CLAIMS

1. Use of (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for treating a disease or condition mediated by modulation of Nav1.7 in a subject, wherein
the subject is not receiving treatment with a UGT inhibitor; and
the medicament is for administration of the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or the pharmaceutically acceptable salt thereof, at a dosage of about 200 mg two times per day (BID), 300 mg two times per day (BID), 400 mg two times per day (BID), 150 mg three times per day (TID), or 250 mg three times per day (TID).

2. The use of claim 1, wherein the disease or condition is associated with a defect or dysfunction of Nav1.7.

3. The use of claim 1, wherein the UGT inhibitor is selected from canagliflozin, dapagliflozin, mefenamic acid, probenecid, diclofenac, quinidine, fluconazole, and valproic acid.

4. The use of any one of claims 1-3, wherein the subject discontinues treatment with the UGT inhibitor before commencing treatment with the medicament.

5. The use of any one of claims 1-4, wherein the subject discontinues treatment with the UGT inhibitor at least three weeks before commencing treatment with the medicament.

6. The use of any one of claims 1-5, wherein the subject is female.

7. The use of any one of claims 1-5, wherein the subject is male.

8. The use of any one of claims 1-7, wherein the medicament is for administration of the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or the pharmaceutically acceptable salt thereof, at a dosage of about 200 mg two times per day (BID).

9. The use of any one of claims 1-7, wherein the medicament is for administration of the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or the pharmaceutically acceptable salt thereof, at a dosage of about 150 mg three times per day (TID).

10. The use of any one of claims 1-7, wherein the medicament is for administration of the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or the pharmaceutically acceptable salt thereof, at a dosage of about 250 mg three times per day (TID).

11. The use of claim 10, wherein the subject was not previously treated with (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof.

12. The use of claim 10, wherein the subject had previously been treated with a 150 mg dosage of (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof; *e.g.*, wherein the subject was identified as a non-responder to treatment with a dosage of about 150 mg of (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof.

13. The use of any one of claims 1-7, wherein the medicament is for administration of the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or the pharmaceutically acceptable salt thereof, at a dosage of about 300 mg or about 400 mg two times per day (BID).

14. The use of claim 13, wherein the dosage is about 300 mg BID.

15. The use of claim 14, wherein the subject is a female subject.

16. The use of claim 14 or 15, wherein the medicament is for administration of the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or the pharmaceutically acceptable salt thereof, at a dosage of about 400 mg BID for an initial period of time prior to administration of (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or the pharmaceutically acceptable salt thereof, at a dosage of about 300 mg BID.

17. The use of claim 16, wherein the initial period of time is about one week.

18. The use of claim 13, wherein the dosage is about 400 mg BID.

19. The use of claim 18, wherein the subject is a male subject.

20. The use of any one of claims 1-19, wherein the medicament is formulated for oral administration.

21. The use of any one of claims 1-20, wherein the medicament is for administration in combination with one or more therapeutically effective medicaments.

22. The use of any one of claims 1-21, wherein the disease or condition is pain.

23. The use of claim 22, wherein the pain is neuropathic pain.

24. The use of claim 23, wherein the neuropathic pain is selected from diabetic neuropathy; sciatica; non-specific lower back pain; painful lumbosacral radiculopathy; multiple sclerosis pain; fibromyalgia; HIV-related neuropathy; post-herpetic neuralgia; trigeminal neuralgia; and pain resulting from physical trauma, amputation, cancer, toxins or chronic inflammatory conditions.

25. The use of claim 23, wherein the neuropathic pain is selected from diabetic neuropathy, trigeminal neuralgia, painful lumbosacral radiculopathy, erythromelalgia, and small fibre neuropathy.

26. The use of claim 23, wherein the neuropathic pain is diabetic neuropathy.

27. The use of claim 26, wherein the medicament is for administration of the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof, at a dosage of about 250 mg three times per day (TID).

28. The use of claim 23, wherein the neuropathic pain is painful lumbosacral radiculopathy.

29. The use of claim 28, wherein the medicament is for administration of the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or the pharmaceutically acceptable salt thereof, at a dosage of about 200 mg two times per day (BID).

30. The use of any one of claims 1-29, wherein the medicament comprises one or more pharmaceutically acceptable carrier(s), diluent(s), and/or excipient(s).

31. The use of any one of claims 1-30, wherein the (*5R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide or the pharmaceutically acceptable salt thereof is (*5R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide hydrochloride.

32. Use of (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for treating a disease or condition mediated by modulation of Nav1.7 in a subject, wherein
the subject is receiving treatment with a UGT inhibitor; and
the medicament is for administration of the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or the pharmaceutically acceptable salt thereof, at a dosage of about 50 mg to about 350 mg two times per day (BID) or about 50 mg to about 250 mg three times per day (TID).

33. The use of claim 32, wherein the disease or condition is associated with a defect or dysfunction of Nav1.7.

34. The use of claim 32 or 33, wherein the UGT inhibitor is selected from canagliflozin, dapagliflozin, mefenamic acid, probenecid, diclofenac, quinidine, fluconazole, and valproic acid.

35. The use of any one of claims 32-34, wherein the medicament is for administration of the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or the pharmaceutically acceptable salt thereof, at a dosage at least 30% lower than a dosage for a subject not receiving treatment of a UGT inhibitor.

36. The use of any one of claims 32-34, wherein the medicament is for administration of the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or the pharmaceutically acceptable salt thereof, at a dosage at least 50% lower than a dosage for a subject not receiving treatment of a UGT inhibitor.

37. The use of any one of claims 32-34, wherein the medicament is for administration of the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or the pharmaceutically acceptable salt thereof, at a dosage of about 50 mg to about 350 mg BID.

38. The use of claim 37, wherein the dosage is about 50 mg BID, about 100 mg BID, about 150 mg BID, about 200 mg BID, or about 350 mg BID.

39. The use of any one of claims 32-34, wherein the medicament is for administration of the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or the pharmaceutically acceptable salt thereof, at a dosage of about 50 mg to about 250 mg TID.

40. The use of claim 39, wherein the dosage is about 50 mg TID, about 75 mg TID, about 100 mg TID, about 150 mg TID, or about 250 mg TID.

41. The use of any one of claims 32-40, the medicament is formulated for oral administration.

42. The use of any one of claims 32-41, wherein the medicament is for administration in combination with one or more therapeutically effective medicaments.

43. The use of any one of claims 32-42, wherein the disease or condition is pain.

44. The use of claim 43, wherein the pain is neuropathic pain.

45. The use of claim 44, wherein the neuropathic pain is selected from diabetic neuropathy; sciatica; non-specific lower back pain; painful lumbosacral radiculopathy; multiple sclerosis pain; fibromyalgia; HIV-related neuropathy; post-herpetic neuralgia; trigeminal neuralgia; and

pain resulting from physical trauma, amputation, cancer, toxins or chronic inflammatory conditions.

46. The use of claim 45, wherein the neuropathic pain is selected from diabetic neuropathy, trigeminal neuralgia, painful lumbosacral radiculopathy, erythromelalgia and small fibre neuropathy.

47. The use of claim 46, wherein the neuropathic pain is diabetic neuropathy.

48. The use of claim 47, wherein the medicament is for administration of the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof, at a dosage of about 50 mg to about 250 mg TID.

49. The use of claim 48, wherein the dosage is about 50 mg TID, about 75 mg TID, about 100 mg TID, about 150 mg TID, or about 250 mg TID.

50. The use of claim 46, wherein the neuropathic pain is painful lumbosacral radiculopathy.

51. The use of claim 50, wherein the medicament is for administration of the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof, at a dosage of about 50 mg to about 350 mg BID.

52. The use of claim 51, wherein the dosage is about 50 mg BID, about 75 mg BID, about 100 mg BID, about 150 mg BID, about 200 mg BID, or about 350 mg BID.

53. The use of any one of claims 32-52, wherein the medicament comprises one or more pharmaceutically acceptable one or more pharmaceutically acceptable carrier(s), diluent(s), and/or excipient(s).

54. The use of any one of claims 32-53, wherein the (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide or the pharmaceutically acceptable salt thereof is (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide hydrochloride.