CLAIMS

1. A combination of an antagonist of a Programmed Death 1 protein (PD-1) and a live-attenuated bacterial strain for use in the treatment of prostate cancer, wherein the antagonist of PD-1 is an anti-PD-1 monoclonal antibody comprising a heavy chain and a light chain which comprise SEQ ID NO: 21 and SEQ ID NO: 22, respectively, wherein the live-attenuated bacterial strain is a bioengineered *Listeria monocytogenes* strain transformed with an expression vector to express a PSA antigen fused to a truncated Listeriolysin O (tLLO), and wherein the live-attenuated bacterial strain stimulates Antigen Presenting Cells (APCs) capable of driving a cellular immune response to PSA expressing cells, wherein said tLLO-PSA fusion polypeptide consists of the sequence of SEQ ID NO: 54 or a sequence having at least 99% sequence identity to SEQ ID NO: 54.

2. The combination of claim 1, wherein said tLLO enhances the immunogenicity of the fusion polypeptide.

3. The combination of claim 1, wherein the live-attenuated-*Listeria monocytogenes* strain comprises an LmddA-142 (104035 $dal^{(-)}$ $dat^{(-)}$ $actA^{(-)}$ *pADV142)* strain.

4. The combination of claim 1, wherein the live-attenuated *Listeria monocytogenes* strain comprises a LmddA-143 (104035 $dal^{(-)}$ $dat^{(-)}$ $actA^{(-)}$ *with klk3* fused to the *hly* gene in the chromosome) strain.

5. The combination of any of claims 1 to 4, wherein the PD-1 antagonist and the live-attenuated bacterial strain are administered simultaneously or sequentially.

6. The combination of claims 1-4 or 5, wherein the prostate cancer is metastatic Castration-Resistant Prostate Cancer (mCRPC).

7. The combination of claims 1-5 or 6, further comprising an adjuvant, wherein said adjuvant comprises Montanide ISA 51, GM-CSF, KLH, a cytokine, a growth factor, a cell population, QS21, Freund's incomplete adjuvant, aluminum phosphate, aluminum hydroxide, BCG, alum, an interleukin, an unmethylated CpG oligonucleotide, quill glycosides, monophosphoryl lipid A, a liposomes, a bacterial mitogen, a bacterial toxin, or a chemokine, or any combination thereof.

8. A medicament comprising an antagonist of a Programmed Death 1 protein (PD-1) and a live-attenuated bacterial strain for treating a patient diagnosed with a prostate cancer, wherein the antagonist of PD-1 is an anti-PD-1 monoclonal antibody comprising a heavy chain and a light chain which comprise SEQ ID NO: 21 and SEQ ID NO: 22, respectively, wherein the live-attenuated bacterial strain is a bioengineered *Listeria monocytogenes* strain transformed with an expression vector to express a PSA antigen fused to a truncated Listeriolysin O (tLLO), and wherein the live attenuated bacterial strain stimulates Antigen Presenting Cells (APCs) capable of driving a cellular immune response to PSA expressing cells, and wherein said tLLO-PSA fusion polypeptide consists of the sequence of SEQ ID NO: 54 or a sequence having at least 99% sequence identity to SEQ ID NO: 54.

9. The medicament of claim 8, wherein said tLLO enhances the immunogenicity of the fusion polypeptide.

10. The medicament of claim 8, wherein the live-attenuated *Listeria monocytogenes* strain comprises an LmddA-142 (10403S $dal^{(-)}$ $dat^{(-)}$ $actA^{(-)}$ *pADV142)* strain.

11. The medicament of claim 8, wherein the live-attenuated *Listeria monocytogenes* strain comprises an LmddA-143 (10403S $dal^{(-)}$ $dat^{(-)}$ $actA^{(-)}$ with *klk3* fused to the *hly* gene in the chromosome) strain.

12. The medicament of any of claims 8 to 11, further comprising an adjuvant, wherein said adjuvant comprises Montanide ISA 51, GM-CSF, KLH, a cytokine, a growth factor, a cell population, QS21, Freund's incomplete adjuvant, aluminum phosphate, aluminum hydroxide, BCG, alum, an interleukin, an unmethylated CpG oligonucleotide, quill glycosides, monophosphoryl lipid A, a liposomes, a bacterial mitogen, a bacterial toxin, or a chemokine, or any combination thereof.

13. The medicament of claim 8, wherein the anti-PD-1 monoclonal antibody is formulated as a liquid medicament which comprises 7% (w/v) sucrose, 0.02% (w/v) polysorbate 80 in 10 mM histidine buffer pH 5.5.

14. The medicament of claims 8-12 or 13, wherein the cancer is metastatic Castration-Resistant Prostate Cancer (mCRPC).

15 The medicament of claims 8-13 or 14, wherein the prostate cancer tests positive for PD-L1 expression.

16. The medicament of claims 8-14 or 15, wherein the PD-1 antagonist ispembrolizumab.

17. A kit, which comprises a first container, a second container and a package insert,

wherein the first container comprises at least one dose of a medicament comprising an antagonist of a Programmed Death 1 protein (PD-1), wherein the antagonist of PD-1 is an anti-PD-1 monoclonal antibody, wherein the live-attenuated bacterial strain is a *bioengineered Listeria monocytogenes* strain transformed with an expression vector to express a PSA antigen fused to a truncated Listeriolysin O (tLLO),

wherein the second container comprises at least one dose of a medicament comprising a live-attenuated bacterial strain, and

wherein the package insert comprises instructions for treating a patient for prostate cancer using the medicaments.

18. The kit of claim 17, wherein the anti-PD-1 monoclonal antibody comprises a heavy chain and a light chain which comprise SEQ ID NO:21 and SEQ ID NO: 22, respectively.

19. The kit of claim 18, wherein said tLLO-PSA fusion polypeptide consists of the sequence of SEQ ID NO: 54 or a sequence having at least 99% sequence identity to SEQ ID NO: 54, wherein said tLLO enhances the immunogenicity of the fusion polypeptide.

20. The kit of claim 18, wherein the live-attenuated *Listeria monocytogenes* comprises an LmddA-142 (104035 $dal^{(-)}$ $dat^{(-)}$ $actA^{(-)}$ *pADV142)* strain.

21. The kit of claim 18, wherein the live-attenuated *Listeria monocytogenes* comprises an LmddA-143 (10403S $dal^{(-)}$ $dat^{(-)}$ $actA^{(-)}$ with *klk3* fused to the *hly* gene in the chromosome) strain.

22. The kit of any of claims 17 to 21, further comprising an adjuvant, wherein said adjuvant comprises Montanide ISA 51, GM-CSF, KLH, a cytokine, a growth factor, a cell population, QS21, Freund's incomplete adjuvant, aluminum phosphate, aluminum hydroxide, BCG, alum, an interleukin, an unmethylated CpG oligonucleotide, quill

glycosides, monophosphoryl lipid A, a liposomes, a bacterial mitogen, a bacterial toxin, or a chemokine, or any combination thereof.

23. The kit of any of claims 17 to 22, wherein the instructions state that the medicaments are intended for use in treating a patient having a prostate cancer that tests positive for PD-L1 expression by an immunohistochemical (IHC) assay.

24. The kit of claims 17-22 or 23, wherein the prostate cancer is metastatic Castration-Resistant Prostate Cancer (mCRPC).

25. The kit of claim 22, wherein the PD-1 antagonist and the live-attenuated bacterial strain are to be administered simultaneously or sequentially.