Claims

1. An immunogenic composition comprising an *M. tuberculosis* antigen in combination with an adjuvant which adjuvant comprises an immunologically active saponin fraction derived from the bark of Quillaja Saponaria Molina presented in the form of a liposome and a lipopolysaccharide wherein said saponin fraction and said lipopolysaccharide are both present in the composition at a level of between 1µg and 30µg per dose, for use as a human medicament.

2. The immunogenic composition for use according to claim 1 wherein said adjuvant composition further comprises a sterol, wherein the ratio of saponin:sterol is from 1:1 to 1:100 w/w.

3. The immunogenic composition for use according to claim 2 wherein said sterol is cholesterol.

4. The immunogenic composition for use according to any of claims 1 to 3 wherein said immunologically active saponin fraction is QS21.

5. The immunogenic composition for use according to any of claims 1 to 4 wherein said lipopolysaccharide is a lipid A derivative.

6. The immunogenic composition for use according to claim 5 wherein said lipid A derivative is 3D-MPL.

7. The immunogenic composition for use according to claim 6 wherein the ratio QS21:3D-MPL is 1:1.

8. The immunogenic composition for use according to claim 1, comprising an *M. tuberculosis* antigen in combination with an adjuvant which adjuvant comprises QS21 presented in the form of a liposome and 3D-MPL wherein said QS21 and said 3D-MPL are both present in the composition at a level of 25µg per dose.

9. The immunogenic composition for use according to any of claims 1 to 8, wherein the *M. tuberculosis* antigen is M72.

10. Use of an immunogenic composition comprising an *M. tuberculosis* antigen in combination with an adjuvant which adjuvant comprises an immunologically active saponin fraction derived from the bark of Quillaja Saponaria Molina presented in the form of a liposome and a lipopolysaccharide, wherein said saponin fraction and said lipopolysaccharide are both present in the composition at a level of between 1μg and 30μg per dose, in the manufacture of a medicament for the treatment and/or prevention of tuberculosis in humans.

11. The use according to claim 10 wherein said adjuvant composition further comprises a sterol, wherein the ratio of saponin:sterol is from 1:1 to 1:100 w/w.

12. The use according to claim 11 wherein said sterol is cholesterol.

13. The use according to any of claims 10 to 12 wherein said immunologically active saponin fraction is QS21.

14. The use according to any of claims 10 to 13 wherein said lipopolysaccharide is a lipid A derivative.

15. The use according to claim 14 wherein said lipid A derivative is 3D-MPL.

16. The use according to claim 15 wherein the ratio QS21:3D-MPL is 1:1.

17. The use according to claim 10, comprising an *M. tuberculosis* antigen in combination with an adjuvant which adjuvant comprises QS21 presented in the form of a liposome and 3D-MPL wherein said QS21 and said 3D-MPL are both present in the composition at a level of 25μg per dose.

18. The use according to any of claims 10 to 17, wherein the *M. tuberculosis* antigen is M72.

19. The use of an immunogenic composition according to any of claims 10 to 18 in the manufacture of a medicament for the treatment of tuberculosis in humans.

20. The use of an immunogenic composition according to any of claims 10 to 18 in the manufacture of a medicament for the prevention of tuberculosis in humans.

21. Use of an immunogenic composition comprising an *M. tuberculosis* antigen in combination with an adjuvant which adjuvant comprises an immunologically active saponin fraction derived from the bark of Quillaja Saponaria Molina presented in the form of a liposome and a lipopolysaccharide, wherein said saponin fraction and said lipopolysaccharide are both present in the composition at a level of between 1μg and 30μg per dose, in the manufacture of a medicament for the immunotherapy of tuberculosis in humans.

22. The use according to claim 21 wherein said adjuvant composition further comprises a sterol, wherein the ratio of saponin:sterol is from 1:1 to 1:100 w/w.

23. The use according to claim 22 wherein said sterol is cholesterol.

24. The use according to any of claims 21 to 23 wherein said immunologically active saponin fraction is QS21.

25. The use according to any of claims 21 to 24 wherein said lipopolysaccharide is a lipid A derivative.

26. The use according to claim 25 wherein said lipid A derivative is 3D-MPL.

27. The use according to claim 26 wherein the ratio QS21:3D-MPL is 1:1.

28. The use according to claim 21, comprising an *M. tuberculosis* antigen in combination with an adjuvant which adjuvant comprises QS21 presented in the form of a liposome and 3D-MPL wherein said QS21 and said 3D-MPL are both present in the composition at a level of 25μg per dose.

29. The use according to any of claims 21 to 28, wherein the *M. tuberculosis* antigen is M72.