ATL, showed preliminary encouraging results: reduction of the proviral load and reduction of the size of the surface lymph nodes (Suehiro, *et al*, 2013, abstract book from the 16th International Conference on Human Retrovirology: HTLV and Related Viruses). More impressively, 1 of the 2 patients who completed the study achieved a partial remission and the other one has a stable disease without severe side effects.

[051] All these data confirm that the stimulation of the cellular immune response against HTLV-1 cells could be a strong therapeutic option to treat ATL patients.

[052] The first disadvantage of ex vivo peptidic vaccination used in the only clinical trial testing a vaccination against HTLV-1 is the selection of patients eligible for treatment according to their HLA haplotype. Secondly, ex vivo maturation of autologous DCs requires purification steps from PBMCs of patients, leading to repeated depletion of circulated mononuclear cells. In a pathological context, this could be detrimental for the immune system of patients. Moreover, purification of autologous DCs is very expensive and within technical challenge to get good performance (as an example, see PROVENGE® vaccine from Dendreon in prostate cancer treatment (Huber *et al*, 2012, J. Natl. Cancer Inst., 104(4):273-279)).

[053] Thus, a need exists in the art for improved vectors and methods for treatment of HTLV-1 in humans. The present invention fulfills these needs in the art.

SUMMARY

[054] In one aspect the present invention refers to the use of lentiviral vector particles in the manufacture of a medicament for inducing an immune response, wherein the lentiviral vector particles are to be administered intramuscularly to a human, wherein the lentiviral vector particles comprise a lentiviral vector; wherein DNA of the lentiviral vector comprises a promoter directing expression of a polypeptide comprising a HTLV-1 p12p30-Tax-HBZ fusion protein. In another aspect, the present invention refers to a composition comprising lentiviral vector particles for induction of an immune response by intramuscular administration to a human, wherein the lentiviral vector particles comprise a lentiviral vector; wherein the DNA of the lentiviral vector comprises a promoter directing expression of a polypeptide comprising a HTLV-1 p12p30-Tax-HBZ fusion protein. The disclosure encompasses compositions comprising lentiviral vectors and uses and methods of using the compositions. The disclosure encompasses methods, compositions, and uses for inducing an immune response in a human. The lentiviral vector particles can comprise a lentiviral vector, wherein the DNA of the lentiviral vector comprises a

promoter directing expression of a polypeptide comprising a HTLV-1 p12p30-Tax-HBZ fusion protein.

[055] In one example, the disclosure encompasses the use of a composition comprising lentiviral vector particles for induction of an immune response by intramuscular administration to a human, wherein the lentiviral vector particles comprise a lentiviral vector; wherein the DNA of the lentiviral vector comprises a promoter directing expression of a polypeptide comprising a HTLV-1 p12p30-Tax-HBZ fusion protein.

[056] In one example, the disclosure encompasses a composition comprising lentiviral vector particles for induction of an immune response by intramuscular administration to a human, wherein the lentiviral vector particles comprise a lentiviral vector; wherein the DNA of the lentiviral vector comprises a promoter directing expression of a polypeptide comprising a HTLV-1 p12p30-Tax-HBZ fusion protein.

[057] In some examples, the lentiviral vector comprises a β2m promoter or an MHC class I promoter.

[058] In some examples, the HTLV-1 p12p30-Tax-HBZ fusion protein is encoded by a DNA having the nucleotide sequence of SEQ ID NO:20.

[059] In some examples, the HTLV-1 p12p30-Tax-HBZ fusion protein comprises the amino acid sequence of SEQ ID NO:66.

[060] In some examples, the composition comprises at least 10^7 lentiviral vector particles.

[061] **BRIEF DESCRIPTION OF THE DRAWINGS**

[062] Figure 1 depicts T-cell specific immune response (ELISpot IFN-γ) elicited in C57Bl/6j mice after injection of different doses (1.10e6, 1.10e7, 1.10e8 TU/mouse) of lentiviral vectors containing the p12Ip30II HTLV-1 antigen, according to pool of peptides used (p12I or p30II specific) for stimulation of T-cells (cumulative response, median).

[063] Figure 2 depicts T-cell specific immune response (ELISpot IFN-γ) elicited in C57Bl/6j mice after injection of different doses (1.10e6, 1.10e7, 1.10e8 TU/mouse) of lentiviral vectors containing different combination of antigens Tax and HBZ, i.e. Tax-HBZ, Tax-2A-HBZ, HBZ-Tax, HBZ-2A-Tax, according to pool of peptides used (Tax or HBZ specific) for stimulation of T-cells (cumulative response, median).

[064] Figure 3 depicts T-cell specific immune response (ELISpot IFN-γ) elicited in C57Bl/6j mice after injection of different doses (1.10e6, 1.10e7, 1.10e8 TU/mouse) of lentiviral vectors containing different combination of antigens Tax and HBZ, i.e. Tax-HBZ-p12Ip30II and p12Ip30II-Tax-HBZ, according to pool of peptides used (Tax, HBZ, p12I or p30II specific) for stimulation of T-cells (cumulative response).

[065] Figure 4A-C depict lack of effect of lentiviral vectors expressing HTLV antigens in immortalized MEFs in vitro. A. Proliferation curve of transduced

CLAIMS

1. Use of lentiviral vector particles in the manufacture of a medicament for inducing an immune response, wherein the lentiviral vector particles are to be administered intramuscularly to a human, wherein the lentiviral vector particles comprise a lentiviral vector; wherein DNA of the lentiviral vector comprises a promoter directing expression of a polypeptide comprising a HTLV-1 p12p30-Tax-HBZ fusion protein.

2. The use of claim 1, wherein the lentiviral vector comprises a β2m promoter.

3. The use of claim 1, wherein the lentiviral vector comprises an MHC class I promoter.

4. The use of claim 1, wherein the HTLV-1 p12p30-Tax-HBZ fusion protein is encoded by a DNA having the nucleotide sequence of SEQ ID NO:20.

5. The use of claim 1, wherein the HTLV-1 p12p30-Tax-HBZ fusion protein comprises the amino acid sequence of SEQ ID NO:66.

6. The use of claim 1, comprising at least 10^7 lentiviral vector particles.

7. A composition comprising lentiviral vector particles for induction of an immune response by intramuscular administration to a human, wherein the lentiviral vector particles comprise a lentiviral vector; wherein the DNA of the lentiviral vector comprises a promoter directing expression of a polypeptide comprising a HTLV-1 p12p30-Tax-HBZ fusion protein.

8. The composition of claim 7, wherein the lentiviral vector comprises a β2m promoter.

9. The composition of claim 7, wherein the lentiviral vector comprises an MHC class I promoter.

10. The composition of claim 7, wherein the HTLV-1 p12p30-Tax-HBZ fusion protein is encoded by a DNA having the nucleotide sequence of SEQ ID NO:20.

11. The composition of claim 7, wherein the HTLV-1 p12p30-Tax-HBZ fusion protein comprises the amino acid sequence of SEQ ID NO:66.

12. The composition of claim 7, comprising at least 10^7 lentiviral vector particles.

13. The use of any one of claims 1 to 6, wherein the human is infected with Human T Lymphotropic Virus Type 1 (HTLV-1).