CLAIMS

1. Use of a type I interferon (IFN) receptor (IFNR) inhibitor in the manufacture of a medicament for treating systemic lupus erythematosus (SLE) in a subject in need thereof, wherein a therapeutically effective amount of the medicament is to be administered to the subject, wherein the medicament reduces SLE disease activity in the subject, wherein the reducing SLE disease activity in the subject comprises:

    a. a BILAG-Based Composite Lupus Assessment (BICLA) response in the subject,

    b. reducing the subject's Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) score compared to the subject's CLASI score pre-treatment,

    c. reducing the subject's tender and swollen joint count compared to the subject's tender and swollen joint count pre-treatment,

    d. the subject having a maximum of 1 BILAG-2004 B score following treatment,

    e. the subject having a BILAG-2004 score of C or better following treatment,

    f. the subject having an improvement in at least one patient reported outcome (PRO) compared to pre-treatment, and/or

    g. reducing the subject's SLE flare rate compared to the subject's flare rate pre-treatment.

2. The use of claim 1, wherein the ability of the medicament to reduce SLE disease activity in a subject has been demonstrated in a phase III clinical trial.

3. The use according to any preceding claim, wherein the subject's BILAG score is to be measured before and after the medicament is to be administered.

4. The use according to any preceding claim, wherein the BICLA response is sustained in the subject for at least 52 weeks.

5. The use according to any preceding claim, wherein the BICLA response comprises reduction of the subject's BILAG-2004 A and B domain scores to B/C/D and C/D, respectively.

6. The use according to any preceding claim, wherein reducing the subject's CLASI score compared to the subject's CLASI score pre-treatment comprises a reduction in the subject's CLASI-A score compared to the subject's CLASI-A score pre-treatment.

7. The use according to any preceding claim, wherein the reducing the SLE disease activity in the subject comprises reducing the anti-dsDNA levels in the subject.

8. The use according to any preceding claim, wherein the reducing SLE disease activity in the subject comprises a BILAG-Based Composite Lupus Assessment (BICLA) response, and wherein the medicament reduces the OCS dose is to be administered to the subject compared to the OCS dose is to be administered to the subject pre-treatment, optionally wherein the OCS comprises prednisone, prednisolone and/or methylprednisolone.

9. The use according to any preceding claim, wherein the reducing SLE disease activity in the subject comprises a BILAG-Based Composite Lupus Assessment (BICLA) response by at least week 4 of treatment.

10. The use according to any preceding claim, wherein the reduction in the subject's CLASI score is achieved by at least week 8 of treatment, or wherein the reduction in the subject's CLASI score is achieved following 12 weeks of treatment.

11. The use according to any preceding claim, wherein the reducing SLE disease activity in the subject comprises at least 50% reduction in the subject's CLASI score compared to the subject's CLASI score pre-treatment.

12. The use according to claim 11, wherein the reducing SLE disease activity in the subject comprises reduction of the subject's CLASI-A score following 12 weeks of treatment.

13. The use according to claim 11 or 12, wherein the subject has a CLASI-A score of ≥10 pretreatment.

14. The use according to any preceding claim, wherein the reducing SLE disease activity in the subject comprises the subject's BILAG-2004 score being C or better after 24 weeks of treatment.

15. The use according to any preceding claim, wherein the reducing SLE disease activity in the subject comprises the subject having a maximum of 1 BILAG-2004 B score after 24 weeks of treatment.

16. The use according to any preceding claim, wherein the reducing SLE disease activity in the subject comprises a reduction in the subject's BILAG-based annualized flare rate compared to the subject's BILAG-based annualized flare rate pre-treatment.

17. The use according to any preceding claim, wherein a flare is defined as ≥1 new BILAG-2004 A or ≥2 new (worsening) BILAG-2004 B domain scores compared to the subject's scores one month previously.

18. The use according to any preceding claim, wherein the reducing SLE disease activity in the subject comprises a reduced flare rate in the subject compared to the flare rate pre-treatment, wherein the medicament reduces OCS dose is to be administered to the subject compared to the OCS dose is to be administered to the subject pre-treatment.

19. The use according to any preceding claim, wherein the subject is selected for treatment, wherein the subject is selected for having active or moderate to severe SLE and/or wherein the subject is selected for having SLE that is unresponsive to OCS treatment.

20. The use of any preceding claim wherein the type I IFN receptor inhibitor is anifrolumab.