CLAIMS

1. A pharmaceutical composition comprising a mixture of a particulate antigen and a non-pathogenic bacterium.

2. The pharmaceutical composition according to claim 1, wherein said antigen has one or more epitopes from HIV Gag and/or Pol proteins.

3. A pharmaceutical composition comprising a mixture of an antigen having one or more epitopes from HIV Gag and/or Pol proteins, and a non-pathogenic bacterium.

4. The pharmaceutical composition according to claim 3, wherein said antigen is a particulate antigen.

5. The pharmaceutical composition according to anyone of claims 1 to 4, wherein said antigen is at least about 110 kDa in size.

6. The pharmaceutical composition according to anyone of claims 1 to 5, wherein said particulate antigen is selected from virus particles, virus-like particles, recombinant virus particles, conjugate viral proteins and concatemer viral proteins.

7. The pharmaceutical composition according to claim 6, wherein said recombinant virus particles or said virus particles are inactivated.

8. The composition according to anyone of claims 2 to 7, wherein said epitopes from HIV Gag protein are selected from epitopes from the capsid protein (p24) and the matrix protein (p17).

9. The composition according to anyone of claims 2 to 7, wherein said epitopes from HIV Pol protein are selected from epitopes from the integrase, the reverse transcriptase and the protease.

10. The pharmaceutical composition according to anyone of claims 1 to 9, wherein said bacterium is living.

11. The pharmaceutical composition according to anyone of claims 1 to 10, wherein said bacterium is selected from attenuated pathogenic bacteria, inactivated (optionally, also attenuated) pathogenic bacteria, and non-pathogenic lactic acid bacteria.

12. The pharmaceutical composition according to claim 11, wherein said bacterium is a *Lactobacillus* bacterium.

13. The pharmaceutical composition according to claim 12, wherein said bacterium is *Lactobacillus plantarum*.

14. The pharmaceutical composition according to anyone of claims 6 to 13, wherein said particulate antigen is a virus particle and wherein the amount of virus particles is from about 10^6 to about 10^{12} per ml of said mixture.

15. The pharmaceutical composition according to anyone of claims 1 to 14, wherein the amount of said bacterium is from about 10^4 to about 10^{14} CFU per ml of said mixture.

16. The pharmaceutical composition according to anyone of claims 6 to 15, wherein said particulate antigen is a virus particle and wherein the ratio of said virus particle to said bacterium in said mixture is from about 1:10 to about 1:1000, preferably about 1:100.

17. The pharmaceutical composition according to anyone of claims 1 to 16, which is a mucosal or intradermal or intraepithelial pharmaceutical composition.

18. The pharmaceutical composition according to claim 17, which is an oral pharmaceutical composition.

19. The pharmaceutical composition according to anyone of claims 1 to 18, for use in a method for preventing and/or treating an HIV disease in a human in need thereof.

20. The pharmaceutical composition according to anyone of claims 1 to 18, for use in a method for protecting a human against HIV.

21. The pharmaceutical composition according to anyone of claims 1 to 18, for use in a method for protecting a human from HIV seroconversion.

22. The pharmaceutical composition according to anyone of claims 19 to 21, wherein said particulate antigen is a virus particle and wherein a dose of about 10^8 to about 10^{14} virus particles per day is administered to said human.

23. The pharmaceutical composition according to anyone of claims 19 to 22, wherein a dose of said bacterium of about 10^6 to about 10^{16} CFU per day is administered to said human.

24. The pharmaceutical composition according to anyone of claims 1 to 23, which induces and preferably maintains an antigen-specific immune protection against HIV in a human.

25. The pharmaceutical composition according to claim 24, wherein said immune protection is characterized by the reduction and preferably the suppression of an HIV viral load in said human.

26. The pharmaceutical composition according to claim 24 or 25, wherein said immune protection is characterized by CD8+ regulatory T cells suppressing the activation of HIV Gag and/or Pol antigen-presenting CD4+T cells in said human.

27. The pharmaceutical composition according to claim 26, wherein said immune protection is determined in said human by *in vitro* detecting the presence or the activity of CD8+ regulatory T cells from said human.

28. The pharmaceutical composition according to claim 26 or 27, wherein said CD8+ regulatory T cells are MHC-Ib/E-restricted CD8+ regulatory T cells.

29. The pharmaceutical composition according to anyone of claims 2 to 28, wherein said HIV is HIV-1 or HIV-2.

30. A pharmaceutical kit for preventing and/or treating an HIV disease in a human in need thereof, comprising:

- in a first container, a particulate antigen; and
- in a second container, a non-pathogenic living bacterium,

said antigen and said bacterium being in pharmaceutically acceptable carriers for mucosal or intradermal or intraepithelial administration.

31. The pharmaceutical kit according to claim 30, wherein said antigen has one or more epitopes from HIV Gag and/or Pol proteins.

32. A pharmaceutical kit for preventing and/or treating an HIV disease in a human in need thereof, comprising:

- in a first container, an antigen having one or more epitopes from HIV Gag and/or Pol proteins, and
- in a second container, a non-pathogenic living bacterium,

said antigen and said bacterium being in pharmaceutically acceptable carriers for mucosal or intradermal or intraepithelial administration.

33. The pharmaceutical kit according to claim 32, wherein said antigen is a particulate antigen.

CLAIMS

1. A pharmaceutical composition comprising a mixture of a particulate antigen having one or more epitopes from HIV Gag and/or Pol proteins and a non-pathogenic bacterium.

2. The pharmaceutical composition according to claim 1, wherein said particulate antigen is selected from virus particles, virus-like particles, recombinant virus particles, conjugate viral proteins and concatemer viral proteins.

3. The pharmaceutical composition according to claim 2, wherein said recombinant virus particles or said virus particles are inactivated.

4. The pharmaceutical composition according to anyone of claims 1 to 3, wherein said bacterium is selected from attenuated pathogenic bacteria, inactivated (optionally, also attenuated) pathogenic bacteria, and non-pathogenic lactic acid bacteria.

5. The pharmaceutical composition according to claim 4, wherein said bacterium is a *Lactobacillus* bacterium.

6. The pharmaceutical composition according to anyone of claims 1 to 5, which is a mucosal or intradermal or intraepithelial pharmaceutical composition.

7. The pharmaceutical composition according to claim 6, which is an oral pharmaceutical composition.

8. The pharmaceutical composition according to anyone of claims 1 to 7, for preventing and/or treating an HIV disease in a human in need thereof.

9. The pharmaceutical composition according to anyone of claims 1 to 7, for protecting a human against HIV.

10. The pharmaceutical composition according to anyone of claims 1 to 7, for protecting a human from HIV seroconversion.

11. The pharmaceutical composition according to anyone of claims 1 to 10, which induces and preferably maintains an antigen-specific immune protection against HIV in a human.

12. The pharmaceutical composition according to claim 11, wherein said immune protection is characterized by the reduction and preferably the suppression of an HIV viral load in said human.

13. The pharmaceutical composition according to claim 11 or 12, wherein said immune protection is characterized by CD8+ regulatory T cells suppressing the activation of HIV Gag and/or Pol antigen-presenting CD4+T cells in said human.

14. The pharmaceutical composition according to claim 13, wherein said immune protection is determined in said human by *in vitro* detecting the presence or the activity of CD8+ regulatory T cells from said human and wherein said CD8+ regulatory T cells are MHC-Ib/E-restricted CD8+ regulatory T cells.

15. A pharmaceutical kit for preventing and/or treating an HIV disease in a human in need thereof, comprising:

- in a first container, a particulate antigen having one or more epitopes from HIV Gag and/or Pol proteins; and

- in a second container, a non-pathogenic living bacterium,

said antigen and said bacterium being in pharmaceutically acceptable carriers for mucosal or intradermal or intraepithelial administration.

16. Use of a pharmaceutical composition according to any one of claims 1 to 7 in the manufacture of a medicament for preventing and/or treating an HIV disease in a human in need thereof.

17. Use of a pharmaceutical composition according to any one of claims 1 to 7 in the manufacture of a medicament for protecting a human against HIV.

18. Use of a pharmaceutical composition according to any one of claims 1 to 7 in the manufacture of a medicament for protecting a human from HIV seroconversion.

19. The use according to anyone of claims 16 to 18, wherein the medicament induces and preferably maintains an antigen-specific immune protection against HIV in a human.

20. The use according to claim 19, wherein said immune protection is characterized by the reduction and preferably the suppression of an HIV viral load in said human.

21. The use according to claim 19 or claim 20, wherein said immune protection is characterized by CD8+ regulatory T cells suppressing the activation of HIV Gag and/or Pol antigen-presenting CD4+T cells in said human.

22. The use according to claim 19 or claim 20, wherein said immune protection is determined in said human by *in vitro* detecting the presence or the activity of CD8+ regulatory T cells from said human and wherein said CD8+ regulatory T cells are MHC-Ib/E-restricted CD8+ regulatory T cells.