CLAIMS

1. Use of a long-acting recombinant human growth hormone (rhGH) comprising the amino acid sequence of SEQ ID NO:2 in the manufacture of a medicament for the treatment of a growth hormone deficiency (GHD) in a subject in need thereof, wherein the medicament is to be administered to the subject at an initial dose level; at least two measurements of an insulin growth factor 1 (IGF-1) level are taken in the subject; and the medicament is to be administered to the subject at a modified dose level that is about 15% lower than the initial dose level when the IGF-1 level in the subject on two consecutive measurements taken 4 to 6 weeks apart each has a standard deviation score (SDS) of greater than positive 2 (>+2).

2. The use of claim 1, wherein the medicament is to be administered once a week at the initial dose level or at the modified dose level.

3. The use of claim 1, wherein the subject is a pediatric subject.

4. The use of claim 1, wherein the initial dose level is about 0.66 milligrams (mg) per kilogram (kg) of body weight per week.

5. The use of claim 1, further comprising taking at least one additional measurement of an IGF-1 level in the subject at least 4 weeks after administering the medicament at the modified dose level.

6. The use of claim 5, further comprising the medicament to be administered to the subject at a further modified dose level when the at least one additional measurement of an IGF-1 level in the subject has an SDS of > +2.

7. The use of claim 6, wherein the medicament is administered once a week at the further modified dose level.

8. The use of claim 6, wherein the further modified dose level is about 15% lower than the modified dose level.

9. Use of a long-acting recombinant human growth hormone (rhGH) comprising the amino acid sequence of SEQ ID NO:2 in the manufacture of a medicament for the treatment of a growth hormone deficiency (GHD) in an adult subject in need thereof, wherein the medicament is to be administered to the subject at an initial dose level; at least one measurement of an insulin growth factor 1 (IGF-1) level is taken in the subject; and the medicament is to be administered to the subject at a modified dose level that is about 0.5 milligrams/week (mg/week) or about 0.75 mg/week lower than the initial dose level when the IGF-1 level in the subject has a standard deviation score (SDS) value of greater than positive 1.5 (> +1.5), or that is about 1.0 mg/week or about 1.5 mg/week higher than the initial dose level when the IGF-1 level in the subject has an SDS of less than negative 0.5 (< -0.5).

10. The use of claim 9, wherein the initial dose level ranges from about 1 mg/week to about 5 mg/week.

11. The use of claim 9, wherein the initial dose is: about 2.5 mg/week for a male 50 years of age or less, about 2.0 mg/week for a male greater than 50 years of age, about 3.0 mg/week for a female not on oral estrogen who is 50 years of age or less, about 2.5 mg/week for a female not on oral estrogen who is greater than 50 years of age, about 4.0 mg/week for a female on oral estrogen who is 50 years of age or less, or about 3.5 mg/week for a female on oral estrogen who is greater than 50 years of age.

12. The use of claim 9, further comprising taking at least one additional measurement of an IGF-1 level in a subject after administering the long-acting rhGH at the modified dose level.

13. The use of claim 12, further comprising the medicament to be administered to the subject at a further modified dose level when the at least one additional measurement of an IGF-1 level in the subject has an SDS of greater than positive 1.5 (> +1.5).

14. The use of claim 13, wherein the further modified dose level is about 0.5 mg/week lower or about 0.75 mg/week lower than the modified dose level.

15. The use of claim 12, further comprising the medicament to be administered to the subject at a further modified dose level when the at least one additional measurement of an IGF-1 level in the subject has an SDS of less than negative 0.5 (< -0.5).

16. The use of claim 15, wherein the further modified dose level is about 1.0 mg/week higher or about 1.5 mg/week higher than the modified dose level.

17. Use of a long-acting recombinant human growth hormone (rhGH) comprising the amino acid sequence of SEQ ID NO:2 in the manufacture of a medicament for the treatment of a growth hormone deficiency (GHD) in an adult subject in need thereof, wherein

the medicament is to be administered to the subject at an initial dose level;

the subject is monitored for an adverse event; and

the medicament is to be administered to the subject at a modified dose level,

wherein the modified dose level is 25% lower than the initial dose level if the adverse event is moderate, or

wherein the modified dose level is 50% lower than the initial dose level if the adverse event is severe.

18. Use of a long-acting recombinant human growth hormone (long-acting rhGH in the manufacture of a medicament for the treatment of a growth hormone deficiency (GHD) in a subject in need thereof, wherein the subject with GHD has previously received a once daily recombinant human growth hormone (once daily rhGH) therapy is selected; and a therapeutically effective amount of the medicament is to be administered to the subject, so that the efficacy of the long-acting rhGH in the subject is comparable to an efficacy of the long-acting rhGH in a subject with GHD who has previously received only the long-acting rhGH and has not previously received the once daily rhGH therapy.

19. The use of claim 18, wherein the once daily rhGH is somatropin, somatrem, a somatropin biosimilar, or a somatrem biosimilar.

20. The use of claim 18, wherein the efficacy is assessed by measuring one or more of: mean height velocity, gain in height standard deviation score (SDS), body mass index, bone maturation, insulin growth factor-1 (IGF-1) standard deviation score (SDS), insulin-like growth factor binding protein 3 (IGFBP-3) SDS, pubertal status changed from Tanner 1, mean glucose levels, hemoglobin A1c (HbA1c) levels, thyroid function, and cholesterol values.

21. The use of claim 18 wherein the long-acting rhGH is administered according to a dosage regimen comprising subcutaneous administration of 0.66 milligrams (mg) per kilogram (kg) body weight once weekly at any time of day.

22. A long-acting recombinant human growth hormone (rhGH) comprising the amino acid sequence of SEQ ID NO:2 for use in the treatment of a growth hormone deficiency (GHD) in a subject,

wherein the rhGH is for administering to the subject at an initial dose level; at least two measurements of an insulin growth factor 1 (IGF-1) are taken in the subject; and the rhGH is for administering to the subject at a modified dose level that is about 15% lower than the initial dose level, when the IGF-1 level in the subject on two consecutive measurements taken 4 to 6 weeks apart each has a standard deviation score (SDS) of greater than positive 2 (>+2).

23. A long-acting recombinant human growth hormone (rhGH) comprising the amino acid sequence of SEQ ID NO:2 for use in the treatment of a growth hormone deficiency (GHD) in an adult subject,

wherein the rhGH is for administering to the subject at an initial dose level; at least one measurement of an insulin growth factor 1 (IGF-1) level is taken in the subject; and the rhGH is for administering to the subject at a modified dose level that is about 0.5 milligrams/week (mg/week) or about 0.75 mg/week lower than the initial dose level, when the IGF-1 level in the subject has a standard deviation score (SDS) value of greater than positive 1.5 (> +1.5), or that is about 1.0 mg/week or about 1.5 mg/week higher than the initial dose level when the IGF-1 level in the subject has an SDS of less than negative 0.5 (< -0.5).

24. A long-acting recombinant human growth hormone (long-acting rhGH) for use in the treatment of a growth hormone deficiency (GHD) in a subject,

wherein the rhGH is for administering to the subject with GHD that has previously received a once daily recombinant human growth hormone (once daily rhGH) therapy; and the rhGH is for administering at a therapeutically effective amount, so that the efficacy of the long-acting rhGH in the subject is comparable to an efficacy of the long-acting rhGH in a subject with GHD who has previously received only the long-acting rhGH and has not previously received the once daily rhGH therapy.