

Claims

1. A composition comprising isolated bacteria selected from at least two species wherein the bacteria from the first species comprise a 16S rDNA sequence having at least 98.7% sequence identity with a nucleic acid sequence according to SEQ ID NO: 1, and the bacteria from the second species comprise a 16S rDNA sequence having at least 98.7% sequence identity with a nucleic acid sequence according to SEQ ID NO: 2.
2. The composition according to claim 1, further comprising isolated bacteria from at least 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13 different species wherein the bacteria comprise a 16S rDNA sequence selected from a sequence having at least 98.7% sequence identity with a nucleic acid sequence according to SEQ ID NO: 3 to 15.
3. The composition according to claim 1 further comprising isolated bacteria from at least 4 different species wherein the bacteria comprise a 16S rDNA sequence selected from a sequence having at least 98.7% sequence identity with a nucleic acid sequence according to SEQ ID NO: 3 to 15.
4. The composition according to claim 1, further comprising isolated bacteria from at least 7 different species wherein the bacteria comprise a 16S rDNA sequence selected from a sequence having at least 98.7% sequence identity with a nucleic acid sequence according to SEQ ID NO: 3 to 15.
5. The composition according to claim 1, further comprising a bacterial isolate comprising a 16S rDNA sequence selected from a sequence having at least 98.7% sequence identity with a nucleic acid sequence according to SEQ ID NO: 7.
6. The composition according to claim 1 comprising a consortium selected from consortia 1 to 4 or 6 to 10 as shown in Table 3.
7. The composition according to any preceding claim, wherein said composition is formulated for oral or rectal administration.
8. The composition according to claim 7, wherein said composition is in the form of a capsule, tablet, gel or liquid.
9. The composition according to claim 8, wherein said composition is encapsulated in an enteric coating.
10. The composition according to any preceding claim, wherein the composition comprises live, attenuated or killed bacteria.
11. The composition according to any preceding claim, wherein the composition comprises bacterial spores.
12. The composition according to any of claims 1 to 11, wherein the composition does not comprise bacterial spores.
13. The composition according to any preceding claim, wherein the composition comprises bacterial strains that originate from one or more human donor.

14. The composition according to any preceding claim, wherein the bacteria are lyophilized.
15. The composition according to any preceding claim, wherein the composition comprises at least about 1×10^3 to 1×10^{13} CFU of bacteria.
16. The composition according to any preceding claim, wherein administration of the composition induces an immune response in a subject and/or increases the efficacy of an anti cancer therapy that includes an immune checkpoint inhibitor.
17. A pharmaceutical composition comprising a composition of any of claims 1 to 16 and a pharmaceutical carrier.
18. The pharmaceutical composition according to claim 17, further comprising an effective amount of an immune checkpoint inhibitor or a vaccine.
19. The pharmaceutical composition according to claim 18, wherein the immune checkpoint inhibitor inhibits PD-1, PDL-1, CTLA-4, LAG3 or TIM-3 activity.
20. The pharmaceutical composition according to claim 19 wherein the immune checkpoint inhibitor is an anti PD-1, PDL-1 or CTLA-4 antibody or fragment thereof.
21. The pharmaceutical composition according to claim 20 wherein the anti PD-1, PDL-1 or CTLA4 antibody is selected from nivolumab, pembrolizumab, cemiplimab, avelumab, durvalumab, atezolizumab, spartalizumab, camrelizumab, sintilimab, tislelizumab, pidilizumab toripalimab, Ipilimumab or Tremelimumab.
22. The pharmaceutical composition according to claim 18, wherein the immune checkpoint inhibitor is an interfering nucleic acid molecule, a small molecule or PROteolysis TARgeting Chimera (PROTAC), alternative protein scaffold or other immune checkpoint inhibitor.
23. The pharmaceutical composition according to claim 22, wherein the interfering nucleic acid molecule is an siRNA molecule, an shRNA molecule or an antisense RNA molecule.
24. A composition according to any of claims 1 to 16, or a pharmaceutical composition of any of claims 17 to 23 for use in the treatment of disease.
25. A composition according to any of claims 1 to 16, or a pharmaceutical composition of any of claims 17 to 23 for use in the treatment of cancer or an infectious disease or for use as a vaccine adjuvant or for increasing the efficacy of a cancer treatment.
26. A method for treating cancer or an infectious disease in a subject in need thereof, comprising administering a composition according to any of claims 1 to 17 or a pharmaceutical composition of claim 17, to said subject.
27. The method of claim 26 wherein said subject is receiving, has received or will receive therapy with an immune checkpoint inhibitor, thereby treating the cancer or infectious disease.
28. A method for treating cancer in a subject in need thereof comprising administering a composition according to claim 18 to said subject.
29. The method according to claim 26 or 27, wherein administration of the composition enhances an immune response by the subject and/or inhibits immune evasion by the cancer and/or increases efficacy of an anti cancer treatment with an immune checkpoint inhibitor.

30. The composition for use according to claim 25, or the method according to any of claims 26 to 29 wherein the cancer is selected from melanoma melanoma, such as Harding-Passey melanoma, juvenile melanoma, lentigo maligna melanoma, malignant melanoma, acral-lentiginous melanoma, amelanotic melanoma, benign juvenile melanoma, Cloudman's melanoma, S91 melanoma, nodular melanoma, subungual melanoma, Cutaneous melanoma, uveal/intraocular melanoma and superficial spreading melanoma or bone cancer, pancreatic cancer, skin cancer, cancer of the head or neck, cutaneous or intraocular malignant melanoma, uterine cancer, ovarian cancer, rectal cancer, cancer of the anal region, stomach cancer, testicular cancer, breast cancer, brain cancer, carcinoma of the fallopian tubes, carcinoma of the endometrium, carcinoma of the cervix, carcinoma of the vagina, carcinoma of the vulva, cancer of the esophagus, cancer of the small intestine, cancer of the endocrine system, cancer of the thyroid gland, cancer of the parathyroid gland, cancer of the adrenal gland, kidney cancer, sarcoma of soft tissue, cancer of the urethra, cancer of the bladder, renal cancer, lung cancer, non-small cell lung cancer, thymoma, urothelial carcinoma leukemia, prostate cancer, mesothelioma, adrenocortical carcinoma, lymphomas, such as such as Hodgkin's disease, non-Hodgkin's, gastric cancer, and multiple myelomas.
31. The composition for use according to claim 25 or the method according to any of claims 26 to 29, wherein the composition or pharmaceutical composition is administered by oral administration or rectal administration.
32. The composition for use according to claim 25 or the method according to any of claims 26 to 29, wherein said subject has received prior anti cancer therapy with an immune checkpoint inhibitor.
33. The composition for use according to claim 25 or the method according to any of claims 26 or 29 further comprising administering an anti cancer therapy with an immune checkpoint inhibitor.
34. The composition for use or method according to claim 33, wherein the immune checkpoint inhibitor is administered before, after or at the same time as the bacterial formulation.
35. The composition for use or method according to claim 33 or 34, wherein the immune checkpoint inhibitor is administered by injection.
36. The composition for use or method according to any of claims 33 to 35, wherein the injection is an intravenous, intramuscular, intratumoural or subcutaneous injection.
37. The composition for use or method according to any of claims 33 to 36 wherein the immune checkpoint inhibitor inhibits PD-1, PDL-1 or CTLA-4 activity.
38. The composition for use or method according to claim 37, wherein the immune checkpoint inhibitor is an anti PD-1, PDL-1 or CTLA-4 antibody.
39. The composition for use method according to claim 38, wherein the anti PD-1, PDL-1 or CTLA4 antibody is selected from nivolumab, pembrolizumab, cemiplimab, avelumab, durvalumab, atezolizumab, Spartalizumab, Camrelizumab, Sintilimab, Tislelizumab, Pidilizumab, Toripalimab, Ipilimumab or Tremelimumab.

40. The composition for use or method according to any of claims 33 to 37, wherein the immune checkpoint inhibitor is an interfering nucleic acid molecule, a small molecule or PROteolysis TArgeting Chimera (PROTAC) or other immune checkpoint inhibitor.
41. The composition for use or method according to claim 40, wherein the interfering nucleic acid molecule is an siRNA molecule, an shRNA molecule or an antisense RNA molecule or a small molecule or peptide.
42. The composition for use according to claim 25 or 30 to 41, or the method according to any of claims 26 to 41, further comprising surgical, radiation, and/or chemotherapeutic cancer intervention or administration of a second anti cancer therapeutic.
43. The composition for according to claim 25 or 30 to 42 or method according to any of claims 26 to 42, further comprising administering to the subject an antibiotic.
44. The composition for use according to claim 25 or 30 to 43 or method according to any of claims 26 to 43, wherein the subject is identified as at risk of developing a cancer.
45. A kit comprising a composition according to any of claims 1 to 17, and optionally an anti cancer treatment that includes an immune checkpoint inhibitor.
46. A food product or a vaccine adjuvant comprising the composition of any of claims 1 to 17.
47. A method for treating faecal transplant prior to administration to a subject comprising supplementing the faecal transplant with isolated bacteria selected from at least two species wherein the bacteria from the first species comprise a 16S rDNA sequence having at least 98.7% sequence identity with a nucleic acid sequence according to SEQ ID NO: 1, and the bacteria from the second species comprise a 16S rDNA sequence having at least 98.7% sequence identity with a nucleic acid sequence according to SEQ ID NO: 2.
48. A use of a composition of any of claims 1 to 17 or a pharmaceutical composition of claim 18, in increasing efficacy of an anti cancer treatment with an immune checkpoint inhibitor.
49. A use of a composition of any of claims 1 to 17 or a pharmaceutical composition of claim 18, in enhancing immune checkpoint blockade.
50. A method for enhancing immune checkpoint blockade comprising administering a composition of any of claims 1 to 17 or a pharmaceutical composition of claim 18.
51. A composition comprising a bacterium selected from one or more bacteria selected from Table 1.
52. A method for treating or preventing cancer comprising modulating the level of one or more bacteria selected from those of Table 1 in a subject.