IL-17 Antibody Formulation

The present invention relates to the field of medicine. More particularly, the present invention relates to a pharmaceutical formulation of an anti-IL- 17 antibody. This anti-IL-17 antibody pharmaceutical formulation is expected to be useful in treating Rheumatoid Arthritis (RA), Psoriasis (Ps), Ankylosing Spondilitis (AS), Psoriatic Arthritis (PA) or Multiple Myeloma (MM).

Pharmaceutical formulations of anti-IL-17 antibodies are needed for the treatment of patients with RA, Ps, AS, PA or MM. Certain concentrations of anti-IL-17 antibodies are needed for pharmaceutical formulations so that the antibody can be delivered subcutaneously to the patient. This pharmaceutical formulation with a certain concentration of the anti-IL-17 antibody must maintain physical and chemical stability of the anti-IL-17 antibody, while also avoiding viscosity that can unacceptably increase delivery time and force needed from a needle or auto-injector device.

Anti-IL-17 antibodies are disclosed in WO 07/70750 that neutralize biological activity associated with human IL-17 (SEQ ID NO: 1). In addition, WO 07/70750 discloses pharmaceutical compositions of anti-IL-17 monoclonal antibodies. With certain formulations for mAb 126, an anti-IL-17 antibody disclosed in WO 07/70750, it was discovered by Applicant as part of the present invention that three stability problems exist at concentrations in solutions greater than or equal to 50 mg/mL: liquid-liquid phase separation; gel formation or solid phase change; and chemical instability. Thus, pharmaceutical formulations for certain concentrations of anti-IL-17 antibodies are needed that avoid these observed problems. A need exists for alternative anti-IL-17 antibody pharmaceutical formulations. Further, a need exists for alternative anti-IL-17 antibody pharmaceutical solution formulations.

Summary

In a first aspect of the present disclosure, there is provided a pharmaceutical formulation comprising an anti-IL-17 antibody at a concentration in the range of about 80 mg/mL to about 150 mg/mL, citrate buffer at a concentration of about 20 mM, sodium chloride at a concentration of about 200 mM, polysorbate-80 at a concentration in the range of about 0.02% (w/v) to about 0.03% (w/v), and pH at about 5.7, wherein the anti-IL-17 antibody comprises an antibody with a light chain (LC) and a heavy chain (HC), wherein said LC is the amino acid sequence of SEQ ID NO: 4 and said HC is the amino acid sequence of SEQ ID NO: 5.

In a second aspect of the present disclosure, there is provided a pharmaceutical formulation comprising an anti-IL-17 antibody at a concentration of about 80 mg/mL, citrate buffer at a concentration of about 20 mM, sodium chloride at a concentration of about 200 mM, polysorbate-80 at a concentration of about 0.03%, and pH at about 5.7, wherein the anti-IL-17 antibody comprises an antibody comprising two light chains (LCs) and two heavy chains (HCs), wherein each LC is the amino acid sequence of SEQ ID NO: 4 and each HC is the amino acid sequence of SEQ ID NO: 5.

In a third aspect of the present disclosure, there is provided a pharmaceutical solution formulation comprising an anti-IL-17 antibody at a concentration of about 80 mg/mL, citrate buffer at a concentration of about 20 mM, sodium chloride at a concentration of about 200 mM, polysorbate-80 at a concentration of about 0.03%, and pH at about 5.7, wherein the anti-IL-17 antibody comprises an antibody comprising two light chains (LCs) and two heavy chains (HCs), wherein each LC is the amino acid sequence of SEQ ID NO: 4 and each HC is the amino acid sequence of SEQ ID NO: 5.

In a fourth aspect of the present disclosure, there is provided a pharmaceutical formulation as described herein for use in therapy.

In a fifth aspect of the present disclosure, there is provided a pharmaceutical formulation as described herein for use in the treatment of rheumatoid arthritis, psoriasis, ankylosing spondilitis, psoriatic arthritis or multiple myeloma.

Description

Accordingly, the present invention provides a pharmaceutical formulation comprising an anti-IL-17 antibody at a concentration in the range of about 80 mg/mL to about 150 mg/mL, citrate buffer at a concentration of about 20 mM, sodium chloride at a concentration of about 200 mM, polysorbate-80 at a concentration in the range of about 0.02% (w/v) to about 0.03% (w/v), and a pH at about 5.7, wherein the anti-IL-17 antibody comprises an antibody with a light chain (LC) and a heavy chain (HC), wherein said LC is the amino acid sequence of SEQ ID NO: 4 and said HC is the amino acid sequence of SEQ ID NO: 5. The present invention also provides a pharmaceutical formulation

sodium chloride at a concentration of about 200 mM, polysorbate-80 at a concentration of about 0.03%, and pH at about 5.7, wherein the anti-IL-17 antibody comprises an antibody comprising two light chains (LCs) and two heavy chains (HCs), wherein each LC is the amino acid sequence of SEQ ID NO: 4 and each HC is the amino acid sequence of SEQ ID NO: 5.

~~8. A method of treating rheumatoid arthritis, psoriasis, ankylosing spondilitis, psoriatic arthritis or multiple myeloma comprising administering to a patient in need thereof an effective amount of a pharmaceutical formulation of any one of claims 1-7.~~

~~9~~8. A pharmaceutical formulation of any one of claims 1-7 for use in therapy.

~~10~~9. A pharmaceutical formulation of any one of claims 1-7 for use in the treatment of rheumatoid arthritis, psoriasis, ankylosing spondilitis, psoriatic arthritis or multiple myeloma.