experience for an individual receiving the same for effective in glucose control and weight reduction in T2DM disease management.

Summary

[005a] In an aspect of the present disclosure, there is provided a pharmaceutical composition comprising:

an incretin analog or pharmaceutically acceptable salt thereof;

at least one tonicity agent selected from the group consisting of glycerin, mannitol and propylene glycol; and

an optional preservative selected from the group consisting of m-cresol and phenol.

[005b] In another aspect of the present disclosure, there is provided a use of a pharmaceutical composition as disclosed herein in the manufacture of a medicament for treating diabetes in an individual in need thereof.

[005c] In a further aspect of the present disclosure, there is provided a use of a pharmaceutical composition as disclosed herein in the manufacture of a medicament for treating obesity in an individual in need thereof.

[005d] In another aspect of the present disclosure, there is provided a use of a pharmaceutical composition as disclosed herein in the manufacture of a medicament for treating a disease selected from the group consisting of diabetes mellitus, dyslipidemia, fatty liver disease, metabolic syndrome, non-alcoholic steatohepatitis and obesity.

[005e] In a further aspect of the present disclosure, there is provided a use of a pharmaceutical composition as disclosed herein in the manufacture of a medicament for treating type II diabetes mellitus.

[005f] In another aspect of the present disclosure, there is provided an article of manufacture comprising the pharmaceutical composition as disclosed herein, wherein the article of manufacture is selected from a multiuse vial, a reusable pen injector, a pre-filled disposable pen, an autoinjector, and a pump.

[005g] In a further aspect of the present disclosure, there is provided a pharmaceutical composition as disclosed herein for use in therapy.

Description

[006] To address this need, the disclosure first describes a pharmaceutically acceptable composition that includes an incretin analog, or a pharmaceutically acceptable salt thereof, a tonicity agent and optionally a preservative.

[007] In some instances, the incretin analog can be SEQ ID NO:1 or a pharmaceutically acceptable salt thereof. In some instances, the incretin analog can be at a concentration from about 1 mg/mL to about 30 mg/mL. In certain instances, the incretin analog can be at a concentration of 1 mg/mL, 2 mg/mL, 3 mg/mL, 4 mg/mL, 5 mg/mL, 6 mg/mL, 8 mg/mL, 9 mg/mL, 12 mg/mL, 18 mg/mL, 24 mg/mL or 30 mg/mL. In some instances, pharmaceutically acceptable salts for use herein may be selected from sodium, trifluoroacetate, hydrochloride and/or acetate salts. In some instances, a pharmaceutically acceptable salt nay be a tetra sodium salt.

[008] In some instances, the tonicity agent can be selected from glycerin, mannitol and propylene glycol. When the tonicity agent is glycerin, it can be at a concentration from about 5 mg/mL to about 50 mg/mL, especially 20 mg/mL. When the tonicity agent is mannitol, it can be at a concentration from about 10 mg/mL to about 100 mg/mL, especially 46 mg/mL. When the tonicity agent is propylene glycol, it can be at a concentration from about 5 mg/mL to about 50 mg/mL, especially 15 mg/mL. In certain instances, the tonicity agent is mannitol at 46 mg/mL.

[009] In some instances, the preservative can be selected from m-cresol and phenol. When the preservative is m-cresol, it can be at a concentration from about 1 mg/mL to about 10 mg/mL, especially 3.15 mg/mL. When the preservative is phenol, it can be at a concentration from about 1 mg/mL to about 10 mg/mL, especially 5 mg/mL. In certain instances, the preservative is m-cresol at 3.15 mg/mL.

[0010] In some instances, the composition can be at a pH of about 7.0 to about 8.0, especially about 7.5. In certain instances, a buffer system can be used to maintain the pH, especially a TRIS buffer system at a concentration from about 10 mM to about 100 mM, especially 10 mM.

[0011] In view of the above, and in certain instances, the composition include an incretin analog at a concentration from about 2 mg/mL to about 30 mg/mL and a tonicity agent at a concentration from 10 to 50 mg/mL in a TRIS buffer system at a pH of about 7.5. In some

CLAIMS

The invention claimed is:

1. A pharmaceutical composition comprising:

an incretin analog or pharmaceutically acceptable salt thereof;

at least one tonicity agent selected from the group consisting of glycerin, mannitol and propylene glycol; and

an optional preservative selected from the group consisting of m-cresol and phenol.

2. The pharmaceutical composition of Claim 1, wherein the incretin analog or pharmaceutically acceptable salt thereof is at a concentration from about 1 mg/mL to about 30 mg/mL.

3. The pharmaceutical composition of Claims 1 or 2, wherein the tonicity agent is glycerin and is at a concentration is from about 5 mg/mL to about 50 mg/mL.

4. The pharmaceutical composition of Claim 3, wherein the glycerin is at a concentration of 20 mg/mL.

5. The pharmaceutical composition of Claims 1 or 2, wherein the tonicity agent is mannitol and is at a concentration is from about 10 mg/mL to about 100 mg/mL.

6. The pharmaceutical composition of Claim 5, wherein the mannitol is at a concentration of 48 mg/mL.

7. The pharmaceutical composition of Claims 1 or 2, wherein the tonicity agent is propylene glycol and is at a concentration is from about 5 mg/mL to about 50 mg/mL.

8. The pharmaceutical composition of Claim 7, wherein the propylene glycol is at a concentration of 15 mg/mL.

9. The pharmaceutical composition of any one of Claims 1 to 8, wherein the optional preservative is m-cresol and is at a concentration is from about 1 mg/mL to about 10 mg/mL.

10. The pharmaceutical composition of Claim 9, wherein the m-cresol is at a concentration of 3.15 mg/mL.

11. The pharmaceutical composition of any one of Claims 1 to 8, wherein the optional preservative is phenol and is at a concentration is from about 1 mg/mL to about 10 mg/mL.

12. The pharmaceutical composition of Claim 11, wherein the phenol is at a concentration of 5 mg/mL.

13. The pharmaceutical composition of any of Claims 1 to 12, wherein the incretin analog comprises SEQ ID NO:1.

14. The pharmaceutical composition of Claim 13, wherein the incretin analog is at a concentration selected from the group consisting of 1 mg/mL, 2 mg/mL, 3 mg/mL, 4 mg/mL, 5 mg/mL, 6 mg/mL, 8 mg/mL, 9 mg/mL, 12 mg/mL, 18 mg/mL, 24 mg/mL and 30 mg/mL.

15. The pharmaceutical composition of any one of Claims 1 to 14 further comprising a buffer selected from the group consisting of a phosphate (PO_4) buffer and a tris(hydroxymethyl)aminomethane (TRIS) buffer.

16. The pharmaceutical composition of Claim 15, wherein the buffer is the TRIS buffer and is at a concentration of 10 mM.

17. The pharmaceutical composition of any one of Claims 1 to 15 further comprising ethylenediaminetetraacetic acid (EDTA) at a concentration of 0.3 mg/mL.

18. The pharmaceutical composition of Claim 1 comprising:

an incretin analog, or pharmaceutically acceptable salt thereof, comprising SEQ ID NO:1, wherein the incretin analog or pharmaceutically acceptable salt thereof is at a concentration from about 1 mg/mL to about 30 mg/mL;

mannitol at a concentration from about 10 mg/mL to about 100 mg/mL; and

tris(hydroxymethyl)aminomethane (TRIS) buffer at a concentration from about 10 mM to about 100 mM.

19. The pharmaceutical composition of Claim 18, wherein the pharmaceutical composition has a pH of about 6.5 to about 7.5.

20. The pharmaceutical composition of Claim 18 or 19, wherein mannitol is at a concentration of 48 mg/mL.

21. The pharmaceutical composition of any one of Claims 18 to 20, wherein the incretin analog or pharmaceutically acceptable salt thereof is at a concentration selected from the group consisting of 1 mg/mL, 2 mg/mL, 3 mg/mL, 4 mg/mL, 5 mg/mL, 6 mg/mL, 8 mg/mL, 9 mg/mL, 12 mg/mL, 18 mg/mL, 24 mg/mL and 30 mg/mL.

22. The pharmaceutical composition of any one of Claims 18 to 21 further comprising a preservative selected from the group consisting of m-cresol and phenol, wherein the preservative is at a concentration of about 1 mg/mL to about 10 mg/mL.

23. The pharmaceutical composition of any one of Claims 1 to 22 further comprising a pharmaceutically acceptable carrier, diluent or excipient.

24. The pharmaceutical composition of any one of Claims 1 to 23, wherein the volume of the composition dose is about 0.5 mL.

25. The pharmaceutical composition of Claim 24, wherein the pharmaceutical composition is suitable for administration using an automatic injection apparatus.

26. The pharmaceutical composition of any one of Claims 1-25, wherein the pharmaceutically acceptable salt is selected from a sodium, trifluoroacetate, hydrochloride and acetate salt.

27. The pharmaceutical composition of any one of Claims 1-26, wherein the pharmaceutically acceptable salt is a tetra sodium salt.

28. Use of a pharmaceutical composition of any one of Claims 1 to 27 in the manufacture of a medicament for treating diabetes in an individual in need thereof.

29. The use of Claim 28, wherein the composition is to be administered to the individual using an automatic injection apparatus.

30. The use of Claim 28 or 29, wherein the composition is to be administered to the individual once weekly.

31. Use of a pharmaceutical composition of any one of Claims 1 to 27 in the manufacture of a medicament for treating obesity in an individual in need thereof.

32. The use of Claim 31, wherein the composition is to be administered to the individual using an automatic injection apparatus.

33. The use of Claim 31 or 32, wherein the composition is to be administered to the individual once weekly.

34. Use of a pharmaceutical composition of any one of Claims 1 to 27 in the manufacture of a medicament for treating a disease selected from the group consisting of diabetes mellitus, dyslipidemia, fatty liver disease, metabolic syndrome, non-alcoholic steatohepatitis and obesity.

35. Use of a pharmaceutical composition of any one of Claims 1 to 27 in the manufacture of a medicament for treating type II diabetes mellitus.

36. An article of manufacture comprising the pharmaceutical composition of any one of Claims 1 to 27, wherein the article of manufacture is selected from a multiuse vial, a reusable pen injector, a pre-filled disposable pen, an autoinjector, and a pump.

37. A pharmaceutical composition of any one of claims 1-27 for use in therapy.