Claims

1. A method for treating diabetes in a human in need thereof comprising once weekly administration to the human of a pharmaceutical composition comprising exendin-4 in an amount to achieve a mean steady state plasma concentration of exendin-4 at 170 pg/ml to 350 pg/ml for at least one month in the human to treat diabetes.

2. The method of Claim 1, wherein the pharmaceutical composition further comprises a poly(lactide-co-glycolide) copolymer.

3. The method of Claim 1, wherein the pharmaceutical composition comprises a poly(lactide-co-glycolide) copolymer and 2.0 mg exendin-4.

4. The method of Claim 1, wherein the pharmaceutical composition comprises 5% (w/w) exendin-4, 2% (w/w) sucrose, and 93% (w/w) poly(lactide-co-glycolide)copolymer.

5. The method of any one of Claims 1-5, wherein the diabetes is Type 2 diabetes.

6. A method for reducing one or more of HbA1C, fasting plasma glucose, and body weight in a human in need thereof comprising once weekly administration to the human of a pharmaceutical composition comprising exendin-4 in an amount to achieve a mean steady state concentration of exendin-4 at 170 pg/ml to 350 pg/ml for at least one month in the human to reduce one or more of HbA1C, fasting plasma glucose, and body weight.

7. The method of Claim 6 for reducing HbA1C in the human.

8. The method of Claim 6 for reducing fasting plasma glucose in the human.

9. The method of Claim 6 for reducing body weight in the human.

10. The method of Claim 6, 7, 8, 9, or 10, wherein the pharmaceutical composition further comprises a poly(lactide-co-glycolide) copolymer.

11. The method of Claim 6, 7, 8, or 9, wherein the pharmaceutical composition comprises a poly(lactide-co-glycolide) copolymer and 2.0 mg exendin-4.

12. The method of Claim 6, 7, 8, or 9, wherein the pharmaceutical composition comprises 5% (w/w) exendin-4, 2% (w/w) sucrose, and 93% (w/w) poly(lactide-co-glycolide)copolymer.

13. The method of any one of Claims 6-13, wherein the pharmaceutical composition is administered to the human once weekly.

14. A method for treating Type 2 diabetes in a human in need thereof comprising once weekly administration to the human of a pharmaceutical composition comprising 5% (w/w) exendin-4, 2% (w/w) sucrose, and 93% (w/w) poly(lactide-co-glycolide)copolymer to achieve a mean steady state plasma concentration of exendin-4 at 170 pg/ml to 350 pg/ml for at least one month in the human to treat Type 2 diabetes.

CLAIMS

1. A pharmaceutical composition in a unit dosage form comprising an amount of exendin-4, and a pharmaceutically acceptable carrier, for use in the treatment of diabetes in a human in need thereof, wherein the pharmaceutical composition is for use once weekly and achieves an average plasma concentration of the exendin-4 at 170 pg/ml to 600 pg/ml for at least one month in the human, and wherein the amount of exendin-4 is 1.5 to 3.0 mg.

2. The pharmaceutical composition of claim 1, which further comprises a poly(lactide-co-glycolide) copolymer.

3. The pharmaceutical composition of claim 1, wherein the average plasma concentration of exendin-4 is 170 pg/ml to 350 pg/ml.

4. The pharmaceutical composition of claim 1, wherein the average plasma concentration of exendin-4 is 170 pg/ml to 290 pg/ml.

5. The pharmaceutical composition of claim 1, wherein the amount of exendin-4 is about 2.0 mg.

6. The pharmaceutical composition of claim 1, comprising 2% (w/w) sucrose, 93% (w/w) poly(lactide-co-glycolide)copolymer, and 5% (w/w) exendin-4.

7. The pharmaceutical composition of any one of claims 1-6, wherein the diabetes is Type 2 diabetes.

8. A pharmaceutical composition in a unit dosage form comprising an amount of exendin-4, and a pharmaceutically acceptable carrier, for reducing one or more of HbA1C, fasting plasma glucose, and body weight in a human in need thereof, wherein the pharmaceutical composition is for use once weekly and achieves an average plasma concentration of exendin-4 at 170 pg/ml to

600 pg/ml for at least one month in the human, and wherein the amount of exendin-4 is 1.5 to 3.0 mg.

9. The pharmaceutical composition of claim 8 for reducing HbA1C in the human.

10. The pharmaceutical composition of claim 8 for reducing fasting plasma glucose in the human.

11. The pharmaceutical composition of claim 8 for reducing body weight in the human.

12. The pharmaceutical composition of any one of claims 8-11, which further comprises a poly(lactide-co-glycolide) copolymer.

13. The pharmaceutical composition of claim 8, wherein the average plasma concentration is 170 pg/ml to 350 pg/ml.

14. The pharmaceutical composition of claim 8, wherein the average plasma concentration is 170 pg/ml to 290 pg/ml.

15. The pharmaceutical composition of claim 8, wherein the amount of exendin-4 is about 2.0 mg.

16. The pharmaceutical composition of any one of claims 8-16, comprising 2% (w/w) sucrose, 93% (w/w) poly(lactide-co-glycolide)copolymer and 5% (w/w) exendin-4.

17. A pharmaceutical composition in a unit dosage form comprising 5% (w/w) exendin-4 in an amount of about 2 mg, 2% (w/w) sucrose, and 93% (w/w) poly(lactide-co-glycolide)copolymer for use in the treatment of Type 2 diabetes in a human in need thereof, wherein the pharmaceutical composition is for use once weekly in an amount that achieves an average plasma concentration of exendin-4 at 170 pg/ml to 350 pg/ml for at least one month in the human.