CLAIMS

1. An immunomodulator comprising a non-pathogenic heat-killed whole cell *Mycobacterium* for use in the treatment and/or control of a neoplastic disease in a patient intended to undergo immunogenic cell death therapy simultaneously, separately or sequentially with administration of the immunomodulator; wherein the *Mycobacterium* is selected from *M. vaccae, M. obuense* and combinations thereof.

~~2. The immunomodulator according to claim 1,~~; wherein said immunogenic cell death therapy is selected from microwave irradiation, targeted radiotherapy, embolisation, cryotherapy, ultrasound, high intensity focused ultrasound, cyberknife, hyperthermia, radiofrequency ablation, cryoablation, electrotome heating, hot water injection, alcohol injection, embolization, radiation exposure, photodynamic therapy, laser beam irradiation, and combinations thereof; wherein said immunogenic cell death therapy is to be carried out at a sub-optimal level that is not intended to fully remove or eradicate the tumour of said neoplastic disease.

~~3~~2. The immunomodulator according to claim 1~~ or 2~~, wherein the tumour is metastatic.

~~4~~3. The immunomodulator according to any preceding claim, wherein the non-pathogenic heat-killed *Mycobacterium* is the rough variant.

~~5~~4. The immunomodulator according to any preceding claim, wherein the non-pathogenic *heat*-killed *Mycobacterium* is for administration via the parenteral, oral, sublingual, nasal or pulmonary route.

~~6~~5. The immunomodulator according to claim ~~5~~4, wherein the parenteral route is selected from subcutaneous, intradermal, subdermal, intraperitonal, intravenous, or intravesicular injection.

~~7~~6. The immunomodulator according to claim ~~6~~5, wherein the parenteral route does not comprise intratumoural injection.

~~8~~7. The immunomodulator according to any preceding claim, wherein said immunogenic cell death therapy is by ionizing radiation.

~~9~~8. The immunomodulator according to any of the preceding claims, wherein administration of said immunomodulator is prior to and/or after the immunogenic cell death therapy.

~~10~~9. The immunomodulator according to claim ~~9~~8, wherein administration of said immunomodulator is between 4 weeks and 1 week prior to and/or after the immunogenic cell death therapy.

~~11~~10. The immunomodulator according to claim ~~10~~9, wherein said administration of immunomodulator comprises administration of one or more aliquots of an effective amount administered at one or more time intervals between about 4 weeks and 1 week prior to and/or after the immunogenic cell death therapy and continued to be applied to the patient after treatment for regression of the tumour.

~~12~~11. The immunomodulator of any preceding claim, wherein said immunomodulator is administered to said patient after immunogenic cell death of the tumour cells, and/or during stabilisation of the disease.

~~13~~12. The immunomodulator according to any of the preceding claims, wherein said tumour is associated with a cancer selected from prostate cancer, liver cancer, renal cancer, lung cancer, breast cancer, colorectal cancer, breast cancer, pancreatic cancer, brain cancer, hepatocellular cancer, lymphoma, leukaemia, gastric cancer, cervical cancer, ovarian cancer, thyroid cancer, melanoma, carcinoma, head and neck cancer, skin cancer and soft tissue sarcoma.

~~14~~13. The immunomodulator according to claim ~~13~~12, wherein said tumour is associated with colorectal cancer.

~~15~~14. The immunomodulator according to any preceding claim, wherein said therapy comprises an abscopal effect on a neoplastic disease in a patient.

~~16. A method of treating, inhibiting or controlling the development of a tumour in a subject, comprising undertaking immunogenic cell death therapy in a subject and the simultaneous, sequential or separate administration to said subject of an effective amount of an immunomodulator comprising a non-pathogenic heat-killed *Mycobacterium* selected from *M. vaccae, M. obuense* and combinations thereof.~~

~~17. The method according to claim 16, wherein the immunogenic cell death therapy is selected from microwave irradiation, radiofrequency ablation, targeted radiotherapy, embolisation, cryotherapy, ultrasound, high intensity focused ultrasound, cyberknife, hyperthermia, cryoablation, electrotome heating, hot water injection, alcohol injection, embolization, radiation exposure, photodynamic therapy, laser beam irradiation, and combinations thereof.~~

~~18. The method according to any of claims 16 to 17, wherein said tumour is as defined in any of claims 12 to 14.~~

~~19. The method according to any of claims 16 to 17, wherein said therapy comprises an abscopal effect on a neoplastic disease in a patient.~~

~~20. The method according to claim 20, wherein the immunomodulator is administered as defined in any of claims 4 to 9.~~

15. Use of an immunomodulator comprising a non-pathogenic heat-killed whole cell *Mycobacterium* in the manufacture of a medicament for treatment and/or control of a neoplastic disease in a patient intended to undergo immunogenic cell death therapy simultaneously, separately or sequentially with administration of the immunomodulator; wherein the *Mycobacterium* is selected from *M. vaccae*, *M. obuense* and combinations thereof; wherein said immunogenic cell death therapy is selected from microwave irradiation, targeted radiotherapy, embolisation, cryotherapy, ultrasound, high intensity focused ultrasound, cyberknife, hyperthermia, radiofrequency ablation, cryoablation, electrotome heating, hot water injection, alcohol injection, embolization, radiation exposure, photodynamic therapy, laser beam irradiation, and combinations thereof; wherein said immunogenic cell death therapy is to be carried out at a sub-optimal level that is not intended to fully remove or eradicate the tumour of said neoplastic disease.

16. The use according to claim 15, wherein the tumour is metastatic.

17. The use according to claim 15 or 16, wherein the non-pathogenic heat-killed *Mycobacterium* is the rough variant.

18. The use according to any of claims 15 to 17, wherein the non-pathogenic *heat*-killed *Mycobacterium* is for administration via the parenteral, oral, sublingual, nasal or pulmonary route.

19. The use according to claim 18, wherein the parenteral route is selected from subcutaneous, intradermal, subdermal, intraperitonal, intravenous, or intravesicular injection.

20. The use according to claim 19, wherein the parenteral route does not comprise intratumoural injection.

21. The use according to any of claims 15 to 20, wherein said immunogenic cell death therapy is by ionizing radiation.

22. The use according to any of claims 15 to 21, wherein administration of said immunomodulator is prior to and/or after the immunogenic cell death therapy.

23. The use according to claim 22, wherein administration of said immunomodulator is between 4 weeks and 1 week prior to and/or after the immunogenic cell death therapy.

24. The use according to claim 23, wherein said administration of immunomodulator comprises administration of one or more aliquots of an effective amount administered at one or more time intervals between about 4 weeks and 1 week prior to and/or after the immunogenic cell death therapy and continued to be applied to the patient after treatment for regression of the tumour.

25. The use according to any of claims 15 to 24, wherein said immunomodulator is administered to said patient after immunogenic cell death of the tumour cells, and/or during stabilisation of the disease.

26. The use according to any of claims 15 to 25, wherein said tumour is associated with a cancer selected from prostate cancer, liver cancer, renal cancer, lung cancer, breast cancer, colorectal cancer, breast cancer, pancreatic cancer, brain cancer, hepatocellular cancer, lymphoma, leukaemia, gastric cancer, cervical cancer, ovarian cancer, thyroid cancer, melanoma, carcinoma, head and neck cancer, skin cancer and soft tissue sarcoma.

27. The use according to claim 26, wherein said tumour is associated with colorectal cancer.

28. The use according to any of claims 15 to 27, wherein said therapy comprises an abscopal effect on a neoplastic disease in a patient.