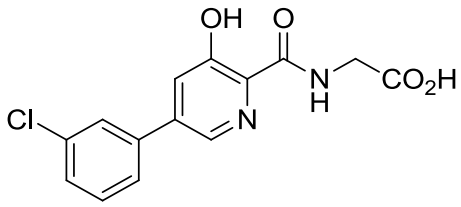
What is claimed is:

1. Use of a compound which is {[5-(3-chlorophenyl)-3-hydroxypyridine-2-carbonyl]amino}acetic acid, having the structure:



Compound **1**

or a pharmaceutically acceptable salt thereof for manufacturing a medicament for treating anemia in a patient having anemia, wherein the medicament is manufactured to be administered orally at a dose of 150 mg, 300 mg, 450 mg, or 750 mg.

2. The use of claim 1, wherein the compound is suitable to increase overall levels of erythropoietin in a diurnal pattern.

3. The use of claim 1, wherein the trough levels of erythropoietin are elevated compared to trough levels of erythropoietin in the subject immediately prior to the administration by at most 1%, 2%, 3%, 4%, 5%, 6%, 7%, 8%, 9%, 10%, 11%, 12%, 13%, 14%, 15%, 16%, 17%, 18%, 19%, or 20%.

4. The use of any one of claims 1-3, wherein the medicament is to be administered in the afternoon.

5. The use of any one of claims 1-3, wherein the anemia is anemia secondary to or associated with chronic kidney disease; anemia associated with or resulting from chemotherapy; or anemia associated with AIDS.

6. The use of claim 1, wherein the anemia is anemia secondary to a chronic kidney disease, the chronic kidney disease is stage 3, 4, or 5 chronic kidney disease; or the chronic kidney disease is pre-dialysis chronic kidney disease.

7. The use of claim 1, wherein the dose is (i) to be administered continuously, or (ii) to be administered indefinitely, or (iii) to be administered orally, once daily, or (iv) to be administered orally, as a divided dose to be administered twice daily.

8. The use of any one of claims 1–7, wherein the patient has not been previously treated for anemia; and/or the patient is refractory to treatment with recombinant erythropoietin;

and/or the patient has been previously treated for anemia.

9. The use of any one of claims 1–7, wherein hemoglobin levels of the patient

a. are maintained at a level of at least about 9.0 g/dL and at or below about 13.0 g/dL; or

b. are maintained at a level of at least about 10.0 g/dL and at or below about 13.0 g/dL; or

c. are maintained at a level of at least about 11.0 g/dL and at or below about 13.0 g/dL; or

d. are increased by at least about 1.2 g/dL relative to a baseline hemoglobin level.

10. The use of claim 9, wherein the hemoglobin levels are tested at least about 1 day, 2 days, 3 days, 4 days, 5 days, 6 days, 7 days, 8 days, 9 days, 10 days, 11 days, 12 days, 13 days, 14 days, 3 weeks, 4 weeks, 5 weeks, 6 weeks, 7 weeks, or about 8 weeks after initial administration of the medicament.

11. The use of any one of claim 1 or 7, wherein

(a) the medicament does not comprise an iron supplement;

(b) the medicament is to be administered in combination with another medicament; or

(c) the other medicament is an erythropoiesis stimulating agent (ESA) that is an erythropoietin mimetic.

12. The use of claim 11, wherein the other medicament is an iron supplement.

13. The use of claim 12, wherein administration of the iron supplement is to be administered at least two hours following administration of the medicament.

14. The use of claim 12, wherein administration of the iron supplement is to be administered in an amount such that ferritin is maintained at a level of between about 50 ng/mL and about 300 ng/mL.

15. The use of claim 12, wherein the iron supplement is to be administered orally at a daily dose of about 50 mg of elemental iron.

16. The use of any one of claims 12–15, wherein the iron supplement is to be administered (i) on an as needed basis; (ii) continuously; and/or (iii) indefinitely.

17. The use of claim 11, wherein the erythropoietin mimetic is an rhEPO product.

18. The use of claim 17, wherein the rhEPO product is selected from epoetin alfa, epoetin beta, darbepoetin, and peginesatide.

19. The use of any one of claims 11, 17, and 18, wherein the ESA is to be administered (i) as a rescue therapy; (ii) continuously; and/or (iii) indefinitely.

20. The use of any one of claims 1–19, wherein the medicament is to be administered once a day every day during treatment at the same time of the day.

21. The use of claim 20, wherein the time of day is in the morning or early afternoon.

22. The use of claim 1, wherein

a. an initial daily dose of the compound is to be administered to a patient having anemia;

b. a first measurement of the hemoglobin level in the patient and subsequently a second measurement of the hemoglobin level in the patient are taken;

c1. an adjusted daily dose of the compound that is greater than the initial daily dose is to be administered:

i. if the hemoglobin level in the patient at the second measurement is less than about 10.0 g/dL and the level of hemoglobin has decreased by less than about 0.5 g/dL as compared to the level at the first measurement; or

ii. if the hemoglobin level in the patient at the second measurement is less than about 10.0 g/dL and the level of hemoglobin has changed by up to about 0.4 g/dL as compared to the level at the first measurement; or

iii. if the hemoglobin level in the patient at the second measurement is between about 10.0 and about 10.9 g/dL and the level of hemoglobin has decreased by less than about 0.5 g/dL as compared to the level at the first measurement; or

c2. an adjusted daily dose of the compound that is less than the initial daily dose is to be administered:

i. if the hemoglobin level in the patient at the second measurement is less than

about 10.0 g/dL and the level of hemoglobin has increased by greater than about 1.5 g/dL as compared to the level at the first measurement; or

ii. if the hemoglobin level in the patient at the second measurement is between about 10.0 and about 10.9 g/dL and the level of hemoglobin has increased by greater than about 1.5 g/dL as compared to the level at the first measurement; or

iii. if the hemoglobin level in the patient at the second measurement is between about 11.0 and about 12.2 g/dL and the level of hemoglobin has increased by between about 1.0 and about 1.4 g/dL as compared to the level at the first measurement; or

iv. if the hemoglobin level in the patient at the second measurement is between about 12.3 and about 12.9 g/dL and the level of hemoglobin has decreased by up to about 0.4 g/dL or increased by up to about 0.4 g/dL as compared to the at the first measurement; or

v. if the hemoglobin level in the patient at the second measurement is between about 12.3 and about 12.9 g/dL and the level of hemoglobin has increased by about 0.5 to about 0.9 g/dL as compared to the level at the first measurement; or

c3. an adjusted daily dose of the compound that is less than the initial daily dose is to be administered:

i. if the hemoglobin level in the patient at the second measurement is between about 11.0 and about 12.2 g/dL and the level of hemoglobin has increased by greater than about 1.5 g/dL as compared to the level at the first measurement; or

ii. if the hemoglobin level in the patient at the second measurement is between about 12.3 and about 12.9 g/dL and the level of hemoglobin has increased by between about 1.0 and about 1.4 g/dL as compared to the level at the first measurement; or

iii. if the hemoglobin level in the patient at the second measurement is between about 12.3 and about 12.9 g/dL and the level of hemoglobin has increased by greater than about 1.5 g/dL as compared to the level at the first measurement.

23. The use of claim 22, wherein

the adjusted daily dose of the compound is about 150 mg greater than the initial daily dose in step c1;

the adjusted daily dose of the compound is about 150 mg less than the initial daily

dose in step c2; or

the adjusted daily dose of the compound is about 300 mg less than the initial daily dose in step c3.

24. The use of claim 22 or 23, wherein the minimum daily dose is 150 mg and the maximum daily dose is at most 750 mg.

25. The use of any one of claims 22–24, wherein the period between the first and second measurement is 1 day, 2 days, 3 days, 4 days, 5 days, 6 days, 7 days, 8 days, 9 days, 10 days, 11 days, 12 days, 13 days, 14 days, 3 weeks, 4 weeks, 5 weeks, 6 weeks, 7 weeks, or 8 weeks.

26. The use of any one of claims 22–25, wherein the first measurement is taken immediately after commencement of the treatment or within at most 1 day, 2 days, 3 days, 4 days, 5 days, 6 days, or 1 week, or 2 weeks thereof.

27. The use of claim 22 or 23, wherein the anemia is anemia secondary to chronic kidney disease.

28. The use of claim 27, wherein the chronic kidney disease is stage 3, 4, or 5 chronic kidney disease.

29. The use of claim 27, wherein the chronic kidney disease is pre-dialysis chronic kidney disease.

30. The use of any one of claims 22–29, wherein the daily dose is to be administered (i) continuously; (ii) indefinitely; (iii) orally, once daily; and/or (iv) orally, as a divided dose to be administered twice daily.

31. The use of any one of claims 22–30, wherein the patient has not been previously treated for anemia; or the patient is refractory to treatment with recombinant erythropoietin.

32. The use of any one of claims 22–30, wherein

(a) the use does not comprise administration of an iron supplement; or

(b) the medicament is to be administered in combination with another medicament; or

(c) the other medicament is an erythropoiesis stimulating agent (ESA) that is an erythropoietin mimetic.

33. The use of claim 32, wherein the other medicament is an iron supplement.

34. The use of claim 33, wherein the iron supplement is to be administered at least two

hours following administration of the compound.

35. The use of any one of claims 32–34, wherein the iron supplement is to be administered in an amount such that ferritin is maintained at a level of between about 50 ng/mL and about 300 ng/mL.

36. The use of any one of claims 32–35, wherein the iron supplement is to be administered orally at a daily dose about 50 mg of elemental iron.

37. The use of any one claims 32–36, wherein the iron supplement is to be administered (i) continuously; and/or (ii) indefinitely.

38. The use of claim 32, wherein the other medicament is to be administered in combination with another medicament that is an erythropoiesis stimulating agent (ESA) that isan rhEPO product.

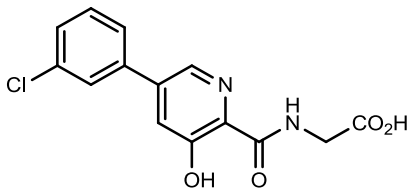
39. The use of claim 33, wherein the rhEPO product is epoetin alfa.

40. The use of claim 38 or 39, wherein the ESA is to be administered as a rescue therapy.

41. The use of any one of claim 54 to claim 56, wherein the ESA is to be administered indefinitely.

42. Use of a compound for manufacturing a medicament for treating anemia related to diminished endogenous production of erythropoietin (EPO), wherein the compound is a HIF prolyl hydroxylase inhibitor or a HIF-alpha stabilizer, which is to be administered so as to raise the total iron binding capacity (TIBC) relative to a baseline TIBC in a patient, without significantly increasing the serum iron level relative to a baseline serum iron level,

wherein the HIF prolyl hydroxylase inhibitor or HIF-alpha stabilizer is Compound **1** having a structure



Compound **1**

or a pharmaceutically acceptable salt thereof; and

wherein the compound is to be administered orally at a daily dose of about 150 mg, about 300 mg, about 450 mg, about 600 mg, or about 750 mg.

43. The use of claim 42, wherein the cardiovascular side-effects and risk of thromboembolic events associated with increased serum iron levels are minimized.

44. The use of claim 42 or 43, wherein the transferrin saturation (TSAT) decreases relative to a baseline TSAT, and/or wherein the serum iron level decreases relative to a baseline serum iron level.

45. The use of claim 44, wherein the TIBC increases by at least about 10 µg/dL, 20 µg/dL, 30 µg/dL, 40 µg/dL, 50 µg/dL, or at least about 60 µg/dL relative to a baseline TIBC.

46. The use of claim 45, wherein the TIBC increase occurs over about 1 week, about 2 weeks, about 3 weeks, about 4 weeks, about 5 weeks, or about 6 weeks relative to a baseline TIBC.

47. The use of claim 44, wherein the serum iron level increases by less than about 20 µg/dL, less than about 15 µg/dL, less than about 10 µg/dL, or less than about 5 µg/dL relative to a baseline serum iron level.

48. The use of claim 42 or 43, wherein the disease or condition is anemia.

49. The use of claim 48, wherein the anemia is anemia secondary to chronic kidney disease (CKD).

50. The use of claim 49, wherein the chronic kidney disease is stage 3, 4, or 5 chronic kidney disease.

51. The use of claim 49, wherein the chronic kidney disease is pre-dialysis chronic kidney disease.

52. The use of claim 42, wherein the HIF prolyl hydroxylase inhibitor or HIF-alpha stabilizer is to be administered once daily and/or orally.

53. The use of claim 1 or claim 42, wherein the compound is to be administered orally at a dose of about 150 mg.

54. The use of claim 1 or claim 42, wherein the compound is to be administered orally at a dose of about 300 mg.

55. The use of claim 1 or claim 42, wherein the compound is to be administered orally at a dose of about 450 mg.

56. The use of claim 1 or claim 42, wherein the compound is to be administered orally at a dose of about 600 mg.

57. The use of claim 1, wherein the compound is to be administered orally at a dose of about 750 mg.

58. A single unit dosage form comprising about 150 mg of {[5-(3-chlorophenyl)-3-hydroxypyridine-2-carbonyl]amino}acetic acid, or a pharmaceutically acceptable salt thereof.

59. Use of a compound {[5-(3-chlorophenyl)-3-hydroxypyridine-2-carbonyl]amino}acetic acid or a pharmaceutically acceptable salt, solvate, or hydrate thereof for manufacturing a medicament for treating anemia in a patient having anemia, wherein the compound is to be administered orally in a dose of 300 mg once daily, wherein the dose comprises two tablets.