CLAIMS

1. Use of obexelimab in the manufacture of a medicament for the treatment of autoimmune hemolytic anemia (AIHA), comprising obexelimab to be subcutaneously administered to a human patient at a dose of 250 mg once a week.

2. The use of claim 1, wherein the patient has a Hgb level of ≥ 7 to < 10 g/dL.

3. The use of claim 1 or 2, wherein the patient has been diagnosed with warm autoimmune hemolytic anemia (wAIHA).

4. The use of any one of the preceding claims, wherein the patient has at least one sign or symptom of anemia.

5. The use of any one of the preceding claims, wherein the patient also has failed at least 1 prior wAIHA treatment regimen, optionally wherein:

(i) the prior wAIHA treatment regimen is GC or immunosuppression therapy;

(ii) the failure of the prior wAIHA treatment regimen comprises reduction in Hgb of ≥ 1 g/dL; and/or

(iii) the failure of the prior wAIHA treatment regimen comprises an increase in LDH of ≥ 1.5 × upper limit of normal (ULN).

6. The use of any one of the preceding claims, wherein obexelimab is to be administered concurrently with a GC therapy, optionally wherein the GC therapy is to be administered at a dose of 1-1.5mg/kg/day prednisone or equivalent.

7. The use of any one of the preceding claims, wherein the patient maintains a Hgb level of ≥ 7 g/dL, ≥ 8 g/dL, ≥ 9 g/dL or ≥ 10 g/dL.

8. The use of any one of the preceding claims, wherein the patient achieves a Hgb ≥ 2 g/dL increase compared to Hgb levels prior to treatment with obexelimab.

9. The use of any one of the preceding claims, wherein obexelimab is to be administered for a time period sufficient to improve, stabilize or reduce one or more symptoms of wAIHA relative to a control.

10. The use of any one of the preceding claims, wherein the patient achieves improvement in:

(i) Hgb after at least 4, 5, 6, 7, 8, 9, 10, 11, 12 weeks of obexelimab administration;

(ii) FACIT-F score compared to the FACIT-F score prior to treatment; and/or

(iii) EQ-5D-5L index score compared to the EQ-5D-5L index score prior to treatment.

11. The use of any one of the preceding claims, wherein the patient achieves one or more of the following:

a) Decrease in Circulating absolute T, B, and NK cell count,
b) Decrease in Ig levels and ratios (e.g., IgG, IgM, IgA, IgE),
c) Increase in CD19 target receptor occupancy,
d) Decrease in reticulocyte count,
e) Decrease in LDH,
f) Increase in Haptoglobin,
g) Decrease in indirect bilirubin (unconjugated bilirubin)

following the administration of obexelimab.

12. The use of any one of the preceding claims, wherein the human patient is relapsed or refractory to rituximab.

13. The use of any one of the preceding claims, wherein the patient is 18 years of age or older.

14. The use of any one of the preceding claims, wherein the patient does not have:

(i) cold autoimmune hemolytic amenia or CAD.

(ii) mixed type autoimmune hemolytic amenia; and/or

(iii) Paroxysmal cold hemoglobinuria (PCH).

15. The use of any one of the preceding claims, wherein obexelimab is to be administered in a liquid formulation comprising 125 mg/mL obexelimab, 2.35 mg/mL sodium acetate trihydrate, 0.17 mg/mL acetic acid, 30 mg/mL L-proline, 0.1 mg/mL polysorbate 80 at pH 5.5, optionally wherein obexelimab is to be administered as 2 x 1 mL injections or 1 x 2mL injection, further optionally wherein obexelimab is to be administered using a prefilled syringe or autoinjector.