

Claims

1. A method of treating or preventing cancer in a patient, comprising administering to the patient a T cell therapy and a dose of IL-2 of less than about 2.0MIU/m²/day.
2. The method according to claim 1 wherein said IL-2 is administered at a dose of about 1.9MIU/m²/day, about 1.8MIU/m²/day, about 1.7MIU/m²/day, about 1.6MIU/m²/day, about 1.5MIU/m²/day, about 1.4MIU/m²/day, about 1.3MIU/m²/day, about 1.2MIU/m²/day, about 1.1MIU/m²/day, about 1.0MIU/m²/day, about 0.9MIU/m²/day, about 0.8MIU/m²/day, about 0.7MIU/m²/day, about 0.6MIU/m²/day, about 0.5MIU/m²/day, about 0.4MIU/m²/day, about 0.3MIU/m²/day or about 0.2MIU/m²/day.
3. The method according to claim 1 or claim 2 wherein said IL-2 is administered at a dose of about 1.0MIU/m²/day.
4. The method according to any one of claims 1 to 3 wherein said IL-2 is administered once daily.
5. The method according to any one of claims 1 to 4 wherein said IL-2 is administered daily for about 14, 13, 12, 11, 10, 9, 8, 7, 6, 5, 4, 3, 2, or 1 days.
6. The method according to claim 5 wherein said IL-2 is administered for less than 14 days.
7. The method according to claim 5 or claim 6 wherein said IL-2 is administered daily for about 10 days.
8. The method according to any one of claims 1 to 7 wherein said dose of IL-2 is the same each day.
9. The method according to any one of claims 1 to 8 wherein the total dose of IL-2 administered to said patient does not exceed about 10MIU/m².
10. The method according to any one of claims 1 to 9 wherein the first dose of said IL-2 is administered on the same day as the T cell therapy.
11. The method according to any one of claims 1 to 10 wherein said T cell therapy is administered on day 0.
12. The method according to any one of claims 1 to 11 wherein said IL-2 is administered daily on days 0 to 9.

13. The method according to any one of claims 1 to 12 wherein a single dose of T cell therapy is administered to the patient.
14. The method according to any one of claims 1 to 13 wherein a single dose of T cell therapy is administered to the patient on day 0 only.
15. The method according to any one of claims 1 to 14 wherein said IL-2 is administered subcutaneously.
16. The method according to any one of claims 1 to 15 wherein said T cell therapy is selected from adoptive T cell therapy, tumour-infiltrating lymphocyte (TIL) immunotherapy, autologous cell therapy, engineered autologous cell therapy (eACT), and allogeneic T cell transplantation.
17. The method according to any one of claims 1 to 16 wherein said T cell therapy comprises T cells which target neoantigens.
18. The method according to claim 17 wherein said T cell therapy comprises T cells which target clonal neoantigens.
19. The method according to claim 17 or claim 18 wherein said T cell therapy comprises T cells which have been selectively expanded to target clonal neoantigens.
20. The method according to any one of claims 1 to 19 wherein said T cell therapy comprises T cells that have been expanded in the presence of IL-2 at a concentration of less than about 1,000 IU/ml.
21. The method according to any one of claims 1 to 20 wherein said T cell therapy comprises T cells which express a chimeric antigen receptor or a TCR which specifically binds to a clonal neoantigen or an affinity-enhanced TCR which specifically binds to a clonal neoantigen.
22. The method according to any one of claims 1 to 19 further comprising administering a lymphodepleting agent prior to administration of said T cell therapy.
23. The method according to claim 22 wherein said lymphodepleting agent is administered daily for 3 days.
24. The method according to claim 23 wherein said lymphodepleting agent is administered on days -6, -5 and -4 prior to administration of said T cell therapy.

25. The method according to any one of claims 22 to 24 wherein said lymphodepleting agent is cyclophosphamide and/or fludarabine.
26. The method according to claim 25 wherein cyclophosphamide is administered at a dose of between about 200 mg/m²/day and about 500 mg/m²/day.
27. The method according to claim 26 wherein cyclophosphamide is administered at a dose of about 200 mg/m²/day, about 250 mg/m²/day, about 300 mg/m²/day, about 350 mg/m²/day, about 400 mg/m²/day, about 450 mg/m²/day or about 500 mg/m²/day.
28. The method according to claim 27 wherein cyclophosphamide is administered at a dose of about 300 mg/m²/day.
29. The method according to any one of claims 25 to 28 wherein fludarabine is administered at a dose of between about 20 mg/m²/day and 50 mg/m²/day.
30. The method according to claim 28 wherein fludarabine is administered at a dose of about 20 mg/m²/day, about 25 mg/m²/day, about 30 mg/m²/day, about 35 mg/m²/day, about 40 mg/m²/day, about 45 mg/m²/day or about 50 mg/m²/day.
31. The method according to claim 30 wherein fludarabine is administered at a dose of about 30 mg/m²/day.
32. A method of treating cancer in a patient, comprising administering to the patient:
- (i) a lymphodepleting regimen of about 300 mg/m²/day of cyclophosphamide and about 30 mg/m²/day of fludarabine prior to administration of said T cell therapy;
 - (ii) a single dose of T cell therapy; and
 - (iii) a dose of IL-2 of about 1.0MIU/m²/day administered once daily for about 10 days wherein the first dose of said IL-2 is administered on the same day as the T cell therapy.
33. The method according to any one of claims 1 to 32, wherein said cancer is lung cancer (small cell, non-small cell and mesothelioma), melanoma, bladder cancer, gastric cancer, oesophageal cancer, breast cancer (e.g. triple negative breast cancer), colorectal cancer, cervical cancer, ovarian cancer, endometrial cancer, kidney cancer (renal cell), brain cancer (eg. gliomas, astrocytomas, glioblastomas), lymphoma, small bowel cancers (duodenal and jejunal), leukaemia, liver cancer (hepatocellular carcinoma), pancreatic cancer, hepatobiliary tumours, germ cell cancers, prostate cancer, merkel cell carcinoma, head and neck cancers (squamous cell), thyroid cancer, high microsatellite instability (MSI-H), and sarcomas.

34. The method according to any one of claims 1 to 33 wherein said method results in reduced toxicity or reduced side effects in the patient.
35. The method according to any one of claims 1 to 34 wherein said patient is a human.
36. A T cell therapy according to any of the preceding claims for use in the treatment or prevention of cancer in a patient, wherein said T cell therapy is for administration with IL-2, and wherein said IL-2 is for administration at a dose of less than about 2.0MIU/m²/day.
37. A T cell therapy and IL-2 according to any of the preceding claims for use in the treatment or prevention of cancer in a patient, wherein said IL-2 is for administration at a dose of less than about 2.0MIU/m²/day.
38. A T cell therapy according to any of the preceding claims for use in the manufacture of a medicament for use in the treatment or prevention of cancer, wherein said T cell therapy is for administration with IL-2, wherein said IL-2 is for administration at a dose of less than about 2.0MIU/m²/day.
39. IL-2 according to any of the preceding claims for use in the manufacture of a medicament for use in the treatment or prevention of cancer, wherein said IL-2 is for administration in combination with a T cell therapy, wherein said IL-2 is for administration at a dose of less than about 2.0MIU/m²/day.