CLAIMS

1. A method of eliciting an immune response in a subject, wherein the method comprises administering to a subject in need thereof a polymer particle comprising one or more fusion polypeptides, wherein at least one of the fusion polypeptides comprises a particle-forming protein fused to at least one antigen capable of eliciting an immune response.

CLAIMS

1. A method of eliciting an immune response in a subject, wherein the method comprises administering to a subject in need thereof a polymer particle comprising one or more fusion polypeptides, wherein at least one of the fusion polypeptides comprises a particle-forming protein fused to at least one antigen capable of eliciting an immune response.
2. A method of eliciting an immune response in a subject, wherein the method comprises administering to a subject in need thereof a polymer particle comprising one or more fusion polypeptides, wherein at least one of the fusion polypeptides comprises a particle-forming protein fused to a binding domain capable of binding at least one antigen capable of eliciting an immune response in a subject.
3. A method of immunising a subject against a pathogen, wherein the method comprises administering to a subject in need thereof at least one polymer particle comprising one or more fusion polypeptides, wherein at least one of the fusion polypeptides comprises a particle-forming protein fused to at least one antigen capable of eliciting an immune response.
4. A method of immunising a subject against a pathogen, wherein the method comprises administering to a subject in need thereof at least one polymer particle comprising one or more fusion polypeptides, wherein at least one of the fusion polypeptides comprises a particle-forming protein fused to a binding domain capable of binding at least one antigen capable of eliciting an immune response in a subject.
5. The method of any one of claims 1 to 4 wherein the immune response comprises a cell-mediated immune response.
6. The method of any one of claims 1 to 5 wherein the immune response comprises a humoral response.
7. The method of any one of claims 1 to 6, wherein the subject is infected with a pathogen or has been immunised against a pathogen.
8. The method of any one of claims 2 or 4 to 7, wherein the binding domain capable of binding an antigen capable of eliciting an immune response binds to an endogenous antigen.
9. A polymer particle comprising one or more fusion polypeptides comprising a particle-forming protein fused to at least one antigen capable of eliciting an immune response.

10. The polymer particle of claim 9 wherein the the particle-forming protein is a polymer synthase.
11. The polymer particle of claim 9 or 10 wherein the particle comprises a polymer selected from the group consisting of poly-beta-amino acids, polylactates, polythioesters and polyesters.
12. The polymer particle of any one of claims 9 to 11 wherein the antigen is capable of eliciting a cell-mediated immune response.
13. The polymer particle of any one of claims 9 to 12 wherein the antigen is capable of eliciting a humoral immune response.
14. The polymer particle of any one of claims 9 to 13 wherein the polymer particle comprises two or more different fusion polypeptides.
15. The polymer particle of any one of claims 9 to 14 wherein the polymer particle comprises two or more different antigens, or two or more different binding domains capable of binding an antigen.
16. The polymer particle of any one of claims 9 to 15 wherein the polymer particle comprises at least one antigen capable of eliciting an immune response and at least one binding domain capable of binding an antigen capable of eliciting a cell-mediated immune response.
17. The polymer particle of any one of claims 9 to 16 wherein the polymer particle further comprises at least one substance bound to or incorporated into the polymer particle.
18. The polymer particle of claim 17 wherein the substance is an antigen, adjuvant or immunostimulatory molecule, or a combination of any two or more thereof.
19. The polymer particle of any one of claims 9 to 18 wherein the polymer particle is multi-valent.
20. The polymer particle of any one of claims 17 to 19 wherein the substance is bound to the polymer particle by cross-linking.
21. A polymer particle comprising one or more fusion polypeptides comprising a particle-forming protein fused to at least one antigen capable of eliciting an immune response for eliciting an immune response in a subject in need thereof, or for immunising a subject against a pathogen, or for diagnosing infection from a pathogen in a subject in need thereof.
22. A polymer particle comprising one or more fusion polypeptides comprising a particle-forming protein fused to at least one binding domain capable of binding an antigen

capable of eliciting an immune response for eliciting an immune response in a subject in need thereof, or for immunising a subject against a pathogen, or for diagnosing infection from a pathogen in a subject in need thereof.

23. The polymer particle of any one of claims 9 to 22 wherein the antigen is an antigen from an organism selected from the group consisting of Mycobacterium (e.g. M. bovis, M. tuberculosis, M. leprae, M. kansasii, M. avium, M. avium paratuberculosis, Mycobacterium sp.), Listeria (e.g. L. monocytogenes, Listeria sp.), Salmonella (e.g. S. typhi), Yersinia (e.g Y. pestis, Y. enterocolitica, Y. pseudotuberculosis), Bacillus anthracis, Legionella (e.g. L. pneumophila, L. longbeachae, L. bozemanii, Legionella sp.), Rickettsia (e.g. R. rickettsii, R. akari, R. conorii, R. siberica, R. australis, R. japonica, R. africae, R. prowazekii, R. typhi, Rickettsia sp.), Chlamydia (e.g. C. pneumoniae, C. trachomatis, Chlamydia sp.), Clamydophila (e.g. C. psittaci, C. abortus), Streptococcus (e.g. S. pneumoniae, S. pyogenes, S. agalactiae), Staphylococcus (S. aureus) including Methicillin resistant Staphylococcus aureus (MRSA), Ehrlichia (e.g. E. chaffeensis, Ehrlichia phagocytophila geno group, Ehrlichia sp.), Coxiella burnetii, Leishmania sp., Toxpolasma gondii, Trypanosoma cruzi, Histoplasma sp., Francisella tularensis, and viruses including Hepatitis C, Adenoviruses, Picornaviruses including coxsackievirus, hepatitis A virus, poliovirus, Herpesviruses including epstein-barr virus, herpes simplex type 1, herpes simplex type 2, human cytomegalovirus, human herpesvirus type 8, varicella-zoster virus, Hepadnaviruses including hepatitis B virus, Flaviviruses including hepatitis C virus, yellow fever virus, dengue virus, West Nile virus, Retroviruses including human immunodeficiency virus (HIV), Orthomyxoviruses including influenza virus, Paramyxoviruses including measles virus, mumps virus, parainfluenza virus, respiratory syncytial virus, Papillomaviruses including papillomavirus, Rhabdoviruses including rabies virus, Togaviruses including Rubella virus, and other viruses including vaccinia, avipox, adeno-associated virus, modified Vaccinia Strain Ankara, Semliki Forest virus, poxvirus, and coronaviruses, or at least one antigenic portion or T-cell epitope of any of the above mentioned antigens.

24. The method according to any one of claims 1 to 8 wherein the at least one polymer particle is a polymer particle according to any one of claims 9 to 23.

25. A composition comprising the polymer particle of any one of claims 9 to 23.

26. The composition of claim 25 for eliciting an immune response in a subject in need thereof, or for vaccinating a subject in need thereof, or for immunising a subject in need thereof against a pathogen, or for diagnosing infection from a pathogen in a subject in need thereof.
27. The composition of claim 25 or claim 26 wherein the composition is a vaccine.
28. Use of a polymer particle of any one of claims 9 to 23 in the manufacture of a medicament suitable for eliciting an immune response in a subject in need thereof, or for vaccinating a subject in need thereof, or for immunising a subject in need thereof against a pathogen, or for diagnosing infection from a pathogen in a subject in need thereof.
29. The use according to claim 28 wherein the medicament is a vaccine.
30. An expression construct, the expression construct comprising

    at least one nucleic acid sequence encoding a particle-forming protein; and

    at least one nucleic acid sequence encoding an antigen capable of eliciting an immune response or at least one nucleic acid sequence encoding a binding domain capable of binding an antigen capable of eliciting an immune response.
31. The expression construct of claim 30, wherein the at least one nucleic acid sequence encoding the particle-forming protein and the at least one nucleic acid sequence encoding the antigen capable of eliciting an immune response or the at least one nucleic acid sequence encoding the binding domain capable of binding an antigen capable of eliciting an immune response are present as a single open reading frame.
32. The expression construct of claim 30 or 31, wherein the expression construct encodes a fusion polypeptide comprising the particle-forming protein and the antigen capable of eliciting an immune response or the binding domain capable of binding an antigen capable of eliciting an immune response.
33. The expression construct of any one of claims 30 to 32, wherein the construct additionally comprises a nucleic acid encoding

    i. at least one thiolase, or
    ii. at least one reductase, or
    iii. both (i) and (ii).
34. The expression construct of any one of claims 30 to 33, wherein the construct comprises a nucleic acid encoding

    i. at least one thiolase, or

ii. at least one reductase, or

iii. at least one polymer synthase, or

iv. at least one antigen capable of eliciting an immune response, or

v. at least one binding domain capable of binding at least one antigen capable of eliciting an immune response, or

vi. a fusion protein comprising one or more of i) to v) above, or

vii. any combination of i) to vi) above.

35. The expression construct of any one of claims 30 to 34 wherein the antigen is an antigen capable of eliciting a cell-mediated immune response.

36. A method for producing polymer particles, the method comprising
providing a host cell comprising at least one expression construct, the at least one expression construct comprising at least one nucleic acid sequence encoding an antigen capable of eliciting an immune response, or at least one nucleic acid sequence encoding a binding domain capable of binding an antigen capable of eliciting an immune response, and maintaining the host cell under conditions suitable for expression of the expression construct, and separating the polymer particles from the host cells.

37. A method of diagnosing infection from a pathogen, wherein the method comprises contacting a sample from a subject with at least one polymer particle of any one of claims 9 to 23 and detecting a response indicative of the presence of the pathogen.

38. The method of claim 37 wherein the response indicative of the presence of the pathogen is a detecting the presence of an antibody to the pathogen in a sample obtained from the subject.

39. The method of claim 37 wherein the response indicative of the presence of the pathogen is a detecting the presence of an immune cell responsive to the pathogen in said sample.

40. A method of diagnosing tuberculosis in a subject, wherein the method comprises contacting a sample from a subject with at least one polymer particle comprising one or more fusion polypeptides, wherein at least one of the fusion polypeptides comprises a particle-forming protein fused to at least one *M. tuberculosis* antigen or wherein at least one of the fusion polypeptides comprises a particle-forming protein fused to at least one *M. tuberculosis* antigen binding domain.

41. The method of claim 40 wherein the response indicative of the presence of tuberculosis is detecting the presence of an antibody to a tuberculosis antigen in said sample.

42. The method of claim 40 wherein the response indicative of the presence of tuberculosis is detecting the presence of an immune cell responsive to tuberculosis in said sample.
43. The method of any one of claims 40 to 42, wherein the subject has been immunised against tuberculosis.
44. The method of any one of claims 40 to 43, wherein the *M. tuberculosis* antigen binding domain binds to an endogenous *M. tuberculosis* antigen.
45. The method of any one of claims 40 to 44, wherein at least one of the polymer particles comprises two or more different fusion polypeptides.
46. The method of any one of claims 40 to 45, wherein at least one of the polymer particles comprises two or more different *M. tuberculosis* antigens, or two or more different *M. tuberculosis* antigen binding domains.
47. The method of any one of claims 40 to 46, wherein at least one of the polymer particles comprises at least one *M. tuberculosis* antigen and at least one *M. tuberculosis* antigen binding domain.
48. The method of any one of claims 40 to 47, wherein at least one of the polymer particles further comprises at least one substance bound to or incorporated into the polymer particle, or a combination thereof.
49. The method of claim 48, wherein the substance is an antigen, adjuvant or immunostimulatory molecule.
50. The method of any one of claims 40 to 47, wherein at least one of the polymer particles is multi-valent.
51. The method of any one of claims 48 to 50, wherein the substance is bound to the polymer particle by cross-linking.
52. The method of any one of claims 40 to 51, wherein at least one of the polymer particles comprises *M. tuberculosis* ESAT-6 antigen.
53. The method of any one of claims 40 to 52, wherein at least one of the polymer particles comprises *M. tuberculosis* Ag85A antigen.
54. The method of any one of claims 40 to 53, wherein at least one of the polymer particles comprises at least one of the fusion polypeptide comprising ESAT-6 antigen and Ag85A antigen.
55. The method of any one of claims 40 to 54, wherein at least one of the polymer particles comprises an *M. tuberculosis* antigen selected from the group comprising Ag85B (MPT59), Ag85B, Ag85C, MPT32, MPT51, MPT59, MPT63, MPT64, MPT83, MPB5,

MPB59, MPB64, MTC28, Mtb2, Mtb8.4, Mtb9.9, Mtb32A, Mtb39, Mtb41, TB10.4, TB10C, TB11B, TB12.5, TB13A, TB14, TB15, TB15A, TB16, TB16A, TB17, TB18, TB21, TB20.6, TB24, TB27B, TB32, TB32A, TB33, TB38, TB40.8, TB51, TB54, TB64, CFP6, CFP7, CFP7A, CFP7B, CFP8A, CFP8B, CFP9, CFP10, CFP11, CFP16, CFP17, CFP19, CFP19A, CFP19B, CFP20, CFP21, CFP22, CFP22A, CFP23, CFP23A, CFP23B, CFP25, CFP25A, CFP27, CFP28, CFP28B, CFP29, CFP30A, CFP30B, CFP50, CWP32, hspX (alpha-crystalline), APA, Tuberculin purified protein derivative (PPD), ST-CF, PPE68, LppX, PstS-1, PstS-2, PstS-3, HBHA, GroEL, GroEL2, GrpES, LHP, 19kDa lipoprotein, 71kDa, RD1-ORF2, RD1-ORF3, RD1-ORF4, RD1-ORF5, RD1-ORF8, RD1-ORF9A, RD1-ORF9B, Rv1984c, Rv0577, Rv1827, BfrB, Tpx. Rv1352, Rv1810, PpiA, Cut2, FbpB, FbpA, FbpC, DnaK, FecB, Ssb, RplL, FixA, FixB, AhpC2, Rv2626c, Rv1211, Mdh, Rv1626, Adk, ClpP, SucD (Belisle et al, 2005; US 7,037,510; US 2004/0057963; US 2008/0199493; US 2008/0267990), or at least one antigenic portion or T-cell epitope of any of the above mentioned antigens

56. A method of diagnosing infection from hepatitis or influenza in a subject, wherein the method comprises contacting a sample fromthe subject with at least one polymer particle of any one of claims 9 to 23 and detecting a response indicative of the presence of the hepatitis or influenza virus.
57. The method of claim 56 wherein the response indicative of the presence of the hepatitis or influenza virus is detecting the presence of an antibody to the hepatitis antigen or influenza antigen in said sample.
58. The method of claim 56 wherein the response indicative of the presence of the hepatitis or influenza virus is detecting the presence of an immune cell responsive to the hepatitis or influenza virus in said sample.
59. The method of any one of claims 56 to 58, wherein the subject is infected with a hepatitis or influenza.
60. The method of any one of claims 56 to 59, wherein the subject has been immunised against hepatitis or influenza.
61. The method of any one of claims 56 to 60, wherein the binding domain capable of binding a hepatitis antigen or an influenza antigen binds to an endogenous hepatitis antigen or influenza antigen.

62. The method of any one of claims 56 to 61, wherein at least one of the polymer particles comprises two or more different fusion polypeptides.

63. The method of any one of claims 56 to 62, wherein at least one of the polymer particles comprises two or more different hepatitis antigens or two or more influenza antigens, or two or more different binding domains capable of binding a hepatitis antigen or an influenza antigen.

64. The method of any one of claims 56 to 63, wherein at least one of the polymer particles comprises at least one hepatitis antigen or at least one influenza antigen and at least one binding domain capable of binding a hepatitis antigen or an influenza antigen.

65. The method of any one of claims 56 to 64, wherein at least one of the polymer particles further comprises at least one substance bound to or incorporated into the polymer particle, or a combination thereof.

66. The method of claim 65, wherein the substance is an antigen, adjuvant or immunostimulatory molecule.

67. The method of any one of claims 56 to 66, wherein at least one of the polymer particles is multi-valent.

68. The method of any one of claims 65 to 67, wherein the substance is bound to the polymer particle by cross-linking.

69. The method of any one of claims 56 to 68, wherein at least one of the polymer particles comprises at least one antigen, or at least one binding domain capable of binding at least one antigen, wherein the antigen is from an organism selected from the group consisting of viruses including Hepatitis C, Adenoviruses, Picornaviruses including coxsackievirus, hepatitis A virus, poliovirus, Herpesviruses including epstein-barr virus, herpes simplex type 1, herpes simplex type 2, human cytomegalovirus, human herpesvirus type 8, varicella-zoster virus, Hepadnaviruses including hepatitis B virus, Flaviviruses including hepatitis C virus, Orthomyxoviruses including influenza virus, or at least one antigenic portion or T-cell epitope of any of the above mentioned antigens.

70. A method for producing polymer particles, the method comprising

providing a host cell comprising at least one expression construct, the at least one expression construct comprising

at least one nucleic acid sequence encoding a hepatitis antigen or an influenza antigen, or

at least one nucleic acid sequence encoding a binding domain capable of binding a hepatitis antigen or an influenza antigen,

maintaining the host cell under conditions suitable for expression of the expression construct, and

separating the polymer particles from the host cells.

71. A polymer particle comprising one or more fusion polypeptides comprising a particle-forming protein fused to at least one hepatitis antigen or at least one influenza antigen.
72. The polymer particle of claim 71 wherein the polymer particle comprises two or more different fusion polypeptides.
73. The polymer particle of claim 72 wherein the polymer particle comprises two or more different hepatitis antigens or two or more different influenza antigens, or two or more different binding domains capable of binding a hepatitis antigen or an influenza antigen.
74. The polymer particle of any one of claims 71 to 73, wherein the polymer particle further comprises at least one substance bound to or incorporated into the polymer particle, or a combination thereof.
75. The polymer particle of claim 74 wherein the substance is an antigen, adjuvant or immunostimulatory molecule.
76. The polymer particle of any one of claims 71 to 75 wherein the polymer particle is multi-valent.
77. The polymer particle of any one of claims 74 to 76 wherein the substance is bound to the polymer particle by cross-linking.
78. A polymer particle comprising one or more fusion polypeptides comprising a particle-forming protein fused to at least one hepatitis antigen or at least one influenza antigen for eliciting a cell-mediated immune response in a subject in need thereof, or for immunising a subject against hepatitis or influenza, or for diagnosing infection from hepatitis or influenza in a subject in need thereof.
79. A polymer particle comprising one or more fusion polypeptides comprising a particle-forming protein fused to at least one binding domain capable of binding a hepatitis antigen or an influenza antigen for eliciting a cell-mediated immune response in a subject in need thereof, or for immunising a subject against hepatitis or influenza, or for diagnosing infection from hepatitis or influenza in a subject in need thereof.

80. Use of a polymer particle of any one of claims 71 to 79 in the manufacture of a medicament suitable for eliciting a cell-mediated immune response in a subject in need thereof, or for immunising a subject against hepatitis or influenza, or for diagnosing infection from hepatitis or influenza in a subject in need thereof.

81. An expression construct, the expression construct comprising

at least one nucleic acid sequence encoding a particle-forming protein; and

at least one nucleic acid sequence encoding a hepatitis antigen or an influenza antigen or at least one nucleic acid sequence encoding a binding domain capable of binding a hepatitis antigen or an influenza antigen.

82. The expression construct of claim 81, wherein the at least one nucleic acid sequence encoding the particle-forming protein and the at least one nucleic acid sequence encoding the hepatitis antigen or the influenza antigen or the at least one nucleic acid sequence encoding the binding domain capable of binding a hepatitis antigen or an influenza antigen are present as a single open reading frame.

83. The expression construct of claim 81 or 82, wherein the expression construct encodes a fusion polypeptide comprising the particle-forming protein and the hepatitis antigen or the influenza antigen or the binding domain capable of binding a hepatitis antigen or an influenza antigen.

84. The expression construct of any one of claims 81 to 83, wherein the construct additionally comprises a nucleic acid encoding

i. at least one thiolase, or
ii. at least one reductase, or
iii. both (i) and (ii).

85. The expression construct of any one of claims 81 to 84, wherein the construct comprises a nucleic acid encoding

i. at least one thiolase, or
ii. at least one reductase, or
iii. at least one polymer synthase, or
iv. at least one hepatitis antigen or at least one influenza antigen, or
v. at least one binding domain capable of binding at least one hepatitis antigen or at least one influenza antigen, or
vi. a fusion protein comprising one or more of i) to v) above, or

vii. any combination of i) to vi) above.