CLAIMS:

1. Use of a first amount of ornithine phenylacetate and a second amount of ornithine phenylacetate for the manufacture of a medicament for treating or ameliorating hyperammonemia in a patient in need thereof, wherein the medicament comprises a first amount of ornithine phenylacetate for administration during a first period of time and the second amount of ornithine phenylacetate 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 of ornithine phenylacetate.

2. The use of claim 1, wherein the first period of time is from about 1 hour to about 10 hours, and a total of the first period of time and the second period of time is from about 18 hours to 36 hours.

3. The use of claim 1 or 2, wherein the first amount of ornithine phenylacetate is about 20 g, and the first period of time is about 6 hours.

4. The use of any one of claims 1 to 3, wherein the second amount of ornithine phenylacetate is about 15 g, and the second period of time is about 18 hours.

5. The use of any one of claims 1 to 4, wherein the second amount of ornithine phenylacetate is for administration immediately after the completion of the administration of the first amount of ornithine phenylacetate.

6. The use of any one of claims 1 to 5, wherein the first amount of ornithine phenylacetate or the second amount of ornithine phenylacetate is for intravenous infusion.

7. The use of any one of claims 1 to 6, wherein the medicament further comprises a third amount of ornithine phenylacetate for administration during a third period of time immediately following the completion of the administration of the second amount of ornithine phenylacetate.

8. The use of claim 7, wherein the third period of time is from about 2 days to about 10 days, or about 4 days.

9. The use of claim 7 or 8, wherein the third amount of ornithine phenylacetate for administration per day (24 hours) is the same or less than the second amount of ornithine phenylacetate.

10. The use of claim 9, wherein the third amount of ornithine phenylacetate for administration per day is about 15 g.

11. The use of any one of claims 7 to 10, wherein the third amount of ornithine phenylacetate is for intravenous infusion.

12. The use of any one of claims 1 to 11, wherein the patient is also receiving standard of care.

13. Use of a first amount of ornithine phenylacetate and a second amount of ornithine phenylacetate for the manufacture of a medicament for treating or ameliorating hyperammonemia in a patient in need thereof, the medicament comprises a first amount of ornithine phenylacetate for administration during a first period of time and a second amount of ornithine phenylacetate for administration during a second period of time;

wherein the patient in need of treatment of hyperammonemia is suffering from impaired renal function and has estimated glomerular filtration rate (eGFR) between 15 mL/min/1.73m^2 and 29 mL/min/1.73m^2; and wherein the first amount of ornithine phenylacetate is between about 5 g to about 20 g, and the second amount of ornithine phenylacetate is less than the first amount of ornithine phenylacetate, and wherein the medicament is for intravenous infusion.

14. The use of claim 13, wherein the first period of time is from about 1 hour to about 10 hours and a total of the first period of time and the second period of time is from about 18 hours to 36 hours.

15. The use of claim 13 or 14, wherein the first amount of ornithine phenylacetate is from about 7.5 g to about 15 g, and the first period of time is from about 4 hours to about 6 hours.

16. The use of any one of claims 13 to 15, wherein the second amount of ornithine phenylacetate is from about 7.5 g to about 15 g, and the second period of time is from about 12 hours to about 18 hours.

17. The use of any one of claims 13 to 16, wherein the second amount of ornithine phenylacetate is for administration immediately after the completion of the administration of the first amount of ornithine phenylacetate.

18. The use of any one of claims 13 to 17, wherein the medicament further comprises a third amount of ornithine phenylacetate for administration during a third period of time immediately following the completion of the administration of the second amount of ornithine phenylacetate.

19. The use of claim 18, wherein the third period of time is from about 2 days to about 10 days, or from about 3 days to about 4 days.

20. The use of claim 18 to 19, wherein the third amount of ornithine phenylacetate administered per day (24 hours) is the same or less than the second amount of ornithine phenylacetate.

21. The use of claim 20, wherein the third amount of ornithine phenylacetate for administration per day is from about 7.5 g to about 15 g, by intravenous infusion.

22. The use of any one of claims 13 to 21, wherein the patient is also receiving standard of care.

23. Use of a first amount of ornithine phenylacetate and a second amount of ornithine phenylacetate for the manufacture of a medicament for treating or ameliorating hyperammonemia in a patient in need thereof based on the renal function of the patient, the medicament comprises the first amount of ornithine phenylacetate for administration during a first period of time and the second amount of ornithine phenylacetate for administration during a second period of time;

wherein the first amount of ornithine phenylacetate is from about 10 g to about 30 g when the patient's estimated creatinine clearance is greater than 35 mL/min/1.73m^2; or

wherein the first amount of ornithine phenylacetate is from about 5 g to about 15 g when the patient's estimated creatinine clearance is equal to or less than 35 mL/min/1.73m^2.

24. Use of a first amount of ornithine phenylacetate and a second amount of ornithine phenylacetate for the manufacture of a medicament for treating or ameliorating hyperammonemia in a patient in need thereof based on the body weight or body size of the patient, the medicament comprises the first amount of ornithine phenylacetate for administration during a first period of time and the second amount of ornithine phenylacetate for administration during a second period of time;

wherein the second amount of ornithine phenylacetate adapted for administration to the patient is adjustable during a second period of time based on the plasma concentration of phenylacetic acid.

25. Use of a first amount of ornithine phenylacetate and a second amount of ornithine phenylacetate for the manufacture of a medicament for treating or ameliorating hyperammonemia in a patient in need thereof based on the degree of hepatic impairment of the patient, the medicament comprises the first amount of ornithine phenylacetate for administration during a first period of time and the second amount of ornithine phenylacetate for administration during a second period of time;

wherein the second amount of ornithine phenylacetate for administration during the second period of time is adjustable based on the plasma concentration of phenylacetic acid.

26. The use of any one of claims 1 to 25, wherein the patient's serum ammonia level is ≥ 21 μmol/L.

27. The use of any one of claims 1 to 26, wherein the patient has cirrhosis.

28. The use of any one of claims 1 to 27, wherein the patient is at risk of hepatic encephalopathy or has had at least one episode of hepatic encephalopathy, or is hospitalized due to one or more hepatic encephalopathy episodes.

29. The use of any one of claims 1 to 28, wherein the patient has received at least 4 hours to 6 hours of standard of care prior to the administration of the first amount of ornithine phenylacetate.

30. The use of any one of claims 1 to 29, wherein ornithine phenylacetate is for administration as an aqueous solution comprising about 200 mg/mL to about 400 mg/mL ornithine phenylacetate, or about 300 mg/mL ornithine phenylacetate.

31. The use of claim 30, wherein the aqueous solution of ornithine phenylacetate has a pH of at least about 5, or a pH range of about 5.4 to about 6.5.

32. A pharmaceutical formulation comprising an aqueous solution of about 200 mg/mL to 400 mg/mL of ornithine phenylacetate and at least one pH adjusting agent, wherein the aqueous solution has a pH of at least about 5.

33. The pharmaceutical formulation of claim 32, wherein the pH of the aqueous solution has a pH range of about 5.4 to about 6.5.

34. The pharmaceutical formulation of claim 32 or 33, wherein the pH adjusting agent is HCl or citric acid, or a combination thereof.

35. The pharmaceutical formulation of claim 32 or 34, wherein formulation comprises less than 1% ornithine phenylacetate precipitate.

36. The pharmaceutical formulation of any one of claims 32 to 35, wherein the formulation comprises less than about 0.1% by weight of 3-amino-2-piperidone for up to 6 months at a storage temperature ranging from about 2°C to about 8°C.