic liver disease or condition is intrahepatic cholestasis or extrahepatic cholestasis.
55. The method of claim 47, wherein the liver disease or condition is steatohepatitis, cholangitis, fatty liver disease, cholestasis, cirrhosis, fibrotic liver disease, liver inflammation, biliary atresia, Alagille syndrome, IFALD (intestinal failure associated liver disease), parental nutrition associated liver disease (PNALD), hepatitis, hepatocellular carcinoma, cholangiocarcinoma, or combinations thereof.
56. The method of claim 55, wherein the cholestasis is intrahepatic cholestasis of pregnancy or progressive familial intrahepatic cholestasis (PFIC).
57. A method of treating or preventing a liver fibrosis in a mammal, comprising administering to the mammal a crystalline form of any one of claims 1-43.
58. The method of claim 57, wherein the mammal is diagnosed with hepatitis C virus (HCV), nonalcoholic steatohepatitis (NASH), primary sclerosing cholangitis (PSC), cirrhosis,

Wilson's disease, hepatitis B virus (HBV), HIV associated steatohepatitis and cirrhosis, chronic viral hepatitis, non-alcoholic fatty liver disease (NAFLD), alcoholic steatohepatitis (ASH), primary biliary cirrhosis (PBC), or biliary cirrhosis.

59. The method of claim 57, wherein the mammal is diagnosed with nonalcoholic steatohepatitis (NASH).

60. A method of treating or preventing a liver inflammation in a mammal, comprising administering to the mammal a crystalline form of any one of claims 1-43.

61. The method of claim 60, wherein the mammal is diagnosed with hepatitis C virus (HCV), nonalcoholic steatohepatitis (NASH), primary sclerosing cholangitis (PSC), cirrhosis, Wilson's disease, hepatitis B virus (HBV), HIV associated steatohepatitis and cirrhosis, chronic viral hepatitis, non-alcoholic fatty liver disease (NAFLD), alcoholic steatohepatitis (ASH), primary biliary cirrhosis (PBC), or biliary cirrhosis.

62. The method of claim 60, wherein the mammal is diagnosed with nonalcoholic steatohepatitis (NASH).

63. The method of claim 60, wherein the liver inflammation is associated with inflammation in the gastrointestinal tract.

64. The method of claim 60, wherein the mammal is diagnosed with inflammatory bowel disease.

65. A method of treating or preventing a gastrointestinal disease or condition in a mammal, comprising administering to the mammal a compound of any one of claims 1-43, or a pharmaceutically acceptable salt or solvate thereof.

66. The method of claim 65, wherein the gastrointestinal disease or condition is necrotizing enterocolitis, gastritis, ulcerative colitis, Crohn's disease, inflammatory bowel disease, irritable bowel syndrome, gastroenteritis, radiation induced enteritis, pseudomembranous colitis, chemotherapy induced enteritis, gastro-esophageal reflux disease (GERD), peptic ulcer, non-ulcer dyspepsia (NUD), celiac disease, intestinal celiac disease, post-surgical inflammation, gastric carcinogenesis, graft versus host disease or any combination thereof.

67. The method of claim 65, wherein the gastrointestinal disease or condition is irritable bowel syndrome with diarrhea (IBS-D), irritable bowel syndrome with constipation (IBS-C), mixed IBS (IBS-M), unsubtyped IBS (IBS-U), or bile acid diarrhea (BAD).

68. A method of treating or preventing a disease or condition in a mammal that would benefit from treatment with an FXR agonist, comprising administering to the mammal a crystalline form of any one of claims 1-43.

69. The method of any one of claims 46-68, further comprising administering at least one additional therapeutic agent in addition to a crystalline form of any one of claims 1-43.