CLAIMS

1. Use of a fixed dosage apolipoprotein formulation for the preparation of a medicament for prophylactically or therapeutically treating ~~a disease, disorder or condition~~ cardiovascular disease, hypercholesterolaemia or hypocholesterolaemia in a human with a body weight in the body weight range 60-140 kg, wherein the apolipoprotein formulation has been determined to display relatively reduced inter-patient variability in exposure to the apolipoprotein of the formulation compared to that which would be observed or associated with a weight-adjusted dosage regime.

~~2. A fixed dosage apolipoprotein formulation, for use in prophylactically or therapeutically treating a disease, disorder or condition in a human.~~

~~3. The use of Claim 1 or the apolipoprotein formulation for use according to Claim 2, wherein the disease, disorder or condition includes cardiovascular disease, hypercholesterolaemia or hypocholesterolaemia.~~

42. The use ~~or the apolipoprotein formulation for use~~ according to Claim ~~3~~1, wherein the cardiovascular disease, hypercholesterolaemia ~~disorder~~ or hypocholesterolaemia ~~condition~~ includes acute coronary syndrome (ACS), atherosclerosis, unstable angina pectoris, and myocardial infarction.

~~5. The use of any one of Claims 1, 3 or 4, or the fixed dosage apolipoprotein formulation for use according to Claim 2, Claim 3 or Claim 4, wherein the apolipoprotein formulation is therapeutically effective upon administration to a human of any body weight, or of any body weight in a body weight range.~~

~~6. The use or the apolipoprotein formulation for use according to Claim 5, wherein the body weight is in the body weight range 60-140 kg.~~

~~7. The use of any one of Claims 1 or 3-6, or the apolipoprotein formulation for use according to anyone of Claims 2-6, wherein the apolipoprotein formulation displays relatively reduced inter-patient variability in exposure to the apolipoprotein of the formulation compared to that which would be observed or associated with a weight-adjusted dosage regime.~~

83. The use~~, or the apolipoprotein formulation for use~~ according to Claim ~~7~~1 or 2, wherein the inter-patient variability in exposure to apolipoprotein is less than 90% of that observed or associated with the weight-adjusted dosage regime.

~~9~~4. The use of any one of Claims 1 ~~or 3-8, or the apolipoprotein formulation for use according to one of Claims 2-8,~~ wherein the fixed dosage comprises an amount of apolipoprotein in a range selected from: 0.1-15g; 1-10g; 2-9g; 3-8g; 4-7g; and 5-6g of apolipoprotein.

~~10~~5. The use~~, or the apolipoprotein formulation for use~~ according to Claim 9, wherein the fixed dosage comprises 0.25g, 0.5g, 1g, 1.7g, 2g, 3.4g, 4g, 5.1g, 6g, 6.8g or 8g apolipoprotein.

~~11~~6. The use according to any one of Claims 1 ~~or 3-10~~5, ~~or the fixed dosage apolipoprotein formulation for use according to any one of Claims 2-10,~~ wherein the apolipoprotein is Apo-A1 or a fragment thereof.

~~12~~7. The use according to any one of Claims 1 ~~or 3-11~~6, ~~or the fixed dosage apolipoprotein formulation for use according to any one of Claims 2-11,~~ wherein the apolipoprotein formulation is a reconstituted high density apolipoprotein (rHDL) formulation.

~~13~~8. The use~~, or the fixed dosage apolipoprotein formulation for use~~ according to Claim ~~12~~7, wherein the rHDL formulation comprises the apolipoprotein, one or more lipids and optionally a detergent.

~~14~~9. The use~~, or the fixed dosage apolipoprotein formulation for use~~ according to Claim ~~13~~8, wherein the apolipoprotein is Apo A-I purified from plasma, the lipid is phosphatidylcholine, and the rHDL formulation further comprises sodium cholate detergent.

~~15~~10. The use~~, or the fixed dosage apolipoprotein formulation for use~~ according to Claim ~~14~~9, wherein the ratio between the apolipoprotein and the lipid is from 1:40 to 1:75 (mol:mol), and the sodium cholate is present at a concentration of 0.5 to 0.9 g/L.

~~16~~11. The use~~, or the fixed dosage apolipoprotein formulation for use~~ according to Claim ~~13~~8, wherein the apolipoprotein is recombinant Apo A-I and the one or more lipids is a mixture of sphingomyelin and phosphatidylglycerol.

~~17~~12. The use~~, or the fixed dosage apolipoprotein formulation for use~~ according to Claim 1~~6~~, wherein the ratio between the apolipoprotein and the lipid is between 1:80 and 1:120 (mol:mol) and the sphingomyelin and the phosphatidylglycerol are present in a ratio from 90:10 to 99:1 (w:w).

~~18. An apolipoprotein formulation comprising an apolipoprotein or a fragment thereof, at a therapeutically effective fixed dosage.~~

~~19~~13. A method of producing a fixed dosage apolipoprotein formulation comprising an apolipoprotein or a fragment thereof, including the step of producing the apolipoprotein formulation at a fixed dosage which is therapeutically effective upon administration to a human body of a body weight in the body weight range of 60-140 kg and to display relatively reduced inter-patient variability in exposure to the apolipoprotein constituent of the formulation compared to that which would be observed or associate with a weight-adjusted dosage.

~~20. The method of Claim 19 which includes the step of determining a fixed dosage of the apolipoprotein formulation that is therapeutically effective upon administration to a human of any body weight or of any body weight in a body weight range.~~

~~21. The method of Claim 20, wherein the body weight is in the body weight range 60-140 kg.~~

~~22. An apolipoprotein formulation produced according to the method of any one of Claims 19-21.~~

~~23~~14. ~~The~~ An apolipoprotein formulation ~~of Claim 18 or Claim 22~~, comprising an apolipoprotein or a fragment thereof at a fixed dosage which is therapeutically effective upon administration to a human of ~~any body weight, or of any~~ body weight in ~~the~~a body weight range of 60-140 kg; wherein the apolipoprotein formulation displays relatively reduced inter-patient variability in exposure to the apolipoprotein constituent of the formulation compared to that which would be observed or associated with a weight-adjusted dosage regime.

~~24. The apolipoprotein formulation of Claim 23, wherein the body weight is in the body weight range 60-140 kg.~~

~~25. The apolipoprotein formulation of Claim 18 or any one of Claims 22-24 which displays relatively reduced inter-patient variability in exposure to the apolipoprotein constituent of the formulation compared to that which would be observed or associated with a weight-adjusted dosage regime.~~

~~26~~15. The apolipoprotein formulation of Claim ~~25~~14, wherein the variability is less than 90% of that observed or associated with the weight-adjusted dosage regime.

~~27~~16. The apolipoprotein formulation according to ~~Claim 18 or any one of~~ Claims ~~22~~14-~~26~~ or 15, wherein the fixed dosage comprises an amount of apolipoptotein in a range selected from: 0.1-15g; 1-10g; 2-9g; 3-8g; 4-7g; and 5-6g apolipoprotein.

~~28~~17. The apolipoprotein formulation of Claim ~~27~~ 16, wherein the fixed dosage comprises an amount of apolipoprotein selected from: 0.25g; 0.5g; 1g; 1.7g; 2g; 3.4g; 4g; 5.1g; 6g; 6.8g; and 8g apolipoprotein.

~~29~~18. The apolipoprotein formulation according to ~~Claim 18 or~~ any one of Claims ~~22~~14-~~28~~17, wherein the apolipoprotein is Apo-A1 or a fragment thereof.

~~30~~19. The apolipoprotein formulation according to ~~Claim 18 or~~ any one of Claims ~~22~~14-~~29~~18, wherein the apolipoprotein formulation is a reconstituted high density lipoprotein (rHDL) formulation.

~~31~~20. The apolipoprotein formulation according to Claim ~~30~~19, wherein ~~in~~ the rHDL formulation comprises the apolipoprotein, one or more lipids and optionally a detergent.

~~32~~21. The apolipoprotein formulation according to Claim ~~31~~20, wherein ~~in~~ the rHDL formulation the apolipoprotein is Apo A-I purified from plasma, the lipid is phosphatidylcholine, and the rHDL formulation further comprises sodium cholate detergent.

~~33~~22. The apolipoprotein formulation according to Claim ~~32~~1, wherein the ratio between the apolipoprotein and the lipid is from 1:40 to 1:75 (mol:mol), and the sodium cholate is present at a concentration of 0.5 to 0.9 g/L.

~~34~~23. The apolipoprotein formulation according to Claim ~~31~~20, wherein the apolipoprotein is recombinant Apo A-I and the one or more lipids is a mixture of sphingomyelin and phosphatidylglycerol.

~~35~~24. The apolipoprotein formulation according to Claim ~~34~~23, wherein the ratio between the apolipoprotein and the lipid is between 1:80 and 1:120 (mol:mol) and the sphingomyelin and the phosphatidylglycerol are present in a ratio from 90:10 to 99:1 (w:w).

~~36~~25. A kit comprising one or more unit doses of a fixed dosage apolipoprotein formulation according to ~~Claim 18 or~~ any one of Claims ~~22-30~~14-24; and one or more other kit components.

~~37~~26. The kit of Claim ~~36~~25, wherein said one or more other kit components include instructions for use; vials, containers or other storage vessels containing each of the unit doses; one or more delivery devices such as needles, catheters, syringes, tubing and the like; and/or packaging suitable for safely and conveniently storing and/or transporting the kit.

~~38~~27. The kit of Claim ~~36~~ 25 or ~~Claim 37~~26, for use in therapeutically or prophylactically treating ~~a disease, disorder or condition including~~ cardiovascular disease, hypercholesterolaemia or hypocholesterolaemia.

~~39~~28. The kit of Claim ~~38~~26, wherein the cardiovascular disease, ~~disorder~~ hypercholesterolaemia or ~~condition~~ hypocholesterolaemia includes acute coronary syndrome (ACS), atherosclerosis, unstable angina pectoris, and myocardial infarction.