

CLAIMS

1. A use of a pharmaceutical composition for the manufacture of a medicament for the treatment of primary sclerosing cholangitis (PSC) in a human subject, wherein said pharmaceutical composition comprises a humanized anti-CCL24 monoclonal antibody, wherein the anti-CCL24 monoclonal antibody comprises a heavy chain variable region comprising a complementary determining region VH CDR1 amino acid sequence denoted by SEQ ID NO: 1; a complementary determining region VH CDR2 amino acid sequence denoted by SEQ ID NO: 2; and a complementary determining region VH CDR3 amino acid sequence denoted by SEQ ID NO: 3; and a light chain variable region comprising a complementary determining region VK CDR1 amino acid sequence denoted by SEQ ID NO: 4; a complementary determining region VK CDR2 amino acid sequence denoted by SEQ ID NO: 5; and a complementary determining region VK CDR3 amino acid sequence denoted by SEQ ID NO: 6; wherein said anti-CCL24 monoclonal antibody is to be administered at a dose of about 20mg/kg or at an administration schedule to maintain a steady-state serum concentration of the anti-CCL24 monoclonal antibody of between 50 and 500 µg/ml.
2. The use of the pharmaceutical composition of claim 1, wherein the anti-CCL24 monoclonal antibody comprises a heavy chain according to SEQ ID NO: 11 and a light chain according to SEQ ID NO: 12.
3. The use of the pharmaceutical composition of any one of claims 1-2, wherein the anti-CCL24 monoclonal antibody is to be administered subcutaneously or intravenously.
4. The use of the pharmaceutical composition of any one of claims 1-3, wherein the anti-CCL24 monoclonal antibody is to be administered once every one to four weeks, optionally once every two weeks, once every three weeks, or once every four weeks.
5. The use of the pharmaceutical composition of any one of claims 1-4, wherein the anti-CCL24 monoclonal antibody is to be administered for at least four weeks, optionally for at least 15 weeks, or for at least 24 weeks.
6. The use of the pharmaceutical composition of any one of claims 1-5, wherein administration of the anti-CCL24 monoclonal antibody increases total sera level of CCL24 at day 4 post administration to at least 150% of baseline total sera level of CCL24 before administering the anti-CCL24 monoclonal antibody.

7. The use of the pharmaceutical composition of any one of claims 1-6, wherein said method further comprises a step of evaluating the level of one or more circulating fibrosis markers to determine improvement in the hepatic condition of the subject, optionally the one or more circulating fibrosis markers are selected from the group consisting of plasma alanine aminotransferase (ALT), alkaline phosphatase (ALP), aspartate aminotransferase (AST), PRO-C3, PRO-C4, PRO-C5, C3M, cytokeratin 18 (CK18), amino-terminal propeptide of type III procollagen (PIIINP), hyaluronic acid (HA), Tissue Inhibitor of Metalloproteinases 1 (TIMP-1), platelet derived growth factor (PDGF), Tissue Inhibitor of Metalloproteinases 2 (TIMP-2), γ -glutamyltransferase (GGT), bilirubin, C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), and procalcitonin (PCT).

8. A pharmaceutical composition for treating primary sclerosing cholangitis (PSC), comprising about 10 mg/mL of a humanized anti-CCL24 monoclonal antibody, wherein the humanized anti-CCL24 monoclonal antibody comprises a heavy chain variable region comprising a complementary determining region VH CDR1 amino acid sequence denoted by SEQ ID NO: 1; a complementary determining region VH CDR2 amino acid sequence denoted by SEQ ID NO: 2; and a complementary determining region VH CDR3 amino acid sequence denoted by SEQ ID NO: 3; and a light chain variable region comprising a complementary determining region VK CDR1 amino acid sequence denoted by SEQ ID NO: 4; a complementary determining region VK CDR2 amino acid sequence denoted by SEQ ID NO: 5; and a complementary determining region VK CDR3 amino acid sequence denoted by SEQ ID NO: 6, 10 mM histidine buffer, 4% sorbitol, 40mM glycine, and 0.01% PS-80 at pH 6.3. .

9. A pharmaceutical composition for treating primary sclerosing cholangitis (PSC), comprising about 175 mg/mL of a humanized anti-CCL24 monoclonal antibody, wherein the humanized anti-CCL24 monoclonal antibody comprises a heavy chain variable region comprising a complementary determining region VH CDR1 amino acid sequence denoted by SEQ ID NO: 1; a complementary determining region VH CDR2 amino acid sequence denoted by SEQ ID NO: 2; and a complementary determining region VH CDR3 amino acid sequence denoted by SEQ ID NO: 3; and a light chain variable region comprising a complementary determining region VK CDR1 amino acid sequence denoted by SEQ ID NO: 4; a complementary determining region VK CDR2 amino acid sequence denoted by SEQ ID NO: 5; and a complementary determining region VK CDR3 amino acid sequence denoted by

SEQ ID NO: 6, 10 mM histidine buffer, 150 mM arginine, 150 mM glutamic acid, 0.02% PS-80 at pH 6.1.

10. The pharmaceutical composition of any one of claims 8-9, wherein the pharmaceutical composition is supplied in a unit dose having a fill volume of 0.2 to 2 mL, or 5 to 20 mL.

11. The pharmaceutical composition of any one of claims 8-10, wherein the pharmaceutical composition is to be administered subcutaneously or intravenously.

12. A kit comprising the pharmaceutical composition of any one of claims 8-10 and instructions for use for treating primary sclerosing cholangitis (PSC).