Claims

1. Use of a recombinant attenuated Listeria strain comprising a nucleic acid comprising a first open reading frame encoding a fusion polypeptide, said fusion polypeptide comprising a Her-2/neu chimeric antigen fused to an additional polypeptide, said nucleic acid further comprising a second open reading frame encoding a metabolic enzyme, wherein said metabolic enzyme complements an endogenous gene that is mutated in the chromosome of said recombinant attenuated Listeria strain, in the preparation of a medicament for treating a Her-2/neu-expressing tumor growth or cancer in a subject, wherein said medicament comprising an effective dose of said recombinant attenuated Listeria strain is to be administered to said subject in combination with administration of radiation therapy, wherein said tumor growth or cancer is osteosarcoma or pulmonary metastasis, and wherein the administration of said radiation therapy comprises at least two administrations of said radiation therapy.

2. The use of claim 1, wherein said Her-2/neu chimeric antigen is encoded by the sequence set forth in SEQ ID NO: 2.

3. The use of any one of claims 1-2, wherein said subject is a human adult, human child or a canine.

4. The use of any one of claims 1-3, wherein said Her-2/neu chimeric antigen comprises at least 5, 9, 13, 14, or 17 of the mapped human MHC-class I epitopes or comprises at least 5, 9, 13, 14, or 17 of the canine MHC-class I epitopes.

5. The use of any one of claims 1-4, wherein said nucleic acid molecule is integrated into the Listeria genome.

6. The use of any one of claims 1-5, wherein said nucleic acid molecule is in a plasmid in said recombinant attenuated Listeria strain and wherein said plasmid is stably maintained in said recombinant attenuated Listeria strain in the absence of antibiotic selection.

7. The use of any one of claims 1-6, wherein said recombinant Listeria comprises a deletion in the actA virulence gene.

8. The use of any one of claims 1-7, wherein said additional polypeptide is selected from the group consisting of: a) a non-hemolytic LLO protein or N-terminal fragment, b) a PEST sequence, or c) an ActA fragment.

9. The use of any one of claims 1-8, wherein said metabolic enzyme encoded by said second open reading frame is an alanine racemase enzyme or a D-amino acid transferase enzyme.

10. The use of any one of claims 1-9, wherein administration of said radiation therapy is prior to administration of said medicament comprising said recombinant attenuated Listeria strain, or wherein said administration of radiation therapy is on 2 consecutive days in 8Gy doses each for a total of 16 Gy.

11. The use of any one of claims 1-10, wherein said recombinant attenuated Listeria strain is ADXS31-164.

12. The use of any one of claims 1-11, wherein said recombinant attenuated Listeria is to be administered multiple times at a dose of $3.3x10^9$ CFU per administration, or wherein said recombinant attenuated Listeria is for administration from one and up to 8 times every 3 weeks.

13. The use of claim 12, wherein a further booster treatment is to be administered.

14. The use of claim 13, wherein said booster treatment is to be administered every two months.

15. The use of any one of claims 1-14, wherein said medicament comprising said recombinant attenuated Listeria strain is to be administered with an independent adjuvant, wherein said adjuvant comprises a granulocyte/macrophage colony-stimulating factor (GM-CSF) protein, a nucleotide molecule encoding a GM-CSF protein, saponin QS21, monophosphoryl lipid A, or an unmethylated CpG-containing oligonucleotide.

16. The use of any one of claims 1-15, wherein said tumor growth or cancer is a relapse or metastasis.

17. The use of any one of claims 1-16, wherein said for treating comprises prolonging survival in the subject suffering from said Her-2/neu-expressing tumor or comprises delaying metastatic disease.