CLAIMS

1. Use of a recombinant *Listeria* strain comprising a recombinant nucleic acid, said recombinant nucleic acid comprising a first open reading frame encoding a polypeptide comprising a truncated LLO, in the manufacture of a medicament for increasing a T-infiltrating lymphocyte/suppressor cell ratio in a subject having a tumor or cancer and treating said tumor or cancer in said subject.

2. Use of a recombinant *Listeria* strain comprising a recombinant nucleic acid, said recombinant nucleic acid comprising a first open reading frame encoding a polypeptide comprising a truncated LLO, in the manufacture of a medicament for enhancing an immune response against a tumor or cancer in a subject in an antigen-independent manner and treating said tumor or cancer in said subject, wherein said Listeria increases a T-infiltrating lymphocyte/suppressor cell ratio in said subject.

3. The use according to claim 1 or 2, wherein said T-infiltrating lymphocyte is a CD8+ T cell or a CD4+ T cell.

4. The use according to claim 1 or 2, wherein said suppressor cell is a T-regulatory cell (Treg) or a myeloid-derived suppressor cell (MDSC).

5. The use according to claim 1, wherein said polypeptide further comprises a heterologous antigen or a functional fragment thereof, wherein, optionally, said heterologous antigen or functional fragment thereof is expressed by or derived from a tumor cell.

6. The use according to claim 1 or 2, wherein said nucleic acid further comprises an additional open reading frame encoding a metabolic enzyme, wherein said metabolic enzyme complements an endogenous gene that is lacking in the chromosome of said recombinant *Listeria* strain.

7. The use according to claim 6, wherein said metabolic enzyme encoded by said additional open reading frame is an alanine racemase enzyme or a D-amino acid transferase enzyme.

8. The use according to claim 1 or 2, wherein said recombinant *Listeria* comprises a mutation or a deletion of a genomic *ActA* gene, a *PlcA* gene, *PrfA* gene or a *PlcB* gene.

9. The use according to claim 1 or 2, wherein said nucleic acid is integrated into the *Listeria* genome, or is in a plasmid that is stably maintained in said recombinant *Listeria* vaccine strain in the absence of antibiotic selection.

10. The use according to claim 5, wherein said antigen is associated with the local tissue environment that is further associated with the development or metastasis of cancer, or is associated with tumor evasion or resistance to cancer, or is an angiogenic antigen.

11. The use according to claim 1 or 2, wherein increasing the T-infiltrating lymphocytes/suppressor cell ratio in a subject reduces the percentage of suppressor cells in said tumor or cancer.

12. The use according to claims 1, 2 or 10, wherein said tumor or cancer is localized to a specific site or is systemic.

13. The recombinant *Listeria* strain for use according to claims 1, 2 or 10, wherein said tumor or cancer is a prostate tumor or cancer, a cervical tumor or cancer, a breast tumor or cancer, a Her2 containing tumor or cancer, a gastric tumor or cancer, a tumor or cancer of the pancreas, or a head and neck tumor or cancer.

14. The use according to claim 11, wherein reducing the number of suppressor cells at a tumor site enhances an anti-tumor immune response in said subject having said tumor or cancer.

15. The use according to claims 1 or 2, wherein said subject is human.

16. The use according to claim 4, wherein said suppressor cells suppress an anti-tumor T cell response in a subject.

CLAIMS

1. Use of a recombinant *Listeria* strain comprising a recombinant nucleic acid, said recombinant nucleic acid comprising a first open reading frame encoding a truncated LLO polypeptide, for the preparation of a medicament for reducing suppression of activated T cells by T regulatory (Treg) suppressor cells in an antigen non-specific manner in a subject having a disease or a disease site.

2. The use according to claim 1, wherein said suppression of activated T cells comprises suppression of T cell replication of the activated T cells.

3. The use according to claim 1 or 2, wherein said activated T cells are CD8+ T cells or CD4+ T cells.

4. The use according to any one of claims 1 to 3, wherein said reducing suppression of activated T-cells by suppressor cells further comprises reducing suppression in an antigen specific manner.

5. The use according to claim 4, wherein said polypeptide further comprises a heterologous antigen or a functional fragment thereof.

6. The use according to claim 5, wherein said heterologous antigen or functional fragment thereof is expressed by or derived from a tumor or cancer cell.

7. The use according to claim 5, wherein said heterologous antigen or functional fragment thereof is expressed by or derived from an infectious pathogen.

8. The use according to claim 7, wherein said infectious pathogen is a malaria parasite.

9. The use according to claim 5 or 6, wherein said heterologous antigen is associated with the local tissue environment and wherein said heterologous antigen is further associated with the development or metastasis of cancer, or is associated with

tumor evasion or resistance to cancer, or is an angiogenic antigen, or is an allergen that causes an allergic, inflammatory reaction in a host.

10. Use of a recombinant *Listeria* strain comprising a recombinant nucleic acid, said recombinant nucleic acid comprising a first open reading frame encoding a truncated LLO polypeptide, for the preparation of a medicament for increasing a T-infiltrating lymphocyte/ MDSC ratio in an antigen independent manner in a subject having a disease or a disease site.

11. The use according to claim 10, wherein said MDSC cells at said disease site are less suppressive following administration of said *Listeria* strain.

12. The use according to claim 11, wherein said suppression by said MDSCs comprises suppression of activated T cell replication.

13. The use according to any one of claims 10 to 12, wherein reducing the number of suppressor cells at said disease site enhances an immune response in said subject having said disease or disease site.

14. The use according to any one of claims 10 to 12, wherein said increasing said ratio comprises reducing the percentage of myeloid-derived suppressor cells (MDSC) cells, or increasing the percentage of said T-infiltrating lymphocytes, or any combination thereof.

15. The use according to any one of claims 1 to 14, wherein said suppressor cells suppress an anti-disease T cell response.

16. The use according to any one of claims 1 to 15, wherein said nucleic acid further comprises an additional open reading frame encoding a metabolic enzyme, wherein said metabolic enzyme complements an endogenous gene that is lacking in the chromosome of said recombinant *Listeria* strain.

17. The use according to claim 16, wherein said metabolic enzyme encoded by said additional open reading frame is an alanine racemase enzyme or a D-amino acid transferase enzyme.

18. The use according to any one of claims 1 to 17, wherein said recombinant *Listeria* comprises a mutation or a deletion of a genomic ActA gene, a PlcA gene, a PrfA gene or a PlcB gene.

19. The use according to any one of claims 1 to 18, wherein said nucleic acid is integrated into the *Listeria* genome, or is in a plasmid that is stably maintained in said recombinant *Listeria* vaccine strain in the absence of antibiotic selection.

20. The use according to any one of claims 1 to 19, wherein said disease is localized to a specific site or is a systemic disease.

21. The use according to any one of claims 1 to 20, wherein said disease is an infectious disease, a respiratory disease, an inflammatory disease, or a cancer or tumor.

22. The use according claim 21, wherein said tumor or cancer is a prostate tumor or cancer, a cervical tumor or cancer, a breast tumor or cancer, a Her2 containing tumor or cancer, a gastric tumor or cancer, a tumor or cancer of the pancreas, or a head and neck tumor or cancer.

23. The use according to claim 21, wherein said respiratory disease or said inflammatory disease is asthma.

24. The use according to any one of claims 1 to 23, wherein said subject is human.

25. The use according to any one of claims 1 to 24, wherein said medicament further comprises other therapeutic modalities useful for enhancing an immune response.