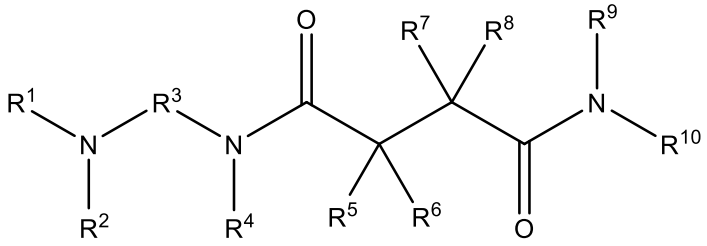
CLAIMS

1. A nanoparticle composition for delivery of a therapeutic, prophylactic and/or biological agent, the nanoparticle composition comprising:

a compound represented by general formula (1) or ionized form thereof



(1)

wherein

R^1, R^2, and R^4 to R^8 are each independently H, optionally substituted alkyl, optionally substituted alkenyl, or optionally substituted alkynyl,

R^3 is optionally substituted alkylene, optionally substituted alkenylene, or optionally substituted alkynylene, and

R^9 and R^{10} are each independently a hydrophobic tail or contains at least one of the groups defined above for R^4 to R^8;

a therapeutic, prophylactic and/or biological agent that is encapsulated by the compound of general formula (1) to form nanoparticles; and

a cryoprotectant.

2. The nanoparticle composition of claim 1, wherein

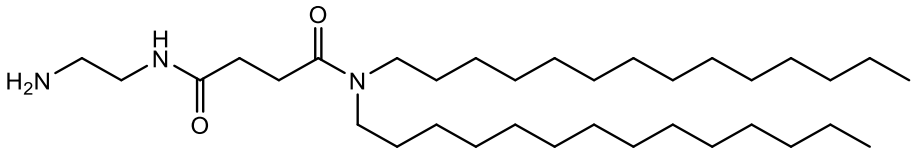
R^1 and R^2 are each H;

R^3 comprises alkylene; and

R^9 and R^{10} each independently comprises alkyl, where the alkyl contains at least 5 carbon atoms.

3. The nanoparticle composition of claim 1 or 2, wherein R^4 to R^8 are each H.

4. The nanoparticle composition of any one of the preceding claims, wherein the compound is represented by formula (1A):



(1A)

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5. The nanoparticle composition of any one of the preceding claims, wherein the therapeutic, prophylactic and/or biological agent comprises a nucleic acid,

optionally wherein the nucleic acid comprises messenger ribonucleic acid (mRNA); and

optionally wherein the therapeutic and/or prophylactic agent and/or biological agent is encapsulated at an encapsulation efficiency of at least 60%.

6. The nanoparticle composition of any one of the preceding claims, wherein the nanoparticle composition further comprises an ionizable lipid that is different from the compound of general formula (1)

optionally wherein the ionizable lipid that is different from the compound of general formula (1) comprises ALC-0315;

and optionally wherein the ratio of the compound of general formula (1) to the ionizable lipid that is different from said compound is 1: 1 – 20.

7. The nanoparticle composition of any one of the preceding claims, wherein the composition further comprises:

neutral/helper lipid;

sterol; and

polyethylene glycol (PEG)-modified lipid.

8. The nanoparticle composition of claim 7, wherein the compound of general formula (1), the neutral/helper lipid, the sterol, and the PEG-modified lipid are mixed at a molar ratio of 1 – 70 : 1 – 20 : 10 – 60 : 1 – 20,

optionally wherein the neutral/helper lipid is selected from the group consisting of 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-dioleoyl-sn-glycero-3-phosphoethanolamine (DOPE), 1,2-dilinoleoyl-sn-glycero-3-phosphocholine (DLPC), 1,2-dimyristoyl-sn-glycero-phosphocholine (DMPC), 1,2-dioleoyl-sn-glycero-3-phosphocholine (DOPC), 1,2-dipalmitoyl-sn-glycero-3-phosphocholine (DPPC), 1,2-diundecanoyl-sn-glycero-phosphocholine (DUPC), 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphocholine (POPC), 1,2-di-O-octadecenyl-sn-glycero-3-phosphocholine (18:0 Diether PC), 1-oleoyl-2-cholesterylhemisuccinoyl-sn-glycero-3-phosphocholine (OChemsPC), 1-hexadecyl-sn-glycero-3-phosphocholine (C16 Lyso PC), 1,2-dilinolenoyl-sn-glycero-3-phosphocholine, 1,2-diarachidonoyl-sn-glycero-3-phosphocholine, 1,2-didocosahexaenoyl-sn-glycero-3-phosphocholine, 1,2-diphytanoyl-sn-glycero-3-phosphoethanolamine (ME 16.0 PE), 1,2-distearoyl-sn-glycero-3-phosphoethanolamine, 1,2-dilinoleoyl-sn-glycero-3-phosphoethanolamine, 1,2-dilinolenoyl-sn-glycero-3-phosphoethanolamine, 1,2-diarachidonoyl-sn-glycero-3-phosphoethanolamine, 1,2-didocosahexaenoyl-sn-glycero-3-phosphoethanolamine, 1,2-dioleoyl-sn-glycero-3-phospho-rac-(1-glycerol) sodium salt (DOPG), sphingomyelin and combinations thereof;

optionally wherein the sterol is selected from cholesterol, fecosterol, sitosterol, ergosterol, campesterol, stigmasterol, brassicasterol, avenasterol and combinations thereof;

and optionally wherein the PEG-modified lipid is selected from 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159), R-3-[(ω-methoxy-poly(ethylene glycol)2000)carbamoyl]-1,2-dimyristyloxlpropyl-3-amine (PEG-c-DOMG), 3-N-[(ω-methoxypoly

(ethyleneglycol)2000)carbamoyl]-1,2-dimyristyloxy-propylamine (PEG-S-DMG), PEG-DMPE (1,2-dimyristoyl-sn-glycero-3-phosphoethanolamine-N-[(polyethylene glycol)-methoxy] (sodium salt)), PEG-DPPC, PEG-DSPE lipid and combinations thereof.

9. The nanoparticle composition of any one of the preceding claims, wherein the cryoprotectant comprises a carbohydrate source selected from at least one of maltose, sucrose, trehalose, mannitol, glucose, fructose, lactose, galactose, ribose, xylose, mannose, arabinose, and combinations thereof; and/or the cryoprotectant is present in an amount falling in the range of from 1 w/v% to 30 w/v% with respect to the total volume of the composition.

10. The nanoparticle composition of any one of the preceding claims, wherein the nanoparticle composition is in a lyophilized form or a freeze-thawed form.

11. The nanoparticle composition of any one of the preceding claims, wherein the nanoparticles have a zeta potential in the range of from -10 mV to +10 mV;

and/or the nanoparticles have a polydispersity index (PDI) in the range of from 0.01 to 0.5.;

and/or the nanoparticles have a particle size in the range of from 50 nm to 1200 nm.

12. The nanoparticle composition as claimed in any one of the preceding claims for use in medicine.

13. Use of a nanoparticle composition as claimed in any one of the preceding claims in the manufacture of a medicament for inducing an immune response in a subject in need thereof,

optionally wherein the immune response is specific to a coronavirus or to cancer or to bacteria; and

optionally wherein the coronavirus is a SARS-CoV-2 coronavirus.

14. The nanoparticle composition as claimed in any one of the preceding claims for use in inducing an immune response in a subject in need thereof, wherein said nanoparticle composition or lyophilized nanoparticle composition is to be administered to the subject,

optionally wherein the immune response is specific to a coronavirus or to cancer or to bacteria; and

optionally wherein the coronavirus is a SARS-CoV-2 coronavirus.

15. A method of preparing the nanoparticle composition as claimed in claim 1, the method comprising:

preparing an aqueous composition comprising a therapeutic and/or prophylactic agent and/or biological agent;

mixing the aqueous composition with the compound of general formula (1), a helper lipid, a sterol, and a PEG-modified lipid to obtain nanoparticles encapsulating the therapeutic and/or prophylactic agent and/or biological agent;

adding a cryoprotectant to the nanoparticles,

optionally wherein the mixing step is carried out in the presence of a further ionizable lipid that is different from the compound of general formula (1);

and optionally wherein the compound of general formula (1) and the ionizable lipid that is different from said compound are mixed together in a ratio of 1: 1 - 20.