CLAIMS:

1. Use of a first amount of ornithine phenylacetate and a second amount of ornithine phenylacetate in the preparation of a medicament for treating or ameliorating hyperammonemia in a patient in need thereof

wherein the first amount of ornithine phenylacetate is for administration during a first period of time; and

the second amount of ornithine phenylacetate is for administration during a second period of time;

wherein the first amount of ornithine phenylacetate is between about 10 g to about 30 g, and the second amount of ornithine phenylacetate is less than the first amount; and

wherein a baseline QT interval of the patient is assessed or received prior to the treatment.

2. The use according to claim 1, wherein the baseline QT interval is determined as an average of two or more measurements of QT intervals prior to the administration of the first amount of ornithine phenylacetate.

3. The use according to claim 2, wherein two measurements of QT interval are taken 30 minutes and 15 minutes prior to the administration of the first amount of ornithine phenylacetate.

4. The use according to any one of claims 1 to 3, wherein information on a change of QT interval from the baseline QT interval during or after the administration of the first amount of ornithine phenylacetate has been received or assessed.

5. The use according to claim 4, wherein the change of QT interval is the difference between one or more QT intervals during the first period of time and the baseline QT interval.

6. The use according to claim 5, wherein the first amount of ornithine phenylacetate is adjusted when the change of QT interval is an increase of more than 20% from the baseline QT interval.

7. The use according to claim 4, wherein the change of QT interval is the difference between one or more QT intervals during the second period of time and the baseline QT interval.

8. The use according to claim 7, wherein the second amount of ornithine phenylacetate is adjusted when the change of QT interval is an increase of more than 20% from the baseline QT interval.

9. The use according to any one of claims 1 to 8, wherein the QT interval is measured by an electrocardiogram (ECG).

10. The use according to any one of claims 1 to 9, wherein the QT interval is corrected for heart rate using Fridericia's formula (QTcF), and wherein the assessed baseline QTcF of the patient is less than 500 ms.

11. The use according to any one of claims 1 to 10, wherein information on whether the patient has one or more risk factors for QT prolongation is determined prior to administering the first amount of ornithine phenylacetate.

12. The use according to claim 11, wherein the risk factors for QT prolongation comprise hypokalemia, hypomagnesemia, congenital long-QT syndrome, suspected or actual acute myocardial infarction, or concurrent therapy with one or more QT-prolonging drugs, or combinations thereof.

13. The use according to claim 11 or 12, wherein the patient does not have hypokalemia, hypomagnesemia, or congenital long-QT syndrome.

14. The use according to claim 11 or 12, wherein the patient is not being administered any QT-prolonging drug concurrently.

15. Use of a first amount of ornithine phenylacetate and a second amount of ornithine phenylacetate in the preparation of a medicament for treating or ameliorating hyperammonemia in a patient in need thereof,

wherein the first amount of ornithine phenylacetate is for administration during a first period of time; and

the second amount of ornithine phenylacetate is for administration during a second period of time;

wherein the first amount of ornithine phenylacetate is between about 10 g to about 30 g, and the second amount of ornithine phenylacetate is less than the first amount; and

wherein information on the patient's concurrent therapy with one or more QT prolonging drugs is assessed or received prior to the treatment.

16. Use of a first amount of ornithine phenylacetate and a second amount or ornithine phenylacetate in the preparation of a medicament for treating or ameliorating hyperammonemia in a patient in need thereof;

wherein the first amount of ornithine phenylacetate is for administration during a first period of time; and

the second amount of ornithine phenylacetate is for administration during a second period of time;

wherein the first amount of ornithine phenylacetate is between about 10 g to about 30 g, and the second amount of ornithine phenylacetate is less than the first amount; and

wherein the patient is not to take one or more QT-prolonging drugs concurrently.

17. The use according to any one of claims 12, 15 or 16, wherein the QT-prolonging drugs are selected from the group consisting of amiodarone, anagrelide, arsenic trioxide, astemizole, azithromycin, bepridil, chloroquine, chlorpromazine, cilostazol, ciprofloxacin, cisapride,

citalopram, clarithromycin, cocaine, disopyramide, dofetilide, domperidone, donepezil, dronedarone, droperidol, erythromycin, escitalopram, flecainide, fluconazole, gatifloxacin, grepafloxacin, halofantrine, haloperidol, ibogaine, ibutilide, levofloxacin, levomepromazine (methotrimeprazine), levomethadyl acetate, levosulpiride, mesoridazine, methadone, moxifloxacin, ondansetron, oxaliplatin, papaverine HCl (intra-coronary), pentamidine, pimozide, probucol, procainamide, propofol, quinidine, roxithromycin, sevoflurane, sotalol, sparfloxacin, sulpiride, sultopride, terfenadine, telaprevir, terlipressin, terodiline, thioridazine, and vandetanib.

18. The use according to any one of claims 12, 15 or 16, wherein the QT-prolonging drugs are selected from the group consisting of amantadine, amisulpride, amitriptyline, amphotericin B, atazanavir, bendroflumethiazide, bendrofluazide, chloral hydrate, diphenhydramine, doxepin, esomeprazole, famotidine, fluoxetine, fluvoxamine, galantamine, garenoxacin, hydroxychloroquine, hydroxyzine, indapamide, itraconazole, ivabradine, ketoconazole, loperamide, metoclopramide, metolazone, metronidazole, nelfinavir, olanzapine, omeprazole, paroxetine, piperacillin, tazobactam, posaconazole, propafenone, quetiapine, quinine sulfate, ranolazine, sertraline, solifenacin, trazodone, torsemide (torasemide), voriconazole, and ziprasidone.

19. The use according to any one of claims 12, 15 or 16, wherein the QT-prolonging drugs are selected from the group consisting of alfuzosin, apomorphine, aripiprazole, artenimol, piperaquine, asenapine, atomoxetine, bedaquiline, bendamustine, benperidol, betrixaban, bortezomib, bosutinib, buprenorphine, cabozantinib, capecitabine, ceritinib, clofazimine, clomipramine, clozapine, crizotinib, cyamemazine (cyamepromazine), dabrafenib, dasatinib, degarelix, delamanid, desipramine, deutetrabenazine, dexmedetomidine, dolasetron, efavirenz, eliglustat, epirubicin, eribulin mesylate, ezogabine (retigabine), felbamate, fingolimod, fluorouracil (5-FU), flupentixol, gemifloxacin, granisetron, hydrocodone, iloperidone, imipramine (melipramine), inotuzumab ozogamicin, isradipine, ketanserin, lapatinib, lenvatinib, lithium, lopinavir, ritonavir, melperone, midostaurin, mifepristone, mirabegron, mirtazapine, moexipril, hydrocholorothiazide, necitumumab, nicardipine, nilotinib, norfloxacin, nortriptyline, nusinersen, ofloxacin, osimertinib, oxytocin, paliperidone, palonosetron, panobinostat, pasireotide, pazopanib, perflutren lipid microspheres, perphenazine, pilsicainide, pimavanserin, pipamperone, primaquine phosphate, promethazine, prothipendyl, ribociclib, rilpivirine, risperidone, romidepsin, saquinavir, sertindole, sorafenib, sunitinib, tacrolimus, tamoxifen, telavancin, telithromycin, tetrabenazine, tiapride, tipiracil, trifluridine, tizanidine, tolterodine, toremifene, tramadol, trimipramine, tropisetron, valbenazine, vardenafil, vemurafenib, venlafaxine, vorinostat, and zotepine.

20. The use according to any one of claims 15 to 19, wherein information on a change of QT interval during the administration of the first amount or the second amount of ornithine phenylacetate has been received or assessed, as compared from a baseline QT interval prior to the administration of the first amount of ornithine phenylacetate.

21. The use according to claim 20, wherein the first amount of ornithine phenylacetate is adjusted when the change of QT interval is an increase of more than 20% from the baseline QT interval.

22. The use according to claim 20, wherein the second amount of ornithine phenylacetate is further adjusted when the change of QT interval is an increase of more than 20% from the baseline QT interval.

23. The use according to any one of claims 1 to 22, wherein the first amount of ornithine phenylacetate is about 20 g and the first period of time is about 6 hours.

24. The use according to any one of claims 1 to 23, wherein the second amount of ornithine phenylacetate is about 15 g and the second period of time is about 18 hours, and the second amount of ornithine phenylacetate is for administration immediately after the completion of the administration of the first amount of ornithine phenylacetate.

25. The use according to any one of claims 1 to 24, further comprising a third amount of ornithine phenylacetate for administration immediately following the completion of the administration of the second amount of ornithine phenylacetate during a third period of time, wherein the third period of time is about 4 days and the third amount of ornithine phenylacetate administered per day (24 hours) is the same or less than the second amount of ornithine phenylacetate.

26. The use according to claim 25, wherein information on a change of QT interval from the baseline QT interval during or after the administration of the third amount of ornithine phenylacetate has been received or assessed, and wherein the change of QT interval is determined as the difference between one or more QT intervals during the third period of time and the baseline QT interval.

27. The use according to claim 26, wherein the third amount of ornithine phenylacetate is adjusted when the change of QT interval is an increase of more than 20% from the baseline QT interval.

28. The use according to any one of claims 1 to 27, wherein ornithine phenylacetate is for administration via continuous intravenous infusion.

29. The use according to any one of claims 1 to 28, wherein the patient is also receiving standard of care of hyperammonemia.

30. The use according to any one of claims 1 to 29, wherein the patient has liver cirrhosis, liver decompensation, an acute liver disease, a chronic liver disease, portal hypertension, or urea cycle disorder.

31. The use according to any one of claims 1 to 30, wherein the patient is suffering from or has suffered from one or more episodes of hepatic encephalopathy.