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, wherein said immunologically active saponin fraction is QS21, wherein said lipopolysaccharide is a lipid A derivative, and wherein said lipid A derivative is 3D-MPL.

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 claim 1 wherein the ratio QS21:3D-MPL is 1:1.

5. 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.

6. The immunogenic composition for use according to any of claims 1 to 5, wherein the *M. tuberculosis* antigen is M72.

7. 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, wherein said immunologically active saponin fraction is QS21,

wherein said lipopolysaccharide is a lipid A derivative, and wherein said lipid A derivative is 3D-MPL.

8. The use according to claim 7 wherein said adjuvant composition further comprises a sterol, wherein the ratio of saponin:sterol is from 1:1 to 1:100 w/w.

9. The use according to claim 8 wherein said sterol is cholesterol.

10. The use according to claim 7 wherein the ratio QS21:3D-MPL is 1:1.

11. The use according to claim 7, 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.

12. The use according to any of claims 7 to 11, wherein the *M. tuberculosis* antigen is M72.

13. The use of an immunogenic composition according to any of claims 7 to 12 in the manufacture of a medicament for the treatment of tuberculosis in humans.

14. The use of an immunogenic composition according to any of claims 7 to 12 in the manufacture of a medicament for the prevention of tuberculosis in humans.

15. 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, wherein said immunologically active saponin fraction is QS21, wherein said lipopolysaccharide is a lipid A derivative, and wherein said lipid A derivative is 3D-MPL.

16. The use according to claim 15 wherein said adjuvant composition further comprises a sterol, wherein the ratio of saponin:sterol is from 1:1 to 1:100 w/w.

17. The use according to claim 16 wherein said sterol is cholesterol.

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

19. The use according to claim 15, 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.

20. The use according to any of claims 15 to 19, wherein the *M. tuberculosis* antigen is M72.