Summary of Invention

In one aspect, there is provided an ex-vivo method for assessing the efficacy of a treatment involving the administration of an immunogenic composition comprising at least one recombinant viral vector encoding a targeted antigen to a patient comprising:

- measuring levels of activated CD3+ CD69+ T lymphocytes in a biological sample taken from the body of said patient wherein one or more doses of said immunogenic composition had been administered to said patient and wherein said biological sample had been taken following at least one of the said administrations;
- wherein levels of activated CD3+ CD69+ T lymphocytes above about 10.4 % indicate that the subject is indicative of a successful clinical outcome for the treatment.

In another aspect, there is provided the use of levels of activated CD3+ CD69+ T lymphocytes as a biomarker for monitoring, modifying or adjusting a treatment involving the administration of
an immunogenic composition comprising at least one recombinant viral vector encoding a targeted antigen to a patient, wherein levels of activated CD3+ CD69+ T lymphocytes above about 10.4 % indicate that the subject is indicative of a successful clinical outcome for the treatment.

Detailed Description of the Invention

CLAIMS

1- An ex-vivo method for assessing the efficacy of a treatment involving the administration of an immunogenic composition to a patient comprising:

- administering one or more doses of said immunogenic composition to said subject;
- measuring levels of activated T lymphocytes (CD3+ CD69+) in the body of said subject following at least one of the said administration.

2 - An ex-vivo method for assessing the efficacy of a treatment involving the administration of an immunogenic composition to a patient comprising:

- administering one or more doses of said immunogenic composition to said subject;
- measuring levels of activated T lymphocytes (CD3+ CD69+) in the body of said subject following at least one of the said administration;
- wherein levels of activated T lymphocytes (CD3+ CD69+) above about 10.4 %. indicates that the subject is indicative of a successful clinical outcome for the treatment, i.e., the increase in survival rate.

3 - The method of claim 1 or 2 wherein said immunogenic composition administered to said patient comprises (i) all or part of the said antigen and/or (ii) at least one recombinant vector encoding the said antigen and/or (iii) at least one immune response modifier.

4- The method of any of previous claims wherein said patient is suffering of cancer.

5- The method of claim 4 wherein said cancer is Non Small Cell Lung Cancer or kidney cancer.

6 - The method of any of previous wherein said targeted antigen is a tumour specific antigen.

7- The method of claim 6 wherein said tumour specific antigen is MUC1.

8- Use of levels of activated T lymphocytes (CD3+ CD69+) as a biomarker for monitoring, modifying or adjusting a treatment involving the administration of an immunogenic composition to a patient.

9 - The use of claim 8, wherein levels of activated T lymphocytes (CD3+ CD69+) measured after said administration is above median levels indicates that the subject is indicative of a successful clinical outcome for the treatment.

10- The use of claim 9, wherein said successful clinical outcome is the increase in survival rate.

CLAIMS

1. An ex-vivo method for assessing the efficacy of a treatment involving the administration of an immunogenic composition comprising at least one recombinant viral vector encoding a targeted antigen to a patient comprising:
   - measuring levels of activated CD3+ CD69+ T lymphocytes in a biological sample taken from the body of said patient wherein one or more doses of said immunogenic composition had been administered to said patient and wherein said biological sample had been taken following at least one of the said administrations;
   - wherein levels of activated CD3+ CD69+ T lymphocytes above about 10.4 % indicate that the subject is indicative of a successful clinical outcome for the treatment.

2. The method of claim 1, wherein the successful clinical outcome is the increase in survival rate.

3. The method of claim 1 or 2 wherein said immunogenic composition further comprises at least one immune response modifier.

4. The method of any of the previous claims wherein said patient is suffering of cancer.

5. The method of claim 4 wherein said cancer is Non Small Cell Lung Cancer or kidney cancer.

6. The method of any one of claims 1 to 5 wherein said targeted antigen is a tumour specific antigen.

7. The method of claim 6 wherein said tumour specific antigen is MUC1.

8. Use of levels of activated CD3+ CD69+ T lymphocytes as a biomarker for monitoring, modifying or adjusting a treatment involving the administration of an immunogenic composition comprising at least one recombinant viral vector encoding a targeted antigen to a patient, wherein levels of activated CD3+ CD69+ T lymphocytes above about 10.4 % indicate that the subject is indicative of a successful clinical outcome for the treatment.

9. The use of claim 8, wherein said successful clinical outcome is the increase in survival rate.