CLAIMS

1. An antibody for use in a method of improving the physical function of a subject suffering from rheumatoid arthritis, wherein:

- the antibody comprises a heavy chain variable region comprising sequence SEQ ID NO:1 and a light chain variable region comprising sequence SEQ ID NO:2,
- the antibody is administered subcutaneously at about 150 mg or about 200 mg once every two weeks to the subject,
- the subject is not administered with any other disease-modifying antirheumatic drug (DMARD) in course of administration with the antibody, and
- the subject was previously ineffectively treated for rheumatoid arthritis by administering at least one DMARD different from the antibody.

2. The antibody for use according to Claim 1, wherein the subject achieves after at least 24 weeks of administration of the antibody a change from baseline (BL) in the Health Assessment Questionnaire Disability Index (HAQ-DI) of at least 0.22, particularly of at least 0.30, more particularly of at least 0.60.

3. An antibody for use in a method of improving the health related quality of life of a subject suffering from rheumatoid arthritis, wherein:

- the antibody comprises a heavy chain variable region comprising sequence SEQ ID NO:1 and a light chain variable region comprising sequence SEQ ID NO:2,
- the antibody is administered subcutaneously at about 150 mg or about 200 mg once every two weeks to the subject,
- the subject is not administered with any other disease-modifying antirheumatic drug (DMARD) in course of administration with the antibody, and
- the subject was previously ineffectively treated for rheumatoid arthritis by administering at least one DMARD different from the antibody.

4. The antibody for use according to Claim 3, wherein the subject achieves after at least 24 weeks of administration of the antibody a change from baseline (BL) in the Short Form-36 Physical Component Summary (SF-36 PCS) of at least 2.5, particularly of at least 3, more particularly of at least 8.

5. An antibody for use in a method of treating rheumatoid arthritis in a subject, wherein:

- the antibody comprises a heavy chain variable region comprising sequence SEQ ID NO:1 and a light chain variable region comprising sequence SEQ ID NO:2,
- the antibody is administered subcutaneously at about 150 mg or about 200 mg once every two weeks to the subject,
- the subject is not administered with any other disease-modifying antirheumatic drug (DMARD) in course of administration with the antibody, and
- the subject was previously ineffectively treated for rheumatoid arthritis by administering at least one DMARD different from the antibody.

6. The antibody for use according to Claim 5, wherein the subject achieves after at least 24 weeks of administration of the antibody a 20% improvement in the American College of Rheumatology core set disease index (ACR20), particularly a 50% improvement in the American College of Rheumatology core set disease index (ACR50), more particularly a 70% improvement in the American College of Rheumatology core set disease index (ACR70).

7. The antibody for use according to any one of Claims 5-6, wherein the subject achieves after at least 24 weeks of administration of the antibody a change from baseline (BL) in the Disease Activity Score 28 - Erythrocyte Sedimentation Rate (DAS28-ESR) of at least 2, particularly of at least 2.5, more particularly of at least 3.

8. The antibody for use according to any one of Claims 5-7, wherein the subject achieves after at least 24 weeks of administration of the antibody a DAS28-ESR score below 3.2, particularly below 2.6.

9. The antibody for use according to any one of Claims 1-8, wherein the subject who was previously ineffectively treated for rheumatoid arthritis by administering at least one DMARD different from the antibody, is a subject who was previously ineffectively treated for rheumatoid arthritis by administering methotrexate.

10. The antibody for use according to any one Claims 1-9, wherein the subject suffering from rheumatoid arthritis is a subject suffering from moderately to severely active rheumatoid arthritis.

11. The antibody for use according to any one of Claims 1-10, wherein the antibody is administered with a prefilled syringe or with an auto-injector.

12. The antibody for use according to any one of Claims 1-11, 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.

13. The antibody for use according to Claim 12, wherein the solution comprises at least about 130 mg/mL of the antibody, particularly the solution comprises about 131.6 mg/mL of the antibody~~.~~ or about 175 mg/mL of the antibody.

14. The antibody for use according to ~~Claim 12, wherein the solution comprises about 175 mg/mL of the antibody.~~

~~15. The antibody for use according to~~ any one of Claims 1-~~14~~13, wherein the antibody comprising the heavy chain variable region comprising the sequence SEQ ID NO:1 and the light chain variable region comprising the sequence SEQ ID NO:2 is sarilumab.

~~16~~15. The antibody according to Claim 1 wherein the subject is intolerant of one or more DMARDs~~.~~

~~17. The antibody according to Claim 16, wherein~~ or the DMARD is methotrexate.

~~18~~16. The antibody according to Claim 1 wherein the subject is has moderately to severely active rheumatoid arthritis and has had an inadequate response to one or more DMARDs or methotrexate.

~~19. The antibody according to Claim 18, wherein the DMARD is methotrexate.~~

~~20~~17. The antibody according to Claim 1, wherein the subject suffers from diminishment in quality of life due to RA.

~~21~~18. The antibody according to Claim ~~20~~17, wherein the subject scores as more severe than average on a metric selected from Change From Baseline in European Quality of Life-5 Dimension 3 Level (EQ-5D-3L), Change From Baseline in Rheumatoid Arthritis Impact of Disease (RAID), Work Days Missed Due to Arthritis, Work Productivity Reduced by ≥ 50% Due to Arthritis, Rate of Arthritis Interference With Work Productivity, House Work Days Missed Due to Arthritis, Days With Household Work Productivity Reduced by ≥ 50% Due to Arthritis, Days With Family/Social/Leisure Activities Missed Due to Arthritis, Days With Outside Help Hired Due to Arthritis, Rate of RA Interference With Household Work Productivity, Morning Stiffness VAS, Individual ACR Component - TJC and SJC, Individual ACR Component - Physician Global VAS, Participant Global VAS and Pain VAS, and Individual ACR Component- ESR Level.

~~22~~19. The antibody according to any of the preceding claims wherein the antibody is administered subcutaneously at 150 mg once every two weeks to the subject.

~~23~~20. The antibody according to any of Claims 1-~~21~~19 wherein the antibody is administered subcutaneously at 200 mg once every two weeks to the subject.

~~24. A method of improving the physical function of a subject suffering from rheumatoid arthritis comprising administering an antibody, wherein:~~

- ~~the antibody comprises the heavy chain variable region comprising the sequence SEQ ID NO:1 and the light chain variable region comprising the sequence SEQ ID NO:2,~~
- ~~the antibody is administered subcutaneously at about 150 mg or about 200 mg once every two weeks to the subject,~~
- ~~the subject is not administered with any other disease-modifying antirheumatic drug (DMARD) in course of administration with the antibody, and~~
- ~~the subject was previously ineffectively treated for rheumatoid arthritis by administering at least one DMARD different from the antibody.~~

~~25. The method according to Claim 24, wherein the subject achieves after at least 24 weeks of administration of the antibody a change from baseline (BL) in the Health Assessment Questionnaire Disability Index (HAQ-DI) of at least 0.22, particularly of at least 0.30, more particularly of at least 0.60.~~

~~26. A method of improving the health related quality of life of a subject suffering from rheumatoid arthritis comprising administering an antibody, wherein:~~

- ~~the antibody comprises a heavy chain variable region comprising sequence SEQ ID NO:1 and a light chain variable region comprising sequence SEQ ID NO:2,~~
- ~~the antibody is administered subcutaneously at about 150 mg or about 200 mg once every two weeks to the subject,~~
- ~~the subject is not administered with any other disease-modifying antirheumatic drug (DMARD) in course of administration with the antibody, and~~
- ~~the subject was previously ineffectively treated for rheumatoid arthritis by administering at least one DMARD different from the antibody.~~

27. The method according to Claim 26, wherein the subject achieves after at least 24 weeks of administration of the antibody a change from baseline (BL) in the Short Form-36 Physical Component Summary (SF-36 PCS) of at least 2.5, particularly of at least 3, more particularly of at least 8.

28. A method of treating rheumatoid arthritis in a subject comprising administering an antibody, wherein:

- the antibody comprises a heavy chain variable region comprising sequence SEQ ID NO:1 and a light chain variable region comprising sequence SEQ ID NO:2,
- the antibody is administered subcutaneously at about 150 mg or about 200 mg once every two weeks to the subject,

- the subject is not administered with any other Disease-Modifying AntiRheumatic Drug (DMARD) in course of administration with the antibody, and
- the subject was previously ineffectively treated for rheumatoid arthritis by administering at least one DMARD different from the antibody.

29. The method according to Claim 28, wherein the subject achieves after at least 24 weeks of administration of the antibody a 20% improvement in the American College of Rheumatology core set disease index (ACR20), particularly a 50% improvement in the American College of Rheumatology core set disease index (ACR50), more particularly a 70% improvement in the American College of Rheumatology core set disease index (ACR70).

30. The method according to Claim 28 or Claim 29, wherein the subject achieves after at least 24 weeks of administration of the antibody a change from baseline (BL) in the Disease Activity Score 28 - Erythrocyte Sedimentation Rate (DAS28-ESR) of at least 2, particularly of at least 2.5, more particularly of at least 3.

31. The method according to any one of Claims 28-30, wherein the subject achieves after at least 24 weeks of administration of the antibody a DAS28-ESR score below 3.2, particularly below 2.6.

32. The method according to any one of Claims 24-31, wherein the subject who was previously ineffectively treated for rheumatoid arthritis by administering at least one DMARD different from the

antibody, is a subject who was previously ineffectively treated for rheumatoid arthritis by administering methotrexate.

33. The method according to any one Claims 24-32, wherein the subject suffering from rheumatoid arthritis is a subject suffering from moderately to severely active rheumatoid arthritis.

34. The method according to any one of Claims 24-33, wherein the antibody is administered with a prefilled syringe or with an auto-injector.

35. The antibody for use according to any one of Claims 24-34, 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.

36. The method according to Claim 35, wherein the solution comprises at least about 130 mg/mL of the antibody, particularly the solution comprises about 131.6 mg/mL of the antibody.

37. The method according to Claim 35, wherein the solution comprises about 175 mg/mL of the antibody.

38. The method according to any one of Claims 24-37, wherein the antibody comprising the heavy chain variable region comprising sequence SEQ ID NO:1 and the light chain variable region comprising sequence SEQ ID NO:2 is sarilumab.

39. The method according to claim 24, wherein the subject intolerant of one or more DMARDs.

40. The method according to claim 39, wherein the DMARD is methotrexate.

41. The method according to claim 24, wherein the subject is considered an inappropriate candidate for continued treatment with one or more DMARDs.

42. The method according to claim 42, wherein the DMARD is methotrexate.

~~43. The method according to claim 24, wherein the subject suffers from diminishment in quality of life due to RA.~~

~~44. The method according to claim 43, wherein the subject scores as more severe than average on a metric selected from Change From Baseline in European Quality of Life-5 Dimension 3 Level (EQ-5D-3L), Change From Baseline in Rheumatoid Arthritis Impact of Disease (RAID), Work Days Missed Due to Arthritis, Work Productivity Reduced by ≥ 50% Due to Arthritis, Rate of Arthritis Interference With Work Productivity, House Work Days Missed Due to Arthritis, Days With Household Work Productivity Reduced by ≥ 50% Due to Arthritis, Days With Family/Social/Leisure Activities Missed Due to Arthritis, Days With Outside Help Hired Due to Arthritis, Rate of RA Interference With Household Work Productivity, Morning Stiffness VAS, Individual ACR Component - TJC and SJC, Individual ACR Component - Physician Global VAS, Participant Global VAS and Pain VAS, and Individual ACR Component- ESR Level.~~

~~45. The method according to any of the preceding claims 24-44 wherein the antibody is administered subcutaneously at 150 mg once every two weeks to the subject.~~

~~46. The method according to any of claims 24-45 wherein the antibody is administered subcutaneously at 200 mg once every two weeks to the subject.~~

~~47. A composition for improving the physical function of a subject suffering from rheumatoid arthritis comprising a monotherapy comprising the antibody according to claims 1-23.~~