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 live-attenuated bacterial strain stimulates Antigen Presenting Cells (APCs) capable of driving a cellular immune response to PSA expressing cells.

2. The combination of claim 1, wherein the antagonist of a Programmed Death 1 protein (PD-1) is an anti-PD-1 monoclonal antibody, wherein a heavy chain and a light chain comprise SEQ ID NO: 21 and SEQ ID NO: 22, respectively, and 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).

3. The combination of claim 2, wherein said tLLO-PSA fusion polypeptide consists of the sequence of SEQ ID NO: 54 or a sequence at least 99% homologous thereto, wherein said tLLO enhances the immunogenicity of the fusion polypeptide.

4. The combination of claim 2, wherein the live-attenuated-*Listeria monocytogenes* strain comprises an LmddA-142 (104035 $dal^{(-)}$ $dat^{(-)}$ $actA^{(-)}$ *pADV142)* strain.

5. The combination of claim 2, 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.

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

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

8. The combination of claims 1-6 or 7, wherein said strain is administered with 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.

9. A medicament comprising an antagonist of a Programmed Death 1 protein (PD-1) for use in combination with a live-attenuated bacterial strain for treating a patient diagnosed with a prostate cancer, wherein the live attenuated bacterial strain stimulates Antigen Presenting Cells (APCs) capable of driving a cellular immune response to PSA expressing cells.

10. The medicament of claim 9, wherein the antagonist of a Programmed Death 1 protein (PD-1) is an anti-PD-1 monoclonal antibody, wherein a heavy chain and a light chains comprise SEQ ID NO: 21 and SEQ ID NO: 22, respectively, and 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).

11. The medicament of claim 10, wherein said tLLO-PSA fusion polypeptide consists of the sequence of SEQ ID NO: 54 or a sequence at least 99% homologous thereto, wherein said tLLO enhances the immunogenicity of the fusion polypeptide.

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

13. The medicament of claim 10, 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.

14. The medicament of any of claims 9 to 13, wherein said strain is administered with 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.

15. The medicament of claim 10, 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.

16. The medicament of claims 9-14 or 15, wherein the cancer is metastatic Castration-Resistant Prostate Cancer (mCRPC).

17. The medicament of claims 9-15 or 16, wherein the prostate cancer tests positive for PD-L1 expression.

18. The medicament of claims 9-16 or 17, wherein the PD-1 antagonist is MK-3475.

19. 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), the second container comprises at least one dose of a medicament comprising a live-attenuated bacterial strain, and the package insert comprises instructions for treating a patient for prostate cancer using the medicaments.

20. The kit of claim 19, wherein the antagonist of a Programmed Death 1 protein (PD-1) is an anti-PD-1 monoclonal antibody comprising a heavy chain and a light chain SEQ ID NO:21 and SEQ ID NO: 22, respectively, and 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).

21. The kit of claim 20, wherein said tLLO-PSA fusion polypeptide consists of the sequence of SEQ ID NO: 54 or a sequence at least 99% homologous thereto wherein said tLLO enhances the immunogenicity of the fusion polypeptide.

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

23. The kit of claim 20, 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.

24. The kit of any of claims 19 to 23, wherein said strain is administered with 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 .

25. The kit of any of claims 19 to 24, 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.

26. The kit of claims 19-24 or 25, wherein the prostate cancer is metastatic Castration-Resistant Prostate Cancer (mCRPC).