CLAIMS

What is claimed is:

1. A method of increasing a T infiltrating lymphocytes/suppressor cell ratio in a subject having a disease or in a disease site within the subject, the method comprising the step of administering to the subject a composition comprising a live attenuated *Listeria* vaccine strain.

2. The method of claim 1, wherein said T infiltrating lymphocyte is a CD8+ T cell or a CD4+ T cell.

3. The method of any one of claims 1-2, wherein said suppressor cell is a T regulatory cell (Treg) or a myeloid-derived suppressor cell (MDSC).

4. The method of any one of claims 1-3, wherein said *Listeria* comprises a recombinant nucleic acid sequence comprising an open reading frame each encoding a polypeptide or a functional fragment thereof, wherein said polypeptide or functional fragment thereof is an endogenous PEST-containing polypeptide.

5. The method of any one of claims 1-3, wherein said *Listeria* comprises a recombinant nucleic acid sequence comprising a first and at least a second open reading frame each encoding a first and at least a second polypeptide, wherein said first and said second polypeptide each comprise a heterologous antigen or a functional fragment thereof fused to an endogenous PEST-containing polypeptide.

6. The method of claim 5, wherein said nucleic acid further comprises a third open reading frame encoding a third polypeptide, wherein said third polypeptide comprises a heterologous antigen or a functional fragment thereof fused to an endogenous PEST-containing polypeptide.

7. The method of any one of claims 1-3, or 5-6, wherein said first, said second or said third heterologous antigen or functional fragment thereof is expressed by or derived from an infectious pathogen, or a tumor cell.

8. The method of any one of claims 1-7, wherein said nucleic acid molecule 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.

9. The method of claim 8, wherein said metabolic enzyme encoded by said additional open reading frame is an alanine racemase enzyme.

10. The method of any one of claims 1-9, wherein said *Listeria* further comprises an additional open reading frame encoding a second metabolic enzyme.

11. The method of claim 10, wherein said metabolic enzyme is a D-amino acid transferase enzyme.

12. The method of any one of claims 1-11, wherein said recombinant *Listeria* comprises a mutation or a deletion of a genomic *ActA* gene, a *PlcA* gene, *PrfA* gene or a *PlcB* gene.

13. The method of any one of claims 1-12, wherein said nucleic acid molecule is integrated into the *Listeria* genome.

14. The method of any one of claims 1-13, wherein said nucleic acid molecule is in a plasmid that is stably maintained in said recombinant *Listeria* vaccine strain in the absence of antibiotic selection.

15. The method of any one of claims 1-14, wherein said PEST-containing polypeptide is an N-terminal truncated LLO polypeptide, an N-terminal ActA polypeptide, or PEST-peptide, or a functional fragment thereof.

16. The method of any one of claim 1-3 or 5-16, wherein said first, said second or said third antigen is associated with the local tissue environment that is further associated with the development or metastasis of cancer, is associated with tumor evasion or resistance to cancer, is an angiogenic antigen, or is an allergen that causes an allergic, inflammatory reaction in a host

17. The method of any one of claims 1-16, wherein said disease is localized to a specific disease site or wherein said disease is systemic.

18. The method of any one of claims 1-17, wherein said disease is an infectious disease, a respiratory or inflammatory disease, or a cancer or tumor.

19. The method of any one of claims 1-18, wherein said respiratory or inflammatory disease is asthma.

20. The method of any one of claims 1-19, wherein reducing the number of said suppressor cells at a tumor site enhances an anti-tumor immune response in said subject having said tumor.

21. The method of any one of claims 1-20, wherein said subject is human.

22. A method of reducing the percentage of suppressor cells in a disease in a subject, the method comprising the step of administering a live attenuated *Listeria* vaccine strain to said subject.

23. The method of claim 22, wherein said *Listeria* comprises a recombinant nucleic acid sequence comprising an open reading frame each encoding a polypeptide or a functional fragment thereof, wherein said polypeptide or functional fragment thereof is an endogenous PEST-containing polypeptide.

24. The method of claim 22 wherein said *Listeria* comprises a recombinant nucleic acid sequence comprising a first and at least a second open reading frame each encoding a first and at least a second polypeptide, wherein said first and said second polypeptide each comprise a heterologous antigen or a functional fragment thereof fused to an endogenous PEST-containing polypeptide.

25. The method of claim 24, wherein said nucleic acid further comprises a third open reading frame encoding a third polypeptide, wherein said third polypeptide comprises a heterologous antigen or a functional fragment thereof fused to an endogenous PEST-containing polypeptide.

26. The method of claim 22-25, wherein said nucleic acid molecule 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.

27. The method of claim 26, wherein said metabolic enzyme encoded by said additional open reading frame is an alanine racemase enzyme.

28. The method of any one of claims 22-27, wherein said *Listeria* further comprises an additional open reading frame encoding a second metabolic enzyme.

29. The method of claim 28, wherein said metabolic enzyme is a D-amino acid transferase enzyme.

30. The method of any one of claims 22-29, wherein said recombinant *Listeria* comprises a mutation or a deletion of a genomic *ActA* gene, a *PlcA* gene, *PrfA* gene or a *PlcB* gene.

31. The method of any one of claims 22-30, wherein said nucleic acid molecule is integrated into the *Listeria* genome.

32. The method of any one of claims 22-31, wherein said nucleic acid molecule is in a plasmid that is stably maintained in said recombinant *Listeria* vaccine strain in the absence of antibiotic selection.

33. The method of any one of claims 22-32, wherein said subject is a human.

34. The method of any one of claims 22-33, wherein said PEST-containing polypeptide is an N-terminal truncated LLO polypeptide, an N-terminal ActA polypeptide, or PEST-peptide, or a functional fragment thereof.

35. The method of any one of claims 22 or 24-34, wherein said first, said second or said third heterologous antigen or functional fragment thereof is expressed by or derived from an infectious pathogen, or a tumor cell.

36. The method of any one of claims 22 or 24-35, wherein said first, said second or said third antigen is associated with the local tissue environment that is further associated with the development or metastasis of cancer, is associated with tumor evasion or resistance to cancer, is an angiogenic antigen or is an allergen that causes an allergic inflammatory reaction in a host.

37. The method of any one of claims 22-36, wherein said disease is localized to a specific disease site or wherein said disease is systemic.

38. The method of any one of claims 22-37, wherein said disease is an infectious disease, a respiratory or inflammatory disease, or a cancer or tumor.

39. The method of claim 38, wherein said respiratory or inflammatory disease is asthma.

40. The method of any one of claims 22-39, wherein reducing the number of said suppressor cells at a tumor site enhances an anti-tumor immune response in said subject having said tumor.

41. The method of any one of claims 22-40, wherein said suppressor cells are T regulatory cells (Tregs).

42. The method of any one of claims 22-41, wherein said suppressor cells are myeloid-derived suppressor cells (MDSCs).

43. The method of any one of claims 22-42, 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 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.