

CLAIMS

1. Use of an antibody in the manufacture of a medicament for treating polyarticular-course JIA (pcJIA) in a subject in need thereof and having a body weight of greater than or equal to 10 kg, wherein the use comprises subcutaneous administration of an effective amount of an antibody that specifically binds IL-6 receptor, wherein the antibody comprises three heavy chain complementarity determining regions (HCDRs) of a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 1, and three light chain CDRs (LCDRs) of a light chain variable region comprising the amino acid sequence of SEQ ID NO: 2, wherein the effective amount to be administered is based on the body weight of the subject as follows:

wherein the body weight of the subject is greater than or equal to 10 kg and less than 30 kg and the antibody is to be administered at a dose of from 2.5 mg/kg to 4 mg/kg once every week or once every other week; or

wherein the body weight of the subject is greater than or equal to 30 kg and the antibody is to be administered at a dose of from 2 mg/kg to 3 mg/kg once every week or once every other week.

2. Use of an antibody in the manufacture of a medicament for treating pcJIA in a subject in need thereof and having a body weight of greater than or equal to 30 kg, wherein the use comprises subcutaneous administration of an effective amount of an antibody that specifically binds IL-6 receptor, wherein the antibody comprises three heavy chain complementarity determining regions (HCDRs) of a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 1, and three light chain CDRs (LCDRs) of a light chain variable region comprising the amino acid sequence of SEQ ID NO: 2, the effective amount to be administered is based on the body weight of the subject as follows:

wherein the body weight of the subject is greater than or equal to 30 kg and less than 33 kg and the antibody is to be administered at a dose of 61.25 mg once every other

week or once every week; wherein the body weight of the subject is greater than or equal to 33 kg and less than 37.5 kg and the antibody is to be administered at a dose of 70 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 37.5 kg and less than 42 kg and the antibody is to be administered at a dose of 78.75 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 42 kg and less than 46.5 kg and the antibody is to be administered at a dose of 87.5 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 46.5 kg and less than 50.5 kg and the antibody is to be administered at a dose of 96.25 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 50.5 kg and less than 55 kg and the antibody is to be administered at a dose of 105 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 55 kg and less than 59.5 kg and the antibody is to be administered at a dose of 113.75 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 59.5 kg and less than 64 kg and the antibody is to be administered at a dose of 122.5 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 64 kg and less than 68 kg and the antibody is to be administered at a dose of 131.25 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 68 kg and less than 72.5 kg and the antibody is to be administered at a dose of 140 mg once every other week or once every week; or wherein the body weight of the subject is greater than or equal to 72.5 kg and the antibody is to be administered at a dose of 148.75 mg once every other week or once every week.

3. Use of an antibody in the manufacture of a medicament for treating pcJIA in a subject in need thereof and having a body weight of greater than or equal to 30 kg, wherein the use comprises subcutaneous administration of an effective amount of an antibody that specifically binds IL-6 receptor, wherein the antibody comprises three heavy chain complementarity determining regions (HCDRs) of a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 1, and three light chain CDRs

(LCDRs) of a light chain variable region comprising the amino acid sequence of SEQ ID NO: 2, wherein the effective amount to be administered is based on the body weight of the subject as follows:

wherein the body weight of the subject is greater than or equal to 30 kg and less than 31 kg and the antibody is to be administered at a dose of 87.5 mg once every other week; wherein the body weight of the subject is greater than or equal to 31 kg and less than 34 kg and the antibody is to be administered at a dose of 96.25 mg once every other week; wherein the body weight of the subject is greater than or equal to 34 kg and less than 37 kg and the antibody is to be administered at a dose of 105 mg once every other week; wherein the body weight of the subject is greater than or equal to 37 kg and less than 39.5 kg and the antibody is to be administered at a dose of 113.75 mg once every other week; wherein the body weight of the subject is greater than or equal to 39.5 kg and less than 42.5 kg and the antibody is to be administered at a dose of 122.5 mg once every other week; wherein the body weight of the subject is greater than or equal to 42.5 kg and less than 45 kg and the antibody is to be administered at a dose of 131.25 mg once every other week; wherein the body weight of the subject is greater than or equal to 45 kg and less than 48.5 kg and the antibody is to be administered at a dose of 140 mg once every other week; wherein the body weight of the subject is greater than or equal to 48.5 kg and less than 51.5 kg and the antibody is to be administered at a dose of 148.75 mg once every other week; wherein the body weight of the subject is greater than or equal to 51.5 kg and less than 54.5 kg and the antibody is to be administered at a dose of 157.5 mg once every other week; wherein the body weight of the subject is greater than or equal to 54.5 kg and less than 57 kg and the antibody is to be administered at a dose of 166.25 mg once every other week; wherein the body weight of the subject is greater than or equal to 57 kg and less than 63 kg and the antibody is to be administered at a dose of 175 mg once every other week; wherein the body weight of the subject is greater than or equal to 63 kg and the antibody is to be administered at a dose of 192.5 mg once every other week.

4. Use of an antibody in the manufacture of a medicament for treating pcJIA in a subject in need thereof and having a body weight of greater than or equal to 10 kg, wherein the use comprises subcutaneous administration of an effective amount of an antibody that specifically binds IL-6 receptor, wherein the antibody comprises three heavy chain complementarity determining regions (HCDRs) of a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 1, and three light chain CDRs (LCDRs) of a light chain variable region comprising the amino acid sequence of SEQ ID NO: 2, wherein the effective amount to be administered is based on the body weight of the subject as follows:

wherein the body weight of the subject is greater than or equal to 10 kg and less than 12.5 kg and the antibody is to be administered at a dose of 26.25 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 12.5 kg and less than 16 kg and the antibody is to be administered at a dose of 35 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 16 kg and less than 19.5 kg and the antibody is to be administered at a dose of 43.75 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 19.5 kg and less than 23 kg and the antibody is to be administered at a dose of 52.5 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 23 kg and less than 26.5 kg and the antibody is to be administered at a dose of 61.25 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 26.5 kg and less than 30 kg and the antibody is to be administered at a dose of 70 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 30 kg and less than 37.5 kg and the antibody is to be administered at a dose of 70 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 37.5 kg and less than 42 kg and the antibody is to be administered at a dose of 78.75 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 42 kg and less than 46.5 kg and the antibody is to be administered at a dose of 87.5 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 46.5 kg and less than 50.5 kg

and the antibody is to be administered at a dose of 96.25 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 50.5 kg and less than 55 kg and the antibody is to be administered at a dose of 105 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 55 kg and less than 59.5 kg and the antibody is to be administered at a dose of 113.75 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 59.5 kg and less than 64 kg and the antibody is to be administered at a dose of 122.5 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 64 kg and less than 68 kg and the antibody is to be administered at a dose of 131.25 mg once every other week or once every week; wherein the body weight of the subject is greater than or equal to 68 kg and less than 72.5 kg and the antibody is to be administered at a dose of 140 mg once every other week or once every week; or wherein the body weight of the subject is greater than or equal to 72.5 kg and the antibody is to be administered at a dose of 148.75 mg once every other week or once every week.

5. Use of an antibody in the manufacture of a medicament for treating pcJIA in a subject in need thereof and having a body weight of greater than or equal to 10 kg, wherein the use comprises subcutaneous administration of an antibody that specifically binds IL-6 receptor, wherein the antibody comprises three heavy chain complementarity determining regions (HCDRs) of a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 1, and three light chain CDRs (LCDRs) of a light chain variable region comprising the amino acid sequence of SEQ ID NO: 2, wherein the effective amount to be administered is based on the body weight of the subject as follows:

wherein the body weight of the subject is greater than or equal to 10 kg and less than 12.5 kg and the antibody is to be administered at a dose of 43.75 mg once every other week; wherein the body weight of the subject is greater than or equal to 12.5 kg and less than 14.5 kg and the antibody is to be administered at a dose of 52.5 mg once every other week; wherein the body weight of the subject is greater than or equal to

14.5 kg and less than 16.5 kg and the antibody is to be administered at a dose of 61.25 mg once every other week; wherein the body weight of the subject is greater than or equal to 16.5 kg and less than 19 kg and the antibody is to be administered at a dose of 70 mg once every other week; wherein the body weight of the subject is greater than or equal to 19 kg and less than 21 kg and the antibody is to be administered at a dose of 78.75 mg once every other week; wherein the body weight of the subject is greater than or equal to 21 kg and less than 23.5 kg and the antibody is to be administered at a dose of 87.5 mg once every other week; wherein the body weight of the subject is greater than or equal to 23.5 kg and less than 25.5 kg and the antibody is to be administered at a dose of 96.25 mg once every other week; wherein the body weight of the subject is greater than or equal to 25.5 kg and less than 27.5 kg and the antibody is to be administered at a dose of 105 mg once every other week; wherein the body weight of the subject is greater than or equal to 27.5 kg and less than 30 kg and the antibody is to be administered at a dose of 113.75 mg once every other week; wherein the body weight of the subject is greater than or equal to 30 kg and less than 39.5 kg and the antibody is to be administered at a dose of 113.75 mg once every other week; wherein the body weight of the subject is greater than or equal to 39.5 kg and less than 42.5 kg and the antibody is to be administered at a dose of 122.5 mg once every other week; wherein the body weight of the subject is greater than or equal to 42.5 kg and less than 45 kg and the antibody is to be administered at a dose of 131.25 mg once every other week; wherein the body weight of the subject is greater than or equal to 45 kg and less than 48.5 kg and the antibody is to be administered at a dose of 140 mg once every other week; wherein the body weight of the subject is greater than or equal to 48.5 kg and less than 51.5 kg and the antibody is to be administered at a dose of 148.75 mg once every other week; wherein the body weight of the subject is greater than or equal to 51.5 kg and less than 54.5 kg and the antibody is to be administered at a dose of 157.5 mg once every other week; wherein the body weight of the subject is greater than or equal to 54.5 kg and less than 57 kg and the antibody is to be administered at a dose of 166.25 mg once every other week; wherein the body weight of the subject is greater than or equal to 57 kg and less than 60.5 kg and the antibody is to be administered at a dose of 175 mg once every other week; wherein the body weight of the subject is

greater than or equal to 60.5 kg and less than 63 kg and the antibody is to be administered at a dose of 175 mg once every other week; wherein the body weight of the subject is greater than or equal to 63 kg and the antibody is to be administered at a dose of 192.5 mg once every other week.

6. The use of claim 1, wherein the effective amount to be administered is based on the body weight of the subject as follows:

wherein the body weight of the subject is greater than or equal to 10 kg and less than 30 kg and the antibody is to be administered at a dose of 4 mg/kg once every other week, or

wherein the body weight of the subject is greater than or equal to 30 kg and the antibody is to be administered at a dose of 3 mg/kg once every other week.

7. The use of any one of claims 3, 5 or 6, wherein the dose is to be capped at 200 mg once every other week for the subject having the body weight of greater than or equal to 63 kg.

8. The use of claim 1, wherein the effective amount to be administered is based on the body weight of the subject as follows:

wherein the body weight of the subject is greater than or equal to 10 kg and less than 30 kg and the antibody is to be administered at a dose of 2.5 mg/kg once every other week or once every week, or

wherein the body weight of the subject is greater than or equal to 30 kg and the antibody is to be administered at a dose of 2 mg/kg once every other week or once every week.

9. The use of any one of claims 2, 4, or 8, wherein the dose is to be capped at 150 mg once every other week or once every week for the subject having the body weight of greater than or equal to 72.5 kg.

10. Use of an antibody in the manufacture of a medicament for treating polyarticular-course juvenile idiopathic arthritis (pcJIA) in a pediatric subject in need thereof, wherein the use comprises administration of an antibody that specifically binds IL-6 receptor, wherein the antibody comprises three heavy chain complementarity determining regions (HCDRs) of a heavy chain variable region sequence comprising the amino acid sequence of SEQ ID NO: 1 and three light chain CDRs (LCDRs) of a light chain variable region sequence comprising the amino acid sequence of SEQ ID NO: 2, wherein the antibody is to be administered subcutaneously at a dose of 200 mg once every other week.

11. The use of claim 10, wherein the pediatric subject has a body weight of 63 kg or greater.

12. The use of claim 11, wherein the pcJIA is selected from: rheumatoid factor-negative polyarticular juvenile idiopathic arthritis (RF-negative pJIA); rheumatoid factor-positive polyarticular juvenile idiopathic arthritis (RF-positive pJIA); and oligoarticular juvenile idiopathic arthritis (oJIA).

13. The use of any one of claims 1-12, wherein the subject is 1-17 years old.

14. The use of any one of claims 1-12 wherein the subject is 2-17 years old.

15. The use of any one of claims 1-14, wherein the antibody is to be used without any other disease modifying antirheumatic drug (DMARD).
16. The use of any one of claims 1-14, wherein the antibody is to be used with at least one other disease modifying antirheumatic drug (DMARD) different from the antibody.
17. The use of any one of claims 1-14, or 16, wherein the DMARD different from the antibody comprises methotrexate.
18. The use of any one of claims 1-17, wherein the three HCDRs are HCDR1, HCDR2, and HCDR3 and the three LCDRs are LCDR1, LCDR2, and LCDR3, wherein the HCDR1 is the amino acid sequence of SEQ ID NO: 3, the HCDR2 is the amino acid sequence of SEQ ID NO: 4; the HCDR3 is the amino acid sequence of SEQ ID NO: 5; the LCDR1 is the amino acid sequence of SEQ ID NO: 6, the LCDR2 is the amino acid sequence of SEQ ID NO: 7; and the LCDR3 is the amino acid sequence of SEQ ID NO: 8.
19. The use of any one of claims 1-17, wherein the antibody is sarilumab.
20. The use of any one of claims 1-17, wherein the antibody comprises the heavy chain variable region sequence comprising the amino acid sequence of SEQ ID NO: 1 and the light chain variable region sequence comprising the amino acid sequence of SEQ ID NO: 2.

21. The use of any one of claims 1-17, wherein the antibody comprises a heavy chain comprising the amino acid sequence SEQ ID NO: 9 and a light chain comprising the amino acid sequence SEQ ID NO: 10.
22. The use of any one of claims 1-21, wherein the antibody is formulated to be used with a syringe or an auto-injector.
23. The use of any one of claims 1-22, wherein the subject had an inadequate response to prior treatment for JIA.
24. The use of claim 23, wherein the prior treatment for JIA comprises a corticosteroid, a synthetic DMARD, or a biological DMARD other than the antibody.
25. The use according to any one of claims 1-24, wherein the subject is suffering from at least one symptom of pcJIA, wherein the at least one symptom comprises limping; stiffness when awakening; reluctance to use an arm or leg; reduced activity level; joint swelling; and/or difficulty with fine motor activities.
26. The use according to claim 25, wherein upon administration of the antibody, progression of the at least one symptom of pcJIA in the subject is reduced, slowed, halted, or otherwise ameliorated.
27. The use of any one of claims 1-26, wherein upon administration of the antibody, the subject achieves at least one of the following: improving the subject's juvenile idiopathic arthritis (JIA) American College of Rheumatology (ACR) score, improving a JIA ACR component in the subject, reducing of the level of corticosteroid administered

compared to before the antibody was used, reducing the subject's Juvenile Arthritis Disease Activity score; and any combination thereof.