CLAIMS

1. A method of treating rheumatoid arthritis in a subject previously treated by administering methotrexate, leflunomide, sulfasalazine and/or hydroxychloroquine, comprising administering to the subject an effective amount of sarilumab (SAR153191).
2. The method of claim 1, wherein the subject was previously ineffectively treated for rheumatoid arthritis by administering methotrexate, leflunomide, sulfasalazine and/or hydroxychloroquine.
3. The method of claim 2, wherein methotrexate, leflunomide, sulfasalazine and/or hydroxychloroquine is administered together with sarilumab.
4. The method of claim 3, wherein sarilumab and methotrexate are administered together.
5. The method of claim 4, wherein methotrexate is administered between 6 to 25 mg per week.
6. The method of any of claims 1 to 5, wherein the sarilumab is administered at between 50 and 150 mg per week.
7. The method of any of claims 1 to 6, wherein the sarilumab is administered at between 100 and 200 mg per two weeks.
8. The method of any of claim 1 to 7, wherein the sarilumab is administered at 150 mg per two weeks or 200 mg per two weeks.
9. The method of claim 8, wherein the subject achieves a 20% improvement in the American College of Rheumatology core set disease index after 12 weeks of treatment.
10. The method of claim 8, wherein the subject achieves a 50% improvement in the American College of Rheumatology core set disease index after 12 weeks of treatment.
11. The method of claim 8, wherein the subject achieves a 70% improvement in the American College of Rheumatology core set disease index after 12 weeks of treatment.
12. The method of any of claims 1 to 3, wherein the subject was previously ineffectively treated for rheumatoid arthritis by administering a TNF-α antagonist.
13. The method of claim 11, wherein the subject has been treated with an anti-TNF-α antagonist for at least 3 months in the last 2 years or the subject was intolerant to at least one TNF-α antagonist.

14. The method of claim 11 or 12, wherein the TNF-α antagonist is a biologic anti-TNF-α.
15. The method of claim 13, wherein the TNF-α antagonist is selected from the group consisting in etanercept, infliximab, adalimumab, golimumab and/or certolizumab pegol.
16. A pharmaceutical composition comprising an effective amount of sarilumab and a member of the group consisting of methotrexate, leflunomide, sulfasalazine and hydroxychloroquine.
17. A combination of:
    a. a pharmaceutical composition comprising sarilumab, and
    b. a pharmaceutical composition comprising methotrexate, leflunomide, sulfasalazine or hydroxychloroquine

for sequential or simultaneous use as a medicament.

CLAIMS

1. Use of an antibody for the manufacture of a medicament for treating rheumatoid arthritis in a subject previously treated by administration of methotrexate, leflunomide, sulfasalazine and/or hydroxychloroquine, wherein the antibody comprises the heavy chain variable region of sequence SEQ ID NO:2 and the light chain variable region of sequence SEQ ID NO:3, wherein the antibody is to be administered to the subject at between 100 mg and 200 mg per two weeks, and wherein said subject was previously treated for rheumatoid arthritis by administration of a biologic TNF-α antagonist.

2. The use of claim 1, wherein the subject was previously ineffectively treated for rheumatoid arthritis by administration of methotrexate, leflunomide, sulfasalazine and/or hydroxychloroquine.

3. The use of claim 2, wherein methotrexate, leflunomide, sulfasalazine and/or hydroxychloroquine is to be administered together with the antibody.

4. The use of claim 3, wherein the antibody and methotrexate are to be administered together.

5. The use of claim 4, wherein methotrexate is to be administered between 6 to 25 mg per week.

6. The use of claim 1, wherein the antibody is to be administered at 150 mg per two weeks.

7. The use of claim 1, wherein the antibody is to be administered at 200 mg per two weeks.

8. The use of any of claims 1-7, wherein the subject achieves a 20% improvement in the American College of Rheumatology core set disease index after 12 weeks of treatment.

9. The use of any of claims 1-7, wherein the subject achieves a 50% improvement in the American College of Rheumatology core set disease index after 12 weeks of treatment.

10. The use of any of claims 1-7, wherein the subject achieves a 70% improvement in the American College of Rheumatology core set disease index after 12 weeks of treatment.

11. The use of any of claims 1 to 7, wherein the subject was previously ineffectively treated for rheumatoid arthritis by administration of a TNF-α antagonist.

12. The use of claim 11, wherein the subject has been treated with an anti-TNF-α antagonist for at least 3 months in the last 2 years or the subject was intolerant to at least one TNF-α antagonist.

13. The use of claim 11 or 12, wherein the TNF-α antagonist is a biologic anti-TNF-α.

14. The use of claim 13, wherein the TNF-α antagonist is selected from the group consisting of etanercept, infliximab, adalimumab, golimumab and/or certolizumab pegol.

15. The use of an antibody for the manufacture of a medicament for treating rheumatoid arthritis in a subject, wherein an effective amount of the antibody and methotrexate is to be administered to the subject, wherein the antibody comprises the heavy chain variable region of sequence SEQ ID NO:2 and the light chain variable region of sequence SEQ ID NO:3, wherein the antibody is to be administered at between 100 mg and 200 mg per two weeks, and wherein the subject was previously treated for rheumatoid arthritis by administration of a biologic TNF-α antagonist.

16. The use of claim 15, wherein the antibody is to be administered at 150 mg per two weeks or 200 mg per two weeks.

17. The use of claim 15 or 16, wherein the biologic TNF-α antagonist is selected from the group consisting in etanercept, infliximab, adalimumab, golimumab and/or certolizumab pegol.

18. The use of any of claims 15 to 17, wherein the subject achieves a 20% improvement in the American College of Rheumatology core set disease index.

19. The use of any of claims 1 to 18, wherein the antibody is sarilumab.

20. The use of any of claims 1 to 19, wherein the antibody is to be administered subcutaneously to the subject.