CLAIMS

~~1. A method of treating, preventing or ameliorating a disease, disorder or condition associated with inflammation or immune-modulation, comprising administration to a subject in need thereof of an effective amount of a placental extract or an effective amount of a composition comprising a placental extract.~~

~~2. A composition for use in treating, preventing or ameliorating a disease, disorder or condition associated with inflammation or immune-modulation, wherein the composition comprises a placental extract.~~

1~~3~~. Use of a placental extract, in the manufacture of a medicament or composition for treating, preventing or ameliorating a disease, disorder or condition associated with inflammation or immune-modulation.

2~~4~~. The ~~method, composition or~~ use according to ~~any one of the preceding~~ claim~~s~~ 1 wherein, the composition or medicament is a food, drink, food additive, drink additive, food component, drink component, dietary supplement, nutritional product, medical food, nutraceutical, medicament or pharmaceutical.

3~~5~~. The ~~method, composition or~~ use according to ~~any one of the preceding~~ claim~~s~~ 1 or 2 wherein, the placenta extract is to be administered at a concentration sufficient to inhibit one or more pro-inflammatory cytokines, including cytokine IL-1α, β, IL-2, IL-3, IL-6, IL-7, IL-9, IL-12, IL-17, IL-18, TNF-α, LT, LIF, Oncostatin, or IFNc1α, β, Y.

4~~6~~. The ~~method, composition or~~ use according to any one of the preceding claims wherein, the placenta extract is to be administered at a

concentration sufficient to stimulate expression of one of more anti-inflammatory cytokine, including IL-4, IL-10, IL-11, W-13 or TGF β.

5~~7~~. The ~~method, composition or~~ use according to any one of the preceding claims wherein, the placental extract is derived from a deer, sheep, goat, horse, donkey, rabbit or bovine placenta, preferably the placental extract is derived from deer placenta.

6~~8~~. The ~~method, composition or~~ use according to any one of the preceding claims wherein, the placental extract is extracted from placenta material by a method of extraction selected from the group consisting of: solvent extraction, supercritical solvent extraction including supercritical CO_2 extraction, distillation, counter current extraction, decoction, percolation, maturation, molecular distillation, microwave extraction, ultrasound extraction, and chromatographic separation.

7~~9~~. The ~~method, composition or~~ use according to any one of the preceding claims wherein, the placental extract is extracted from placenta material by solvent extraction.

8~~10~~. The ~~method, composition or~~ use according to claim 6~~8~~ or 7~~9~~ wherein, the method of extraction includes steps of contacting the placenta material with a solvent, separating the placenta material from the solvent, and at least partially removing the solvent to yield the extract.

9~~11~~. The ~~method, composition or~~ use according to any one of claims 6~~8~~ to 8~~10~~ wherein, the placenta material is freeze dried and powdered prior to contact with the solvent.

10~~12~~. The ~~method, composition or~~ use according to any one of claims 6~~8~~ to 9~~11~~ wherein the solvent is water.

11~~13~~. The ~~method, composition or~~ use according to any one of claims 6~~8~~ to 9~~11~~ wherein, the solvent is an organic solvent.

12~~14~~. The ~~method, composition or~~ use according to claim 11~~13~~ wherein, the solvent is ethanol.

13~~15~~. The ~~method, composition or~~ use according to any one of claims 1 to 9~~11~~ or 11~~13~~ to 12~~14~~ wherein the extract is prepared by solvent extraction, such as ethanol extraction, followed by distillation or supercritical extraction.

14~~16~~. The ~~method, composition or~~ use according to any one of claims 1 to 10~~12~~ wherein water extraction is used to prepare the extract.

15~~17~~. The ~~method, composition or~~ use according to any one of the preceding claims wherein the placental extract is or comprises dried or powdered placenta material.

16~~18~~. The ~~method, composition or~~ use according to claim 15~~17~~ wherein, the placenta material is pulverised by wet grinding, and then powdered or granulated by freeze-, vacuum- or spray-drying, or fluid bed drying or the like.

17~~19~~. The ~~method, composition or~~ use according to claim 15~~17~~ wherein, the placenta material is first dried, optionally by freeze- or vacuum-drying, and then optionally ground into powder.

18~~20~~. The ~~method, composition or~~ use according to any one of the preceding claims wherein the composition or medicament is provided in a delivery formulation selected from the group consisting of tablets, capsules,

liquids, oils, suspensions, emulsions, pastes, jellies, puddings, solutions, and powders.

19~~21~~. The ~~method, composition or~~ use according to any one of the preceding claims wherein ~~the composition comprises or~~ the medicament or composition comprises:

a. at least about 0.1, 0.2, 0.5, 1, 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 99, 99.5, 99.8 or 99.9% by weight of the placental extract;

b. at least about 0.001, 0.01, 0.05, 0.1, 0.15, 0.2, 0.3, 0.4, 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 or 19 grams or more of the placenta extract; or

c. at least about 1, 10, 50, 100, 125, 150, 200, 250, 300, 350, 400, 450, 500, 600, 700, 800, 900 or 1000mg or more of the placenta extract.

20~~22~~. The ~~method, composition or~~ use according to any one of the preceding claims wherein ~~the composition comprises,~~ the medicament or composition comprises~~, or the method comprises~~

a. ~~administration of~~ placenta extract in an amount of about 125mg~~,~~ to be ~~suitable for~~ administeredration twice daily, or 250mg~~,~~ to besuitable for administeredration once per day;

b. ~~administration of~~ placenta extract in an amount of about 100mg or 125mg~~,~~ to besuitable for administeredration twice daily, or 200mg or 250mg~~,~~ to besuitable for administeredration once per day; or

c. ~~administration of~~ about 40% to 90% by weight of placenta extract.

21~~23~~. The ~~method, composition or~~ use according to any one of the preceding claims wherein ~~the composition or~~ the medicament or

composition further comprises about 0.1, 0.5, 1, 5, 10, 15, 20, 25, 30, 35, 40, 45 or 50% by weight of another anti-inflammatory agent.

2224. The ~~method, composition or~~ use according to any one of the preceding claims wherein the composition or medicament further comprises a carrier, optionally a pharmaceutically acceptable carrier.

2325. The ~~method, composition or~~ use according to any one of the preceding claims wherein the composition or medicament is in the form of a tablet, a caplet, a pill, a hard or soft capsule, a lozenge, a cachet, a dispensable powder, granules, a suspension, an elixir, a liquid, or any other form that can be added to food or drink, including for example water or fruit juice.

2426. The ~~method, composition or~~ use according to any one of the preceding claims wherein the composition or medicament further comprises one or more constituents, optionally antioxidants, which prevent or reduce degradation of the composition during storage or after administration.

2527. The ~~method, composition or~~ use according to any one of the preceding claims wherein the composition or medicament is or is formulated as a food, drink, food additive, drink additive, dietary supplement, nutritional product, medical food, nutraceutical, medicament or pharmaceutical, optionally, the composition or medicament is formulated as a powder, liquid, food bar, spread, sauce, paste, jelly, pudding, soup base, ointment, tablet or capsule.

2628. The ~~method, composition or~~ use according to any one of the preceding claims wherein the composition or medicament is formulated for:

a. oral, nasal or parenteral administration, optionally topical, subcutaneous, intramuscular and intravenous administration; or

b. ingestion,

c. inhalation, optionally formulated for administration as an inhalable powder, solution or aerosol; or

d. topical application, optionally formulated for topical application, preferably it is formulated as an ointment, cream or lotion.

27~~29~~. The ~~method, composition or~~ use according to any one of the preceding claims wherein the placenta extract or composition is to be administered, or is formulated for administration, in an amount sufficient to treat the inflammatory-related disease by inhibiting pro-inflammatory cytokine expression and/or by stimulating anti-inflammatory cytokines.

28~~30~~. The ~~method, composition or~~ use according to any one of claims 1 to 27~~29~~ wherein the disease, disorder or condition is an inflammatory-related disease selected from the group consisting of: diabetes type I; Sjogren's syndrome; uveitis; celiac disease; allergic conjunctivitis; and non-specific colitis, arthritis, rheumatoid arthritis, an inflammatory bowel disease; psoriasis; multiple sclerosis; a neurodegenerative disorder; congestive heart failure; stroke; aortic valve stenosis; kidney failure; lupus; pancreatitis; allergy; fibrosis; anemia; atherosclerosis; a metabolic disease; a bone disease; a cardiovascular disease, a chemotherapy/radiation related complication; diabetes type II; a liver disease; a gastrointestinal disorder; an ophthalmological disease; diabetic retinopathy; a pulmonary disorder, a renal disease; dermatitis; HIV-related cachexia; cerebral malaria; ankylosing spondylitis; leprosy; anemia; and fibromyalgia.

29~~31~~. The ~~method, composition or~~ use according to any one of claims 1 to 27~~29~~ wherein the disease, disorder or condition is a disease, disorder or condition of the lung, for example a disease, disorder or condition that is (a) associated with or caused by an immune response; (b) an interstitial lung disease; (c) an obstructive lung disease; (d) an acute lung injury; or (e) a

lung injury caused by a neoplastic or paraneoplastic disease, pneumonia, or cystic fibrosis.

30~~32~~. The ~~method, composition or~~ use according to any one of claims 1 to 27~~29~~ wherein the disease, disorder or condition is:

a) a disease, disorder or condition associated with or caused by an immune response is an autoimmune disease, or a graft-versus-host disease;

b) an autoimmune disease selected from rheumatoid arthritis, scleroderma, inflammatory bowel disease, or systemic lupus erythematosus;

c) an interstitial lung disease such as interstitial pulmonary fibrosis;

d) an obstructive lung disease selected from asthma, bronchitis, acute respiratory distress syndrome or chronic obstructive pulmonary disease;

e) an acute lung injury selected from one or more of physical trauma, a chemical injury such as a chemical burn, smoke inhalation, or exposure to a toxic substance.

31~~33~~. The ~~method, composition or~~ use according to any one of claims 1 to 27~~29~~ wherein the disease, disorder or condition is one or more of a fibrotic disease of the lung, acute respiratory distress syndrome (ARDS), COVID-19, chronic obstructive pulmonary disease (COPD), emphysema, asthma, a viral or bacterial infection of the lung, pneumonia (including chemically-induced pneumonia), or cystic fibrosis.

32~~34~~. The ~~method, composition or~~ use according to any one of claims 1 to 27~~29~~, wherein the medicament or composition is for treating, preventing or ameliorating a viral disease and/or for inhibiting virus activation, in which said virus is selected from the group consisting of herpes virus, such as cytomegalovirus (CMV); influenza virus, such as H1N1, H3N2, H5N1 or

H5N7 virus; paramixovirus, such as measles; respiratory syncytial virus; coronaviruses, such as SARS or SARS-CoV-2 (Covid-19); HIV Virus; hepatitis virus; or rotavirus.