CLAIMS

1. A bacterial extract from Gram positive or Gram negative bacterial species wherein said bacterial extract is obtainable by alkaline lysis of said bacterial species and neutralization with one or more organic acid selected among acetic acid, propionic acid, lactic acid, 3-hydroxypropanoic acid, pyruvic acid, butanoic acid, 2-hydroxybutanoic acid, 3-hydroxybutanoic acid, glutamic acid, aspartic acid, a combination thereof, and/or pharmaceutically acceptable salts and esters thereof, followed by purification by filtration of the neutralized extract and adjusting to a final physiological pH by adding the organic acid or combination thereof used for said neutralization.

2. The bacterial extract according to claim 1, comprising a reduced fraction of molecular weight components from 0 to 300 kDa to 0 to 100 kDa, or 0 to 60 kDa.

3. The bacterial extract according to claim 1 or 2, wherein said alkaline lysis is conducted at pH greater than 10, with variations of ±0.1 of the pH.

4. The bacterial extract according to any one of the preceding claims, wherein the final pH is adjusted between 5 and 8, between 6 and 8, between 6.3 and 7.8, or between 6.5 and 7.8.

5. The bacterial extract according to any one of the preceding claims, wherein said one or more bacterial species are chosen among Moraxella catarrhalis, Haemophilus influenzae, Klebsiella pneumoniae, Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes, and/or Streptococcus sanguinis.

6. The bacterial extract according to any one of claims 1-4, wherein said one or more bacterial species are chosen among Lactobacillus bacterial strains.

7. The bacterial extract according to claim 6, wherein said Lactobacillus strains comprise one or more of Lactobacillus fermentum, Lactobacillus rhamnosus, Lactobacillus plantarum, Lactobacillus johnsonii, Lactobacillus helveticus, Lactobacillus casei defensis, Lactobacillus casei ssp. casei, Lactobacillus paracasei, Lactobacillus bulgaricus, Lactobacillus paracasei, Lactobacillus acidophilus,

Lactobacillus reuteri, Lactobacillus salivarius, Lactobacillus lactis, and/or Lactobacillus delbrueckii.

8. The bacterial extract according to any one of claims 1-4, wherein said one or more bacterial species are chosen among Escherichia coli bacterial strains.

9. The bacterial extract according to any one of the preceding claims, wherein said stable purified bacterial extract comprises less than 100 micrograms/ml nucleic acids, at least 0.1mg/mL of saccharides.

10. The bacterial extract according to any one of the preceding claims, said bacterial extract being stable in liquid form at room temperature, 4oC, -20 oC, or at -80 oC.

11. Pharmaceutical composition comprising the bacterial extract according to any one of the preceding claims and a pharmaceutically acceptable excipient or vehicle, wherein said pharmaceutical composition may be in the form of a solid, semi-solid, liquid, or aerosol formulation, and wherein said composition may be formulated for intranasal, intratracheal, mucosal, transmucosal, external skin topical, buccal, sublingual, oral, pulmonary, intrabronchial, and/or intrapulmonary routes of administration.

12. Pharmaceutical composition of claim 11, wherein said pharmaceutical composition is liquid or aerosol and is formulated in a spray, droplet, colloidal, mist, nebulae, and/or in atomized vapor, or wherein said composition is liquid or semi-solid and is formulated in form of emulsions, microemulsions, aqueous dispersions, oils, milks, balsams, foams, aqueous or oily lotions, aqueous or oily gels, creams, solutions, hydroalcoholic solutions, hydroglycolic solutions, hydrogels, serums, ointments, mousses, pastes, or transdermal patches, or wherein said composition is solid and is formulated in a powder, and/or crushable tablet.

13. Pharmaceutical composition according to claim 11 or 12, for use in a method of treating and/or preventing acute and chronic immunological disorders resulting from infections and/or inflammations and/or neoplasms and/or dysbiosis.

14. Pharmaceutical composition for use in a method according to claim 13, wherein said infections are chosen among upper and lower respiratory tract infections and/or associated sequelae such as allergic rhinitis, rhinitis, nasopharyngitis, sinusitis, Hypersensitivity Pneumonitis, bronchopneumonia, bronchitis, bronchiolitis, pneumonia, obstructive pulmonary disease with acute lower respiratory infection, obstructive pulmonary disease with acute upper respiratory infections, or diseases with epithelial cilia motion disorders and/or mucus clearance disorders, and wherein said infections may further comprise secondary infections, bacterial secondary infections following viral infections with influenza, non-respiratory viral infections, non-respiratory bacterial infections, systemic infections such as sepsis, septic shock or viro-induced complications.

15. Pharmaceutical composition for use in a method according to claim 13, wherein said wherein said infections are chosen among viral infections, influenza, respiratory syncytial virus, rhinovirus, coronavirus, CoV, SARS-CoV, and MERS-CoV.

16. Pharmaceutical composition for use in a method according to claim 13, wherein said wherein said infection is COVID-19.

17. Pharmaceutical composition for use in a method according to claim 13, wherein said inflammations are chosen among allergic/atopic respiratory and non-respiratory indications atopic dermatitis, acute and/or chronic associated dermatitis, anaphylaxis or food allergies, or wherein said inflammations comprise skin disorders, inflamed skin, eczema, rosacea, atopic dermatitis, psoriasis, actinic keratosis, or wherein said inflammations are chosen among eosinophilic indications such as eosinophilic asthma, or eosinophilic pneumonia, or wherein said inflammations are chosen among T helper 2 predominant autoimmune indications.

18. Pharmaceutical composition for use a method according to claim 13, wherein dysbiosis related disorders are chosen among obesity, asthma, diabetes, autoimmune diseases, diseases associated with low fiber regimens, atopic dermatitis, acute and/or chronic associated dermatitis, or wherein dysbiosis related disorders are chosen among inflammatory bowel diseases, comprising ulcerative colitis, Crohn’s disease, colitis, type 2 diabetes, autoimmune diseases, or diseases associated with low fiber regimens.

19. A delivery device comprising the pharmaceutical composition according to any one of claims 11 to 18, said delivery device being selected from the group comprising of nasal insufflator device, intranasal inhaler, intranasal spray device, atomizer, nasal spray bottle, unit dose container, pump, dropper, squeeze bottle, nebulizer, metered dose inhaler (MDI), pressurized dose inhalers, insufflators, bi-directional devices, dose ampoules, nasal pads, nasal sponges, and nasal capsules.

20. A process for preparing a stable bacterial extract according to any one of claims 1-9, comprising the following steps:

a. culturing each bacterial strain species in a suitable culture medium,

b. heat killing the bacteria, removing the culture medium and harvesting the concentrated biomass,

c. lysing each strain at an initial pH of greater than 10,

d. decreasing the pH of the extract(s) obtained in step (c) by 1 or 2 units by adding one or more organic acid selected among acetic acid, propionic acid, lactic acid, 3-hydroxypropanoic acid, pyruvic acid, butanoic acid, 2-hydroxybutanoic acid, 3-hydroxybutanoic acid, glutamic acid, aspartic acid, a combination thereof, or pharmaceutically acceptable salts and esters thereof,

e. passing the product of step (d) at least once through a microfilter and retaining the product on an ultrafilter so as to obtain a purified soluble extract.