

CLAIMS

1. An oral dosage formulation comprising intra-granular components, extra-granular components, and film coating components, wherein the intra-granular components comprise Compound 1, an insoluble diluent or carrier, a disintegrant, and a diluent or filler; wherein the extra-granular components comprise a disintegrant, a glidant, and/or a lubricant; and wherein the film coating components comprise a tablet coating.

2. The formulation of claim 1
wherein the intra-granular component comprises
about 50% to about 80% by weight of Compound 1,
about 10% to about 40% by weight of an insoluble diluent or carrier,
about 1.5% to about 4.5% by weight of a disintegrant, and
about 1% to about 5% by weight of a diluent or filler;
wherein the extra-granular component comprises
about 1.5% to about 4.5% by weight of a disintegrant,
about 0.1% to about 0.4% by weight of a glidant, and
about 0.15% to about 1.35% by weight of a lubricant;
wherein the film coating component comprises about 1.0% to about 8% by weight of a tablet coating; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

3. The formulation of claim 1
wherein the intra-granular component comprises
about 55% to about 75% by weight of Compound 1,
about 15% to about 35% by weight of an insoluble diluent or carrier,
about 2.0% to about 4.0% by weight of a disintegrant, and
about 1.8% to about 3.8% by weight of a diluent or filler;
wherein the extra-granular component comprises
about 2.0% to about 4.0% by weight of a disintegrant,
about 0.15% to about 0.35% by weight of a glidant, and
about 0.35% to about 1.15% by weight of a lubricant;

wherein the film coating component comprises about 1.0% to about 8% by weight of a tablet coating; and

wherein the weight is the total weight of all intra-granular and extra-granular components.

4. The formulation of claim 1

wherein the intra-granular component comprises

about 60% to about 70% by weight of Compound 1,

about 20% to about 30% by weight of an insoluble diluent or carrier,

about 2.5% to about 3.5% by weight of a disintegrant, and

about 2.3% to about 3.3% by weight of a diluent or filler;

wherein the extra-granular component comprises

about 2.5% to about 3.5% by weight of a disintegrant,

about 0.2% to about 0.3% by weight of a glidant, and

about 0.55% to about 0.95% by weight of a lubricant;

wherein the film coating component comprises about 1.0% to about 8% by weight of a tablet coating; and

wherein the weight is the total weight of all intra-granular and extra-granular components.

5. The formulation of claim 1

wherein the intra-granular component comprises

about 60% by weight of Compound 1,

about 30% by weight of an insoluble diluent or carrier,

about 3% by weight of a disintegrant, and

about 2.8% by weight of a diluent or filler;

wherein the extra-granular component comprises

about 3% by weight of a disintegrant,

about 0.25% by weight of a glidant, and

about 0.75% by weight of a lubricant;

wherein the film coating component comprises about 2.0% to about 6.0% by weight of a tablet coating; and

wherein the weight is the total weight of all intra-granular and extra-granular components.

6. The formulation of claim 1
wherein the intra-granular component comprises
about 65% by weight of Compound 1,
about 25% by weight of an insoluble diluent or carrier,
about 3% by weight of a disintegrant, and
about 2.8% by weight of a diluent or filler;
wherein the extra-granular component comprises
about 3% by weight of a disintegrant,
about 0.25% by weight of a glidant, and
about 0.75% by weight of a lubricant;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of a tablet
coating; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

7. The formulation of claim 1
wherein the intra-granular component comprises
about 70% by weight of Compound 1,
about 20% by weight of an insoluble diluent or carrier,
about 3% by weight of a disintegrant, and
about 2.8% by weight of a diluent or filler;
wherein the extra-granular component comprises
about 3% by weight of a disintegrant,
about 0.25% by weight of a glidant, and
about 0.75% by weight of a lubricant;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of a tablet
coating; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

8. The formulation of claim 1
wherein the intra-granular component comprises
about 75% by weight of Compound 1,

about 15% by weight of an insoluble diluent or carrier,
about 3% by weight of a disintegrant, and
about 2.8% by weight of a diluent or filler;
wherein the extra-granular component comprises
about 3% by weight of a disintegrant,
about 0.25% by weight of a glidant, and
about 0.75% by weight of a lubricant;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of a tablet coating; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

9. The formulation of claim 1
wherein the intra-granular component comprises
about 80% by weight of Compound 1,
about 10% by weight of an insoluble diluent or carrier,
about 3% by weight of a disintegrant, and
about 2.8% by weight of a diluent or filler;
wherein the extra-granular component comprises
about 3% by weight of a disintegrant,
about 0.25% by weight of a glidant, and
about 0.75% by weight of a lubricant;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of a tablet coating; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

10. An oral dosage formulation comprising intra-granular components, extra-granular components, and film coating components, wherein the intra-granular components comprise Compound 1, microcrystalline cellulose, sodium starch glycolate, and hydroxypropyl methylcellulose, wherein the extra-granular components comprise sodium starch glycolate, colloidal silicon dioxide, and magnesium stearate, and wherein the film-coating components comprise Opadry®.

11. The formulation of claim 10
wherein the intra-granular component comprises
about 50% to about 80% by weight of Compound 1,
about 10% to about 40% by weight of microcrystalline cellulose,
about 1.5% to about 4.5% by weight of sodium starch glycolate, and
about 1% to about 5% by weight of a hydroxypropyl methylcellulose;
wherein the extra-granular component comprises
about 1.5% to about 4.5% by weight of a sodium starch glycolate,
about 0.1% to about 0.4% by weight of colloidal silicon dioxide, and
about 0.15% to about 1.35% by weight of magnesium stearate;
wherein the film coating component comprises about 1.0% to about 8% by weight of Opadry®;
and
wherein the weight is the total weight of all intra-granular and extra-granular components.

12. The formulation of claim 10
wherein the intra-granular component comprises
about 55% to about 75% by weight of Compound 1,
about 15% to about 35% by weight of microcrystalline cellulose,
about 2.0% to about 4.0% by weight of sodium starch glycolate, and
about 1.8% to about 3.8% by weight of a hydroxypropyl methylcellulose;
wherein the extra-granular component comprises
about 2.0% to about 4.0% by weight of a sodium starch glycolate,
about 0.15% to about 0.35% by weight of colloidal silicon dioxide, and
about 0.35% to about 1.15% by weight of magnesium stearate;
wherein the film coating component comprises about 1.0% to about 8% by weight of Opadry®;
and
wherein the weight is the total weight of all intra-granular and extra-granular components.

13. The formulation of claim 10
wherein the intra-granular component comprises
about 60% to about 70% by weight of Compound 1,

about 20% to about 30% by weight of microcrystalline cellulose,
about 2.5% to about 3.5% by weight of sodium starch glycolate, and
about 2.3% to about 3.3% by weight of a hydroxypropyl methylcellulose;
wherein the extra-granular component comprises
about 2.5% to about 3.5% by weight of a sodium starch glycolate,
about 0.2% to about 0.3% by weight of colloidal silicon dioxide, and
about 0.55% to about 0.95% by weight of magnesium stearate;
wherein the film coating component comprises about 1.0% to about 8% by weight of Opadry®;
and
wherein the weight is the total weight of all intra-granular and extra-granular components.

14. The formulation of claim 10
wherein the intra-granular component comprises
about 60% by weight of Compound 1,
about 30% by weight of microcrystalline cellulose,
about 3% by weight of sodium starch glycolate, and
about 2.8% by weight of a hydroxypropyl methylcellulose;
wherein the extra-granular component comprises
about 3% by weight of a sodium starch glycolate,
about 0.25% by weight of colloidal silicon dioxide, and
about 0.75% by weight of magnesium stearate;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of
Opadry®; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

15. The formulation of claim 10
wherein the intra-granular component comprises
about 65% by weight of Compound 1,
about 25% by weight of microcrystalline cellulose,
about 3% by weight of sodium starch glycolate, and
about 2.8% by weight of a hydroxypropyl methylcellulose;

wherein the extra-granular component comprises
about 3% by weight of a sodium starch glycolate,
about 0.25% by weight of colloidal silicon dioxide, and
about 0.75% by weight of magnesium stearate;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of
Opadry®; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

16. The formulation of claim 10
wherein the intra-granular component comprises
about 70% by weight of Compound 1,
about 20% by weight of microcrystalline cellulose,
about 3% by weight of sodium starch glycolate, and
about 2.8% by weight of a hydroxypropyl methylcellulose;
wherein the extra-granular component comprises
about 3% by weight of a sodium starch glycolate,
about 0.25% by weight of colloidal silicon dioxide, and
about 0.75% by weight of magnesium stearate;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of
Opadry®; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

17. The formulation of claim 10
wherein the intra-granular component comprises
about 75% by weight of Compound 1,
about 15% by weight of microcrystalline cellulose,
about 3% by weight of sodium starch glycolate, and
about 2.8% by weight of a hydroxypropyl methylcellulose;
wherein the extra-granular component comprises
about 3% by weight of a sodium starch glycolate,
about 0.25% by weight of colloidal silicon dioxide, and

about 0.75% by weight of magnesium stearate;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of Opadry®; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

18. The formulation of claim 10
wherein the intra-granular component comprises
about 80% by weight of Compound 1,
about 10% by weight of microcrystalline cellulose,
about 3% by weight of sodium starch glycolate, and
about 2.8% by weight of a hydroxypropyl methylcellulose;
wherein the extra-granular component comprises
about 3% by weight of a sodium starch glycolate,
about 0.25% by weight of colloidal silicon dioxide, and
about 0.75% by weight of magnesium stearate;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of Opadry®; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

19. A method for treating anemia comprising administering to a patient a formulation comprising intra-granular components, extra-granular components, and film coating components, wherein the intra-granular components comprise Compound 1, an insoluble diluent or carrier, a disintegrant, and a diluent or filler; wherein the extra-granular components comprise a disintegrant, a glidant, and/or a lubricant, and wherein the film coating components comprise a tablet coating.

20. The method of claim 19
wherein the intra-granular component comprises
about 50% to about 80% by weight of Compound 1,
about 10% to about 40% by weight of an insoluble diluent or carrier,
about 1.5% to about 4.5% by weight of a disintegrant, and
about 1% to about 5% by weight of a diluent or filler;

wherein the extra-granular component comprises
about 1.5% to about 4.5% by weight of a disintegrant,
about 0.1% to about 0.4% by weight of a glidant, and
about 0.15% to about 1.35% by weight of a lubricant;
wherein the film coating component comprises about 1.0% to about 8% by weight of a tablet coating; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

21. The method of claim 19

wherein the intra-granular component comprises
about 55% to about 75% by weight of Compound 1,
about 15% to about 35% by weight of an insoluble diluent or carrier,
about 2.0% to about 4.0% by weight of a disintegrant, and
about 1.8% to about 3.8% by weight of a diluent or filler;
wherein the extra-granular component comprises
about 2.0% to about 4.0% by weight of a disintegrant,
about 0.15% to about 0.35% by weight of a glidant, and
about 0.35% to about 1.15% by weight of a lubricant;
wherein the film coating component comprises about 1.0% to about 8% by weight of a tablet coating; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

22. The method of claim 19

wherein the intra-granular component comprises
about 60% to about 70% by weight of Compound 1,
about 20% to about 30% by weight of an insoluble diluent or carrier,
about 2.5% to about 3.5% by weight of a disintegrant, and
about 2.3% to about 3.3% by weight of a diluent or filler;
wherein the extra-granular component comprises
about 2.5% to about 3.5% by weight of a disintegrant,
about 0.2% to about 0.3% by weight of a glidant, and

about 0.55% to about 0.95% by weight of a lubricant;
wherein the film coating component comprises about 1.0% to about 8% by weight of a tablet coating; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

23. The method of claim 19
wherein the intra-granular component comprises
about 60% by weight of Compound 1,
about 30% by weight of an insoluble diluent or carrier,
about 3% by weight of a disintegrant, and
about 2.8% by weight of a diluent or filler;
wherein the extra-granular component comprises
about 3% by weight of a disintegrant,
about 0.25% by weight of a glidant, and
about 0.75% by weight of a lubricant;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of a tablet coating; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

24. The method of claim 19
wherein the intra-granular component comprises
about 65% by weight of Compound 1,
about 25% by weight of an insoluble diluent or carrier,
about 3% by weight of a disintegrant, and
about 2.8% by weight of a diluent or filler;
wherein the extra-granular component comprises
about 3% by weight of a disintegrant,
about 0.25% by weight of a glidant, and
about 0.75% by weight of a lubricant;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of a tablet coating; and

wherein the weight is the total weight of all intra-granular and extra-granular components.

25. The method of claim 19

wherein the intra-granular component comprises

about 70% by weight of Compound 1,

about 20% by weight of an insoluble diluent or carrier,

about 3% by weight of a disintegrant, and

about 2.8% by weight of a diluent or filler;

wherein the extra-granular component comprises

about 3% by weight of a disintegrant,

about 0.25% by weight of a glidant, and

about 0.75% by weight of a lubricant;

wherein the film coating component comprises about 2.0% to about 6.0% by weight of a tablet coating; and

wherein the weight is the total weight of all intra-granular and extra-granular components.

26. The method of claim 19

wherein the intra-granular component comprises

about 75% by weight of Compound 1,

about 15% by weight of an insoluble diluent or carrier,

about 3% by weight of a disintegrant, and

about 2.8% by weight of a diluent or filler;

wherein the extra-granular component comprises

about 3% by weight of a disintegrant,

about 0.25% by weight of a glidant, and

about 0.75% by weight of a lubricant;

wherein the film coating component comprises about 2.0% to about 6.0% by weight of a tablet coating; and

wherein the weight is the total weight of all intra-granular and extra-granular components.

27. The method of claim 19

wherein the intra-granular component comprises

about 80% by weight of Compound 1,
about 10% by weight of an insoluble diluent or carrier,
about 3% by weight of a disintegrant, and
about 2.8% by weight of a diluent or filler;
wherein the extra-granular component comprises
about 3% by weight of a disintegrant,
about 0.25% by weight of a glidant, and
about 0.75% by weight of a lubricant;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of a tablet coating; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

28. A method for treating anemia comprising administering to a patient a formulation comprising intra-granular components, extra-granular components, and film coating components, wherein the intra-granular components comprise Compound 1, microcrystalline cellulose, sodium starch glycolate, and hydroxypropyl methylcellulose, wherein the extra-granular components comprise sodium starch glycolate, colloidal silicon dioxide, and magnesium stearate, and wherein the film-coating components comprise Opadry®.

29. The method of claim 28
wherein the intra-granular component comprises
about 50% to about 80% by weight of Compound 1,
about 10% to about 40% by weight of microcrystalline cellulose,
about 1.5% to about 4.5% by weight of sodium starch glycolate, and
about 1% to about 5% by weight of a hydroxypropyl methylcellulose;
wherein the extra-granular component comprises
about 1.5% to about 4.5% by weight of a sodium starch glycolate,
about 0.1% to about 0.4% by weight of colloidal silicon dioxide, and
about 0.15% to about 1.35% by weight of magnesium stearate;
wherein the film coating component comprises about 1.0% to about 8% by weight of Opadry®;
and

wherein the weight is the total weight of all intra-granular and extra-granular components.

30. The method of claim 28

wherein the intra-granular component comprises

about 55% to about 75% by weight of Compound 1,
about 15% to about 35% by weight of microcrystalline cellulose,
about 2.0% to about 4.0% by weight of sodium starch glycolate, and
about 1.8% to about 3.8% by weight of a hydroxypropyl methylcellulose;

wherein the extra-granular component comprises

about 2.0% to about 4.0% by weight of a sodium starch glycolate,
about 0.15% to about 0.35% by weight of colloidal silicon dioxide, and
about 0.35% to about 1.15% by weight of magnesium stearate;

wherein the film coating component comprises about 1.0% to about 8% by weight of Opadry®;
and

wherein the weight is the total weight of all intra-granular and extra-granular components.

31. The method of claim 28

wherein the intra-granular component comprises

about 60% to about 70% by weight of Compound 1,
about 20% to about 30% by weight of microcrystalline cellulose,
about 2.5% to about 3.5% by weight of sodium starch glycolate, and
about 2.3% to about 3.3% by weight of a hydroxypropyl methylcellulose;

wherein the extra-granular component comprises

about 2.5% to about 3.5% by weight of a sodium starch glycolate,
about 0.2% to about 0.3% by weight of colloidal silicon dioxide, and
about 0.55% to about 0.95% by weight of magnesium stearate;

wherein the film coating component comprises about 1.0% to about 8% by weight of Opadry®;
and

wherein the weight is the total weight of all intra-granular and extra-granular components.

32. The method of claim 28

wherein the intra-granular component comprises

about 60% by weight of Compound 1,
about 30% by weight of microcrystalline cellulose,
about 3% by weight of sodium starch glycolate, and
about 2.8% by weight of a hydroxypropyl methylcellulose;
wherein the extra-granular component comprises
about 3% by weight of a sodium starch glycolate,
about 0.25% by weight of colloidal silicon dioxide, and
about 0.75% by weight of magnesium stearate;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of
Opadry®; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

33. The method of claim 28
wherein the intra-granular component comprises
about 65% by weight of Compound 1,
about 25% by weight of microcrystalline cellulose,
about 3% by weight of sodium starch glycolate, and
about 2.8% by weight of a hydroxypropyl methylcellulose;
wherein the extra-granular component comprises
about 3% by weight of a sodium starch glycolate,
about 0.25% by weight of colloidal silicon dioxide, and
about 0.75% by weight of magnesium stearate;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of
Opadry®; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

34. The method of claim 28
wherein the intra-granular component comprises
about 70% by weight of Compound 1,
about 20% by weight of microcrystalline cellulose,
about 3% by weight of sodium starch glycolate, and

about 2.8% by weight of a hydroxypropyl methylcellulose;
wherein the extra-granular component comprises
about 3% by weight of a sodium starch glycolate,
about 0.25% by weight of colloidal silicon dioxide, and
about 0.75% by weight of magnesium stearate;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of
Opadry®; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

35. The method of claim 28
wherein the intra-granular component comprises
about 75% by weight of Compound 1,
about 15% by weight of microcrystalline cellulose,
about 3% by weight of sodium starch glycolate, and
about 2.8% by weight of a hydroxypropyl methylcellulose;
wherein the extra-granular component comprises
about 3% by weight of a sodium starch glycolate,
about 0.25% by weight of colloidal silicon dioxide, and
about 0.75% by weight of magnesium stearate;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of
Opadry®; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

36. The method of claim 28
wherein the intra-granular component comprises
about 80% by weight of Compound 1,
about 10% by weight of microcrystalline cellulose,
about 3% by weight of sodium starch glycolate, and
about 2.8% by weight of a hydroxypropyl methylcellulose;
wherein the extra-granular component comprises
about 3% by weight of a sodium starch glycolate,

about 0.25% by weight of colloidal silicon dioxide, and
about 0.75% by weight of magnesium stearate;
wherein the film coating component comprises about 2.0% to about 6.0% by weight of Opadry®; and
wherein the weight is the total weight of all intra-granular and extra-granular components.

37. A method for treating anemia secondary to non-dialysis dependent chronic kidney disease, comprising administering to a patient having anemia secondary to non-dialysis dependent chronic kidney disease an effective amount of a compound which is {[5-(3-chlorophenyl)-3-hydroxypyridine-2-carbonyl]amino}acetic acid or a pharmaceutically acceptable salt, solvate, or hydrate thereof, wherein a daily dose comprises about 150 mg, about 300 mg, about 450 mg, about 600 mg, or about 750 mg of the compound.

38. A method of treating a anemia secondary to non-dialysis dependent chronic kidney disease, comprising administering a sufficient number of successive doses of a HIF prolyl hydroxylase inhibitor or a HIF-alpha stabilizer to a patient having anemia secondary to non-dialysis dependent chronic kidney disease wherein the patient has at least 2, 3, 4, 5 or all of (i) an estimated glomerular filtration rate (eGFR) of less than 60 mL/min/1.73m², wherein the subject is not on dialysis and not expected to start dialysis within 3 months of beginning of treatment, (ii) a hemoglobin level of less than 10.0 g/dL prior to commencement of treatment, (iii) a ferritin level equal to or above 100 ng/mL within 4 weeks of commencement of treatment, (iv) a transferrin saturation (TSAT) level equal to or above 20% within 4 weeks commencement of treatment, (v) a folate measurement equal to or above the lower limit of normal within 4 weeks commencement of treatment, (vi) a vitamin B12 measurement equal to or above the lower limit of normal within 4 weeks commencement of treatment, and (vii) an age of at least 18 years.

39. A method of treating a anemia secondary to non-dialysis dependent chronic kidney disease, comprising administering a sufficient number of successive doses of a HIF prolyl hydroxylase inhibitor or a HIF-alpha stabilizer to a patient having anemia secondary to non-dialysis dependent chronic kidney disease wherein the patient has at least 2, 3, 4, 5 or all of (i) an estimated glomerular filtration rate (eGFR) of less than 65 mL/min/1.73m², wherein the subject is not on dialysis and not expected to start dialysis within 3 months of beginning of treatment, (ii)

a hemoglobin level of less than 10.0 g/dL prior to commencement of treatment, (iii) a ferritin level equal to or above 50 ng/mL within 4 weeks of commencement of treatment, (iv) a transferrin saturation (TSAT) level equal to or above 15% within 4 weeks commencement of treatment, (v) a folate measurement equal to or above the lower limit of normal within 4 weeks commencement of treatment, (vi) a vitamin B12 measurement equal to or above the lower limit of normal within 4 weeks commencement of treatment, and (vii) an age of at least 18 years.

40. A method for treating anemia in a patient having non-dialysis dependent chronic kidney disease comprising:

administering to the patient an initial daily dose of Compound 1;

if the Hgb has not increased by more than 0.5 g/dL above the baseline value after 4 weeks of daily administration at the initial daily dose of Compound 1, increasing the daily dose by 150 mg/day of Compound 1, and increasing the daily dose by 150 mg/day every 4 weeks until Hgb is above 10.0 g/dL;

if the Hgb rises rapidly during treatment, reducing the daily dose by 150 mg/day;

if the Hgb falls below 10.0 g/dL, increasing the daily dose by 150 mg/day;

if the Hgb level exceeds 11.0 g/dL, interrupting treatment until the Hgb decreases to 10.5 g/dL or less, and thereafter resuming daily dosing with a daily dose reduced by 150 mg/day; and

if a dose adjustment is required to maintain Hgb at the desired level, adjusting the daily dose by 150 mg/day.

41. A method for treating anemia in a patient having non-dialysis dependent chronic kidney disease comprising:

administering to the patient an initial daily dose of Compound 1;

if the Hgb has not increased by more than 0.5 g/dL above the baseline value after 4 weeks of daily administration at the initial daily dose of Compound 1, increasing the daily dose by 150 mg/day of Compound 1, and increasing the daily dose by 150 mg/day every 4 weeks until Hgb is above 10.0 g/dL;

if the Hgb rises rapidly during treatment, reducing the daily dose by 150 mg/day;

if the Hgb falls below 10.0 g/dL, increasing the daily dose by 150 mg/day;

if the Hgb level exceeds 12.0 g/dL, reducing the daily dose by 150 mg/day, and if Hgb level exceeds 13.0 g/dL, interrupting treatment until the Hgb decreases to 12.5 g/dL or less, and thereafter resuming daily dosing with a daily dose reduced by 150 mg/day; and

if a dose adjustment is required to maintain Hgb at the desired level, adjusting the daily dose by 150 mg/day.

42. A method for treating anemia in a patient having non-dialysis dependent chronic kidney disease comprising:

administering to the patient an initial daily dose of Compound 1;

if a dose adjustment is required to maintain Hgb at the desired level, adjusting the daily dose by 150 mg/day;

if the Hgb rises rapidly during treatment, reducing the daily dose by 150 mg/day;

if the Hgb falls below 10.0 g/dL, increasing the daily dose by 150 mg/day; and

if the Hgb level exceeds 11.0 g/dL, interrupting treatment until the Hgb decreases to 10.5 g/dL or less, and thereafter resuming dosing with a daily dose reduced by 150 mg/day.

43. A method for treating anemia in a patient having non-dialysis dependent chronic kidney disease comprising:

administering to the patient an initial daily dose of Compound 1;

if a dose adjustment is required to maintain Hgb at the desired level, adjusting the daily dose by 150 mg/day;

if the Hgb rises rapidly during treatment, reducing the daily dose by 150 mg/day;

if the Hgb falls below 10.0 g/dL, increasing the daily dose by 150 mg/day; and

if the Hgb level exceeds 12.0 g/dL, reducing the daily dose by 150 mg/day, and if Hgb level exceeds 13.0 g/dL, interrupting treatment until the Hgb decreases to 12.5 g/dL or less, and thereafter resuming dosing with a daily dose reduced by 150 mg/day.

44. The method according to claims 40 or 41, wherein the baseline value is determined immediately prior to the first administration of Compound 1.

45. The method of any of claims 40 to 43, wherein the Hgb rises rapidly if the Hgb rises more than 1.0 g/dL in any 2-week period.

46. The method of any of claims 40 to 43, wherein the maximum daily dose is 600 mg/day.
47. The method of any of claims 40 to 43, wherein the daily dose is not increased more frequently than once every 4 weeks during the course of treatment.
48. The method of any of claims 40 to 43, wherein the daily dose is decreased more frequently than once every 4 weeks during the course of treatment.
49. The method of any of claims 40 to 43, wherein the initial daily dose is 300 mg/day.
50. The method of claim 49, wherein the initial daily dose is administered in form of two tablets of 150 mg of Compound 1 each.
51. The method of any of claims 40 to 43, wherein the initial daily dose is 450 mg/day.
52. The method of claim 51, wherein the initial daily dose is administered in form of three tablets of 150 mg of Compound 1 each.
53. The method of claim 50 or claim 52, wherein the initial daily dose is administered in the morning.
54. The method of claim 50 or claim 52, wherein the initial daily dose is administered between 7 am and 2 pm.
55. The method of any of claims 40 to 54, wherein Compound 1 is administered in the form of Formulation 1.
56. The method of any of claims 40 to 54, wherein Compound 1 is administered in the form of Formulation 2.