WHAT IS CLAIMED IS:

1. Use of an apical sodium-dependent bile acid transporter inhibitor (ASBTI) in the manufacture of a medicament for reducing, minimizing, preventing, ameliorating, or eliminating one or more side effects associated with administration of the ASBTI in a subject in need thereof, the use comprising the ASBTI to be administered to the subject before ingestion of food.

2. The use of claim 1 wherein the one or more side effects associated with administration of the ASBTI is reduced, minimized, prevented, ameliorated or eliminated as compared to the side effects when the ASBTI is to be administered after ingestion of food, at the same time as food, or mixed with food.

3. Use of an ASBTI in the manufacture of a medicament for improving gastrointestinal (GI) tolerability of the ASBTI in a subject in need thereof, the use comprising the ASBTI to be administered to the subject before ingestion of food.

4. The use of claim 3, wherein the improvement of GI tolerability comprises a reduction, minimization, prevention, amelioration, or elimination of one or more GI adverse events.

5. The use of claim 3 or 4, wherein the improvement of GI tolerability comprises a reduction, minimization, prevention, amelioration, or elimination of one or more of diarrhea, loose stools, nausea, abdominal pain, and anorectal discomfort.

6. The use of any one of claims 3-5, wherein the GI tolerability is improved as compared to the GI tolerability when the ASBTI is to be administered at mealtime or immediately after food intake.

7. The use of any one of claims 3-6, wherein the GI tolerability is improved by at least 10% as compared to the GI tolerability when the ASBTI is to be administered at mealtime or immediately after food intake.

8. The use of any one of claims 3-7, wherein the GI tolerability is improved by at least 20% as compared to the GI tolerability when the ASBTI is to be administered at mealtime or immediately after food intake.

9. The use of any one of claims 3-8, wherein the GI tolerability is improved by at least 50% as compared to the GI tolerability when the ASBTI is to be administered at mealtime or immediately after food intake.

10. Use of an ASBTI in the manufacture of a medicament for treating cholestatic liver disease in a subject in need thereof, the use comprising the ASBTI to be administered to the subject before ingestion of food, wherein the subject experiences a reduction in frequency and/or severity of one or more side effects associated with the administration of the ASBTI.

11. The use of claim 10, wherein the frequency and/or severity of side effects is reduced as compared to the side effects when the ASBTI is to be administered after ingestion of food, at the same time as food, or mixed with food.

12. The use of claim 10 or 11, wherein the cholestatic liver disease is a pediatric cholestatic liver disease.

13. The use of claim 10 or 11, wherein the cholestatic liver disease is an adult cholestatic liver disease.

14. The use of any one of claims 10-13, wherein the cholestatic liver disease is non-obstructive cholestasis, extrahepatic cholestasis, intrahepatic cholestasis, primary intrahepatic cholestasis, secondary intrahepatic cholestasis, progressive familial intrahepatic cholestasis (PFIC), PFIC type 1, PFIC type 2, PFIC type 3, benign recurrent intrahepatic cholestasis (BRIC), BRIC type 1, BRIC type 2, BRIC type 3, total parenteral nutrition associated cholestasis, paraneoplastic cholestasis, Stauffer syndrome, intrahepatic cholestasis of pregnancy, contraceptive-associated cholestasis, drug-associated cholestasis, infection-associated cholestasis, Dubin-Johnson Syndrome, primary

biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC), gallstone disease, Alagille syndrome, biliary atresia, post-Kasai biliary atresia, post-liver transplantation biliary atresia, post-liver transplantation cholestasis, post-liver transplantation associated liver disease, intestinal failure associated liver disease, bile acid mediated liver injury, MRP2 deficiency syndrome, or neonatal sclerosing cholangitis

15. The use of any one of claims 10-14, wherein the cholestatic liver disease is Alagille syndrome, PFIC, BRIC, PSC, PBC, or biliary atresia.

16. The use of any one of claims 1, 2, and 10-15, wherein the one of more side effects is diarrhea, loose stools, nausea, gastrointestinal pain, abdominal pain, cramping, anorectal discomfort, or a combination thereof.

17. The use of any one of claims claim 1-16, wherein the ASBTI is to be administered to the subject in a fasted state.

18. The use of any one of claims claim 1-16, wherein the ASBTI is to be administered less than about 60 minutes before ingestion of food.

19. The use of any one of claims 1-18, wherein the ASBTI is to be administered less than about 30 minutes before ingestion of food.

20. The use of any one of claims 1-19, wherein the ASBTI is to be administered immediately prior to the ingestion of food.

21. The use of any one of claims 1-20, wherein the ASBTI is to be administered at least 4 hours after the last meal.

22. The use of any one of claims 1-21, wherein the ASBTI is to be administered once daily.

23. The use of any one of claims 1-22, wherein the ASBTI is to be administered twice daily.

24. The use of any one of claims 1-23, wherein the ASBTI is to be administered in an amount of about 0.1 mg to about 100 mg per dose.

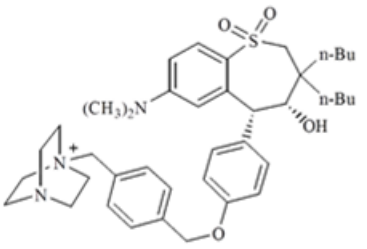
25. The use of claim 24, wherein the ASBTI is to be administered in an amount of about 10 mg to about 100 mg per dose.

26. The use of claims 24 or 25, wherein the ASBTI is to be administered in an amount of about 20 mg to about 80 mg per dose.

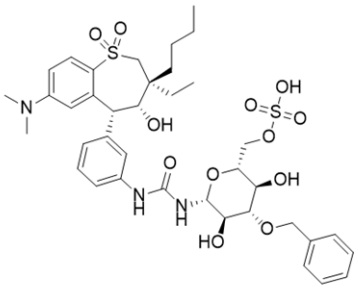
27. The use of any one of claims 1-26, wherein the ASBTI is to be administered in an amount of about 100 µg/kg/day to 1400 µg/kg/day.

28. The use of claim 27, wherein the ASBTI is to be administered in an amount of about 400 µg/kg/day to about 800 µg/kg/day.

29. The use of any one of claims 1-28, wherein the ASBTI is selected from

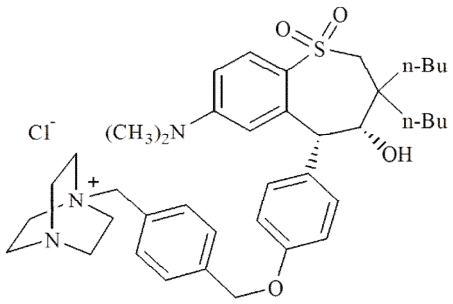


(maralixibat) and



(volixibat) or a pharmaceutically acceptable salt thereof.

30. The use of claim 29, wherein the ASBTI is



(maralixibat chloride).

31. The use of claim 29, wherein the ASBTI is volixibat or a pharmaceutically acceptable salt thereof.

32. The use of any of claims 1-31, wherein the subject has not ingested food for about 0.5 to about 16 hours before the administration of the ASBTI.

33. The use of any of claims 1-32, wherein the subject is a pediatric subject.

34. The use of claim 33, wherein the pediatric subject is 0 to 18 years of age.

35. The use of any of claims 1-26, wherein the ASBTI is to be administered orally.

36. The use of any of claims 1-35, wherein less than 10% of the ASBTI is systemically absorbed.

37. The use of any of claims 1-35, wherein less than 30% of the ASBTI is systemically absorbed.