CLAIMS

1. The use of a whole cell nonpathogenic heat-killed Mycobacterium, in combination with an mTOR inhibitor, in the manufacture of a medicament for the treatment of neoplastic disease.

2. The use of a whole cell nonpathogenic heat-killed Mycobacterium, in the manufacture of a first medicament and the use of an mTOR inhibitor in the manufacture of a second medicament, both medicaments for the combined treatment of neoplastic disease whereby each medicament is to be administered separately or sequentially.

3. The use according to claim 1 or claim 2, wherein said Mycobacterium is selected from M. vaccae, M.obuense, M. parafortuitum, M. aurum, M. indicus pranii, M. phlei and combinations thereof.

4. The use according to claim 3, wherein the Mycobacterium is a rough variant.

5. The use according to any preceding claim, wherein said mTOR inhibitor is selected from sirolimus, everolimus, ridaforolimus, temsirolimus or metformin, and combinations thereof.

6. The use according to claim 5, wherein said mTOR inhibitor is rapamycin (sirolimus).

7. The use according to any of claims 2-6, wherein said Mycobacterium is to be administered to a subject before, concurrently with and/or after said mTOR inhibitor is administered.

8. The use according to any preceding claim, wherein said Mycobacterium and/or mTOR inhibitor is to be administered in repeat doses.

9. The use according to any preceding claim, wherein said neoplastic disease is uterine cancer, prostate cancer, liver cancer, renal cancer, lung cancer, breast cancer, colorectal cancer, pancreatic cancer, brain cancer, hepatocellular cancer, lymphoma, leukemia, gastric cancer, cervical cancer, ovarian cancer, thyroid cancer, melanoma, carcinoma, head and neck cancer, skin cancer or soft tissue sarcoma.

10. The use according to claim 9, wherein said neoplastic disease is pancreatic cancer.

11. The use according to any preceding claim, wherein said treatment reduces the size of a cancerous tumour such that it is operable and/or reduces the formation of metastases.

12. The use according to any preceding claim, wherein the Mycobacterium is present in a unit dose comprising an effective amount of nonpathogenic heat-killed Mycobacterium rom 10^7 to 10^9 cells.

13. The use according to any preceding claim wherein the Mycobacterium is for administration via a parenteral, oral, sublingual, nasal or pulmonary route.

14. The use according to claim 13, wherein the parenteral route is selected from the group consisting of subcutaneous, intradermal, subdermal, intraperitonal, intravenous, and intravesicular injection.

15. The use according to claim 14, wherein the Mycobacterium is for administration via the intradermal route.