CLAIMS

1. Use of an antibody or antigen binding fragment thereof for the preparation of a medicament for treating rheumatoid arthritis, the use comprising selecting a subject that exhibits:

(a) a serum concentration of C-reactive protein (CRP) greater than 27.9 mg/L,

(b) a serum concentration of C-reactive protein (CRP) greater than 6.9 mg/L and less than 13.1 mg/L,

(c) a serum concentration of serum amyloid A (SAA) greater than 105.2 ng/mL and less than 256.0 ng/mL, or a subject with a serum concentration of serum amyloid A (SAA) greater than 11.83 ng/mL and less than 30.08 ng/mL,

(d) a serum concentration of matrix metalloproteinase-3 (MMP-3) greater than 77.0 ng/mL, or a subject with a serum concentration of matrix metalloproteinase-3 (MMP-3) greater than 35.5 ng/mL and less than 54.1 ng/mL, or wherein the serum concentration of MMP-3 is less than 154.3 ng/mL in the subject,

(e) a serum concentration of chemokine (C-X-C motif) ligand 13 (CXCL13) greater than 180.8 pg/mL,

(f) a serum concentration of CXCL3 is less than 323.9 pg/mL, or wherein, the serum concentration of chemokine (C-X-C motif) ligand 13 (CXCL13) greater than 98.2 pg/mL and less than 130.6 pg/mL,

(g) a serum concentration of chemokine CXCL13 less than 72.0 pg/mL and a serum concentration of soluble intracellular adhesion molecule-1 (sICAM-1) of less than 212.1 ng/mL, or

(h) a serum concentration of chemokine CXCL13 greater than 180.8 pg/mL and a serum concentration of sICAM-1 of greater than 313.7 ng/mL,

wherein the antibody or antigen-binding fragment thereof comprises heavy chain complementarity determining region (HCDR) sequences of SEQ ID NOs: 3, 4 and 5, and comprises light chain complementarity determining region (LCDR) sequences of SEQ ID NOs: 6, 7 and 8,

wherein the antibody or antigen binding fragment thereof is administered subcutaneously, and

wherein the antibody or antigen binding fragment thereof is administered to the subject at a dose of about 150 mg to about 200 mg once every two weeks.

2. The use of claim 1, wherein the subject achieves:

(a) ACR20, ACR50, or ACR70 after 24 weeks of treatment with the antibody,

(b) a DAS28-CRP score of less than 3.2 after 24 weeks of treatment with the antibody or antigen binding fragment thereof, or

(c) an improvement in patient global VAS, HAQ-DI, Pain VAS, SF-36 – PCS score, SF-36-PF domain or morning stiffness VAS or RAID score after 24 weeks of treatment with the antibody or antigen binding fragment thereof.

3. The use of claim 1 or 2, wherein the subject has moderate to severe rheumatoid arthritis.

4. The use of any one of the preceding claims, wherein the antibody is administered with a prefilled syringe or with an auto-injector.

5. The use of any one of the preceding claims, wherein the antibody is administered as an aqueous buffered solution at about pH 6.0 containing about 21 mM histidine, about 45 mM arginine, about 0.2% (w/v) polysorbate 20, and about 5% (w/v) sucrose.

6. The use of claim 5, wherein the solution comprises at least about 130 mg/mL of the antibody or antigen binding fragment thereof, or wherein the solution comprises about 131.6 mg/mL of the antibody or antigen binding fragment thereof, or wherein the solution comprises about 175 mg/mL of the antibody or antigen binding fragment thereof.

7. The use of any one of the preceding claims, wherein the antibody is sarilumab.

8. The use of any one of the preceding claims, wherein the subject is intolerant of or has had an inadequate response to one or more DMARDs.

9. The use of claim 8, wherein the DMARD is methotrexate.

10. The use of any one of the preceding claims, wherein the method further comprises administering to the subject an effective amount of methotrexate at a dose of between 6 to 25 mg per week.

11. The use of any one of the preceding claims, wherein the antibody is administered subcutaneously at a dose of about 150 mg once every two weeks to the subject.

12. The use of any one of the preceding claims, wherein the antibody is administered subcutaneously at a dose of about 200 mg once every two weeks to the subject.

13. A method of determining if a subject with rheumatoid arthritis has an increased propensity for effective treatment of rheumatoid arthritis with an antibody or antigen binding fragment thereof, comprising:

(a) measuring a concentration of CRP in a serum sample from the subject wherein if the serum sample has a concentration of CRP greater than 27.9 mg/L, the subject has an increased propensity for effective treatment of RA with the antibody or antigen binding fragment thereof,

(b) measuring a concentration of CRP in a serum sample from the subject, wherein if the serum sample has a concentration of CRP greater than 6.9 mg/L and less than 13.1 mg/L the subject has an increased propensity for effective treatment of RA with the antibody or antigen binding fragment thereof,

(c) measuring a concentration of SAA in a serum sample from the subject, wherein if the serum sample has a concentration of SAA greater than 105.2 ng/mL and less than 256.0 ng/mL the subject has an increased propensity for effective treatment of RA with the antibody or antigen binding fragment thereof,

(d) measuring a concentration of SAA in a serum sample from the subject, wherein if the serum sample has a concentration of SAA greater than 11.83 ng/mL and less than 30.08 ng/mL the subject has an increased propensity for effective treatment of RA with the antibody or antigen binding fragment thereof,

(e) measuring a concentration of MMP-3 in a serum sample from the subject, wherein if the serum sample has a concentration of MMP-3 greater than 77.0 ng/mL the subject has an increased propensity for effective treatment of RA with the antibody or antigen binding fragment thereof,

(f) measuring a concentration of MMP-3 in a serum sample from the subject, wherein if the serum sample has a concentration of MMP-3 greater than 35.5 ng/mL and

less than 54.1 ng/mL the subject has an increased propensity for effective treatment of RA with the antibody or antigen binding fragment thereof,

(g) measuring a concentration of CXCL13 in a serum sample from the subject, wherein if the serum sample has a concentration of CXCL13 greater than 98.2 pg/mL the subject has an increased propensity for effective treatment of RA with the antibody or antigen binding fragment thereof,

(h) measuring a concentration of CXCL13 and a concentration of sICAM-1 in a serum sample from the subject, wherein if the serum sample has a concentration of CXCL13 less than 72.0 pg/mL and a concentration of sICAM-1 of less than 212.1 ng/ mL the subject has an increased propensity for effective treatment of RA with the antibody or antigen binding fragment thereof, or

(i) measuring a concentration of CXCL13 and a concentration of sICAM-1 in a serum sample from the subject, wherein if the serum sample has a concentration of CXCL13 greater than 180.8 pg/mL and a concentration of sICAM-1 of greater than 313.7 ng/ mL the subject has an increased propensity for effective treatment of RA with the antibody or antigen binding fragment thereof,

and wherein the antibody or antigen-binding fragment thereof comprises heavy chain complementarity determining region (HCDR) sequences of SEQ ID NOs: 3, 4 and 5, and comprises light chain complementarity determining region (LCDR) sequences of SEQ ID NOs: 6, 7 and 8.

14. The method of claim 13, wherein the subject has an increased propensity of achieving:

(a) ACR20, ACR50, or ACR70 after 24 weeks of treatment with the antibody or antigen binding fragment thereof,

(b) DAS28-CRP score of less than 3.2 after 24 weeks of treatment with the antibody or antigen binding fragment thereof, or

(c) an improvement in patient global VAS, HAQ-DI, Pain VAS, SF-36 – PCS score, SF-36 – RE domain, morning stiffness VAS or RAID score after 24 weeks of treatment with the antibody or antigen binding fragment thereof.

15. The method of claim 13 or 14, wherein the subject has moderate to severe rheumatoid arthritis.

16. The method of any one of claims 13-15, wherein the antibody is sarilumab.

17. The method of any one of claims 13-15 , wherein the subject is intolerant of or has had an inadequate response to one or more DMARDs.

18. The method of claim 17, wherein the DMARD is methotrexate.

19. The method of any one of claims 13-18, wherein the antibody or antigen binding fragment thereof comprises a heavy chain variable region comprising the sequence SEQ ID NO:1 and a light chain variable region comprising the sequence SEQ ID NO:2.

20. The use of any one of claims 1-12, wherein the antibody or antigen binding fragment thereof comprises a heavy chain variable region comprising the sequence SEQ ID NO:1 and a light chain variable region comprising the sequence SEQ ID NO:2.