CLAIMS

1. The use of (i) a checkpoint inhibitor, and (ii) non-pathogenic whole cell heat killed *Mycobacterium*, in the manufacture of at least one medicament, for treating, reducing, inhibiting or controlling a neoplasia, tumour or cancer in a subject, wherein the checkpoint inhibitor is to be simultaneously, separately or sequentially administered to the subject with the *Mycobacterium*, wherein the combination of a checkpoint inhibitor and non-pathogenic whole cell heat killed *Mycobacterium* results in enhanced therapeutic efficacy relative to administration of the checkpoint inhibitor or *Mycobacterium* alone, wherein the *Mycobacterium* is non-pathogenic whole cell heat killed *Mycobacterium obuense,* and wherein the checkpoint inhibitor is selected from a cell, protein, peptide, antibody or antigen binding fragment thereof, that has blocking activity against PD-1 or PD-L1 or combinations thereof.

2. The use according to claim 1, wherein said checkpoint inhibitor is an antibody.

3. The use according to claim 1 or 2, wherein said blocking agent is present in a sub-therapeutic amount.

4. The use according to any of claims 1 to 3, wherein said neoplasia, tumour or cancer is selected from prostate cancer, liver cancer, renal cancer, lung cancer, breast cancer, colorectal cancer, pancreatic cancer, brain cancer, hepatocellular cancer, lymphoma, leukaemia, gastric cancer, cervical cancer, ovarian cancer, thyroid cancer, melanoma, head and neck cancer, skin cancer or sarcoma.

5. The use according to claim 4, wherein said neoplasia, tumour or cancer is pancreatic cancer.

6. The use according to claim 4, wherein said neoplasia, tumour or cancer is melanoma.

7. The use according to claim 4, wherein said neoplasia, tumour or cancer is breast cancer.

8. The use according to any of claims 1 to 5, wherein the neoplasia, tumour or cancer is metastatic.

9. The use according to claim 8, wherein the non-pathogenic heat-killed *Mycobacterium* is a rough variant.

10. The use according to claim 9, wherein the non-pathogenic heat-killed *Mycobacterium* is to be administered via the parenteral, oral, sublingual, nasal or pulmonary route.

11. The use according to claim 10, wherein the parenteral route is selected from subcutaneous, intradermal, subdermal, intraperitoneal, or intravenous.

12. The use according to claim 10, wherein the parenteral route does not comprise intratumoural injection.

13. The use according to any of claims 9 to 12, wherein the amount of non-pathogenic heat-killed *Mycobacterium* that is to be administered is from 10^7 to 10^9 cells.

14. The use according to claim 1, wherein enhanced therapeutic efficacy is to be measured by increased overall survival time.

15. The use according to claim 1, wherein enhanced therapeutic efficacy is to be measured by increased progression-free survival.

16. The use according to claim 1, wherein enhanced therapeutic efficacy is to be measured by a decrease or stabilisation of tumour size.

17. The use according to claim 1, wherein enhanced therapeutic efficacy is to be measured by increased quality of life.