**[0005]** There are no approved therapeutic interventions for ACH or HCH in North America, Europe, or Australia, and no widely accepted consensus about treatment (Unger). Current treatment options are nontargeted, ineffective, or painful interventions aimed at preventing or treating complications of ACH (FDA Background Document. Joint meeting of the Pediatric Advisory Committee and Endocrinologic and Metabolic Drugs Advisory Committee. 11 May 2018. Available at: https://www.fda.gov/downloads/AdvisoryCommittees/; Unger).

**[0006]** No clear growth effects have been shown after treatment with recombinant human growth hormone (r-hGH). An increase in growth velocity was noted (height increase from −5.0 to −4.0 standard deviations over 5 years), but no clear benefit was established for long-term treatment (Miccoli M, Bertelloni S, Massart F., Horm. Res. Paediatr., 2016, 86, 27–34); it is generally not a recommended treatment option for ACH (Horton; FDA).

**[0007]** Limb-lengthening procedures can provide 15–30 cm of additional height (~20% increased length of bone segment), but the procedures are painful, often require repeat procedures, and have high complication rates (Horton). Furthermore, the growth rate of the growth plate can be disturbed by these procedures, and the cosmetic effect of long legs and short arms may not be suitable for some patients (FDA). Clinicians who consider limb lengthening now typically require psychological evaluations and require that children be old enough to provide assent for the procedure (Wright MJ, Irving MD., Arch. Dis. Child., 2012, 97(2), 129-134).

**[0008]** Therefore, there remains an unmet need to develop novel therapeutic strategies for treating children with skeletal dysplasias such as achondroplasia and hypochondroplasia.

## SUMMARY

**[0008a]** In an aspect of the present disclosure, there is provided a use of infigratinib, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for treating achondroplasia or hypochondroplasia in a pediatric patient in need thereof, wherein about 0.01 milligrams per kilogram (mg/kg) to about 0.51 mg/kg of infigratinib, or a pharmaceutically acceptable salt thereof, is to be orally administered daily to the pediatric patient.

**[0008b]** In another aspect of the present disclosure, there is provided a use of infigratinib, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for treating a pediatric patient suffering from achondroplasia or hypochondroplasia, wherein about 0.1 mg to about 8 mg of infigratinib, or a pharmaceutically acceptable salt thereof, is to be orally administered daily to the pediatric patient.

**[0008c]** In a further aspect of the present disclosure, there is provided a minitablet for orally delivering 1 mg of infigratinib, comprising:

infigratinib monophosphate, in an amount to deliver 1 mg of infigratinib, and

a pharmaceutically acceptable excipient.

**[0008d]** In another aspect of the present disclosure, there is provided a minitablet for orally delivering 0.1 mg of infigratinib, comprising:

infigratinib monophosphate, in an amount to deliver 0.1 mg of infigratinib, and

a pharmaceutically acceptable excipient.

**[0008e]** In a further aspect of the present disclosure, there is provided a minitablet for oral delivery, comprising:

about 1% w/w to about 20% w/w of infigratinib monophosphate; and

about 30% w/w to about 95% w/w of a filler.

**[0008f]** In another aspect of the present disclosure, there is provided a minitablet for oral delivery, comprising:

about 1% w/w to about 20% w/w of infigratinib monophosphate;

about 30% w/w to about 60% w/w of mannitol; and

about 30% w/w to about 45% w/w of microcrystalline cellulose.

**[0008g]** In a further aspect of the present disclosure, there is provided a minitablet for oral delivery, comprising:

about 10% w/w to about 20% w/w of infigratinib monophosphate;

about 30% w/w to about 45% w/w of mannitol; and

about 30% w/w to about 40% w/w of microcrystalline cellulose.

**[0008h]** In another aspect of the present disclosure, there is provided a minitablet for oral delivery, comprising:

about 1% w/w to about 5% w/w of infigratinib monophosphate;

about 45% w/w to about 60% w/w of mannitol; and

about 30% w/w to about 40% w/w of microcrystalline cellulose.

**[0008i]** In a further aspect of the present disclosure, there is provided a minitablet for oral delivery, comprising:

about 1.2 mg of infigratinib monophosphate;

about 3 mg to about 4 mg of mannitol; and

about 2 mg to about 4.4 mg of microcrystalline cellulose.

**[0008j]** In another aspect of the present disclosure, there is provided a minitablet for oral delivery, comprising:

about 0.12 mg of infigratinib monophosphate;

about 3 mg to about 4 mg of mannitol; and

about 2 mg to about 3 mg of microcrystalline cellulose.

**[0009]** The present disclosure provides methods of treating skeletal dysplasias using an FGFR inhibitor, namely, infigratinib.

**[0010]** In one example, provided herein are methods of treating a skeletal dysplasia such as hypochondroplasia or achondroplasia in a pediatric patient in need thereof, the method generally comprises orally administering daily to the pediatric patient about 0.01 mg/kg to about 0.51 mg/kg of infigratinib, or a pharmaceutically acceptable salt thereof.

**[0011]** In certain examples, the method comprises administering to the pediatric patient about 0.01 mg/kg to about 0.3 mg/kg of infigratinib, or a pharmaceutically acceptable salt thereof. In certain examples, the method comprises administering to the pediatric patient

about 0.01 mg/kg to about 0.15 mg/kg of infigratinib, or a pharmaceutically acceptable salt thereof. In certain examples, the method comprises administering to the pediatric patient about 0.015 mg/kg to about 0.13 mg/kg of infigratinib, or a pharmaceutically acceptable salt thereof. In certain examples, the method comprises administering to the pediatric patient about 0.016 mg/kg, about 0.032 mg/kg, about 0.064 mg/kg, about 0.128 mg/kg, about 0.256 mg/kg, or about 0.51 mg/kg of infigratinib, or a pharmaceutically acceptable salt thereof.

**[0012]** In another example, provided herein are methods of treating a pediatric patient suffering from a skeletal dysplasia such as hypochondroplasia or achondroplasia, the method generally comprising orally administering daily to the patient about 0.1 mg to about 8 mg of infigratinib, or a pharmaceutically acceptable salt thereof.

**[0013]** In certain examples, the method comprises administering to the pediatric patient about 1 mg to about 7 mg of infigratinib, or a pharmaceutically acceptable salt thereof.

**[0014]** In certain examples, the pediatric patient has a FGFR3 mutation. In certain examples, the FGFR3 mutation is a G380R mutation.

**[0015]** In certain examples, the infigratinib, or a pharmaceutically acceptable salt thereof, is administered as minitablets each having about 0.1 mg or about 1 mg of infigratinib, or a pharmaceutically acceptable salt thereof.

**[0016]** In certain examples, the infigratinib is present in the minitablets as infigratinib monophosphate. In certain examples, the infigratinib monophosphate is present as an anhydrous crystalline form. In certain examples, the anhydrous crystalline form of infigratinib monophosphate is characterized by an XRPD peak (2 theta) at 15.0° ± 0.2°.

**[0017]** In certain examples, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits increased height velocity relative to baseline. In certain examples, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an increase in absolute height velocity.

**[0018]** In certain examples, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an increase, relative to baseline, in an anthropometric measurement selected from the group consisting of standing height, sitting height, upper and lower arm length, thigh length, knee height, arm span, and combinations thereof. In certain examples, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an

absolute increase in an anthropometric measurement selected from the group consisting of standing height, sitting height, upper and lower arm length, thigh length, knee height, arm span, and combinations thereof.

**[0019]** In certain examples, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits a decrease, relative to baseline, in weight. In certain examples, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an absolute decrease in weight.

**[0020]** In certain examples, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits a proportional increase, relative to baseline, in head circumference. In certain examples, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an absolute proportional increase in head circumference.

**[0021]** In certain examples, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits a normalization, relative to baseline, of a body proportion measurement ratio. In certain examples, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an absolute normalization of a body proportion measurement ratio. In certain examples, the body proportion measurement ratio is selected from the group consisting of upper to lower body segment ratio, upper arm to forearm ratio, upper leg to lower leg length ratio, arm span to standing height ratio, head circumference to standing height ratio, and combinations thereof.

**[0022]** In certain examples, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an increase, relative to baseline, in a biomarker of bone turnover selected from the group consisting of type X collagen degradation fragment, collagen X marker, and combinations thereof.

**[0023]** In certain examples, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an increase, relative to baseline, in mobility.

**[0024]** In certain examples, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits a decrease, relative to baseline, in the number of episodes of otitis media.

**[0025]** In certain examples, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits a decrease, relative to baseline, in the number of episodes and/or severity of sleep apnea.

**[0026]** In certain examples, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an increase in quality of life, wherein quality of life is assessed using the Pediatric Quality of Life Inventory.

**[0027]** In certain examples, the pediatric patient is no more than 12 years of age. In certain examples, the pediatric patient is 3 to 11 years of age. In certain examples, the pediatric patient is less than 8 years of age. In certain examples, the pediatric patient is 8 years of age or older.

**[0028]** In another example, provided herein are minitablets for orally delivering about 1 mg of infigratinib, the minitablets generally comprise: infigratinib monophosphate, in an amount to deliver about 1 mg of infigratinib, and a pharmaceutically acceptable excipient.

**[0029]** In another example, provided herein are minitablets for orally delivering about 0.1 mg of infigratinib, the minitablets generally comprise: infigratinib monophosphate, in an amount to deliver about 0.1 mg of infigratinib, and a pharmaceutically acceptable excipient.

**[0030]** In certain examples, the pharmaceutically acceptable excipient is selected from the group consisting of mannitol, microcrystalline cellulose, a polyvinylpyrrolidone, a cross-linked polyvinylpyrrolidone, magnesium stearate, croscarmellose sodium, and combinations thereof.

**[0031]** In another example, provided herein are minitablets for oral delivery, the minitablets comprising: about 1% w/w to about 20% w/w of infigratinib monophosphate; and about 30% w/w to about 95% w/w of a filler.

**[0032]** In certain examples, the filler is selected from the group consisting of microcrystalline cellulose, lactose, mannitol, and combinations thereof. In certain examples, the filler comprises microcrystalline cellulose and mannitol.

**[0033]** In certain examples, the minitablet further comprises about 5% w/w to about 10% w/w of a binder. In certain examples, the binder is selected from the group consisting of a sugar, a gelatin, a natural gum, sorbitol, maltodextrin, an alginate, an alginate derivative, a polyvinylpyrrolidone, a cellulose, a cellulose derivative, and combinations thereof.

**[0034]** In certain examples, the minitablet further comprises about 5% w/w to about 10% w/w of a disintegrant. In certain examples, the disintegrant is selected from the group

consisting of a starch, a starch derivative, a clay, a cross-linked cellulose, a cross-linked cellulose derivative, a cross-linked polyvinylpyrrolidone, and combinations thereof.

**[0035]** In another example, provided herein are minitablets for oral delivery, the minitablets comprising: about 1% w/w to about 20% w/w of infigratinib monophosphate; about 30% w/w to about 60% w/w of mannitol; and about 30% w/w to about 45% w/w of microcrystalline cellulose.

**[0036]** In certain examples, the minitablet comprises about 10% w/w to about 20% w/w of infigratinib monophosphate. In certain examples, the minitablet comprises about 1% w/w to about 5% w/w of infigratinib monophosphate.

**[0037]** In certain examples, the minitablet comprises about 30% w/w to about 45% w/w of mannitol. In certain examples, the minitablet comprises about 45% w/w to about 60% w/w of mannitol. In certain examples, the minitablet comprises about 35% w/w to about 40% w/w of microcrystalline cellulose.

**[0038]** In another example, provided herein are minitablets for oral delivery, the minitablets comprising: about 10% w/w to about 20% w/w of infigratinib monophosphate; about 30% w/w to about 45% w/w of mannitol; and about 30% w/w to about 40% w/w of microcrystalline cellulose.

**[0039]** In another example, provided herein are minitablets for oral delivery, the minitablets comprising: about 1% w/w to about 5% w/w of infigratinib monophosphate; about 45% w/w to about 60% w/w of mannitol; and about 30% w/w to about 40% w/w of microcrystalline cellulose.

**[0040]** In certain examples, the minitablet further comprises about 5% w/w to about 10% w/w of a polyvinylpyrrolidone. In certain examples, the minitablet further comprises about 5% w/w to about 10% w/w of a cross-linked polyvinylpyrrolidone. In certain examples, about 2% w/w to about 6% w/w of croscarmellose sodium.

**[0041]** In another example, provided herein are minitablets for oral delivery, the minitablets comprising: about 1.2 mg of infigratinib monophosphate; about 3 mg to about 4 mg of mannitol; and about 2 mg to about 4.4 mg of microcrystalline cellulose.

**[0042]** In certain examples, the minitablet further comprises about 0.6 mg to about 0.8 mg of a polyvinylpyrrolidone. In certain examples, the minitablet further comprises about 0.5 mg to about 0.7 mg of a cross-linked polyvinylpyrrolidone.

**[0043]** In another example, provided herein are minitablets for oral delivery, the minitablets comprising: about 0.12 mg of infigratinib monophosphate; about 3 mg to about 4 mg of mannitol; and about 2 mg to about 3 mg of microcrystalline cellulose.

**[0044]** In certain examples, the minitablet further comprises about 0.4 mg to about 0.6 mg of a polyvinylpyrrolidone. In certain examples, the minitablet further comprises about 0.3 mg to about 0.5 mg of a cross-linked polyvinylpyrrolidone. In certain examples, about 0.2 mg to about 0.4 mg of croscarmellose sodium.

## DETAILED DESCRIPTION

**[0045]** As generally described herein, the present disclosure provides methods of treating a skeletal dysplasia such as hypochondroplasia or achondroplasia in a pediatric patient in need thereof. The methods generally comprise administering an effective amount of infigratinib (e.g., 0.01 milligrams per kilogram (mg/kg) to about 0.51 mg/kg) to the pediatric patient. In addition, a minitablet for delivering the effective amount of infigratinib to the pediatric patient is provided, for example, where the minitablet comprises infigratinib monophosphate and one or more pharmaceutically acceptable excipients (e.g., a filler, a binder, a disintegrant, a lubricant).

### Definitions

**[0046]** To facilitate an understanding of the present invention, a number of terms and phrases are defined below.

**[0047]** Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. The abbreviations used herein have their conventional meaning within the chemical and biological arts. The chemical structures and formulae set forth herein are constructed according to the standard rules of chemical valency known in the chemical arts.

**[0048]** Throughout the description, where compositions and kits are described as having, including, or comprising specific components, or where processes and methods are described as having, including, or comprising specific steps, it is contemplated that, additionally, there are compositions and kits of the present invention that consist essentially of, or consist of, the recited components, and that there are processes and methods according to the present invention that consist essentially of, or consist of, the recited processing steps.

## CLAIMS

We claim:

1. Use of infigratinib, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for treating achondroplasia or hypochondroplasia in a pediatric patient in need thereof, wherein about 0.01 milligrams per kilogram (mg/kg) to about 0.51 mg/kg of infigratinib, or a pharmaceutically acceptable salt thereof, is to be orally administered daily to the pediatric patient.

2. The use of claim 1, wherein about 0.01 mg/kg to about 0.3 mg/kg of infigratinib, or a pharmaceutically acceptable salt thereof, is to be administered to the pediatric patient.

3. The use of claim 1, wherein about 0.01 mg/kg to about 0.15 mg/kg of infigratinib, or a pharmaceutically acceptable salt thereof, is to be administered to the pediatric patient.

4. The use of claim 1, wherein about 0.015 mg/kg to about 0.13 mg/kg of infigratinib, or a pharmaceutically acceptable salt thereof, is to be administered to the pediatric patient.

5. The use of claim 1, wherein about 0.016 mg/kg, about 0.032 mg/kg, about 0.064 mg/kg, about 0.128 mg/kg, about 0.256 mg/kg, or about 0.51 mg/kg of infigratinib, or a pharmaceutically acceptable salt thereof, is to be administered to the pediatric patient.

6. Use of infigratinib, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for treating a pediatric patient suffering from achondroplasia or hypochondroplasia, wherein about 0.1 mg to about 8 mg of infigratinib, or a pharmaceutically acceptable salt thereof, is to be orally administered daily to the pediatric patient.

7. The use of claim 6, wherein about 1 mg to about 7 mg of infigratinib, or a pharmaceutically acceptable salt thereof, is to be administered to the pediatric patient.

8. The use of any one of claims 1-7, wherein the pediatric patient has a FGFR3 mutation.

9. The use of claim 8, wherein the FGFR3 mutation is a G380R mutation.

10. The use of any one of claims 1-9, wherein the infigratinib, or a pharmaceutically acceptable salt thereof, is to be administered as minitablets each having 0.1 mg or about 1 mg of infigratinib, or a pharmaceutically acceptable salt thereof.

11. The use of claim 10, wherein the infigratinib is present in the minitablets as infigratinib monophosphate.

12. The use of claim 11, wherein the infigratinib monophosphate is present as an anhydrous crystalline form.

13. The use of claim 12, wherein the anhydrous crystalline form of infigratinib monophosphate is characterized by an XRPD peak (2 theta) at 15.0° ± 0.2°.

14. The use of any one of claims 1-13, wherein, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits increased height velocity relative to baseline.

15. The use of any one of claims 1-13, wherein, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an increase in absolute height velocity.

16. The use of any one of claims 1-13, wherein, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an increase, relative to baseline, in an anthropometric measurement selected from the group consisting of standing height, sitting height, upper and lower arm length, thigh length, knee height, arm span, and combinations thereof.

17. The use of any one of claims 1-13, wherein, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an absolute increase in an anthropometric measurement selected from the group consisting of standing height, sitting height, upper and lower arm length, thigh length, knee height, arm span, and combinations thereof.

18. The use of any one of claims 1-13, wherein, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits a decrease, relative to baseline, in weight.

19. The use of any one of claims 1-13, wherein, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an absolute decrease in weight.

20. The use of any one of claims 1-13, wherein, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits a proportional increase, relative to baseline, in head circumference.

21. The use of any one of claims 1-13, wherein, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an absolute proportional increase in head circumference.

22. The use of any one of claims 1-13, wherein, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits a normalization, relative to baseline, of a body proportion measurement ratio.

23. The use of any one of claims 1-13, wherein, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an absolute normalization of a body proportion measurement ratio.

24. The use of claim 22 or 23, wherein the body proportion measurement ratio is selected from the group consisting of upper to lower body segment ratio, upper arm to forearm ratio, upper leg to lower leg length ratio, arm span to standing height ratio, head circumference to standing height ratio, and combinations thereof.

25. The use of any one of claims 1-13, wherein, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an increase, relative to baseline, in a biomarker of bone turnover selected from the group

consisting of type X collagen degradation fragment, collagen X marker, and combinations thereof.

26. The use of any one of claims 1-13, wherein, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an increase, relative to baseline, in mobility.

27. The use of any one of claims 1-13, wherein, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits a decrease, relative to baseline, in the number of episodes of otitis media.

28. The use of any one of claims 1-13, wherein, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits a decrease, relative to baseline, in the number of episodes and/or severity of sleep apnea.

29. The use of any one of claims 1-13, wherein, after daily administration of the dose of infigratinib, or a pharmaceutically acceptable salt thereof, the pediatric patient exhibits an increase in quality of life, wherein quality of life is assessed using the Pediatric Quality of Life Inventory.

30. The use of any one of claims 1-29, wherein the pediatric patient is no more than 12 years of age.

31. The use of any one of claims 1-30, wherein the pediatric patient is 3 to 11 years of age.

32. The use of any one of claims 1-30, wherein the pediatric patient is less than 8 years of age.

33. The use of any one of claims 1-29, wherein the pediatric patient is 8 years of age or older.

34. A minitablet for orally delivering 1 mg of infigratinib, comprising:
infigratinib monophosphate, in an amount to deliver 1 mg of infigratinib, and

a pharmaceutically acceptable excipient.

35. A minitablet for orally delivering 0.1 mg of infigratinib, comprising:
infigratinib monophosphate, in an amount to deliver 0.1 mg of infigratinib, and
a pharmaceutically acceptable excipient.

36. The minitablet of claim 34 or 35, wherein the pharmaceutically acceptable excipient is selected from the group consisting of mannitol, microcrystalline cellulose, a polyvinylpyrrolidone, a cross-linked polyvinylpyrrolidone, magnesium stearate, croscarmellose sodium, and combinations thereof.

37. A minitablet for oral delivery, comprising:
about 1% w/w to about 20% w/w of infigratinib monophosphate; and
about 30% w/w to about 95% w/w of a filler.

38. The minitablet of claim 37, wherein the filler is selected from the group consisting of microcrystalline cellulose, lactose, mannitol, and combinations thereof.

39. The minitablet of claim 37 or 38, wherein the filler comprises microcrystalline cellulose and mannitol.

40. The minitablet of any one of claims 37-39, further comprising about 5% w/w to about 10% w/w of a binder.

41. The minitablet of claim of 40, wherein the binder is selected from the group consisting of a sugar, a gelatin, a natural gum, sorbitol, maltodextrin, an alginate, an alginate derivative, a polyvinylpyrrolidone, a cellulose, a cellulose derivative, and combinations thereof.

42. The minitablet of any one of claims 37-41, further comprising about 5% w/w to about 10% w/w of a disintegrant.

43. The minitablet of claim of 40, wherein the disintegrant is selected from the group consisting of a starch, a starch derivative, a clay, a cross-linked cellulose, a cross-linked cellulose derivative, a cross-linked polyvinylpyrrolidone, and combinations thereof.

44. A minitablet for oral delivery, comprising:
about 1% w/w to about 20% w/w of infigratinib monophosphate;
about 30% w/w to about 60% w/w of mannitol; and
about 30% w/w to about 45% w/w of microcrystalline cellulose.

45. The minitablet of claim 44, comprising about 10% w/w to about 20% w/w of infigratinib monophosphate.

46. The minitablet of claim 44, comprising about 1% w/w to about 5% w/w of infigratinib monophosphate.

47. The minitablet of claim 44, comprising about 30% w/w to about 45% w/w of mannitol.

48. The minitablet of claim 44, comprising about 45% w/w to about 60% w/w of mannitol.

49. The minitablet of any one of claims 44-48, comprising about 35% w/w to about 40% w/w of microcrystalline cellulose.

50. A minitablet for oral delivery, comprising:
about 10% w/w to about 20% w/w of infigratinib monophosphate;
about 30% w/w to about 45% w/w of mannitol; and
about 30% w/w to about 40% w/w of microcrystalline cellulose.

51. A minitablet for oral delivery, comprising:
about 1% w/w to about 5% w/w of infigratinib monophosphate;
about 45% w/w to about 60% w/w of mannitol; and
about 30% w/w to about 40% w/w of microcrystalline cellulose.

52. The minitablet of claim 50 or 51, further comprising about 5% w/w to about 10% w/w of a polyvinylpyrrolidone.

53. The minitablet of any one of claims 50-52, further comprising about 5% w/w to about 10% w/w of a cross-linked polyvinylpyrrolidone.

54. The minitablet of any one of claims 50-53, further comprising about 2% w/w to about 6% w/w of croscarmellose sodium.

55. A minitablet for oral delivery, comprising:
about 1.2 mg of infigratinib monophosphate;
about 3 mg to about 4 mg of mannitol; and
about 2 mg to about 4.4 mg of microcrystalline cellulose.

56. The minitablet of claim 55, further comprising about 0.6 mg to about 0.8 mg of a polyvinylpyrrolidone.

57. The minitablet of claim 55, further comprising about 0.5 mg to about 0.7 mg of a cross-linked polyvinylpyrrolidone.

58. A minitablet for oral delivery, comprising:
about 0.12 mg of infigratinib monophosphate;
about 3 mg to about 4 mg of mannitol; and
about 2 mg to about 3 mg of microcrystalline cellulose.

59. The minitablet of claim 58, further comprising about 0.4 mg to about 0.6 mg of a polyvinylpyrrolidone.

60. The minitablet of claim 58 or 59, further comprising about 0.3 mg to about 0.5 mg of a cross-linked polyvinylpyrrolidone.

61. The minitablet of any one of claims 55-60, further comprising about 0.2 mg to about 0.4 mg of croscarmellose sodium.

62. The minitablet of any one of claims 34-61, wherein the infigratinib monophosphate is present as an anhydrous crystalline form.

63. The minitablet of claim 62, wherein the anhydrous crystalline form of infigratinib monophosphate is characterized by an XRPD peak (2 theta) at 15.0° ± 0.2°.