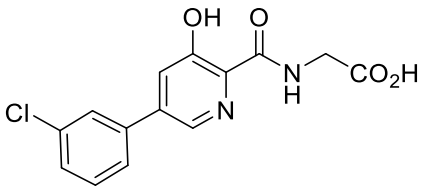
CLAIMS

What is claimed is:

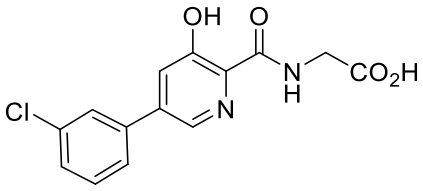
1. Use of {[5-(3-chlorophenyl)-3-hydroxypyridine-2-carbonyl]amino}acetic acid having the structure of Compound 1,



(Compound 1),

or a pharmaceutically acceptable salt, solvate, or hydrate thereof in the manufacture of a medicament for treating anemia wherein a patient having anemia is to be administered a dose comprising about 450 mg to about 1800 mg of Compound 1.

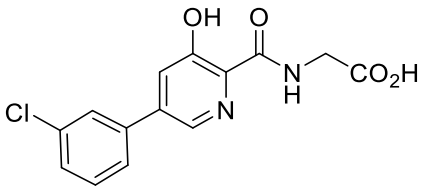
2. Use of {[5-(3-chlorophenyl)-3-hydroxypyridine-2-carbonyl]amino}acetic acid having the structure of Compound **1**,



(Compound **1**),

or a pharmaceutically acceptable salt, solvate, or hydrate thereof in the manufacture of a medicament for increasing hemoglobin levels in a patient wherein the patient is to be administered a dose comprising about 450 mg to about 1800 mg of Compound 1, and wherein the hemoglobin levels are to be increased to about at least 10 g/dL from a baseline hemoglobin level.

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



(Compound **1**),

or a pharmaceutically acceptable salt, solvate, or hydrate thereof in the manufacture of a medicament for maintaining hemoglobin levels in a patient wherein the patient is to be administered a dose comprising about 450 mg to about 1800 mg of Compound 1, and wherein the hemoglobin levels are to be maintained at about 10.0 g/dL to about 13.0 g/dL.

4. The use of any one of claims 1 to 3, wherein

a.) the dose comprises about 450 mg to 1200 mg of Compound 1;

b.) the dose comprises about 750 mg to about 1800 mg or about 750 mg to about 1200 mg of Compound 1 once daily;

c.) the dose comprises about 600 mg to about 1800 mg or about 600 mg to about 1200 mg of Compound 1 three times weekly;

d.) for at least 12 weeks, the dose comprises about 750 mg to about 1800 mg or about 750 mg to about 1200 mg of Compound 1 once daily;

e.) for at least 12 to 260 weeks, the dose comprises about 600 mg to about 1800 mg or about 600 mg to about 1200 mg of Compound 1 three times weekly;

f.) the dose comprises about 750 to about 1800 mg or about 750 to about 1200 mg of Compound 1 once daily, and wherein the patient was previously treated with an erythropoietin stimulating agent (ESA);

g.) the dose comprises about 600 mg to about 1800 mg or about 600 mg to about 1200 mg of Compound 1 three times weekly, and wherein the patient was previously treated with an erythropoietin stimulating agent (ESA);

h.) the dose comprises about 750 mg to about 1800 mg or about 750 mg to about 1200 mg of Compound 1 once daily, and wherein anemia is anemia associated with or secondary to dialysis-dependent chronic kidney disease (DD-CKD);

i.) the dose comprises about 600 mg to about 1800 mg or about 600 mg to about 1200 mg of Compound 1 three times weekly, and wherein anemia is anemia associated with or secondary to dialysis-dependent chronic kidney disease (DD-CKD);

j.) the dose comprises about 750 mg to about 1800 mg or about 750 mg to about 1200 mg of Compound 1 once daily, wherein the patient was previously treated with an erythropoietin stimulating agent (ESA), and wherein anemia is anemia associated with or secondary to dialysis-dependent chronic kidney disease (DD-CKD);

k.) the dose comprises about 600 mg to about 1800 mg or about 600 mg to about 1200 mg of Compound 1 three times weekly, wherein the patient was previously treated with an erythropoietin stimulating agent (ESA), and wherein anemia is anemia associated with or secondary to dialysis-dependent chronic kidney disease (DD-CKD),

l.) the dose comprises about 750 mg of Compound 1 once daily, wherein the patient was previously treated with an erythropoietin stimulating agent (ESA), and wherein anemia is anemia associated with or secondary to dialysis-dependent chronic kidney disease (DD-CKD);

m.) wherein the dose comprises about 900 mg of Compound 1 once daily, wherein the patient was previously treated with an erythropoietin stimulating agent (ESA), wherein anemia is anemia associated with or secondary to dialysis-dependent chronic kidney disease (DD-CKD);

n.) the dose comprises about 600 mg of Compound 1 three times weekly, wherein the patient was previously treated with an erythropoietin stimulating agent (ESA), wherein anemia is anemia associated with or secondary to dialysis-dependent chronic kidney disease (DD-CKD);

o.) the dose comprises about 750 mg of Compound 1 three times weekly, wherein the patient was previously treated with an erythropoietin stimulating agent (ESA), wherein anemia is anemia associated with or secondary to dialysis-dependent chronic kidney disease (DD-CKD);

p.) the dose comprises about 900 mg of Compound 1 three times weekly, wherein the patient was previously treated with an erythropoietin stimulating agent (ESA), wherein anemia is anemia associated with or secondary to dialysis-dependent chronic kidney disease (DD-CKD); or

q.) the dose comprises about 1200 mg of Compound 1 three times weekly, wherein the patient was previously treated with an erythropoietin stimulating agent (ESA), wherein anemia is anemia associated with or secondary to dialysis-dependent chronic kidney disease (DD-CKD).

5. The use according to claims 1 to 3, wherein the dose comprises
   (a) 450 mg, 600 mg, 750 mg, 900 mg, 1200 mg, 1350 mg, 1500 mg, 1650 mg or 1800 mg of Compound 1 or
   (b) about 600 mg to about 900 mg, about 750 mg to about 900 mg, or about 750 mg to about 1200 mg.

6. The use according to anyone of claims 1 to 4 wherein the dose is to be administered to the patient for at least 12 weeks, for at least 24 weeks, for at least 28 weeks, for at least 32 weeks, for at least 36 weeks, for at least 40 weeks, for at least 44 weeks, for at least 48 weeks, for at least 52 weeks, for at least 64 weeks, for at least 76 weeks, for at least 88 weeks, for at least 104 weeks, for at least 116 weeks, for at least 128 weeks, for at least 140 weeks, for at least 156 weeks, for at least 168 weeks, for at least 180 weeks, for at least 192 weeks, for at least 208 weeks, or for at least 260 weeks, or
   wherein the dose is to be administered to the patient for at least 12 to 260 weeks.

7. The use according to claim 4, wherein the patient has been previously treated with an erythropoiesis stimulating agent (ESA), wherein optionally the ESA is selected from epoetin, darbepoetin alfa (DA), or methoxy polyethylene glycol-epoetin beta (epoetin beta pegol).

8. The use according to claim 7, wherein the ESA is epoetin alfa, and wherein optionally
   (a) the patient previously has been treated with epoetin alfa at a dose of about 10 U/kg of body weight to about 500 U/kg of body weight three times weekly;
   (b) the patient previously has been treated with epoetin alfa at a dose of about 25 U/kg of body weight to about 300 U/kg of body weight three times weekly;
   (c) the patient previously has been treated with epoetin alfa at a dose of about 50 U/kg of body weight to 200 U/kg of body weight three times weekly;

(d) the patient previously has been treated with about ≤ 90 U/kg/week epoetin alfa;

(e) the patient previously has been treated with about ≥ 300 U/kg/week epoetin alfa;

(f) the patient has been previously treated with epoetin alfa at a dose of ≤ 90 U/kg/week to ≥ 300 U/kg/week of body weight body;

(g) the patient previously has been treated with epoetin alfa at an amount of 1,500 U/week to 90,000 U/week; or

(h) the patient previously has been treated with epoetin alfa at an amount of about 4,500 U/week.

9. The use according to claim 7, wherein the ESA is darbepoetin alfa (DA), and wherein optionally

(a) the patient previously has been treated with DA at a dose of 0.25 µg/kg of body weight to 0.75 µg/kg of body weight once weekly or once every two weeks,

(b) the patient previously has been treated with DA at a dose of about 0.45 µg/kg of body weight once weekly;

(c) the patient previously has been treated with DA at a dose of about 0.75 µg/kg of body weight once every two weeks;

(d) he patient previously has been treated with darbepoetin at an amount of 6.25 to 200 µg/week, or

(e) the patient previously has been treated with darbepoetin at an amount of ≤ 0.45 µg/kg of body weight/week, or wherein the patient previously has been treated with >0.45 µg/kg of body weight/week and ≤ 1.5 µg/kg of body weight/week.

10. The use according to claim 7, wherein the ESA is epoetin beta pegol, and wherein optionally

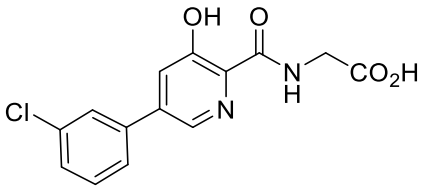
(a) the patient has been previously treated with epoetin beta pegol at a dose of 0.3 µg/kg of body weight to 1.2 µg/kg of body weight once every two weeks or 0.6 µg/kg of body weight to about 2.4 µg/kg of body weight once a month, or wherein

(b) the patient previously has been treated with epoetin beta pegol at a dose of 0.6 µg/kg of body weight once every two weeks or about 1.2 µg/kg of body weight once a month; or

(c) wherein the patient previously has been treated with ≤ 250 μg/month epoetin beta pegol.

11. The use according to anyone of claims 8 to 10, wherein the patient previously has been treated with an ESA for about ≥4 weeks.

12. Use of {[5-(3-chlorophenyl)-3-hydroxypyridine-2-carbonyl]amino}acetic acid having the structure of Compound 1,



(Compound 1),

or a pharmaceutically acceptable salt, solvate, or hydrate thereof in the manufacture of a medicament for treating anemia wherein a patient having anemia is to be administered a starting dose comprising 750 mg to 1800 mg of Compound 1 once daily or 600 mg to 1800 mg of Compound 1 three times weekly, and

(i) the dose is to be adjusted by 150 mg to 300 mg of Compound 1 if the patient has a hemoglobin level of <10.0 g/dL or >11.0 g/dL following administration of the starting dose; or

(ii) the starting dose is to be decreased by 150-300 mg of Compound 1 if the patient's hemoglobin level increases by >1.0 g/dL within a 2-week period.

13. The use of claim 12, alternative (i), wherein

(a) the dose is to be adjusted by about 150 mg or 300 mg of Compound 1 if the patient has a hemoglobin level of <10.0 g/dL or >11.0 g/dL following administration of the starting dose

(b) the dose is to be increased by about 150 mg or 300 mg of Compound 1 if the patient has a hemoglobin level <10.0 g/dL following the administration of the starting dose, or

(c) the dose is to be adjusted by about 150 mg or 300 mg of Compound 1 if the patient has a hemoglobin level >11.0 g/dL following the administration of the starting dose.

14. The use according to claim 12, wherein the starting dose is to be decreased by about 150 mg or 300 mg of Compound 1 if the patient's hemoglobin level increases by >1.0 g/dL within a 2-week period.

15. The use according to anyone to claims 12 to 14, wherein
    (a) the starting dose comprises about 750 mg to about 1200 mg of Compound 1 once daily;
    (b) the starting dose comprises about 750 mg or about 900 mg of Compound 1 once daily;
    (c) the starting dose comprises about 600 mg to about 1200 mg of Compound 1 three times weekly; and/or
    (d) the starting dose is to be administered to the patient for about ≥4 weeks.

16. The use according to any one of the preceding claims, wherein the anemia is anemia associated with or secondary to chronic kidney disease (CKD), optionally wherein the chronic kidney disease is dialysis-dependent chronic kidney disease (DD-CKD).