least about 30 ng/mL, at least about 35 ng/mL, at least about 40 ng/mL, at least about 45 ng/mL, at least about 50 ng/mL, at least about 55 ng/mL, or at least about 60 ng/mL. The method of claim 1, wherein the trough blood plasma concentration of Compound A is at least 20 ng/mL, at least 21 ng/mL, at least 22 ng/mL, at least 23 ng/mL, at least 24 ng/mL, at least 25 ng/mL, at least 26 ng/mL, at least 27 ng/mL, at least 28 ng/mL, at least 29 ng/mL, at least 30 ng/mL, at least 31 ng/mL, at least 32 ng/mL, at least 33 ng/mL, at least 34 ng/mL, at least 35 ng/mL, at least 36 ng/mL, at least 37 ng/mL, at least 38 ng/mL, at least 39 ng/mL, at least 40 ng/mL, at least 41 ng/mL, at least 42 ng/mL, at least 43 ng/mL, at least 44 ng/mL, at least 45 ng/mL, at least 46 ng/mL, at least 47 ng/mL, at least 48 ng/mL, at least 49 ng/mL, at least 50 ng/mL, at least 51 ng/mL, at least 52 ng/mL, at least 53 ng/mL, at least 54 ng/mL, at least 55 ng/mL, at least 56 ng/mL, at least 57 ng/mL, at least 58 ng/mL, at least 59 ng/mL, or at least 60 ng/mL. In some embodiments, the daily dose of Compound A, or a pharmaceutically acceptable salt, or solvate thereof is equivalent to about 40 mg/day, about 50 mg/day, about 60 mg/day, about 70 mg/day, about 80 mg/day, about 90 mg/day, about 100 mg/day, about 110 mg/day, or about 120 mg/day of Compound A-monohydrochloride. In some embodiments, the daily dose of Compound A, or a pharmaceutically acceptable salt, or solvate thereof is equivalent to about 40 mg/day, about 80 mg/day, or about 120 mg/day of Compound A-monohydrochloride.

[0005a] In one aspect, there is provided a use of of 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 treatment of carcinoid syndrome in a human, wherein a daily dose of Compound A, or a pharmaceutically acceptable salt thereof, that is equivalent to about 40 mg/day to about 160 mg/day of Compound A-monohydrochloride is to be orally administered to the human.

[0006] In another aspect, described herein is a method of treating carcinoid syndrome in a human with carcinoid syndrome comprising: orally administering to the human with carcinoid syndrome an initial daily dose of 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, or solvate thereof; determining the blood plasma trough concentration of Compound A in the human; and increasing the daily dose of Compound A, or a pharmaceutically acceptable salt, or solvate thereof if the human does not have at least a threshold trough blood plasma concentration of Compound A. In some embodiments, the threshold trough blood plasma concentration of Compound A is at least 20 ng/mL, at least 21 ng/mL, at least 22 ng/mL, at least 23 ng/mL, at least 24 ng/mL, at least 25 ng/mL, at least 26 ng/mL, at least 27 ng/mL, at least 28 ng/mL, at least 29 ng/mL, at least 30 ng/mL, at least 31 ng/mL, at least 32 ng/mL, at least 33 ng/mL, at

least 34 ng/mL, at least 35 ng/mL, at least 36 ng/mL, at least 37 ng/mL, at least 38 ng/mL, at least 39 ng/mL, at least 40 ng/mL, at least 41 ng/mL, at least 42 ng/mL, at least 43 ng/mL, at least 44 ng/mL, at least 45 ng/mL, at least 46 ng/mL, at least 47 ng/mL, at least 48 ng/mL, at least 49 ng/mL, at least 50 ng/mL, at least 51 ng/mL, at least 52 ng/mL, at least 53 ng/mL, at least 54 ng/mL, at least 55 ng/mL, at least 56 ng/mL, at least 57 ng/mL, at least 58 ng/mL, at least 59 ng/mL, or at least 60 ng/mL. In some embodiments, the initial daily dose of Compound

Compound A, or a pharmaceutically acceptable salt, or solvate thereof, is equivalent to about 80 mg or about 120 mg of Compound A-monohydrochloride.

[0009] In another aspect, described herein is a method of treating carcinoid syndrome in a human with carcinoid syndrome comprising orally administering to the human with carcinoid syndrome 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, or solvate thereof; wherein the human with carcinoid syndrome is treatment naïve; or wherein the human with carcinoid syndrome was previously treated with a somatostation analog and the treatment with the somatostatin anolog is terminated and a sufficient period of time lapses to allow the somatostatin anolog to washout of the human; and wherein treatment is initiated at a daily dose equivalent to at least about 40 mg/day of Compound A-monohydrochloride.

[0010] In some embodiments, the human with carcinoid syndrome is treatment naïve to somatostatin anolog therapy and actively symptomatic. In some embodiments, actively symptomatic comprises an average of of ≥4 bowel movements (BM)/day or >2 flushing episodes in at least 2 days over a period of 2 weeks. In some embodiments, the carcinoid syndrome in the human that was previously treated with a somatostation analog was symptomatically controlled with the somatostation analog. In some embodiments, symptomatically controlled comprises an average of < 4 bowel movements (BM)/day with ≤ 5 BMs on any single day and average ≤ 2 flushing episodes/day over a 2-week period. In some embodiments, the somatostation analog is octreotide, lanreotide, or pasireotide. In some embodiments, treatment is initiated at a daily dose equivalent to about 40 mg/day or 80 mg/day of Compound A-monohydrochloride. In some embodiments, the daily dose is increased by a daily dose amount equivalent to about 40 mg/day Compound A-monohydrochloride if breakthrough symptoms are observed. In some embodiments, the breakthrough symptoms comprise ≥4 bowel movements (BMs)/day for 2 consecutive days or flushing frequency ≥3 flushing episodes/day for at least 1 day.

[0010a] In another aspect, the present disclosure provides a use of of 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 treatment of carcinoid syndrome in a human with carcinoid syndrome , wherein the medicament is to be orally administered to the human with carcinoid syndrome; wherein the human with carcinoid syndrome is treatment naïve; or wherein the human with carcinoid syndrome was previously treated with a somatostation analog and the treatment with the somatostatin anolog is terminated and a sufficient period of time lapses to allow the somatostatin anolog to washout of the human;

and wherein treatment is to be initiated at a daily dose equivalent to at least about 40 mg/day of Compound A-monohydrochloride.

[0011] In another aspect, described herein is a method of treating carcinoid syndrome in a human with carcinoid syndrome comprising orally administering to the human with carcinoid syndrome a daily dose of 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, or solvate thereof, wherein treating carcinoid syndrome comprises managing the symptoms of the carcinoid syndrome.

[0011a] In another aspect, the preesnt diclosure provides a use of 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 treatment of carcinoid syndrome in a human , wherein a daily dose of Compound A, or a pharmaceutically acceptable salt thereof, that is equivalent to about 40 mg/day to about 80 mg/day of Compound A-monohydrochloride is to be orally administered to the human, and wherein treatment of the carcinoid syndrome comprises management of the symptoms of the carcinoid syndrome.

[0012] In some embodiments, managing the symptoms of the carcinoid syndrome comprises reducing the frequeny of: daily bowel movements, episodes of diarrhea, episodes of fecal

A, or a pharmaceutically acceptable salt, or solvate thereof, is increased by an incremental daily dose that is equivalent to about 40 mg/day and treatment is continued at a daily amount of Compound A, or a pharmaceutically acceptable salt, or solvate thereof, that is equivalent to about 80 mg or about 120 mg of Compound A-monohydrochloride.

[0014a] In another aspect, there is provided a use of 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 treatment of severe diarrhea, flushing episodes or both in a human with carcinoid syndrome, wherein an initial daily dose of Compound A or a pharmaceutically acceptable salt thereof is to be orally administered to the human.

[0015] In some embodiments, the severity of the severe diarhhea is measured by the number of bowel movements per day, the number of watery stools as measured by Bristol Stool Scale, or both. In some embodiments, the severity of the flushing episodes is assessed by measuring urinary 5-hydroxyindole acetic acid (5-HIAA) levels, plasma serotonin levels, or both.

[0016] In another aspect, described herein is a method of treating carcinoid syndrome in a human with carcinoid syndrome comprising orally administering to the human with carcinoid syndrome a daily dose of 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, or solvate thereof, wherein human with carcinoid syndrome was previously treated with a somatostation analog; and wherein treatment is initiated at a daily dose equivalent to about 40 mg/day of Compound A-monohydrochloride.

[0016a] In yet another aspect, the present diclosure provides a use of 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 treatment of carcinoid syndrome in a human with carcinoid syndrome, wherein a daily dose of Compound A, or a pharmaceutically acceptable salt thereof is to be orally administered to the human with carcinoid syndrome, wherein human with carcinoid syndrome was previously treated with a somatostation analog; and wherein treatment is to be initiated at a daily dose equivalent to about 40 mg/day of Compound A-monohydrochloride.

[0017] In another aspect, described herein is a method of treating carcinoid syndrome in a human with carcinoid syndrome comprising orally administering to the human with carcinoid syndrome a daily dose of 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, or solvate thereof, wherein human with carcinoid syndrome was previously treated with a somatostation analog; and

wherein treatment is initiated at a daily dose equivalent to about 80 mg/day of Compound A-monohydrochloride.

[0017a] In yet another aspect, the present disclosure provides a use of 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 treatment of carcinoid syndrome in a human with carcinoid syndrome, wherein a daily dose of Compound A,0 or a pharmaceutically acceptable salt thereof is to be administered to the human with carcinoid syndrome, wherein human with carcinoid syndrome was previously treated with a somatostation analog; and wherein treatment is to be initiated at a daily dose equivalent to about 80 mg/day of Compound A-monohydrochloride.

[0018] In some embodiments, the human with carcinoid syndrome responded to and tolerated treatment with a somatostation analog. In some embodiments, carcinoid syndrome symptoms were previously controlled on octreotide or lanreotide depot monotherapy. In some embodiments, the human with carcinoid syndrome is refractory to treatment with somatostation analog. In some embodiments, the somatostation analog is octreotide, lanreotide, or pasireotide.

[0019] In some embodiments, treating carcinoid syndrome comprises managing the symptoms of the carcinoid syndrome. In some embodiments, managing the symptoms of the carcinoid syndrome comprises reducing the frequeny of: daily bowel movements, episodes of diarrhea, episodes of fecal incontinence, cutaneous flushing, or a combination thereof. In some embodiments, managing the symptoms of the carcinoid syndrome comprises treating diarrhea, flushing episodes, or both in the human. In some embodiments, the diarrhea is severe diarrhea. In some embodiments, the severity of diarrhea comprises the number of bowel movements per day,

CLAIMS

WHAT IS CLAIMED IS:

1. Use of 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 treatment of carcinoid syndrome in a human, wherein a daily dose of Compound A, or a pharmaceutically acceptable salt thereof, that is equivalent to about 40 mg/day to about 160 mg/day of Compound A-monohydrochloride is to be orally administered to the human.
2. The use of claim 1, wherein the daily dose of Compound A, or a pharmaceutically acceptable salt thereof comprises an amount equivalent to about 40 mg/day, about 50 mg/day, about 60 mg/day, about 70 mg/day, about 80 mg/day, about 90 mg/day, about 100 mg/day, about 110 mg/day, or about 120 mg/day of Compound A-monohydrochloride.
3. The use of claim 1 or 2, wherein treatment is to be initiated at a daily dose equivalent to about 40 mg/day or 80 mg/day of Compound A-monohydrochloride.
4. The use of any one of claims 1-3, wherein treatment of carcinoid syndrome in the human comprises management of the symptoms of carcinoid syndrome.
5. The use of claim 4, wherein the symptoms of carcinoid syndrome comprise the severity of diarrhea, frequency and intensity of flushing episodes, or combinations thereof.
6. The use of claim 5, wherein the severity of diarrhea comprises the number of bowel movements per day, the number of watery stools as measured by Bristol Stool Scale, or both.
7. The use of any one of claims 1-3, wherein treatment of carcinoid syndrome in the human comprises reduction of the frequency of carcinoid syndrome breakthrough symptoms.
8. The use of claim 7, wherein the breakthrough symptoms comprise ≥4 bowel movements (BMs)/day for 2 consecutive days or flushing frequency ≥3 flushing episodes/day for at least 1 day.
9. Use of 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 treatment of carcinoid syndrome in a human with carcinoid syndrome , wherein the medicament is to be orally administered to the human with carcinoid syndrome;

   wherein the human with carcinoid syndrome is treatment naïve; or

wherein the human with carcinoid syndrome was previously treated with a somatostation analog and the treatment with the somatostatin anolog is terminated and a sufficient period of time lapses to allow the somatostatin anolog to washout of the human; and wherein treatment is to be initiated at a daily dose equivalent to at least about 40 mg/day of Compound A-monohydrochloride.

10. The use of claim 9, wherein the human with carcinoid syndrome is treatment naïve to somatostatin anolog therapy and actively symptomatic.
11. The use of claim 10, wherein actively symptomatic comprises an average of of ≥4 bowel movements (BM)/day or >2 flushing episodes in at least 2 days over a period of 2 weeks.
12. The use of claim 9, wherein the carcinoid syndrome in the human that was previously treated with a somatostation analog was symptomatically controlled with the somatostation analog.
13. The use of claim 12, wherein symptomatically controlled comprises an average of < 4 bowel movements (BM)/day with ≤ 5 BMs on any single day and average ≤ 2 flushing episodes/day over a 2-week period.
14. The use of claim 12 or claim 13, wherein the somatostation analog is octreotide, lanreotide, or pasireotide.
15. The use of any one of claims 9-14, wherein treatment is to be initiated at a daily dose equivalent to about 40 mg/day or 80 mg/day of Compound A-monohydrochloride.
16. The use of claim 15, wherein the daily dose is to be increased by a daily dose amount equivalent to about 40 mg/day Compound A-monohydrochloride if breakthrough symptoms are observed.
17. The use of claim 16, wherein the breakthrough symptoms comprise ≥4 bowel movements (BMs)/day for 2 consecutive days or flushing frequency ≥3 flushing episodes/day for at least 1 day.
18. Use of 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 treatment of carcinoid syndrome in a human , wherein a daily dose of Compound A, or a pharmaceutically acceptable salt thereof, that is equivalent to about 40 mg/day to about 80 mg/day of Compound A-monohydrochloride is to be orally administered to the human, and wherein treatment of the carcinoid syndrome comprises management of the symptoms of the carcinoid syndrome.

19. The use of claim 18, wherein management of the symptoms of the carcinoid syndrome comprises reduction of the frequency of: daily bowel movements, episodes of diarrhea, episodes of fecal incontinence, cutaneous flushing, or a combination thereof.

20. The use of claim 18 or claim 19, wherein management of the symptoms of the carcinoid syndrome comprises treatment of diarrhea, flushing episodes, or both in the human.

21. The use of claim 19 or claim 20, wherein the diarrhea is severe diarrhea.

22. The use of any one of claims 18-21, wherein management of the symptoms of the carcinoid syndrome comprises reduction of the number of bowel movements (BM) to less than 4 BM/day for 2 consecutive days, reduction of the flushing frequency to less than 3 flushing episodes/day for at least 1 day, or both.

23. The use of any one of claims 18-22, wherein the daily dose of Compound A, or a pharmaceutically acceptable salt thereof, is equivalent to about 40 mg or about 80 mg of Compound A-monohydrochloride.

24. The use of claim 23, wherein the daily dose of Compound A, or a pharmaceutically acceptable salt thereof, is to be increased by an incremental daily dose that is equivalent to about 10 mg/day, about 20 mg/day, about 30 mg/day, or about 40 mg/day if the severeity of the diarrhea, flushing episodes or both does not diminish in severity during treatment with the the daily dose of Compound A, or a pharmaceutically acceptable salt thereof.

25. The use of claim 23, wherein the daily dose of Compound A, or a pharmaceutically acceptable salt thereof, is to be increased by an incremental daily dose that is equivalent to about 40 mg/day.

26. The use of claim 23, wherein the daily dose of Compound A, or a pharmaceutically acceptable salt thereof, is to be increased by an incremental daily dose that is equivalent to about 40 mg/day and treatment is to be continued at a daily amount of Compound A, or a pharmaceutically acceptable salt thereof, that is equivalent to about 80 mg or about 120 mg of Compound A-monohydrochloride.

27. Use of 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 treatment of severe diarrhea, flushing episodes or both in a human with carcinoid syndrome, wherein an initial daily dose of Compound A or a pharmaceutically acceptable salt thereof is to be orally administered to the human.

28. The use of claim 27, wherein the initial daily dose of Compound A, or a pharmaceutically acceptable salt thereof, is equivalent to about 40 mg or about 80 mg of Compound A-monohydrochloride.

29. The use of claim 27 or claim 28, wherein the initial daily dose of Compound A, or a pharmaceutically acceptable salt thereof, is to be increased by an incremental daily dose that is equivalent to about 10 mg/day, about 20 mg/day, about 30 mg/day, or about 40 mg/day if the severeity of the severe diarrhea, flushing episodes or both does not diminish in severity during treatment with the the initial daily dose of Compound A, or a pharmaceutically acceptable salt thereof.

30. The use of claim 27 or claim 28, wherein the initial daily dose of Compound A, or a pharmaceutically acceptable salt, or solvate thereof, is to be increased by an incremental daily dose that is equivalent to about 40 mg/day.

31. The use of claim 27 or claim 28, wherein the daily dose of Compound A, or a pharmaceutically acceptable salt thereof, is to be increased by an incremental daily dose that is equivalent to about 40 mg/day and treatment is to be continued at a daily amount of Compound A, or a pharmaceutically acceptable salt thereof, that is equivalent to about 80 mg or about 120 mg of Compound A-monohydrochloride

32. The use of any one of claims 27-31, wherein the severity of the severe diarrhea is measured by the number of bowel movements per day, the number of watery stools as measured by Bristol Stool Scale, or both.

33. The use of any one of claims 27-31, wherein the severity of the flushing episodes is assessed by measuring urinary 5-hydroxyindole acetic acid (5-HIAA) levels, plasma serotonin levels, or both.

34. Use of 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 treatment of carcinoid syndrome in a human with carcinoid syndrome, wherein a daily dose of Compound A, or a pharmaceutically acceptable salt thereof is to be orally administered to the human with carcinoid syndrome, wherein human with carcinoid syndrome was previously treated with a somatostation analog; and

wherein treatment is to be initiated at a daily dose equivalent to about 40 mg/day of Compound A-monohydrochloride.

35. Use of 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 treatment of carcinoid syndrome in a human with carcinoid syndrome, wherein a daily dose of Compound A,0 or a pharmaceutically acceptable salt thereof is to be administered to the human with carcinoid syndrome, wherein human with carcinoid syndrome was previously treated with a somatostation analog; and

wherein treatment is to be initiated at a daily dose equivalent to about 80 mg/day of Compound A-monohydrochloride.

36. The use of claim 34 or claim 35, wherein the human with carcinoid syndrome responded to and tolerated treatment with a somatostation analog.

37. The use of any one of claims 34-36, wherein carcinoid syndrome symptoms were previously controlled on octreotide or lanreotide therapy.

38. The use of any one of claims 34-37, wherein the human with carcinoid syndrome is refractory to treatment with somatostation analog, wherein the somatostation analog is octreotide, lanreotide, or pasireotide.

39. The use of any one of claims 34-38, wherein treatment of carcinoid syndrome comprises management of the symptoms of the carcinoid syndrome.

40. The use of claim 39, wherein management of the symptoms of the carcinoid syndrome comprises reduction of the frequency of: daily bowel movements, episodes of diarrhea, episodes of fecal incontinence, cutaneous flushing, or a combination thereof.

41. The use of claim 39 or claim 40, wherein management of the symptoms of the carcinoid syndrome comprises treatment of diarrhea, flushing episodes, or both in the human.

42. The use of claim 41, wherein the diarrhea is severe diarrhea.

43. The use of claim 42, wherein the severity of diarrhea comprises the number of bowel movements per day, the number of watery stools as measured by Bristol Stool Scale, or both.

44. The use of any one of claims 39-43, wherein management of the symptoms of the carcinoid syndrome comprises reduction of the number of bowel movements (BM) to less than 4 BM/day for 2 consecutive days, reduction of the flushing frequency to less than 3 flushing episodes/day for at least 1 day, or both.

45. The use of any one of claims 34-44, wherein the daily dose of Compound A, or a pharmaceutically acceptable salt thereof, is to be increased by an incremental daily dose

that is equivalent to about 10 mg/day, about 20 mg/day, about 30 mg/day, or about 40 mg/day if the severeity of the diarrhea, flushing episodes or both does not diminish in severity during treatment with the the daily dose of Compound A, or a pharmaceutically acceptable salt thereof.

46. The use of any one of claims 34-44, wherein the daily dose of Compound A, or a pharmaceutically acceptable salt thereof, is to be increased by an incremental daily dose that is equivalent to about 40 mg/day.

47. The use of any one of claims 34-44, wherein the daily dose of Compound A, or a pharmaceutically acceptable salt thereof, is to be increased by an incremental daily dose that is equivalent to about 40 mg/day and treatment is to be continued at a daily amount of Compound A, or a pharmaceutically acceptable salt thereof, that is equivalent to about 80 mg or about 120 mg of Compound A-monohydrochloride.

48. The use of any one of claims 1-47, wherein the serum 5-hydroxy-indoleacetic acid (5-HIAA) concentration in the human prior to treatment with Compound A is greater than about > 280 µmol/L.

49. The use of any one of claims 1-48, wherein treatment with Compound A, or a pharmaceutically acceptable salt thereof, is to be discontinued if the human does not tolerate Compound A, or a pharmaceutically acceptable salt thereof.

50. The use of any one of claims 1-48, wherein the daily dose of Compound A, or a pharmaceutically acceptable salt thereof, is to be reduced if the human does not tolerate Compound A, or a pharmaceutically acceptable salt thereof.

51. The use of any one of claims 1-48, wherein the daily dose of Compound A, or a pharmaceutically acceptable salt thereof, is to be reduced by an amount equivalent to about 40 mg of Compound A-monohydrochloride if the human does not tolerate Compound A, or a pharmaceutically acceptable salt thereof

52. The use of any one of claims 1-51, wherein:
Compound A, or a pharmaceutically acceptable salt thereof, is to be administered in the form of one or more tablets comprising a spray-dried solid dispersion of 3-[4-(4-amino-piperidin-1-yl)-3-(3,5-difluoro-phenyl)-quinolin-6-yl]-2-hydroxy-benzonitrile monohydrochloride thereof;
one or more additional pharmaceutically acceptable ingredients; and
optionally one or more film coating agents.

53. The use of claim 52, wherein the spray-dried solid dispersion comprises:

(a) 3-[4-(4-amino-piperidin-1-yl)-3-(3,5-difluoro-phenyl)-quinolin-6-yl]-2-hydroxy-benzonitrile monohydrochloride thereof; and

(b) a pharmaceutically acceptable polymer;

wherein 3-[4-(4-amino-piperidin-1-yl)-3-(3,5-difluoro-phenyl)-quinolin-6-yl]-2-hydroxy-benzonitrile monohydrochloride thereof, is dispersed in a polymer matrix formed from the pharmaceutically acceptable polymer.

54. The use of claim 52 or claim 53, wherein the one or more pharmaceutically acceptable ingredients are selected from the group consisting of one or more diluents, one or more disintegrants, one or more lubricants, one or more glidants.

55. The use of any one of claims 52-54, wherein the one or more pharmaceutically acceptable ingredients comprise microcrystalline cellulose, mannitol, pregelatinized starch croscarmellose sodium crospovidone, sodium chloride, 1:1 sodium chloride:potassium chloride, colloidal silicon dioxide, and magnesium stearate.

56. The use of any one of claims 52-55, wherein each tablet comprises about 2% by weight to about 20% by weight of 3-[4-(4-amino-piperidin-1-yl)-3-(3,5-difluoro-phenyl)-quinolin-6-yl]-2-hydroxy-benzonitrile monohydrochloride thereof.

57. The useof any one of claims 52-56, wherein each tablet comprises about 10 mg, about 20 mg, about 40 mg, about 60 mg or about 80 mg of 3-[4-(4-amino-piperidin-1-yl)-3-(3,5-difluoro-phenyl)-quinolin-6-yl]-2-hydroxy-benzonitrile monohydrochloride thereof.

58. The use of any one of claims 52-56, wherein each tablet comprises about 10 mg of 3-[4-(4-amino-piperidin-1-yl)-3-(3,5-difluoro-phenyl)-quinolin-6-yl]-2-hydroxy-benzonitrile monohydrochloride thereof.

59. The use of any one of claims 52-56, wherein each tablet comprises about 20 mg of 3-[4-(4-amino-piperidin-1-yl)-3-(3,5-difluoro-phenyl)-quinolin-6-yl]-2-hydroxy-benzonitrile monohydrochloride thereof.

60. The use of any one of claims 52-59, wherein: the one or more tablets are to be administered at least 30 minutes before a meal.

61. The use of any one of claims 52-59, wherein: the one or more tablets are to be administered at least 60 minutes before a meal.

62. The use of any one of claims 52-61, wherein: the one or more tablets are to be administered with a glass of water on an empty stomach at least 30 minutes before a meal.

63. The use of any one of claims 52-62, wherein: the bioavailability of 3-[4-(4-amino-piperidin-1-yl)-3-(3,5-difluoro-phenyl)-quinolin-6-yl]-2-hydroxy-benzonitrile monohydrochloride thereof, is not substantially affected by the coadministration of proton pump inhibitors, histamine H2-receptor antagonists, or antacids.

64. The use of any one of claims 1-63, wherein: Compound A, or a pharmaceutically acceptable salt thereof, is not to be co-administered with a drug that alters the pH of the upper gastrointestinal (GI) tract.

65. The use of any one of claims 1-64, 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 administered is increased.

66. The use of claim 65, wherein the daily dose amount of Compound A, or a pharmaceutically acceptable salt thereof, is to be increased by an amount equivalent to about 10 mg/day, about 20 mg/day, about 30 mg/day, or about 40 mg/day of Compound A-monohydrochloride.

67. The use of any one of claims 64-66, wherein the drug that alters the pH of the upper gastrointestinal (GI) tract comprises proton pump inhibitors, histamine H2-receptor antagonists, or antacids.