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(54) Title: THERAPEUTIC REGIMENS FOR TREATING PSORIATIC ARTHRITIS WITH AN ANTI-CCL20 ANTIBODY

(57) Abstract: The invention provides therapeutic regimens for inflammatory conditions (e.g psoriatic arthritis, Behcet's disease, and inflammatory bowel diseases such as ulcerative colitis and Crohn's disease) using anti-CCL20 antibodies, and uses antibodies for preparation of medicaments for the inflammatory conditions.

THERAPEUTIC REGIMENS FOR TREATING PSORIATIC ARTHRITIS WITH AN ANTI-CCL20 ANTIBODY

CROSS REFERENCE TO PRIOR APPLICATIONS

[0001] This application claims priority from U.S. Provisional Patent Application No. 62/242,975, filed October 16, 2015. The disclosure of that application is incorporated by reference herein in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to novel therapeutic regimens for treating inflammatory conditions using antibodies specifically directed against the human CC chemokine ligand 20 (CCL20).

BACKGROUND OF THE INVENTION

[0003] The immune system is a highly sophisticated bio-circuit used by the body to discriminate non-self (*e.g.*, foreign organisms or substances) from self. The detection of non-self in the body can result in inflammation, in which various cellular and molecular components are orchestrated to respond to potentially harmful events caused by the non-self organism or substance. Although the inflammatory process helps to protect the body from foreign attack, de-regulation of the immune system can lead to negative consequences such as self attack, *e.g.*, autoimmune disease. By altering the function of inflammatory molecules such as chemokines, it may be possible to reduce the initiation and progression of disorders relating to immune/inflammatory responses.

[0004] Chemokines are a family of small (8-10 kDa) proteins that play a pivotal role in inflammation. During the inflammatory process, chemokines are produced locally at the site of the noxious stimulus and work as central players to recruit immune cells that express their cognate receptors, seven trans-membrane G protein—coupled receptors (GPCRs). CCL20, alternatively named liver and activation-regulated chemokine (LARC), macrophage inflammatory protein-3 alpha (MIP-3α), or Exodus-

1, is a soluble chemokine that is expressed by epithelial cells. Epithelial keratinocytes and synovium-lining cells are known to produce large amounts of CCL20 during homeostatic as well as inflammatory and pathological conditions such as cancer, psoriasis, and rheumatoid arthritis. The cognate receptor for CCL20 is CC chemokine receptor 6 (CCR6); CCL20 is the only chemokine known to interact with CCR6. In response to the CCL20 signal, immune cells possessing CCR6, such as immature dendritic cells (DC), effector/memory T-cells, and B-cells, migrate and infiltrate the surrounding tissues, thus activating the inflammatory cascade.

[0005] Because CCL20 expression is significantly enhanced in inflammation induced by inflammatory cytokines such as interleukin 1β (IL-1β) and tumor necrosis factor α (TNF-α), the CCL20-CCR6 interaction is thought to play a role in pathological inflammatory processes such as dermatitis and colitis.

[0006] The CCL20-CCR6 interaction plays an important role in certain types of dermatitis. Psoriasis, for example, initiates with a noxious psoriatic event in the skin (induced by environmental and/or genetic factors) followed by infiltration of Th17 cells. Because CCR6 is expressed on the surface of Th17 cells, B cells, dendritic cells, and tissue damaging effector T cells, CCL20 may represent the main chemoattractant for these cell types in psoriasis. Further evidence for the importance of the CCL20-CCR6 interaction can be found in studies using an interleukin 23 (IL-23)-induced mouse model of psoriasis (Hedrick *et al.*, *J. Clin. Invest.* **119**:2317-2329 (2009)). In this model, injection of IL-23 causes interleukin 22 (IL-22)-dependent psoriatic inflammation. However, *Ccr6*$^{-/-}$ mice did not exhibit psoriasis-like symptoms when injected with IL-23, indicating that CCR6 is required for the development of psoriasis in this model.

[0007] Human keratinocytes can produce large amounts of CCL20, especially under the influence of the Th17-derived cytokines interleukin 17 (IL-17), IL-22, and TNF-α. While CCL20 and CCR6 are rarely detected in normal skin, both exhibit increased expression levels in atopic dermatitis and pustular psoriasis. Strong induction of CCL20 and accumulation of CCR6+ cells can be observed in microscopic immunohistochemical analysis of human dermatitis lesions. These observations

provide additional evidence for the role of CCL20 and CCR6 in the dermatitis inflammatory process.

[0008] Despite existing therapeutics for inflammatory conditions, due to primary non-responsiveness or a gradual decline in response rate to existing therapeutics, there is an urgent need to develop novel methods of treating inflammatory diseases.

SUMMARY OF THE INVENTION

[0009] The present invention provides novel regimens for treating inflammatory diseases such as psoriatic arthritis and inflammatory bowel diseases (IBD) (e.g., ulcerative colitis and Crohn's disease) with an anti-CCL20 antibody.

[0010] In some embodiments, the invention provides a method for treating an inflammatory disease (e.g., psoriatic arthritis and IBD) in a patient, comprising administering to the patient an anti-CCL20 monoclonal antibody (*e.g.*, a humanized antibody) at (a) an initial dose of 5-20 mg per kg of body weight of the patient, and (b) one or more subsequent doses of 3-10 mg per kg of body weight of the patient, wherein the doses are separated by one to three (e.g., one, two, three) weeks, and wherein the antibody comprises the heavy chain CDR1-3 and light chain CDR1-3 in SEQ ID NOs: 3 and 14, respectively. In further embodiments, the initial dose is higher than the subsequent dose(s). For example, the initial dose is 10 mg per kg of body weight of the patient, and/or each of the subsequent doses is 5 mg per kg of body weight of the patient. In specific embodiments, the antibody is administered to the patient (1) at day 1, at an initial dose of 10 mg per kg of the body weight of the patient; (2) at day 15, at a second dose of 5 mg per kg of the body weight of the patient; and (3) at day 29, at a third dose of 5 mg per kg of the body weight of the patient.

[0011] In some embodiments, the invention provides a method for treating an inflammatory disease (e.g., psoriatic arthritis and IBD) in a patient, comprising administering to the patient an anti-CCL20 monoclonal antibody (*e.g.*, a humanized antibody) at (a) an initial dose of 300-1400 mg, and (b) one or more subsequent doses of 200-700 mg, wherein the doses are separated by one to three (e.g., one, two, three)

weeks, and wherein the antibody comprises the heavy chain CDR1-3 and light chain CDR1-3 in SEQ ID NOs: 3 and 14, respectively. In further embodiments, the initial dose is higher than the subsequent dose(s). For example, the initial dose can be 300-400 mg and/or each of the subsequent doses can be 200-300 mg. In another example, the loading dose is 600-800 mg, and the maintenance dose is 400-500 mg.

[0012] In certain embodiments, the method comprises administering to the patient an initial dose and two subsequent doses. In certain embodiments, the doses are administered two weeks apart. In certain embodiments, the antibody is administered by intravenous infusion, *e.g.,* over two hours; and in some alternative embodiments, the antibody is administered by subcutaneous injection.

[0013] In certain of the above-described embodiments, the antibody is administered in a liquid aqueous solution having a pH of 4-8 (e.g., 5-7), comprising a buffering agent, a tonicity agent, a viscosity modifier, and a surfactant. An example of such a solution is a liquid aqueous solution comprising a histidine buffer with a pH of 6.0, 60 mg/ml sucrose, 5.3 mg/ml L-arginine hydrochloride, and 0.2 mg/ml polysorbate 80.

[0014] In certain of the above-described embodiments, the method alleviates skin lesions, joint inflammation, or both, in psoriatic arthritis patients, for example, improving the patient's symptoms as measured by one or more of Disease Activity Score 28 (DAS28), American College of Rheumatology (ACR) responders, Psoriatic Arthritis Disease Activity Score (PASDAS), Psoriasis Lesion Severity Score (PLSS), and Psoriasis Area Severity Index (PASI).

[0015] The invention also provides an anti-CCL20 monoclonal antibody, and the use of an anti-CCL20 monoclonal antibody for the manufacture of medicament, for the treatment of an inflammatory disease such as psoriatic arthritis and IBD (e.g., ulcerative colitis and Crohn's disease) in accordance with any of the treatment regimens described herein, including the treatment regimens described in the Exemplary Embodiments below.

[0016] The anti-CCL20 antibody used in the present invention comprises the heavy chain complementarity determining regions (CDR) 1-3 and light chain CDR1-3 in SEQ ID NOs: 3 and 14, respectively. In certain embodiments, these heavy chain

CDRs (HCDRs) have the amino acid sequences of SEQ ID NOs: 7-9, respectively, when defined by the Kabat method. In certain embodiments, these HCDRs have the amino acid sequences of SEQ ID NOs: 10, 11, and 9, respectively, when defined by the Chothia method. In certain embodiments, the light chain CDRs have the amino acid sequences of SEQ ID NOs: 18-20, respectively, when defined by either the Kabat or Chothia method.

[0017] In some embodiments, the anti-CCL20 antibody comprises a heavy chain variable (V_H) domain comprising the amino acid sequence of SEQ ID NO: 5, and/or a light chain (V_L) domain comprising the amino acid sequence of SEQ ID NO: 16. In some preferred embodiments, the anti-CCL20 antibody is a humanized IgG_1 antibody with a human κ light chain constant region. In particular embodiments, the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3 and/or a light chain comprising the amino acid sequence of SEQ ID NO: 14. In more particular embodiments, the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3 and a light chain comprising the amino acid sequence of SEQ ID NO: 14, optionally wherein the heavy chain amino acid sequence lacks the C-terminal lysine of SEQ ID NO: 3.

DETAILED DESCRIPTION OF THE INVENTION

[0018] We have discovered novel regimens for treating inflammatory conditions including, but not limited to, psoriatic arthritis and ulcerative colitis using an anti-human CCL20 antibody, a new use of the antibody for treating these conditions in accordance with the novel regimens, and a new use of the antibody for preparation of a medicament for treating these conditions in accordance with the novel regimens. The regimens involve repeat dosing of the anti-CCL20 antibody, with the potential usage of an initial dose that is higher than the subsequent doses.

Patients with Inflammatory Diseases

[0019] The treatment regimens of the present invention can be used for a range of inflammatory diseases such as psoriatic arthritis wherein inhibition of the CCL20

signal pathway alleviates the symptoms of the disease and slows down the progression of the disease.

[0020] Psoriatic arthritis (PsA) is a form of arthritis that affects some psoriasis patients. Occasionally the arthritis develops before the skin lesions present. Symptoms of this disease include skin lesions such as red and scaly skin, and joint pain, stiffness and swelling. The disease state can alternate between relapse (flare up) and remission. The present treatment methods lead to improvement of PsA symptomatology as indicated by the improved values of one or more of Disease Activity Score (DAS) 28; American College of Rheumatology (ACR) responders; PsA Disease Activity Score (PASDAS); and Psoriatic Lesion Severity Sum (PLSS); Psoriasis Area and Severity Index (PASI). These scoring methods are well recognized in the art. Briefly, DAS28 is a composite arthritis disease activity index comprising swollen and tender joint counts (28 joints), patient global assessment of disease activity, and C-reactive protein. ACR is a composite score of the patient assessment of joint pain, the patient global assessment of disease activity, the physician global assessment of disease activity, the 66/68 swollen/tender joint count, the Disability Index of the Health Assessment Questionnaire (HAQ-DI) questionnaire, and C-reactive protein. The ACR is reported as % improvement (20%, 50%, 70%), between two discrete timepoints, as calculated by improvement in the 66/68 swollen/tender joint count, and improvement in at least three of the remaining five composite parameters. PASDAS is a composite disease activity index for psoriatic arthropathies comprising the 66/68 swollen/tender joint count, patient global assessment of disease activity, physician global assessment of disease activity, Leeds enthesitis index, dactylitis score, SF-36 questionnaire and C-reactive protein. PLSS is the sum of the erythema, scaling and plaque thickness scores. The PASI scoring system is a widely-used standard clinical tool for assessing the severity of psoriasis that takes into account the overall severity of erythema, thickness and scale as well as the extent of body surface area (BSA) affected with psoriasis. Higher scores indicate more severe disease. PASI is a static measurement made without reference to previous scores. As a result of the present treatment methods, the patients may have alleviated skin lesions

and/or joint inflammation. Biochemically, the efficacy of the present treatment methods can also be indicated by the levels of biomarkers such as CD3, CD68, CD11c, and CCR6 as measured by immunohistochemistry (IHC) performed on skin and synovial biopsies. The neutralization of CCL20 activity may result in a decrease in the expression or presence of these biomarkers in the diseased tissue. In some embodiments, the efficacy of the present treatment may be indicated by the change from baseline in the number of CD3+ T cells in synovial and skin lesion biopsy tissue.

[0021] The treatment regimens of the present invention can be used to treat patients who have had an inadequate response to treatment with oral disease modifying immunomodulators (e.g., disease-modifying antirheumatic drugs (DMARDS)), for example, methotrexate, sulfasalazine or leflunomide, or intolerance or contraindications to such treatments. It can also be used to treat patients with an inadequate response, or a loss of response to biologics such as anti-TNF therapies or other immunotherapies. These patients include those who have flare ups or progression of the disease despite previous treatments. The regimens can also be used to treat patients who have not been treated with a DMARD; or patients who have not been previously treated by another immunotherapy, for example, a therapy targeting a specific immuno-stimulatory cytokine (*e.g.*, an anti-TNFα antibody therapy), a therapy eliminating immune cells (*e.g.*, an anti-CD20 antibody therapy), a therapy blocking an accessory molecules (*e.g.*, abatacept), or a therapy promoting the anti-inflammatory activity of the immune system. Thus, these regimens can be used as first line, second line, third line, or fourth line therapy for PsA.

[0022] The treatment regimens of the present invention also can be used for inflammatory bowel diseases (IBDs), including ulcerative colitis and Crohn's disease. Alleviation of symptoms of colitis (*e.g.*, ulcerative colitis) includes reduction in the frequency or severity of urgent and/or loose bowel movements, persistent diarrhea, bloody stool, and abdominal pain. Alleviation of symptoms of Crohn's disease includes reduction in inflammation of the gastrointestinal tract, persistent diarrhea, rectal bleeding, an urgent need to move the bowels, abdominal cramps and pain, the sensation of incomplete evacuation, and constipation.

[0023] The treatment regimens of the present invention also can be used for Behcet's disease. Alleviation of symptoms of Behcet's disease includes reduction in mouth sores, skin lesions, genital sores, eye inflammation, joint pain and/or swelling, vascular inflammation, abdominal pain, diarrhea, gastrointestinal bleeding, and nervous system inflammation.

Anti-CCL20 Antibodies

[0024] The anti-CCL20 antibody used in the present invention preferably is a humanized antibody. Preferred antibodies are those referred to in U.S. Patent 8,491,901, the disclosure of which is incorporated by reference herein in its entirety.

[0025] The anti-CCL20 antibody used in the present invention may comprise two heavy chains and two light chains. The heavy chain comprises a variable domain (V_H) and a constant region. The light chain also comprises a variable domain (V_L) and a constant region. Complete variable domains comprise four framework regions (FRs) and three complementarity determining regions (CDRs), arranged, proceeding from the amino terminus, in the order FR1, CDR1, FR2, CDR2, FR3, CDR3, FR4. Heavy chain CDRs can be designated HCDRs (*e.g.*, HCDR1, HCDR2, and HCDR3). Light chain CDRs can be designated LCDRs (*e.g.*, LCDR1, LCDR2, and LCDR3). Visual inspection and sequence analysis can be carried out to identify the CDR boundaries by well known methods, including the Kabat method (Kabat, E.A. *et al.*, *Sequences of Proteins of Immunological Interest*, Fifth Edition, U.S. Department of Health and Human Services, U.S. Government Printing Office (1991)), the Chothia method (Chothia & Lesk, *Canonical Structures for the Hypervariable Regions of Immunoglobulins*, *J. Mol. Biol.* **196**:901-917 (1987)), or the IMGT method (see the imgt.org website).

[0026] In some embodiments, the anti-CCL20 antibody in the present invention comprises the HCDR1, HCDR2, and HCDR3 in the amino acid sequence of SEQ ID NO: 3. These HCDRs have the amino acid sequences of SEQ ID NOs: 7-9, respectively, when defined by the Kabat method. These HCDRs have the amino acid sequences of SEQ ID NOs: 10, 11, and 9, respectively, when defined by the Chothia method. The anti-CCL20 antibody also comprises the LCDR1, LCDR2, and LCDR3

in the amino acid sequence of SEQ ID NO: 14. These LCDRs have the amino acid sequences of SEQ ID NOs: 18-20, respectively, when defined by either the Kabat or Chothia method.

[0027] In some embodiments, the anti-CCL20 antibody of the invention comprises a V_H domain comprising the amino acid sequence of SEQ ID NO: 5, and/or a V_L domain comprising the amino acid sequence of SEQ ID NO: 16.

[0028] In some preferred embodiments, the anti-CCL20 antibody is a humanized IgG_1 antibody, with a human κ light chain constant region. In one of these preferred embodiments, the anti-CCL20 antibody comprises the heavy chain sequence of SEQ ID NO: 3 and the light chain sequence of SEQ ID NO: 14. An antibody whose heavy and light chain amino acid sequences consist of SEQ ID NOs: 3 and 14, respectively, is referred to herein as "GSK3050002" (also known as KANAb071 or HGS1035). A single intravenous dose of this antibody from 0.1 mg/kg to 20mg/kg has been shown to be well tolerated in healthy male volunteers, and no significant or serious adverse events were identified. This antibody has been shown to have a mean terminal half life of approximately two weeks under certain test conditions and reduces recruitment of $CCR6^+$ T cells, but not $CCR6^-$ T cells, to skin blister fluid in a dose-dependent manner.

[0029] The amino acid sequences of the antibody are shown below in Tables 1 and 2. However, in some embodiments, the heavy chain amino acid sequence lacks the C-terminal lysine.

Table 1: Amino acid and nucleotide sequences of a humanized anti-human CCL20 antibody heavy chain

DESCRIPTION	SEQUENCE (signal sequence underlined, variable domain in bold)
Heavy Chain Amino Acid Sequence (with the signal sequence) (SEQ ID NO: 1)	MGWSCIILFLVATATGVHS**QVQLVQSGAEVKKPGASVK VSCKASGYTFTNYWMHWVRQAPGQGLEWMGVIDPSD SYTTYAQKFQGRVTMTVDTSTSTVYMELSSLRSEDTAV YYCARGNYGVDYAMDYWGQGTLVTVSS**ASTKGPSVFP LAPSSKSTSGGTAALGCLVKDYFPEPVTVSWNSGALTSGV HTFPAVLQSSGLYSLSSVVTVPSSSLGTQTYICNVNHKPSN TKVDKRVEPKSCDKTHTCPPCPAPELLGGPSVFLFPPKPKD

	TLMISRTPEVTCVVVDVSHEDPEVKFNWYVDGVEVHNAK TKPREEQYNSTYRVVSVLTVLHQDWLNGKEYKCKVSNK ALPAPIEKTISKAKGQPREPQVYTLPPSREEMTKNQVSLTC LVKGFYPSDIAVEWESNGQPENNYKTTPPVLDSDGSFFLY SKLTVDKSRWQQGNVFSCSVMHEALHNHYTQKSLSLSPG K
Coding sequence for the heavy chain (with the signal sequence) (SEQ ID NO: 2)	atgggctggtcctgcatcattctgttcctggtggccactgctaccggagtgcacagc**caggtg cagctggtgcagtctggggctgaggtgaagaaacccggtgcaagtgtgaaggtgtcat gtaaagcatccggctatacattcactaactactggatgcattgggtgaggcaggctcca ggacagggactggaatggatgggcgtgatcgacccttcagattcctacaccacatatg cccagaagtttcagggcagggtgaccatgacagtggacactagcacctctacagtgta catggagctgtccagcctgagaagtgaagatacagcagtgtactattgcgcccgcggc aattacggagtggactatgccatggattactgggggcagggtactctggtgaccgtgtc tagt**gcttctaccaagggcccatcggtcttcccccctggcaccctcctccaagagcacctctgg gggcacagcggccctgggctgcctggtcaaggactacttccccgaaccggtgacggtgtc gtggaactcaggcgccctgaccagcggcgtgcacaccttcccggctgtcctacagtcctca ggactctactccctcagcagcgtggtgaccgtgccctccagcagcttgggcacccagacct acatctgcaacgtgaatcacaagcccagcaacaccaaggtggacaagagagttgagccca aatcttgtgacaaaactcacacatgcccaccgtgcccagcacctgaactcctgggggggacc gtcagtcttcctcttccccccaaaacccaaggacaccctcatgatctcccggaccccctgaggt cacatgcgtggtggtggacgtgagccacgaagaccctgaggtcaagttcaactggtacgtg gacggcgtggaggtgcataatgccaagacaaagccgcgggaggagcagtacaacagcac gtaccgtgtggtcagcgtcctcaccgtcctgcaccaggactggctgaatggcaaggagtac aagtgcaaggtctccaacaaagccctcccagcccccatcgagaaaaccatctccaaagcca aagggcagccccgagaaccacaggtgtacaccctgcccccatcccgggaggagatgacc aagaaccaggtcagcctgacctgcctggtcaaaggcttctatcccagcgacatcgccgtgg agtgggagagcaatgggcagccggagaacaactacaagaccacgcctcccgtgctggact ccgacggctccttcttcctctatagcaagctcaccgtggacaagagcaggtggcagcaggg gaacgtcttctcatgctccgtgatgcatgaggctctgcacaaccactacacgcagaagagcc tctccctgtctcccgggaaatga
Heavy Chain Amino Acid Sequence (without the signal sequence) (SEQ ID NO: 3)	**QVQLVQSGAEVKKPGASVKVSCKASGYTFTNYWMHW VRQAPGQGLEWMGVIDPSDSYTTYAQKFQGRVTMTV DTSTSTVYMELSSLRSEDTAVYYCARGNYGVDYAMDY WGQGTLVTVSS**ASTKGPSVFPLAPSSKSTSGGTAALGCLV KDYFPEPVTVSWNSGALTSGVHTFPAVLQSSGLYSLSSVV TVPSSSLGTQTYICNVNHKPSNTKVDKRVEPKSCDKTHTC PPCPAPELLGGPSVFLFPPKPKDTLMISRTPEVTCVVVDVS HEDPEVKFNWYVDGVEVHNAKTKPREEQYNSTYRVVSV LTVLHQDWLNGKEYKCKVSNKALPAPIEKTISKAKGQPRE PQVYTLPPSREEMTKNQVSLTCLVKGFYPSDIAVEWESNG QPENNYKTTPPVLDSDGSFFLYSKLTVDKSRWQQGNVFSC SVMHEALHNHYTQKSLSLSPGK
Coding sequence for the heavy chain (without the signal	**caggtgcagctggtgcagtctggggctgaggtgaagaaacccggtgcaagtgtgaag gtgtcatgtaaagcatccggctatacattcactaactactggatgcattgggtgaggca ggctccaggacagggactggaatggatgggcgtgatcgacccttcagattcctacacc**

sequence) (SEQ ID NO: 4)	**acatatgcccagaagtttcagggcagggtgaccatgacagtggacactagcacctcta cagtgtacatggagctgtccagcctgagaagtgaagatacagcagtgtactattgcgc ccgcggcaattacggagtggactatgccatggattactgggggcagggtactctggtg accgtgtctagt**gcttctaccaagggcccatcggtcttcccccctggcaccctcctccaagag cacctctgggggcacagcggccctgggctgcctggtcaaggactacttccccgaaccggtg acggtgtcgtggaactcaggcgccctgaccagcggcgtgcacaccttcccggctgtcctac agtcctcaggactctactccctcagcagcgtggtgaccgtgccctccagcagcttgggcacc cagacctacatctgcaacgtgaatcacaagcccagcaacaccaaggtggacaagagagttg agcccaaatcttgtgacaaaactcacacatgcccaccgtgcccagcacctgaactcctgggg ggaccgtcagtcttcctcttcccccaaaacccaaggacaccctcatgatctcccggacccct gaggtcacatgcgtggtggtggacgtgagccacgaagaccctgaggtcaagttcaactggt acgtggacggcgtggaggtgcataatgccaagacaaagccgcgggaggagcagtacaac agcacgtaccgtgtggtcagcgtcctcaccgtcctgcaccaggactggctgaatggcaagg agtacaagtgcaaggtctccaacaaagccctcccagccccatcgagaaaaccatctccaa agccaaagggcagccccgagaaccacaggtgtacaccctgccccatcccgggaggaga tgaccaagaaccaggtcagcctgacctgcctggtcaaaggcttctatcccagcgacatcgcc gtggagtgggagagcaatgggcagccggagaacaactacaagaccacgcctcccgtgct ggactccgacggctccttcttcctctatagcaagctcaccgtggacaagagcaggtggcagc aggggaacgtcttctcatgctccgtgatgcatgaggctctgcacaaccactacacgcagaag agcctctccctgtctcccgggaaatga
Heavy Chain Variable Domain Amino Acid Sequence (SEQ ID NO: 5)	**QVQLVQSGAEVKKPGASVKVSCKASGYTFTNYWMHW VRQAPGQGLEWMGVIDPSDSYTTYAQKFQGRVTMTV DTSTSTVYMELSSLRSEDTAVYYCARGNYGVDYAMDY WGQGTLVTVSS**
Coding sequence for the heavy chain variable domain (SEQ ID NO: 6)	**caggtgcagctggtgcagtctggggctgaggtgaagaaacccggtgcaagtgtgaag gtgtcatgtaaagcatccggctatacattcactaactactggatgcattgggtgaggca ggctccaggacagggactggaatggatgggcgtgatcgacccttcagattcctacacc acatatgcccagaagtttcagggcagggtgaccatgacagtggacactagcacctcta cagtgtacatggagctgtccagcctgagaagtgaagatacagcagtgtactattgcgc ccgcggcaattacggagtggactatgccatggattactgggggcagggtactctggtg accgtgtctagt**
HCDR1 amino acid sequence, defined by Kabat method (SEQ ID NO: 7)	**NYWMH**
HCDR2 amino acid sequence, defined by Kabat method (SEQ ID NO: 8)	**VIDPSDSYTTYAQKFQG**
HCDR3 amino acid sequence, defined by Kabat and Chothia methods	**GNYGVDYAMDY**

(SEQ ID NO: 9)	
HCDR1 amino acid sequence, defined by Chothia method (SEQ ID NO: 10)	**GYTFTNY**
HCDR2 amino acid sequence, defined by Chothia method (SEQ ID NO: 11)	**VIDPSDSYTT**

Table 2: Amino acid and nucleotide sequences of a humanized anti-human CCL20 antibody light chain

DESCRIPTION	SEQUENCE (signal sequence underlined, variable domain in bold)
Light Chain Amino Acid Sequence (with the signal sequence) (SEQ ID NO: 12)	MGWSCIILFLVATATGVHS**DIQMTQSPSSLSASVGDRVTI TCRASENIYGALNWYQQKPGKAPKLLIYGATNLADGV PSRFSGSGSGRQYSLTISSLQPEDFATYYCQNVLITPYTF GGGTKLEIK**RTVAAPSVFIFPPSDEQLKSGTASVVCLLNN FYPREAKVQWKVDNALQSGNSQESVTEQDSKDSTYSLSST LTLSKADYEKHKVYACEVTHQGLSSPVTKSFNRGEC
Coding sequence for the light chain (with the signal sequence) (SEQ ID NO: 13)	atgggctggtcctgcatcattctgttcctggtggcaaccgccacaggagtgcacagc**gacat ccagatgacccagtctccatccagcctgagtgcctcagtgggcgatagggtgactatca cctgtcgggccagcgagaacatctacggcgctctgaattggtatcagcagaagccagg aaaagctcccaagctgctgatctacggggctacaaacctggcagacggtgtgcccagt cgattctccggtagcggctctggacgacagtattcactgactatctctagtctgcagcct gaagatttcgccacttactattgccagaatgtgctgattactccatatacctttggcggag gacaaaactggagatcaag**agaactgtggccgctcccagtgtgttcatttttccccttca gacgaacagctgaaatcagggaccgcttccgtggtgtgtctgctgaacaatttctaccctcgc gaggcaaaagtgcagtggaaggtggataacgccctgcagagtggcaattcacaggagtcc gtgaccgaacaggacagcaaagattctacatatagtctgtcatccaccctgacactgagcaa ggctgattacgagaagcacaaagtgtatgcatgcgaagtgactcatcaggggctgagctctc ccgtgaccaagtcttttaaccggggtgaatgttga
Light Chain Amino Acid Sequence (without the signal sequence) (SEQ ID NO: 14)	**DIQMTQSPSSLSASVGDRVTITCRASENIYGALNWYQQ KPGKAPKLLIYGATNLADGVPSRFSGSGSGRQYSLTISS LQPEDFATYYCQNVLITPYTFGGGTKLEIK**RTVAAPSVF IFPPSDEQLKSGTASVVCLLNNFYPREAKVQWKVDNALQS GNSQESVTEQDSKDSTYSLSSTLTLSKADYEKHKVYACEV THQGLSSPVTKSFNRGEC
Coding sequence for the light chain (without the signal sequence) (SEQ ID NO: 15)	**gacatccagatgacccagtctccatccagcctgagtgcctcagtgggcgatagggtga ctatcacctgtcgggccagcgagaacatctacggcgctctgaattggtatcagcagaa gccaggaaaagctcccaagctgctgatctacggggctacaaacctggcagacggtgt gcccagtcgattctccggtagcggctctggacgacagtattcactgactatctctagtct gcagcctgaagatttcgccacttactattgccagaatgtgctgattactccatatacctttt**

	ggcggagggacaaaactggagatcaagagaactgtggccgctcccagtgtgttcatttttc ccccttcagacgaacagctgaaatcagggaccgcttccgtggtgtgtctgctgaacaatttct accctcgcgaggcaaaagtgcagtggaaggtggataacgccctgcagagtggcaattcac aggagtccgtgaccgaacaggacagcaaagattctacatatagtctgtcatccaccctgaca ctgagcaaggctgattacgagaagcacaaagtgtatgcatgcgaagtgactcatcaggggc tgagctctcccgtgaccaagtcttttaaccggggtgaatgttga
Light Chain Variable Domain Amino Acid Sequence (SEQ ID NO: 16)	**DIQMTQSPSSLSASVGDRVTITCRASENIYGALNWYQQ KPGKAPKLLIYGATNLADGVPSRFSGSGSGRQYSLTISS LQPEDFATYYCQNVLITPYTFGGGTKLEIK**
Coding sequence for the light chain variable domain (SEQ ID NO: 17)	**gacatccagatgacccagtctccatccagcctgagtgcctcagtgggcgatagggtga ctatcacctgtcgggccagcgagaacatctacggcgctctgaattggtatcagcagaa gccaggaaaagctcccaagctgctgatctacggggctacaaacctggcagacggtgt gcccagtcgattctccggtagcggctctggacgacagtattcactgactatctctagtct gcagcctgaagatttcgccacttactattgccagaatgtgctgattactccatatacctttt ggcggagggacaaaactggagatcaag**
LCDR1 amino acid sequence (SEQ ID NO: 18)	**RASENIYGALN**
LCDR2 amino acid sequence (SEQ ID NO: 19)	**GATNLAD**
LCDR3 amino acid sequence (SEQ ID NO: 20)	**QNVLITPYT**

Anti-CCL20 Antibody Compositions

[0030] The antibody used in the present invention can be provided in a liquid or solid form. If the antibody is in a solid form (e.g., a lyophilized form), it can be reconstituted in a pharmaceutically acceptable carrier as a liquid aqueous solution or an emulsion. It is especially advantageous to formulate the compositions in dosage unit form for ease of administration and uniformity of dosage. Dosage unit form, as used herein, refers to physically discrete units suited as unitary dosages for the patients/subjects to be treated; each unit containing a predetermined quantity of an anti-CCL20 antibody calculated to produce the desired therapeutic effect in association with the required pharmaceutical carrier.

[0031] In some embodiments, the antibody composition is a liquid aqueous solution with an antibody concentration in the range of 5-20 mg/ml, 20-50 mg/ml, 50-100

mg/ml, 100-150 mg/ml, 150-200 mg/ml, or 20-200 mg/ml, e.g., at 5 mg/ml, 10 mg/ml, 15 mg/ml, 20 mg/ml, 25 mg/ml, 30 mg/ml, 35 mg/ml, 40 mg/ml, 45 mg/ml, 50 mg/ml, 55 mg/ml, 60 mg/ml, 65 mg/ml, 70 mg/ml, 75 mg/ml, 80 mg/ml, 85 mg/ml, 90 mg/ml, 95 mg/ml, 100 mg/ml, 105 mg/ml, 110 mg/ml, 115 mg/ml, 120 mg/ml, 125 mg/ml, 130 mg/ml, 135 mg/ml, 140 mg/ml, 145 mg/ml, 150 mg/ml, 155 mg/ml, 160 mg/ml, 165 mg/ml, 170 mg/ml, 175 mg/ml, 180 mg/ml, 185 mg/ml, 190 mg/ml, 195 mg/ml, or 200 mg/ml. The solution may contain a buffer with a pH of 4-8 (e.g., acetate, citrate, gluconate, histidine, phosphate, or succinate), a tonicity agent (e.g., a sugar or sugar alcohol such as trehalose, mannitol, sorbitol, or sucrose), a viscosity modifier (e.g., L-arginine hydrochloride) and/or a surfactant (e.g., polysorbate 20 or 80). The solution may also contain a chelating agent such as EDTA and DPTA.

[0032] In some embodiments, the anti-CCL20 antibody solution contains 0.80 mg/ml L-histidine, 1.1 mg/ml L-histidine monohydrochloride, 60 mg/ml sucrose, 5.3 mg/ml L-arginine hydrochloride, 0.2 mg/ml polysorbate 80, with a pH of 6.0.

[0033] The antibody can be formulated for intravenous infusion or subcutaneous injection. The antibody can be provided in single use vials, pre-filled syringes, or other appropriate formats.

Treatment Regimens

[0034] The treatment regimens of the present invention entail multiple doses of an anti-CCL20 antibody. In some embodiments, the regimens start with administration (e.g., by IV infusion or subcutaneous injection) of a loading dose, followed by administration of one or more maintenance doses of the antibody.

[0035] The terms “loading dose” and “initial dose” are used interchangeably herein, and refer to the dose of an anti-CCL20 antibody given at the initiation of a course of treatment (e.g., the first dose of the antibody that is administered). The terms “maintenance dose” or “subsequent dose” are used interchangeably herein, and refer to a dose given to maintain or continue a desired therapeutic effect. The maintenance dose is administered subsequent to the loading dose. The loading dose is typically higher than the maintenance dose.

[0036] The loading or initial dose can be 5-20 mg per kg of body weight of the patient (e.g., 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, or 20 mg/kg), while the maintenance or subsequent dose can be 3-10 mg/kg (e.g., 3, 4, 5, 6, 7, 8, 9, or 10 mg/kg). In some embodiments, the loading dose is 10 mg/kg, while the one or more maintenance doses are 5 mg/kg.

[0037] The loading dose can be a single dose or a set of doses (e.g., 1, 2, 3, 4, or 5 doses). The loading dose may be administered using multiple dosage units (e.g. 1, 2, 3, 4, or 5 dosage units). The loading dose may be administered over the course of one or more hours (e.g., 1, 2, 3, 4, or 5 hours) or over the course of one or more days (e.g., 1, 2, 3, 4, 5, 6 or 7 days). The loading dose can be a set of doses of the same or different amounts (e.g. the first loading dose may be higher than the subsequent loading dose(s)). The time interval between two loading doses can be any time interval including, hours (e.g., 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 or 12 hours), days (e.g., 1, 2, 3, 4, 5, 6 or 7 days) or weeks (e.g., 1, 2, 3 or 4 weeks). The loading dose is typically followed by the administration of one or more maintenance doses.

[0038] The maintenance dose is typically smaller than the loading dose. The maintenance doses can be two or more in number, and can be given as long as the patient needs it or when the patient has renewed symptoms. The time interval between the loading dose and the first maintenance dose can be any time interval including, days (e.g., 1, 2, 3, 4, 5, 6 or 7 days), or weeks (e.g., 1, 2, 3 or 4 weeks). The one or more maintenance doses can be the same or different amounts. The time interval between two maintenance doses can be any time interval including, days (e.g., 1, 2, 3, 4, 5, 6 or 7 days), weeks (e.g., 1, 2, 3 or 4 weeks), or months (e.g., 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, or 12 months).

[0039] In some embodiments, a loading dose of the antibody is followed by a maintenance dose 1, 2, 3, 4, 5, or 6 days, or 1, 2, or 3 weeks (e.g., 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, or 21 days) after the loading dose. In certain embodiments, one or more additional maintenance doses are administered by the same, or a longer or shorter interval. In some of these embodiments, the loading and maintenance doses are separated by an interval of two weeks (e.g., a first maintenance

dose is given two weeks after the loading dose, then a second maintenance dose is given two weeks after the first maintenance dose, and so on). In some embodiments, multiple cycles comprising a loading dose followed by one or more maintenance doses may be administered as long as the patient needs it.

[0040] In some preferred embodiments, the initial dose is 10 mg/kg of the anti-CCL20 antibody on day 1, followed by a first maintenance dose of 5 mg/kg on day 15, and a second maintenance dose of 5 mg/kg on day 29. In some of these preferred embodiments, the anti-CCL20 antibody is GSK3050002. In further embodiments, the patient may be given, after the second maintenance dose, additional doses at 5 mg/kg every other week as deemed necessary by a clinician.

[0041] In other embodiments, the initial doses and the subsequent doses are the same in drug amount.

[0042] In some embodiments, the anti-CCL20 antibody therapy of the invention can be used in combination with another immunotherapy or with a DMARD. Pre-treatment of patients with cortisones to prevent local or systemic anti-drug reaction may also be desired.

[0043] It is to be understood that the embodiments of the present invention which have been described are merely illustrative of some of the applications of the principles of the present invention. Numerous modifications may be made by those skilled in the art based upon the teachings presented herein without departing from the true spirit and scope of the invention.

[0044] Unless otherwise defined herein, scientific and technical terms used in this application shall have the meanings that are commonly understood by those of ordinary skill in the art. Generally, nomenclature used in connection with, and techniques of, pharmacology, cell and tissue culture, molecular biology, cell and cancer biology, neurobiology, neurochemistry, virology, immunology, microbiology, genetics and protein and nucleic acid chemistry, described herein, are those well known and commonly used in the art. The methods and techniques of the present invention are generally performed, unless otherwise indicated, according to conventional methods well known in the art and as described in various general and

more specific references that are cited and discussed throughout this specification. All of the above, and any other publications, patents and published patent applications referred to in this application are specifically incorporated by reference herein. In case of conflict, the present specification, including its specific definitions, will control.

[0045] Throughout this specification, the word "comprise" or variations such as "comprises" or "comprising" will be understood to imply the inclusion of a stated integer (or components) or group of integers (or components), but not the exclusion of any other integer (or components) or group of integers (or components). The singular forms "a," "an," and "the" include the plurals unless the context clearly dictates otherwise.

[0046] Any embodiment described herein can be combined with any other embodiment described herein.

[0047] The following examples are set forth as being representative of the present invention. These examples are not to be construed as limiting the scope of the invention as these and other equivalent embodiments will be apparent in view of the present disclosure, figures, and accompanying claims.

EXAMPLES

Example 1: A Clinical Trial to Assess the Efficacy of an Anti-CCL20 Antibody in Psoriatic Arthritis

[0048] A multi-center, randomized, double-blind (sponsor open), placebo-controlled, repeat dose, proof of mechanism clinical study is conducted to evaluate the safety, tolerability and clinical efficacy of antibody GSK3050002 in patients with psoriatic arthritis. The study can also assess the pharmacokinetics (PK) of repeat dosing of this antibody, the target engagement of this antibody with CCL20 in blood, the pharmacodynamic (PD) effect of this antibody, the immunogenicity of this antibody, the effects of this antibody on biomarkers of inflammation in the joint, blood, skin biopsies and synovial biopsies/fluid, the effects of this antibody on joint inflammation as determined by MRI, and the PK and target engagement of repeat dosing of this antibody in synovial fluid.

[0049] The patients selected for this study may meet some or all of the following criteria: diagnosed with currently active psoriatic arthritis (e.g., ≥ 3 tender and ≥ 3 swollen joints, one of which is either a knee or ankle joint suitable for synovial biopsies; and ≥ 2 active psoriatic skin lesions ≥3cm x 3cm diameter, where each plaque has a total PLSS (sum of the erythema, scaling and induration scores) of ≥5, including an induration score of ≥2 (moderate or above) and a score of ≥1 in erythema and scaling, the skin lesions are located in areas usually shielded from natural light by clothing (e.g. trunk or proximal extremities and should not include scalp, inguinal or genital lesions); C-reactive protein (CRP) ≥3mg/l due to active PsA; a negative test result for Rheumatoid Factor at screening; active PsA despite an adequate course of treatment with at least one of the following disease-modifying antirheumatic drugs (DMARDS): methotrexate, sulfasalazine or leflunomide for a minimum of 3 months with a stable dose. The patients may have received prior treatment for their PsA with up to three oral DMARDS.

[0050] In the treatment arm of this clinical study, patients are injected with GSK3050002 powder reconstituted in an appropriate pharmaceutical liquid aqueous carrier to a final concentration of 100 mg/ml. The injection is done in accordance with the following repeat dosing regimen: 3 intravenous (IV) infusions (each approximately 2 hours in duration), administered on day 1 (10 mg/kg), day 15 (5 mg/kg), and day 29 (5 mg/kg). The course of treatment thus is comprised of administration of a total of 20 mg/kg of GSK3050002 over a period of one month. In the control arm of the study, the patients are given a placebo solution (0.9% sterile saline solution) by IV infusion.

[0051] At time points pre- and post- infusion (e.g., 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, or 17 weeks after the first infusion), the patients can be evaluated to determine some or all of the following parameters: GSK3050002 serum concentrations over time and derived PK parameters such as clearance and volume of distribution, GSK3050002-CCL20 complex levels in serum over time, change in the number of $CD3^+$ T cells in synovial tissue and skin biopsy samples (e.g., taken before and about 6 weeks after starting treatment), changes in biomarkers of clinical efficacy

over time; DAS28; ACR responders; PASDAS; PLSS; and PASI. GSK3050002 will alleviate the disease symptoms as measured by these parameters.

Example 2: Dose Rationale Based on Preclinical and Human Volunteer Data

[0052] By using a mechanistic minimal, physiologically based pharmacokinetic model based on the pharmacokinetic characteristics of a typical IgG_1 antibody, GSK3050002 pharmacokinetics and GSK3050002-CCL20 complexes and concentrations were modeled in both blood and blister fluid in human volunteers injected with the antibody. *See* Cao and Jusko, *J of Pharmacokinetics and Pharmacodynamics* 41(4):375-387 (2014). "First time in human" antibody binding affinity to CCL20 was studied to help determine the target engagement (TE) after repeat dosing.

[0053] It was determined that a loading dose of 10 mg/kg through IV, followed by maintenance doses of 5mg/kg administered intravenously every other week (EOW) would achieve at least 90% inhibition of free CCL20 in both plasma and interstitial fluid. The loading dose can be used to achieve the steady state more rapidly.

[0054] In addition, a dose of 5 mg/kg produced C_{min} steady state blood levels above the concentration (11.1 mg/mL) for fully inhibiting chemotaxis as predicted using a human peripheral blood mononuclear cells ($CD4^+$ memory T cell) assay.

[0055] Finally, a dose-dependent reduction in the percentage of $CCR6^+$ T cells in the total T cell pool ($CD3^+$) was observed in blister fluid on Day 3 and Day 15 post-dosing. The magnitude of the effect was maximal at doses of 5 mg/kg and higher, in line with the observed saturation of antibody-CCL20 complex and predicted occupation of free CCL20 at these doses (*i.e.*, the biological activity of CCL20 was neutralized such that it was no longer able to bind to, and signal through, the CCR6 receptor).

EXEMPLARY EMBODIMENTS OF THE INVENTION

1. A method for treating an inflammatory disease in a patient, comprising administering to the patient an anti-CCL20 monoclonal antibody at (a) an initial dose of 5-20 mg per kg of body weight of the patient, and (b) one or more subsequent doses of 3-10 mg per kg of body weight of the patient, and wherein the antibody comprises the heavy chain CDR1-3 and light chain CDR1-3 in SEQ ID NOs: 3 and 14, respectively.

2. The method of embodiment 1, wherein the inflammatory disease is selected from the group consisting of: psoriatic arthritis, Behcet's disease, and inflammatory bowel disease.

3. The method of embodiment 2, wherein the inflammatory bowel disease is ulcerative colitis or Crohn's disease.

4. The method of embodiment 2, wherein the inflammatory disease is psoriatic arthritis.

5. The method of any one of embodiments 1-4, wherein the initial dose and a first subsequent dose are separated by one to three weeks.

6. The method of any one of embodiments 1-5, wherein the subsequent doses are separated by one to three weeks.

7. The method of any one of embodiments 1-6, wherein the initial dose is 10 mg per kg of body weight of the patient.

8. The method of any one of embodiments 1-7, wherein each of the subsequent doses is 5 mg per kg of body weight of the patient.

9. A method for treating an inflammatory disease in a patient, comprising administering to the patient an anti-CCL20 monoclonal antibody at (a) an initial dose of 300-1400 mg, and (b) one or more subsequent doses of 200-700 mg, and wherein the antibody comprises the heavy chain CDR1-3 and light chain CDR1-3 in SEQ ID NOs: 3 and 14, respectively.

10. The method of embodiment 9, wherein the inflammatory disease is selected from the group consisting of: psoriatic arthritis, Behcet's disease, and inflammatory bowel disease.

11. The method of embodiment 10, wherein the inflammatory bowel disease is ulcerative colitis or Crohn's disease.

12. The method of embodiment 10, wherein the inflammatory disease is psoriatic arthritis.

13. The method of any one of embodiments 9-12, wherein the initial dose and a first subsequent dose are separated by one to three weeks.

14. The method of any one of embodiments 9-13, wherein the subsequent doses are separated by one to three weeks.

15. The method of any one of embodiments 9-14, wherein the initial dose is 300-400 mg.

16. The method of any one of embodiments 9-15, wherein each of the subsequent doses is 200-300 mg.

17. The method of any one of embodiments 1-16, wherein each of the subsequent doses is lower than the initial dose.

18. The method of any one of embodiments 1-17, comprising administering to the patient two or more subsequent doses.

19. The method of any one of embodiments 1-18, wherein the initial dose and first subsequent dose are administered two weeks apart.

20. The method of any one of embodiments 1-19, wherein the subsequent doses are administered two weeks apart.

21. The method of any one of embodiments 1-20, wherein the antibody is administered by intravenous infusion.

22. The method of embodiment 21, wherein the infusion is administered over two hours.

23. The method of any one of embodiments 1-20, wherein the antibody is administered by subcutaneous injection.

24. The method of any one of embodiments 1-23, wherein the antibody is administered to the patient

(1) at day 1, at an initial dose of 10 mg per kg of the body weight of the patient,

(2) at day 15, at a second dose of 5 mg per kg of the body weight of the patient, and

(3) at day 29, at a third dose of 5 mg per kg of the body weight of the patient.

25. The method of any one of embodiments 1-24, wherein the antibody is a humanized antibody.

26. The method of any one of embodiments 1-25, wherein the antibody comprises a heavy chain whose variable domain comprises the amino acid sequence of SEQ ID NO: 5.

27. The method of any one of embodiments 1-26, wherein the antibody comprises a light chain whose variable domain comprises the amino acid sequence of SEQ ID NO: 16.

28. The method of any one of embodiments 1-27, wherein the antibody comprises a human IgG_1 heavy chain constant region and a human κ light chain constant region.

29. The method of any one of embodiments 1-28, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3.

30. The method of any one of embodiments 1-29, wherein the antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO: 14.

31. The method of any one of embodiments 1-28, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3 and a light chain comprising the amino acid sequence of SEQ ID NO: 14.

32. The method of any one of embodiments 1-28, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3 without the C-terminal lysine and a light chain comprising the amino acid sequence of SEQ ID NO: 14.

33. The method of any one of embodiments 1-32, wherein the antibody is administered in a liquid aqueous solution comprising a histidine buffer with a pH of

6.0, 60 mg/ml sucrose, 5.3 mg/ml L-arginine hydrochloride, and 0.2 mg/ml polysorbate 80.

34. The method of any one of embodiments 1, 2, 4-10, or 12-33, wherein the method alleviates skin lesions, joint inflammation, or both.

35. The method of any one of embodiments 1, 2, 4-10, or 12-34, wherein the method improves the patient's symptoms as measured by one or more of DAS28, ACR responders, PASDAS, PLSS, and PASI.

36. An anti-CCL20 monoclonal antibody for use in the treatment of an inflammatory disease in a patient, wherein the antibody is for administration at (a) an initial dose of 5-20 mg per kg of body weight of the patient, and (b) one or more subsequent doses of 3-10 mg per kg of body weight of the patient, and wherein the antibody comprises the heavy chain CDR1-3 and light chain CDR1-3 in SEQ ID NOs: 3 and 14, respectively.

37. The anti-CCL20 monoclonal antibody for use according to embodiment 36, wherein the inflammatory disease is selected from the group consisting of: psoriatic arthritis, Behcet's disease, and inflammatory bowel disease.

38. The anti-CCL20 monoclonal antibody for use according to embodiment 37, wherein the inflammatory bowel disease is ulcerative colitis or Crohn's disease.

39. The anti-CCL20 monoclonal antibody for use according to embodiment 37, wherein the inflammatory disease is psoriatic arthritis.

40. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-39, wherein the initial dose and a first subsequent dose are separated by one to three weeks.

41. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-40, wherein the subsequent doses are separated by one to three weeks.

42. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-41, wherein the initial dose is 10 mg per kg of body weight of the patient.

43. The anti-CCL20 monoclonal antibody for use according to any one of embodiment 36-42, wherein each of the subsequent doses is 5 mg per kg of body weight of the patient.

44. An anti-CCL20 monoclonal antibody for use in the treatment of an inflammatory disease in a patient, wherein the antibody is for administration at (a) an initial dose of 300-1400 mg, and (b) one or more subsequent doses of 200-700 mg, and wherein the antibody comprises the heavy chain CDR1-3 and light chain CDR1-3 in SEQ ID NOs: 3 and 14, respectively.

45. The anti-CCL20 monoclonal antibody for use according to embodiment 44, wherein the inflammatory disease is selected from the group consisting of: psoriatic arthritis, Behcet's disease, and inflammatory bowel disease.

46. The anti-CCL20 monoclonal antibody for use according to embodiment 45, wherein the inflammatory bowel disease is ulcerative colitis or Crohn's disease.

47. The anti-CCL20 monoclonal antibody for use according to embodiment 45, wherein the inflammatory disease is psoriatic arthritis.

48. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 44-47, wherein the initial dose and a first subsequent dose are separated by one to three weeks.

49. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 44-48, wherein the subsequent doses are separated by one to three weeks.

50. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 44-49, wherein the initial dose is 300-400 mg.

51. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 44-50, wherein each of the subsequent doses is 200-300 mg.

52. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-51, wherein each of the subsequent doses is lower than the initial dose.

53. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-52, wherein the antibody is for administration to the patient in two or more subsequent doses.

54. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-53, wherein the initial dose and a first subsequent dose are for administration two weeks apart.

55. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-54, wherein the subsequent doses are for administration two weeks apart.

56. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-55, wherein the antibody is for administration by intravenous infusion.

57. The anti-CCL20 monoclonal antibody for use according to embodiment 56, wherein the infusion is over two hours.

58. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-55, wherein the antibody is for administration by subcutaneous injection.

59. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-58, wherein the antibody is for administration to the patient

(1) at day 1, at an initial dose of 10 mg per kg of the body weight of the patient,

(2) at day 15, at a second dose of 5 mg per kg of the body weight of the patient, and

(3) at day 29, at a third dose of 5 mg per kg of the body weight of the patient.

60. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-59, wherein the antibody is a humanized antibody.

61. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-60, wherein the antibody comprises a heavy chain whose variable domain comprises the amino acid sequence of SEQ ID NO: 5.

62. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-61, wherein the antibody comprises a light chain whose variable domain comprises the amino acid sequence of SEQ ID NO: 16.

63. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-62, wherein the antibody comprises a human IgG_1 heavy chain constant region and a human κ light chain constant region.

64. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-63, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3.

65. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-64, wherein the antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO: 14.

66. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-63, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3 and a light chain comprising the amino acid sequence of SEQ ID NO: 14.

67. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-63, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3 without the C-terminal lysine and a light chain comprising the amino acid sequence of SEQ ID NO: 14.

68. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36-67, wherein the antibody is for administration in a liquid aqueous solution comprising a histidine buffer with a pH of 6.0, 60 mg/ml sucrose, 5.3 mg/ml L-arginine hydrochloride, and 0.2 mg/ml polysorbate 80.

69. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36, 37, 39-45, or 47-68, wherein the antibody alleviates skin lesions, joint inflammation, or both.

70. The anti-CCL20 monoclonal antibody for use according to any one of embodiments 36, 37, 39-45, or 47-68, wherein the antibody improves the patient's symptoms as measured by one or more of DAS28, ACR responders, PASDAS, PLSS, and PASI.

71. The use of an anti-CCL20 monoclonal antibody in the manufacture of a medicament for the treatment of an inflammatory disease in a patient, wherein the antibody is for administration at (a) an initial dose of 5-20 mg per kg of body weight of the patient, and (b) one or more subsequent doses of 3-10 mg per kg of body weight of the patient, and wherein the antibody comprises the heavy chain CDR1-3 and light chain CDR1-3 in SEQ ID NOs: 3 and 14, respectively.

72. The use according to embodiment 71, wherein the inflammatory disease is selected from the group consisting of: psoriatic arthritis, Behcet's disease, and inflammatory bowel disease.

73. The use according to embodiment 72, wherein the inflammatory bowel disease is ulcerative colitis or Crohn's disease.

74. The use according to embodiment 72, wherein the inflammatory disease is psoriatic arthritis.

75. The use according to any one of embodiments 71-74, wherein the initial dose and a first subsequent dose are separated by one to three weeks.

76. The use according to any one of embodiments 71-75, wherein the subsequent doses are separated by one to three weeks.

77. The use according to any one of embodiments 71-76, wherein the initial dose is 10 mg per kg of body weight of the patient.

78. The use according to any one of embodiments 71-77, wherein each of the subsequent doses is 5 mg per kg of body weight of the patient.

79. The use of an anti-CCL20 monoclonal antibody in the manufacture of a medicament for the treatment of an inflammatory disease in a patient, wherein the antibody is for administration at (a) an initial dose of 300-1400 mg, and (b) one or more subsequent doses of 200-700 mg, and wherein the antibody comprises the heavy chain CDR1-3 and light chain CDR1-3 in SEQ ID NOs: 3 and 14, respectively.

80. The use according to embodiment 79, wherein the inflammatory disease is selected from the group consisting of: psoriatic arthritis, Behcet's disease, and inflammatory bowel disease.

81. The use according to embodiment 80, wherein the inflammatory bowel disease is ulcerative colitis or Crohn's disease.

82. The use according to embodiment 80, wherein the inflammatory disease is psoriatic arthritis.

83. The use according to any one of embodiments 79-82, wherein the initial dose and a first subsequent dose are separated by one to three weeks.

84. The use according to any one of embodiments 79-83, wherein the subsequent doses are separated by one to three weeks.

85. The use according to any one of embodiments 79-84, wherein the initial dose is 300-400 mg.

86. The use according to any one of embodiment 79-85, wherein each of the subsequent doses is 200-300 mg.

87. The use according to any one of embodiments 71-86, wherein each of the subsequent doses is lower than the initial dose.

88. The use according to any one of embodiments 71-87, wherein the antibody is for administration to the patient of two or more subsequent doses.

89. The use according to any one of embodiments 71-88, wherein the initial dose and a first subsequent dose are for administration two weeks apart.

90. The use according to any one of embodiments 71-89, wherein the subsequent doses are for administration two weeks apart.

91. The use according to any one of embodiments 71-90, wherein the antibody is for administration by intravenous infusion.

92. The use according to embodiment 91, wherein the infusion is over two hours.

93. The use according to any one of embodiments 71-90, wherein the antibody is for administration by subcutaneous injection.

94. The use according to any one of embodiments 71-93, wherein the antibody is for administration to the patient

(1) at day 1, at an initial dose of 10 mg per kg of the body weight of the patient,

(2) at day 15, at a second dose of 5 mg per kg of the body weight of the patient, and

(3) at day 29, at a third dose of 5 mg per kg of the body weight of the patient.

95. The use according to any one of embodiments 71-94, wherein the antibody is a humanized antibody.

96. The use according to any one of embodiments 71-95, wherein the antibody comprises a heavy chain whose variable domain comprises the amino acid sequence of SEQ ID NO: 5.

97. The use according to any one of embodiments 71-96, wherein the antibody comprises a light chain whose variable domain comprises the amino acid sequence of SEQ ID NO: 16.

98. The use according to any one of embodiments 71-97, wherein the antibody comprises a human IgG_1 heavy chain constant region and a human κ light chain constant region.

99. The use according to any one of embodiments 71-98, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3.

100. The use according to any one of embodiments 71-99, wherein the antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO: 14.

101. The use according to any one of embodiments 71-98, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3 and a light chain comprising the amino acid sequence of SEQ ID NO: 14.

102. The use according to any one of embodiments 71-98, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3 without the C-terminal lysine and a light chain comprising the amino acid sequence of SEQ ID NO: 14.

103. The use according to any one of embodiments 71-102, wherein the antibody is for administration in a liquid aqueous solution comprising a histidine buffer with a pH of 6.0, 60 mg/ml sucrose, 5.3 mg/ml L-arginine hydrochloride, and 0.2 mg/ml polysorbate 80.

104. The use according to any one of embodiments 71, 72, 74-80, or 82-103, wherein the method alleviates skin lesions, joint inflammation, or both.

105. The use according to any one of embodiments 71, 72, 74-80, or 82-103, wherein the method improves the patient's symptoms as measured by one or more of DAS28, ACR responders, PASDAS, PLSS, and PASI.

We claim:

1. A method for treating an inflammatory disease in a patient, comprising administering to the patient an anti-CCL20 monoclonal antibody at (a) an initial dose of 5-20 mg per kg of body weight of the patient, and (b) one or more subsequent doses of 3-10 mg per kg of body weight of the patient, and wherein the antibody comprises the heavy chain CDR1-3 and light chain CDR1-3 in SEQ ID NOs: 3 and 14, respectively.

2. The method of claim 1, wherein the inflammatory disease is selected from the group consisting of: psoriatic arthritis, Behcet's disease, and inflammatory bowel disease.

3. The method of claim 2, wherein the inflammatory bowel disease is ulcerative colitis or Crohn's disease.

4. The method of claim 2, wherein the inflammatory disease is psoriatic arthritis.

5. The method of any one of claims 1-4, wherein the initial dose and a first subsequent dose are separated by one to three weeks.

6. The method of any one of claims 1-5, wherein the subsequent doses are separated by one to three weeks.

7. The method of any one of claims 1-6, wherein the initial dose is 10 mg per kg of body weight of the patient.

8. The method of any one of claims 1-7, wherein each of the subsequent doses is 5 mg per kg of body weight of the patient.

9. A method for treating an inflammatory disease in a patient, comprising administering to the patient an anti-CCL20 monoclonal antibody at (a) an initial dose of 300-1400 mg, and (b) one or more subsequent doses of 200-700 mg, and wherein the antibody comprises the heavy chain CDR1-3 and light chain CDR1-3 in SEQ ID NOs: 3 and 14, respectively.

10. The method of claim 9, wherein the inflammatory disease is selected from the group consisting of: psoriatic arthritis, Behcet's disease, and inflammatory bowel disease.

11. The method of claim 10, wherein the inflammatory bowel disease is ulcerative colitis or Crohn's disease.

12. The method of claim 10, wherein the inflammatory disease is psoriatic arthritis.

13. The method of any one of claims 9-12, wherein the initial dose and a first subsequent dose are separated by one to three weeks.

14. The method of any one of claims 9-13, wherein the subsequent doses are separated by one to three weeks.

15. The method of any one of claims 9-14, wherein the initial dose is 300-400 mg.

16. The method of any one of claims 9-15, wherein each of the subsequent doses is 200-300 mg.

17. The method of any one of claims 1-16, wherein each of the subsequent doses is lower than the initial dose.

18. The method of any one of claims 1-17, comprising administering to the patient two or more subsequent doses.

19. The method of any one of claims 1-18, wherein the initial dose and first subsequent dose are administered two weeks apart.

20. The method of any one of claims 1-19, wherein the subsequent doses are administered two weeks apart.

21. The method of any one of claims 1-20, wherein the antibody is administered by intravenous infusion.

22. The method of claim 21, wherein the infusion is administered over two hours.

23. The method of any one of claims 1-20, wherein the antibody is administered by subcutaneous injection.

24. The method of any one of claims 1-23, wherein the antibody is administered to the patient

(1) at day 1, at an initial dose of 10 mg per kg of the body weight of the patient,

(2) at day 15, at a second dose of 5 mg per kg of the body weight of the patient, and

(3) at day 29, at a third dose of 5 mg per kg of the body weight of the patient.

25. The method of any one of claims 1-24, wherein the antibody is a humanized antibody.

26. The method of any one of claims 1-25, wherein the antibody comprises a heavy chain whose variable domain comprises the amino acid sequence of SEQ ID NO: 5.

27. The method of any one of claims 1-26, wherein the antibody comprises a light chain whose variable domain comprises the amino acid sequence of SEQ ID NO: 16.

28. The method of any one of claims 1-27, wherein the antibody comprises a human IgG_1 heavy chain constant region and a human κ light chain constant region.

29. The method of any one of claims 1-28, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3.

30. The method of any one of claims 1-29, wherein the antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO: 14.

31. The method of any one of claims 1-28, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3 and a light chain comprising the amino acid sequence of SEQ ID NO: 14.

32. The method of any one of claims 1-28, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3 without the C-terminal lysine and a light chain comprising the amino acid sequence of SEQ ID NO: 14.

33. The method of any one of claims 1-32, wherein the antibody is administered in a liquid aqueous solution comprising a histidine buffer with a pH of 6.0, 60 mg/ml sucrose, 5.3 mg/ml L-arginine hydrochloride, and 0.2 mg/ml polysorbate 80.

34. The method of any one of claims 1, 2, 4-10, or 12-33, wherein the method alleviates skin lesions, joint inflammation, or both.

35. The method of any one of claims 1, 2, 4-10, or 12-34, wherein the method improves the patient's symptoms as measured by one or more of DAS28, ACR responders, PASDAS, PLSS, and PASI.

36. An anti-CCL20 monoclonal antibody for use in the treatment of an inflammatory disease in a patient, wherein the antibody is for administration at (a) an initial dose of 5-20 mg per kg of body weight of the patient, and (b) one or more subsequent doses of 3-10 mg per kg of body weight of the patient, and wherein the antibody comprises the heavy chain CDR1-3 and light chain CDR1-3 in SEQ ID NOs: 3 and 14, respectively.

37. The anti-CCL20 monoclonal antibody for use according to claim 36, wherein the inflammatory disease is selected from the group consisting of: psoriatic arthritis, Behcet's disease, and inflammatory bowel disease.

38. The anti-CCL20 monoclonal antibody for use according to claim 37, wherein the inflammatory bowel disease is ulcerative colitis or Crohn's disease.

39. The anti-CCL20 monoclonal antibody for use according to claim 37, wherein the inflammatory disease is psoriatic arthritis.

40. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-39, wherein the initial dose and a first subsequent dose are separated by one to three weeks.

41. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-40, wherein the subsequent doses are separated by one to three weeks.

42. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-41, wherein the initial dose is 10 mg per kg of body weight of the patient.

43. The anti-CCL20 monoclonal antibody for use according to any one of claim 36-42, wherein each of the subsequent doses is 5 mg per kg of body weight of the patient.

44. An anti-CCL20 monoclonal antibody for use in the treatment of an inflammatory disease in a patient, wherein the antibody is for administration at (a) an initial dose of 300-1400 mg, and (b) one or more subsequent doses of 200-700 mg, and wherein the antibody comprises the heavy chain CDR1-3 and light chain CDR1-3 in SEQ ID NOs: 3 and 14, respectively.

45. The anti-CCL20 monoclonal antibody for use according to claim 44, wherein the inflammatory disease is selected from the group consisting of: psoriatic arthritis, Behcet's disease, and inflammatory bowel disease.

46. The anti-CCL20 monoclonal antibody for use according to claim 45, wherein the inflammatory bowel disease is ulcerative colitis or Crohn's disease.

47. The anti-CCL20 monoclonal antibody for use according to claim 45, wherein the inflammatory disease is psoriatic arthritis.

48. The anti-CCL20 monoclonal antibody for use according to any one of claims 44-47, wherein the initial dose and a first subsequent dose are separated by one to three weeks.

49. The anti-CCL20 monoclonal antibody for use according to any one of claims 44-48, wherein the subsequent doses are separated by one to three weeks.

50. The anti-CCL20 monoclonal antibody for use according to any one of claims 44-49, wherein the initial dose is 300-400 mg.

51. The anti-CCL20 monoclonal antibody for use according to any one of claims 44-50, wherein each of the subsequent doses is 200-300 mg.

52. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-51, wherein each of the subsequent doses is lower than the initial dose.

53. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-52, wherein the antibody is for administration to the patient in two or more subsequent doses.

54. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-53, wherein the initial dose and a first subsequent dose are for administration two weeks apart.

55. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-54, wherein the subsequent doses are for administration two weeks apart.

56. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-55, wherein the antibody is for administration by intravenous infusion.

57. The anti-CCL20 monoclonal antibody for use according to claim 56, wherein the infusion is over two hours.

58. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-55, wherein the antibody is for administration by subcutaneous injection.

59. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-58, wherein the antibody is for administration to the patient

(1) at day 1, at an initial dose of 10 mg per kg of the body weight of the patient,

(2) at day 15, at a second dose of 5 mg per kg of the body weight of the patient, and

(3) at day 29, at a third dose of 5 mg per kg of the body weight of the patient.

60. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-59, wherein the antibody is a humanized antibody.

61. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-60, wherein the antibody comprises a heavy chain whose variable domain comprises the amino acid sequence of SEQ ID NO: 5.

62. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-61, wherein the antibody comprises a light chain whose variable domain comprises the amino acid sequence of SEQ ID NO: 16.

63. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-62, wherein the antibody comprises a human IgG_1 heavy chain constant region and a human κ light chain constant region.

64. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-63, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3.

65. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-64, wherein the antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO: 14.

66. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-63, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3 and a light chain comprising the amino acid sequence of SEQ ID NO: 14.

67. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-63, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3 without the C-terminal lysine and a light chain comprising the amino acid sequence of SEQ ID NO: 14.

68. The anti-CCL20 monoclonal antibody for use according to any one of claims 36-67, wherein the antibody is for administration in a liquid aqueous solution comprising a histidine buffer with a pH of 6.0, 60 mg/ml sucrose, 5.3 mg/ml L-arginine hydrochloride, and 0.2 mg/ml polysorbate 80.

69. The anti-CCL20 monoclonal antibody for use according to any one of claims 36, 37, 39-45, or 47-68, wherein the antibody alleviates skin lesions, joint inflammation, or both.

70. The anti-CCL20 monoclonal antibody for use according to any one of claims 36, 37, 39-45, or 47-68, wherein the antibody improves the patient's symptoms as measured by one or more of DAS28, ACR responders, PASDAS, PLSS, and PASI.

71. The use of an anti-CCL20 monoclonal antibody in the manufacture of a medicament for the treatment of an inflammatory disease in a patient, wherein the antibody is for administration at (a) an initial dose of 5-20 mg per kg of body weight

of the patient, and (b) one or more subsequent doses of 3-10 mg per kg of body weight of the patient, and wherein the antibody comprises the heavy chain CDR1-3 and light chain CDR1-3 in SEQ ID NOs: 3 and 14, respectively.

72. The use according to claim 71, wherein the inflammatory disease is selected from the group consisting of: psoriatic arthritis, Behcet's disease, and inflammatory bowel disease.

73. The use according to claim 72, wherein the inflammatory bowel disease is ulcerative colitis or Crohn's disease.

74. The use according to claim 72, wherein the inflammatory disease is psoriatic arthritis.

75. The use according to any one of claims 71-74, wherein the initial dose and a first subsequent dose are separated by one to three weeks.

76. The use according to any one of claims 71-75, wherein the subsequent doses are separated by one to three weeks.

77. The use according to any one of claims 71-76, wherein the initial dose is 10 mg per kg of body weight of the patient.

78. The use according to any one of claims 71-77, wherein each of the subsequent doses is 5 mg per kg of body weight of the patient.

79. The use of an anti-CCL20 monoclonal antibody in the manufacture of a medicament for the treatment of an inflammatory disease in a patient, wherein the antibody is for administration at (a) an initial dose of 300-1400 mg, and (b) one or

more subsequent doses of 200-700 mg, and wherein the antibody comprises the heavy chain CDR1-3 and light chain CDR1-3 in SEQ ID NOs: 3 and 14, respectively.

80. The use according to claim 79, wherein the inflammatory disease is selected from the group consisting of: psoriatic arthritis, Behcet's disease, and inflammatory bowel disease.

81. The use according to claim 80, wherein the inflammatory bowel disease is ulcerative colitis or Crohn's disease.

82. The use according to claim 80, wherein the inflammatory disease is psoriatic arthritis.

83. The use according to any one of claims 79-82, wherein the initial dose and a first subsequent dose are separated by one to three weeks.

84. The use according to any one of claims 79-83, wherein the subsequent doses are separated by one to three weeks.

85. The use according to any one of claims 79-84, wherein the initial dose is 300-400 mg.

86. The use according to any one of claim 79-85, wherein each of the subsequent doses is 200-300 mg.

87. The use according to any one of claims 71-86, wherein each of the subsequent doses is lower than the initial dose.

88. The use according to any one of claims 71-87, wherein the antibody is for administration to the patient of two or more subsequent doses.

89. The use according to any one of claims 71-88, wherein the initial dose and a first subsequent dose are for administration two weeks apart.

90. The use according to any one of claims 71-89, wherein the subsequent doses are for administration two weeks apart.

91. The use according to any one of claims 71-90, wherein the antibody is for administration by intravenous infusion.

92. The use according to claim 91, wherein the infusion is over two hours.

93. The use according to any one of claims 71-90, wherein the antibody is for administration by subcutaneous injection.

94. The use according to any one of claims 71-93, wherein the antibody is for administration to the patient

(1) at day 1, at an initial dose of 10 mg per kg of the body weight of the patient,

(2) at day 15, at a second dose of 5 mg per kg of the body weight of the patient, and

(3) at day 29, at a third dose of 5 mg per kg of the body weight of the patient.

95. The use according to any one of claims 71-94, wherein the antibody is a humanized antibody.

96. The use according to any one of claims 71-95, wherein the antibody comprises a heavy chain whose variable domain comprises the amino acid sequence of SEQ ID NO: 5.

97. The use according to any one of claims 71-96, wherein the antibody comprises a light chain whose variable domain comprises the amino acid sequence of SEQ ID NO: 16.

98. The use according to any one of claims 71-97, wherein the antibody comprises a human IgG_1 heavy chain constant region and a human κ light chain constant region.

99. The use according to any one of claims 71-98, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3.

100. The use according to any one of claims 71-99, wherein the antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO: 14.

101. The use according to any one of claims 71-98, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3 and a light chain comprising the amino acid sequence of SEQ ID NO: 14.

102. The use according to any one of claims 71-98, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 3 without the C-terminal lysine and a light chain comprising the amino acid sequence of SEQ ID NO: 14.

103. The use according to any one of claims 71-102, wherein the antibody is for administration in a liquid aqueous solution comprising a histidine buffer with a pH of 6.0, 60 mg/ml sucrose, 5.3 mg/ml L-arginine hydrochloride, and 0.2 mg/ml polysorbate 80.

104. The use according to any one of claims 71, 72, 74-80, or 82-103, wherein the method alleviates skin lesions, joint inflammation, or both.

105. The use according to any one of claims 71, 72, 74-80, or 82-103, wherein the method improves the patient's symptoms as measured by one or more of DAS28, ACR responders, PASDAS, PLSS, and PASI.