WHAT IS CLAIMED:

1. Use of an activin receptor type IIB (ActRIIB) ligand trap and fedratinib in the manufacture of a medicament for treating anemia in a subject in need thereof, wherein the ActRIIB ligand trap and fedratinib or a pharmaceutically acceptable salt and/or hydrate thereof are to be administered to the subject.

2. Use of an activin receptor type IIB (ActRIIB) ligand trap and fedratinib in the manufacture of a medicament for treating anemia in a subject in need thereof, wherein:

(a) a first measurement of hemoglobin (Hgb) level is to be taken in a subject;

(b) an initial dose of an ActRIIB ligand trap is to be administered to the subject;

(c) fedratinib or a pharmaceutically acceptable salt and/or hydrate thereof is to be administered;

(d) a second measurement of hemoglobin (Hgb) level is to be taken in the subject at the end of a first period of time after the administration of the initial dose of an ActRIIB ligand trap; and

(e) a subsequent dose of the ActRIIB ligand trap is to be administered based on the second measurement of hemoglobin (Hgb) level as compared to the first measurement of hemoglobin (Hgb) level, or based on number of red blood cell transfusion that the subject received during the first period of time.

3. The use of claim 1 or 2, wherein the ActRIIB ligand trap and fedratinib or pharmaceutically acceptable salt or hydrate thereof are to be concomitantly administered.

4. The use of any one of claims 1 to 3, wherein the subject is a subject diagnosed with myelofibrosis.

5. The use of claim 4, wherein the myelofibrosis is a myeloproliferative neoplasms (MPN)-associated myelofibrosis or wherein the myelofibrosis is intermediate or High-Risk Primary Myelofibrosis (PMF), Post-Polycythemia Vera Myelofibrosis (post-PV MF), or Post-Essential Thrombocythemia Myelofibrosis (post-ET MF).

6. The use of any one of claims 1 to 5, wherein the subject is a human.

7. The use of any one of claims 1 to 6, wherein the subject is RBC transfusion dependent optionally wherein the subject has received 4 to 12 RBC units in RBC transfusion within 84 days prior to administering of the ActRIIB ligand trap.

8. The use of claim 7, wherein the subject has a hemoglobin (Hgb) level of less than 11.5 g/dL without red blood cell (RBC) transfusion.

9. The use of any one of claims 1 to 6, wherein the subject is non-transfusion dependent optionally wherein the subject has received less than 4 red blood cell (RBC) units in RBC transfusion within 84 days prior to administering of the ActRIIB ligand trap.

10. The use of claim 9, wherein the subject has a hemoglobin (Hgb) level of less than 9.5 g/dL.

11. The use of any one of claims 1 to 10, wherein the subject has been treated with fedratinib for at least 8 weeks, at least 16 weeks, at least 24 weeks, at least 32 weeks, or at least 40 weeks prior to administration of the initial dose of the ActRIIB ligand trap and concomitantly administration of fedratinib or pharmaceutically acceptable salt or hydrate thereof.

12. The use of any one of claims 1 to 11, wherein the subject has been previously treated with ruxolitinib.

13. The use of any one of claims 1 to 12, wherein the fedratinib or pharmaceutically acceptable salt or hydrate thereof is to be administered daily.

14. The use of any one of claims 1 to 13, wherein the fedratinib or pharmaceutically acceptable salt or hydrate thereof is to be administered orally, optionally at a dosage of 400 mg/day.

15. The use of any one of claims 1 to 14, wherein the ActRIIB ligand trap is to be administered once at the beginning of every treatment cycle, wherein each cycle is 21 days.

16. The use of any one of claims 1 to 15, wherein the ActRIIB ligand trap is to be administered to the subject for at least 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 cycles.

17. The use of any one of claims 1 to 16, wherein the ActRIIB ligand trap is to be administered to the subject subcutaneously.

18. The use of any one of claims 1 to 17, wherein the initial dose of the ActRIIB ligand trap to be administered is 0.6 mg/kg, 0.8 mg/kg, 1 mg/kg, 1.33 mg/kg, or 1.75 mg/kg, preferably 1.33 mg/kg.

19. The use of any one of claims 2 to 17, wherein the first measurement of hemoglobin (Hgb) level is taken prior to or concurrently with the administration of the initial dose of the ActRIIB ligand trap.

20. The use of claim 2, wherein the second measurement of hemoglobin (Hgb) level is taken about 3 weeks, 6 weeks, 9 weeks, 12 weeks, 15 weeks, 18 weeks, 21 weeks, 24 weeks, 7 months, 8 months, 9 months, 10 months, 11 months, or 12 months after the administration of the initial dose of the ActRIIB ligand trap.

21. The use of any one of claims 2 to 20, wherein the first period of time is 1 day, 2 days, 3 days, 4 days, 5 days, 6 days, 1 week, 2 weeks, 3 weeks, 4 weeks, 5 weeks, 6 weeks, 7 weeks, or 8 weeks.

22. The use of any one of claims 2 to 21, wherein when the second measurement of Hgb level is 2 g/dL or more higher than the first measurement of Hgb level, the subsequent dose of the ActRIIB ligand trap is lower than the initial dose of the ActRIIB ligand trap.

23. The use of any one of claims 2 to 21, wherein when the subject has one or more RBC transfusion during the first period of time, or the second measurement of Hgb level is between 0 to about 1 g/dL higher than the first measurement of Hgb level, or the first measurement of Hgb level decreases 1 g/dL or more in a transfusion-free period of approximately 6 weeks, the subsequent dose of the ActRIIB ligand trap is higher than the initial dose of the ActRIIB ligand trap.

24. The use of any one of claims 2 to 21, wherein the subsequent dose of the ActRIIB ligand trap is the same as the initial dose of the ActRIIB ligand trap.

25. The use of any one of claims 2-24, wherein the subsequent dose of fedratinib or pharmaceutically acceptable salt or hydrate thereof is 300 mg/day, 200 mg/day, or 100 mg/day.

26. The use of any one of claims 1 to 25, wherein the ActRIIB ligand trap is a fusion-protein comprising the extracellular domain of ActRIIB and a human IgG1 Fc domain, optionally wherein the fusion-protein is a humanized fusion protein.

27. The use of any one of claims 1 to 25, wherein the ActRIIB ligand trap is a polypeptide comprising an amino acid sequence selected from the group consisting of:

(a) 90% identical to SEQ ID NO:3;
(b) 95% identical to SEQ ID NO:3;
(c) 98% identical to SEQ ID NO:3;
(d) SEQ ID NO:4;
(e) 90% identical to SEQ ID NO:6;
(f) 95% identical to SEQ ID NO:6;
(g) 98% identical to SEQ ID NO:6;
(h) SEQ ID NO:7;
(i) 90% identical to SEQ ID NO:7;
(j) 95% identical to SEQ ID NO:7;
(k) 98% identical to SEQ ID NO:7;
(l) SEQ ID NO:8;
(m) 90% identical to SEQ ID NO:11;
(n) 95% identical to SEQ ID NO:11;
(o) 98% identical to SEQ ID NO:11; and
(p) SEQ ID NO:11,

preferably wherein the ActRIIB ligand trap is a polypeptide comprising the amino acid sequence of SEQ ID NO:11.

28. The use of any one of claims 1 to 25, wherein the ActRIIB ligand trap is a polypeptide encoded by the nucleotide sequence of SEQ ID NO:34 or a degenerate version of SEQ ID NO:34.