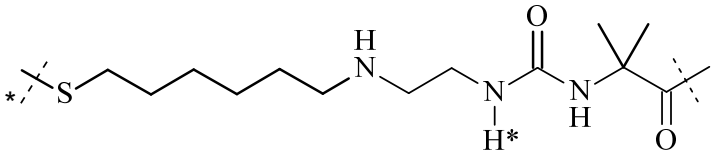
Claims

1. Use of a PTH compound in the manufacture of a medicament for the treatment of hypoparathyroidism, wherein single daily administrations of the medicament are to be administered to a patient and the patient is to be titrated off of standard of care within four weeks from the time the first dose of the medicament was administered and wherein the PTH compound is of formula (IIf-i)

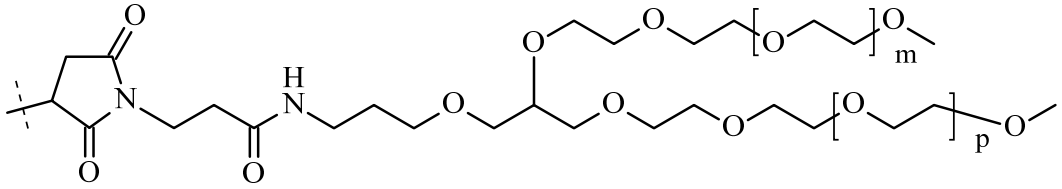


(IIf-i),

wherein

the unmarked dashed line indicates attachment to the N-terminal amine functional group of a PTH moiety having the sequence of SEQ ID NO:51 by forming an amide bond; and

the dashed line marked with the asterisk indicates attachment to a moiety



wherein

m and p are independently an integer ranging from and including 400 to 500.

2. The use of claim 1, wherein the patient is titrated off standard of care within three weeks from the time the first dose of the medicament is administered.

3. The use of claim 1 or 2, wherein the patient is titrated off standard of care within two weeks from the time the first dose of the medicament is administered.

4. The use of any one of claims 1 to 3, wherein the single daily dose of the PTH compound is below 31 µg/day.

5. The use of any one of claims 1 to 4, wherein the single daily dose of the PTH compound is selected from 15 µg/day, 18 µg/day and 21 µg/day.

6. The use of any one of claims 1 to 4, wherein the single daily dose of the PTH compound is 30 µg/day.

7. The use of any one of claims 1 to 4, wherein the single daily dose of the PTH compound is 27 µg/day.

8. The use of any one of claims 1 to 4, wherein the single daily dose of the PTH compound is 24 µg/day.

9. The use of any one of claims 1 to 5, wherein the single daily dose of the PTH compound is 18 µg/day.

10. The use of any one of claims 1 to 5, wherein the single daily dose of the PTH compound is 15 µg/day.

11. The use of any one of claims 1 to 10, wherein the patient is a human patient.

12. The use of any one of claims 1 to 11, wherein administration is by subcutaneous injection.

13. The use of any one of claims 1 to 12, wherein administration is with a pen injector.

14. The use of any one of claims 1 to 13, wherein the dose of the PTH compound administered to a patient is adjusted in response to serum calcium levels.

15. The use of any one of claims 1 to 14, wherein the patient is to be titrated off of standard of care according to a titration scheme that includes a stepwise reduction followed by a complete omission of orally administered vitamin D, followed by a stepwise reduction followed by complete omission of orally administered calcium.

16. The use of any one of claims 1 to 14, wherein the patient is to be titrated off of standard of care according to the following the titration scheme

(i) Visit 1: Decrease active vitamin D dose by 33-50%;

(ii) Day 3-4: Discontinue active vitamin D;

(iii) Day 6-7: Decrease calcium supplementation by 50%;

(iv) Day 9-10: If daily nutritional calcium exceeds 750 mg/day, discontinue calcium supplements; if daily nutritional calcium intake is <750 mg/day, a calcium supplement to achieve the RDA can be maintained at the discretion of the physician.

17. The use of any one of claims 1 to 14, wherein the patient is to be titrated off of standard of care according to the following the titration scheme

(i) Visit 1: Decrease active vitamin D dose by 33-50%

(ii) Day 3-4: Discontinue active vitamin D;

(iii) Day 6-7: If taking calcium ≤2000 mg/day, decrease calcium by ≥50% (≥400 mg/day); if on calcium >2000 mg/day, decrease calcium by ≥800 mg/day;

(iv) Day 9-10: If on calcium ≤2000 mg/day discontinue; if dietary calcium <750 mg/day maintain calcium at 400 or 500 mg/day or decrease calcium to ≤500 mg/day; if on calcium >2000 mg/day, decrease calcium by ≥800 mg/day.

18. The use of any one of claims 1 to 17, wherein 4 weeks after administration of the first dose of the medicament a statistically significant change in the Short Form-36 Physical Component Summary, in the SF-36 Mental Component Summary or both the SF-36 PCS and SF-36 MCS is achieved.