CLAIMS

WHAT IS CLAIMED IS:

1. Use of a pharmaceutical composition comprising 3-[4-(4-amino-piperidin-1-yl)-3-(3,5-difluoro-phenyl)-quinolin-6-yl]-2-hydroxy-benzonitrile (Compound A), or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for the treatment of acromegaly in a human, wherein the pharmaceutical composition is to be administered orally to the human once daily;

wherein the dose of Compound A, or a pharmaceutically acceptable salt thereof, that is to be administered is about 40 mg/day, about 50 mg/day, about 60 mg/day, about 70 mg/day, or about 80 mg/day;

wherein Compound A, or a pharmaceutically acceptable salt thereof, is to be administered once daily at least 60 minutes before a meal;

wherein the treatment of acromegaly with Compound A, or a pharmaceutically acceptable salt thereof, comprises reducing serum insulin growth factor 1 (IGF-1) concentrations, reducing serum growth hormone (GH) concentrations, or both, in the human; and

wherein reducing IGF-1 concentrations comprises achieving a normal serum IGF-1 concentration in the subject, wherein a normal serum IGF-1 concentration in the subject is less than 1 times the upper limit of normal (ULN).

2. The use of claim 1, wherein the dose of Compound A, or a pharmaceutically acceptable salt thereof, that is to be administered is 40 mg/day.

3. The use of claim 1, wherein the dose of Compound A, or a pharmaceutically acceptable salt thereof, that is to be administered is 60 mg/day.

4. The use of claim 1, wherein the dose of Compound A, or a pharmaceutically acceptable salt thereof, that is to be administered is 80 mg/day.

5. The use of any one of claims 1 to 4, wherein the human has not responded to, tolerated, or lost response to treatment with a somatostatin analog, wherein the somatostatin analog is octreotide, lanreotide, or pasireotide.

6. The use of any one of claims 1 to 4, wherein the human with acromegaly responded to and tolerated treatment with a somatostatin analog, wherein the somatostatin analog is octreotide, lanreotide, or pasireotide.

7. The use of any one of claims 1 to 4, wherein the pharmaceutical composition to be administered to the human is dose proportional.

8. The use of any one of claims 1 to 7, wherein Compound A, or a pharmaceutically acceptable salt thereof, is to be administered in the form of one or more tablets, wherein each tablet comprises: a spray-dried solid dispersion of Compound A monohydrochloride; one or more additional pharmaceutically acceptable ingredients; and optionally one or more film coating agents.

9. The use of claim 8, wherein the spray-dried solid dispersion comprises:

a) Compound A monohydrochloride; and
b) a pharmaceutically acceptable polymer; wherein Compound A monohydrochloride, is dispersed in a polymer matrix formed from the pharmaceutically acceptable polymer;

wherein the amount of Compound A monohydrochloride that is to be administered is based on Compound A.

10. The use of any one of claims 1 to 9, wherein: Compound A, or a pharmaceutically acceptable salt thereof, is to be administered once daily at least 180 minutes after a meal.

11. The use of any one of claims 1 to 9, wherein: Compound A, or a pharmaceutically acceptable salt thereof, is to be administered once daily before bedtime.

12. The use of any one of claims 1 to 11, wherein if Compound A, or a pharmaceutically acceptable salt thereof, is to be co-administered with a drug that alters the pH of the upper gastrointestinal (GI) tract, then the daily dose amount of Compound A, or a pharmaceutically acceptable salt thereof, that is to be administered is to be increased, wherein the drug that alters the pH of the upper gastrointestinal (GI) tract comprises a proton pump inhibitor, a histamine H2-receptor antagonist, or an antacid.