CLAIMS

1. A vaccine comprising a clonal neo-antigen peptide or protein, or an RNA or DNA molecule encoding a clonal neo-antigen peptide or protein.

2. A vaccine according to claim 1 wherein said clonal neo-antigen peptide has been identified in a tumour from a subject by a method which comprises the steps of:

i) determining mutations present in a sample isolated from the tumour; and

ii) identifying a clonal mutation which is a mutation present in essentially all tumour cells; and

iii) identifying a clonal neo-antigen, which is an antigen encoded by a sequence which comprises the truncal mutation.

3. A vaccine according to claim 1 wherein said clonal neo-antigen peptide has been identified in a tumour from a subject by a method which comprises the steps of:

i) determining the mutations present in a plurality of samples isolated from a the tumour; and

ii) identifying a clonal mutation which is a mutation present in all samples; and

iii) identifying a clonal neo-antigen, which is an antigen encoded by a sequence which comprises the clonal mutation.

4. A vaccine according to any of claims 1 to 3 wherein the clonal mutation is a single nucleotide variant.

5. A vaccine according to any of claims 1 to 4 wherein mutations are identified by Exome sequencing, RNA-seq, whole genome sequencing and/or targeted gene panel sequencing.

6. A vaccine according to any of claims 1 to 5 wherein the method of identifying the clonal neo-antigen peptide comprises the step of assessing the subject's HLA allele profile to determine if a truncal neo-antigen peptide will bind to a MHC molecule of the subject.

7. A vaccine according to any of claims 1 to 6 which is in the form of a dendritic cell vaccine, wherein the dendritic cell is pulsed or loaded with said clonal neo-antigen peptide or genetically modified to express a clonal neo-antigen peptide or clonal neo-antigen protein.

8. A vaccine according to any one of claims 1 to 7 which is in the form of a pharmaceutical composition and which comprises a pharmaceutically acceptable carrier, diluent, excipient or adjuvant.

9. Use of a vaccine according to any one of claims 1 to 8 in the manufacture of a medicament for the treatment of cancer in a subject.

10. A use according to claim 9 further comprising the step of identifying a subject who has cancer.

11. A method for producing a vaccine comprising a clonal neo-antigen peptide or clonal neo-antigen protein, said method comprising the steps of:

(a) identifying a clonal neo-antigen in a tumour from a subject which comprises the steps of:

i) determining mutations present in a sample isolated from the tumour; and

ii) identifying a clonal mutation which is a mutation present in essentially all tumour cells; and

iii) identifying a clonal neo-antigen, which is an antigen encoded by a sequence which comprises the clonal mutation; or

i) determining the mutations present in a plurality of samples isolated from a tumour;

ii) identifying a clonal mutation which is a mutation present in all samples;

iii) identifying a clonal neo-antigen, which is an antigen encoded by a sequence which comprises the clonal mutation; and

(b) producing a clonal neo-antigen peptide or truncal neo-antigen protein from said clonal neo-antigen; and

(c) producing a vaccine comprising said clonal neo-antigen peptide or clonal neo-antigen protein.

12. A method for producing a vaccine comprising a DNA or RNA molecule encoding a clonal neo-antigen peptide or clonal neo-antigen protein, said method comprising the steps of:

(a) identifying a clonal neo-antigen in a tumour from a subject which comprises the steps of:

i) determining mutations present in a sample isolated from the tumour; and

ii) identifying a clonal mutation which is a mutation present in essentially all tumour cells; and

iii) identifying a clonal neo-antigen, which is an antigen encoded by a sequence which comprises the clonal mutation; or

i) determining the mutations present in a plurality of samples isolated from a tumour;

ii) identifying a clonal mutation which is a mutation present in all samples;

iii) identifying a clonal neo-antigen, which is an antigen encoded by a sequence which comprises the clonal mutation; and

(b) producing a vaccine comprising a DNA or RNA molecule encoding said clonal neo-antigen peptide or clonal neo-antigen protein.