CLAIMS

1. Use of a combination of an antagonist of a Programmed Death 1 protein (PD-1) and a live-attenuated bacterial strain in the manufacture of a medicament for 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. Use of an antagonist of a Programmed Death 1 protein (PD-1) in the manufacture of a medicament for the treatment of prostate cancer, which is to be used in combination with a live-attenuated bacterial strain 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.

3. Use of a live-attenuated bacterial strain in the manufacture of a medicament for the treatment of prostate cancer, which is to be used in combination with an antagonist of a Programmed Death 1 protein (PD-1) 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 use of any one of claims 1-3, wherein said tLLO enhances the immunogenicity of the fusion polypeptide.

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

4. The use of any one of claims 1-3, 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 use of any one of the preceding claims, wherein the PD-1 antagonist and the live-attenuated bacterial strain are to be administered simultaneously or sequentially.

6. The use of any one of the preceding claims, wherein the prostate cancer is metastatic Castration-Resistant Prostate Cancer (mCRPC).

7. The use of any one of the preceding claims, 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, 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 one 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 any one of claims 8-13, wherein the cancer is metastatic Castration-Resistant Prostate Cancer (mCRPC).

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

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

17. Use of a kit, which comprises a first container, a second container and a package insert, in the manufacture of a medicament for the treatment of prostate cancer, 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, 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),

wherein the second container comprises at least one dose of a medicament comprising a live-attenuated bacterial strain, wherein the live-attenuated bacterial strain is able to stimulate 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,

wherein the contents of the first and second container are to be used as a combined preparation for the simultaneous, separate or sequential use in the treatment of the cancer, and

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

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

21. The use 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 use of any one 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 use of any one of claims 17 to 22, wherein the medicaments are to be used to treat a patient having a prostate cancer that tests positive for PD-L1 expression by an immunohistochemical (IHC) assay.

24. The use of any one of claims 17-23, wherein the prostate cancer is metastatic Castration-Resistant Prostate Cancer (mCRPC).