Claims

1. An individualized therapeutic anticancer vaccine comprising an immunologically effective amount of:

(i) a polynucleotide comprising a nucleotide sequence encoding a targeting unit, a dimerization unit and an antigenic unit, wherein said antigenic unit comprises at least one patient-present shared antigen sequence or one or more parts thereof and wherein said antigenic unit further comprises one or more patient-specific antigen sequences or one or more parts thereof; or

(ii) a polypeptide encoded by the polynucleotide as defined in (i); or

(iii) a dimeric protein consisting of two polypeptides encoded by the polynucleotide as defined in (i); and

a pharmaceutically acceptable carrier.

2. The vaccine according to claim 1, wherein said at least one patient-present shared antigen sequence is a sequence of a shared antigen selected from the group consisting of overexpressed cellular proteins, aberrantly expressed cellular proteins, cancer testis antigens, viral antigens, differentiation antigens, mutated oncogenes, mutated tumor suppressor genes, oncofetal antigens, shared fusion antigens, shared intron retention antigens, dark matter antigens, shared antigens caused by spliceosome mutations and shared antigens caused by frameshift mutations, and/or

wherein said at least one patient-present shared antigen sequence is a sequence of a shared antigen that is a human cellular protein, and/or

wherein said at least one patient-present shared antigen sequence or one or more parts thereof are known to be immunogenic or are predicted to bind to the patient's HLA class I and/or HLA class II alleles.

3. The vaccine according to any of claims 1 to 2, wherein the antigenic unit comprises sequences of several patient-present shared antigens or one or more parts thereof, such as wherein the antigenic unit comprises several parts of sequences of several patient-present shared antigens, preferably wherein the antigenic unit comprises several epitopes of several patient-present shared antigens, which epitopes are known to be immunogenic or are predicted to bind to the patient's HLA class I and/or HLA class II alleles.

4. The vaccine according to any of claims 1 to 3, wherein the antigenic unit comprises one or more patient-present shared antigen sequences in full length, and/or

wherein the antigenic unit comprises 1 to 30 parts of at least one patient-present shared antigen sequence, preferably wherein the parts include multiple epitopes that are predicted to bind to the patient's HLA class I and/or HLA class II alleles.

5. The vaccine according to any of claims 1 to 4, wherein the antigenic unit comprises 1 to 50 patient-present shared antigen sequences in the form of epitopes, preferably wherein the epitopes are predicted to bind to the patient's HLA class I and/or HLA class II alleles.

6. The vaccine according to any of claims 1 to 5, wherein the antigenic unit comprises several patient-specific antigen sequences or one or more parts thereof, and/or wherein the antigenic unit comprises one or more patient-specific epitopes, such as wherein antigenic unit comprises at least 5 patient-specific epitopes.

7. The vaccine according to any of claims 1 to 6, wherein the dimerization unit comprises hinge exons h1 and h4 connected through a linker to a CH3 domain of human IgG3.

8. The vaccine according to any of claims 1 to 7, wherein the dimerization unit comprises or consists of an amino acid sequence having at least 85% sequence identity to the amino acid sequence 94-237 of SEQ ID NO: 2.

9. The vaccine according to any of claims 1 to 8, wherein the targeting unit comprises or consists of soluble CD40 ligand, RANTES, MIP-1α, XCL1, XCL2, flagellin, anti-HLA-DP, anti-HLA-DR, anti-pan HLA class II or an antibody variable domain with specificity for anti-CD40, anti-TLR-2, anti-TLR-4 or anti-TLR-5, preferably comprises or consists of MIP-1α.

10. The vaccine according to any of claims 1 to 9, wherein the targeting unit comprises or consists of an amino acid sequence having at least 85% sequence identity to the amino acid sequence 24-93 of SEQ ID NO:1.

11. The vaccine according to any of the preceding claims, wherein said vaccine comprises a polynucleotide, preferably a DNA polynucleotide and preferably
wherein the polynucleotide further comprises a nucleotide sequence encoding a signal peptide.

12. The vaccine according to any of the preceding claims, wherein the pharmaceutically acceptable carrier is selected from the group consisting of saline, buffered saline, PBS, dextrose, water, glycerol, ethanol, sterile isotonic aqueous buffers, and combinations thereof.

13. A method for preparing the individualized therapeutic anticancer vaccine as defined in any of claims 1 to 12, said method comprises the steps of:

a) identifying at least one patient-present shared antigen in the tumor tissue or body fluid of a patient
b) determining the patient's HLA class I and/or class II alleles

c) predicting the immunogenicity of the identified at least one antigen or one or more parts thereof by their predicted binding to the patient's HLA class I and/or II alleles

d) selecting at least one antigen or one or more parts thereof based on their immunogenicity predicted in step c);

e) preparing a polynucleotide sequence comprising an antigenic unit comprising a nucleotide sequence encoding the at least one antigen or one or more parts thereof selected in step d);

f) cloning the polynucleotide sequence into an expression vector comprising nucleotide sequences encoding a targeting unit and a dimerization unit; and

g) mixing the expression vector obtained in step f with a pharmaceutically acceptable carrier, and

wherein said method further comprises:

in step a) identifying one or more patient-specific antigens in the tumor tissue of the patient

in step c) predicting the immunogenicity of the identified one or more patient-specific antigens or one or more parts thereof by their predicted binding to the patient's HLA class I and/or II alleles

in step d) selecting one or more patient-specific antigens or one or more parts thereof based on their immunogenicity predicted in step c);

and wherein the polynucleotide sequence of step e) further comprises nucleotide sequences encoding the one or more patient-specific antigens or one or more parts thereof selected in step d).

14. A polynucleotide as defined in any of the claims 1 to 11.

15. A vector comprising the polynucleotide according to claim 14.

16. A polypeptide encoded by the polynucleotide sequence as defined in any of the claims 1 to 11, or a dimeric protein consisting of two of said polypeptides.

17. The polynucleotide according to claim 11 or the polypeptide or the dimeric protein according to claim 16 for use as a medicament.

18. Use of the vaccine according to any of claims 1 to 12 in the manufacture of a medicament for treating a patient having cancer, wherein the vaccine has been prepared specifically for the patient, preferably wherein the vaccine comprises a polynucleotide and is to be administered intradermally or intramuscularly to the patient.