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[0018] Anti-inflammatory drugs and immune system suppressants may be used in the treatment of IBD, such as sulfasalazine (Azulfidine™), mesalamine (Asacol™, Rowasa™), corticosteroids (e.g. prednisone), azathioprine (Imuran™), mercaptopurine (Purinethol™), infliximab (Remicade™), adalimumab (Humira™), certolizumab pegol (Cimzia™), methotrexate (Rheumatrex™), cyclosporine (Gengraf™, Neoral™, Sandimmune™) or natalizumab (Tysabri™).

[0019] Alternative treatments for IBD have been suggested, including the use of various biological agents, or treatments that purportedly adjust natural intestinal flora, sometimes called probiotic treatments (US 2007/0258953; US 2008/0003207; WO 2007/076534; WO 2007/136719; WO 2010/099824). It has for example been reported that IBD may be treated with a deliberate infestation of parasitic worms, for example by consumption of the live ova of the Trichuris suis helminth (Summers et al. (2003) "Trichuris suis seems to be safe and possibly effective in the treatment of inflammatory bowel disease". Am. J. Gastroenterol. 98 (9): 2034–41; Büning et al., (2008) "Helminths as governors of inflammatory bowel disease" Gut 57:1182-1183; Weinstock and Elliott (2009) "Helminths and the IBD hygiene hypothesis" Inflamm Bowel Dis. 2009 Jan;15(1):128-33).

SUMMARY OF THE DISCLOSURE

[0019a] In one aspect, provided herein is a use of antigenic determinants from at least one microbial pathogen that is pathogenic in the bone for the manufacture of an anti-inflammatory composition for treating ~~an inflammatory disease~~cancer metastases to ~~of~~ the bone, wherein the microbial pathogen is ~~selected from the group consisting of~~ *Staphylococcus aureus*~~, coagulase-negative staphylococci, Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus agalactiae, other streptococci spp., Escherichia coli, Pseudomonas spp., Enterobacter spp., Proteus spp. and Serratia spp.~~, wherein the anti-inflammatory composition comprises whole killed

bacterial cells, and wherein the anti-inflammatory composition is formulated for administration by a route that is not enteric.

~~**[0019b]** In another aspect, provided herein is a use of antigenic determinants from at least one microbial pathogen that is pathogenic in the bone for the manufacture of an anti-inflammatory composition for treating an inflammatory disease of the bone, wherein the microbial pathogen is selected from the group consisting of *Staphylococcus aureus, coagulase-negative staphylococci, Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus agalactiae, other streptococci spp., Escherichia coli, Pseudomonas spp., Enterobacter spp., Proteus spp. and Serratia spp.*, wherein the anti-inflammatory composition comprises whole killed bacterial cells, and wherein the anti-inflammatory composition is for administration with an effective amount of an anti-inflammatory or immune suppressant medicament.~~

~~**[0019c]** In one aspect, provided herein is a use of antigenic determinants from at least one microbial pathogen that is pathogenic in the bone for the manufacture of an anti-inflammatory composition for treating an inflammatory disease of the bone, wherein the microbial pathogen is *Staphylococcus aureus*, wherein the antiinflammatory composition comprises whole killed bacterial cells, and wherein the inflammatory disease is an arthritis.~~

[0020] In one example a method of formulating an anti-inflammatory composition for treating a condition characterized by inflammation in a specific organ or tissue is provided. The method involves selecting at least one pathogen that is pathogenic in the specific organ or tissue; producing an antigenic composition comprising antigenic determinants that together are specific for the pathogen; and formulating the antigenic

Claims

1. Use of antigenic determinants from at least one microbial pathogen that is pathogenic in the bone for the manufacture of an anti-inflammatory composition for treating ~~an inflammatory disease of~~cancer metastases to the bone, wherein the microbial pathogen is ~~selected from the group consisting of~~ *Staphylococcus aureus, ~~coagulase-negative staphylococci, Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus agalactiae, other streptococci spp., Escherichia coli, Pseudomonas spp., Enterobacter spp., Proteus spp. and Serratia spp.,~~* wherein the anti-inflammatory composition comprises whole killed bacterial cells, and wherein the anti-inflammatory composition is formulated for administration by a route that is not enteric.

2. The use according to claim 1, wherein the anti-inflammatory composition is formulated for administration intradermally or subcutaneously.

3. The use according to claim 1 or 2, wherein the anti-inflammatory composition is for administration with an effective amount of an antiinflammatory or immune suppressant medicament.

4. The use according to claim 3, wherein the anti-inflammatory or immune suppressant medicament is sulfasalazine, mesalamine, a corticosteroid, azathioprine, mercaptopurine, infliximab, adalimumab, certolizumab pegol, methotrexate, cyclosporine or natalizumab.

~~5. Use of antigenic determinants from at least one microbial pathogen that is pathogenic in the bone for the manufacture of an anti-inflammatory composition for treating an inflammatory disease of the bone, wherein the microbial pathogen is selected from the group consisting of *Staphylococcus aureus, coagulase-negative staphylococci, Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus agalactiae, other streptococci spp., Escherichia coli, Pseudomonas spp., Enterobacter spp., Proteus spp. and Serratia spp.*, wherein the anti-inflammatory composition comprises whole killed bacterial cells, and wherein the anti-inflammatory composition is for administration with an effective amount of an anti-inflammatory or immune suppressant medicament.~~

~~6. The use according to claim 5, wherein the anti-inflammatory or immune suppressant medicament is sulfasalazine, mesalamine, a corticosteroid, azathioprine, mercaptopurine, infliximab, adalimumab, certolizumab pegol, methotrexate, cyclosporine or natalizumab.~~

~~7. The use according to any one of claims 1 to 6, wherein the inflammatory disease is selected from the group consisting of temporal arthritis (giant cell arthritis), juvenile arthritis, psoriatic arthritis, reactive arthritis (Reiter's syndrome), rheumatoid arthritis,~~

enthesitis-related arthritis, juvenile idiopathic arthritis, juvenile rheumatoid arthritis, osteoarthritis and Paget's disease of bone.

8. The use according to any one of claims 1 to 6, wherein the inflammatory disease is an arthritis, and the pathogen is *Staphylococcus aureus*.

9. Use of antigenic determinants from at least one microbial pathogen that is pathogenic in the bone for the manufacture of an anti-inflammatory composition for treating an inflammatory disease of the bone, wherein the microbial pathogen is *Staphylococcus aureus*, wherein the antiinflammatory composition comprises whole killed bacterial cells, and wherein the inflammatory disease is an arthritis.

10. The use according to any one of claims 1 to 9, wherein the antiinflammatory composition comprises antigenic determinants of two or more pathogens that are each pathogenic in the bone.