

CLAIMS

1. A pharmaceutical substance comprising a therapeutically effective amount of one or more of a clinically modified or genetically engineered Ksp37 protein
5 and/or proteins having a molecular weight in the range ranging from 24 kDa to 45 kDa; and/or a vector encoded with a KSP37 gene which will translate to a Ksp37 protein; and/or proteins having a molecular weight in the range ranging from 24 kDa to 45 kDa; and/or a polar compound, for use in enhancing the immune response of a subject against viral infection and/or diseases associated
10 with immune system disorders and/or viral cancers.
2. The pharmaceutical substance as claimed in claim 1, wherein the substance is formulated to raise the Ksp37 blood plasma concentration level of the subject to between 400 ng/mL and 700 ng/mL when administered to the subject one or
15 more times over a suitable period.
3. The pharmaceutical substance as claimed either of claims 1 or 2, wherein the substance includes a pharmaceutically accepted excipient.
- 20 4. The pharmaceutical substance as claimed in any one of claims 1 to 3, wherein the vector encoded with a KSP37 gene that is useful in fighting viral infection and/or diseases associated with immune system disorders and/or viral cancers, contains a nucleic acid sequence that translates to a protein identical to the naturally occurring Ksp37 protein.
- 25 5. The pharmaceutical substance as claimed in any one of the preceding claims, wherein the vector encoded with the KSP37 gene which will translate to a Ksp37 protein includes a pGEM-T vector or a pCMV3-C-GFPSpark.

6. The pharmaceutical substance as claimed in claim 5, wherein the vector is pGEM-T vector, KSP37/FGFBP2 cDNA ORF CLONE (SinoBiological).
- 5 7. The pharmaceutical substance as claimed in any one of the preceding claims, wherein the polar compound is *N,N*-dimethylformamide (DMF).
8. The pharmaceutical substance as claimed in claim 7, wherein the amount of DMF for activating Ksp37 production is a dose that results in a peak plasma
10 level of 2 mg/l - 200 mg/l, more preferably 100 mg/l - 200 mg/l, and most preferably 100 mg/l - 150 mg/l or 150 mg/l - 200 mg/l of DMF.
9. The pharmaceutical substance as claimed in any one of the preceding claims for use in protecting a subject from disease characterised by viral infection and/or
15 diseases associated with immune system disorder and/or viral cancers, and/or treating a subject suffering from disease characterised by viral infection and/or diseases associated with immune system disorder and/or viral cancers.
10. Use of a therapeutically effective amount of the pharmaceutical substance of any
20 one of claims 1 to 8 in the manufacture of a medicament for protecting a subject from disease characterised by viral infection and/or diseases associated with immune system disorder and/or viral cancers, and/or treating a subject suffering from disease characterised by viral infection and/or diseases associated with immune system disorder and/or viral cancers.
- 25 11. The use as claimed in claim 10, wherein the medicament is formulated for administration in an amount that raises the Ksp37 blood plasma concentration

level of the subject to between 400 ng/mL and 700 ng/mL when administered one or more times over a suitable period.

12. The use as claimed in either of claims 10 or 11, wherein the clinically modified
5 or genetically engineered Ksp37 is formulated for administering in a dose between 0.001 µg/kg body weight of a mammal microgram and 20 µg/kg body weight of a mammal.
13. The use as claimed in any one of claims 10 to 12, wherein the medicament
10 includes a controlled release composition that is capable of slowly releasing the clinically modified or genetically engineered Ksp37 into a mammal.
14. The use as claimed in any one of claims 10 to 13, wherein the clinically modified
15 or genetically engineered Ksp37 protein is extracted from blood components and/or tissue, then purified, acetylated, genetically engineered, cloned and transferred back to a mammalian host as a therapeutic and/or preventative vaccine against viral infection and/or diseases associated with immune system disorders and/or viral cancers.
- 20 15. The use as claimed in any one of claims 10 to 14, wherein the medicament is formulated for administration to the subject via an acceptable administration route, including nasal, oral, topical, inhalation, transdermal, rectal or parenteral administration.
- 25 16. The use as claimed in any one of claims 10 to 15, wherein the virus is a retrovirus, specifically HIV.

17. The use as claimed in any one of claims 10 to 16, wherein the viral cancer is ovarian cancer or leukaemia.
18. The use as claimed in anyone of claims 10 to 17, wherein the subject is a mammal.
19. A method of protecting a subject from disease characterised by viral infection and/or diseases associated with immune system disorder and viral cancers, and/or a method of treating a subject suffering from disease characterised by viral infection and/or diseases associated with immune system disorder and/or viral cancers, the method comprising administering to the subject a therapeutically effective amount of the pharmaceutical substance of any one of claims 1 to 8 to increase the blood plasma levels of Ksp37 protein in the subject to between 400 ng/mL and 700 ng/mL.
20. The method as claimed in claim 19, wherein the therapeutically effective amount of clinically modified or genetically engineered Ksp37 protein and/or proteins having a molecular weight in the range ranging from 24 kDa to 45 kDa, is between 0.001 µg/kg body weight of a mammal microgram and 20 µg/kg body weight of a mammal.
21. The method as claimed in either of claims 19 or 20, wherein the pharmaceutical substance is administered to the subject via an acceptable administration route, including nasal, oral, topical, inhalation, transdermal, rectal or parenteral administration.

22. The method as claimed in any one of claims 19 to 21, wherein the Ksp37 protein is extracted from blood components and/or tissue, then purified, acetylated, genetically engineered, cloned and transferred back to a mammalian host as a therapeutic and/or preventative vaccine against viral infection and/or diseases associated with immune system disorders and/or viral cancers.
23. The method as claimed in any one of claims 19 to 21, wherein the therapeutically effective amount of DMF for activating Ksp37 production is a dose that results in a peak plasma level of 2 mg/l - 200 mg/l, preferably 100 mg/l - 200 mg/l, and most preferably 100 mg/l -150 mg/l or 150 mg/l - 200 mg/l of DMF.
24. The method as claimed in claim 23, wherein the DMF is administered transdermal.
25. The method as claimed in claim 19, wherein the virus is a retrovirus, specifically HIV.
26. The method as claimed in claim 19, wherein the viral cancer is ovarian cancer or leukaemia.
27. The method as claimed in claim 19, wherein the subject is a mammal.
28. A therapeutic and/or preventative vaccine against viral infection and/or diseases associated with immune system disorders and/or viral cancers, the vaccine comprising a clinically modified or genetically engineered Ksp37 protein and/or proteins having a molecular weight in the range

ranging from 24 kDa to 45 kDa, and/or a vector encoded with a KSP37 gene which will translate to a Ksp37 protein and/or proteins having a molecular weight in the range ranging from 24 kDa to 45 kDa.