CLAIMS

What is claimed is:

1. A lyophilized pharmaceutical unit dosage composition lyophilized from a composition comprising a)~~i)~~ an attenuated chikungunya virus; b) 5% (w/v) sucrose; c) 5 mM potassium phosphate; d) 25 mM sodium citrate; e) 5 mM $MgCl_2$; f) 0.5% (w/v) D-sorbitol; g) 10 mM L-methionine; and h) 0.01% (w/v) recombinant human serum albumin (rHSA), ~~and ii) one or more pharmaceutically acceptable excipients, characterized in that said pharmaceutical composition is able to induce a sustained protective immune response against a chikungunya virus in a human after a single dosage,~~ wherein said unit dosage composition comprises ~~about~~ 10^3 to 5 x 10^4 $TCID_{50}$/dose, preferably ~~about~~ 10^3 to 2 x 10^4 $TCID_{50}$/dose, and~~.~~

~~2. The pharmaceutical composition according to claim 1,~~ wherein said attenuated chikungunya virus comprises an RNA genome corresponding to the DNA sequence as defined by SEQ ID NO: 1 (CHIKV-Δ5nsP3) and/or one or more variants thereof, wherein said variant has a nucleic acid sequence that is at least 99% identical to SEQ ID NO: 1 and has the entire 60 amino acid deletion in nsP3 as in SEQ ID NO: 1.

2~~3~~. The pharmaceutical composition according to~~of~~ claim 1 ~~or 2~~, wherein said dosage is ~~about~~ 5 x 10^3 $TCID_{50}$/dose.

3~~4~~. The pharmaceutical composition according to claim 1~~2~~ or 2~~3~~, wherein said attenuated chikungunya virus variant expresses an E2 protein with at least one mutation compared with the wild-type E2 protein as defined by SEQ ID NO: 2, particularly an E2 protein as defined by any of SEQ ID Nos: 3-7.

4~~5~~. The pharmaceutical composition according to ~~of~~ any one of claims 1~~2~~ to 3~~4~~, wherein said attenuated chikungunya virus variant expresses an E2 protein with an E168K mutation as defined by SEQ ID NO: 3.

5~~6~~. Use of a pharmaceutical composition according to any one of claims 1 to 4 ~~A pharmaceutical composition for use~~ in the manufacture of a medicament as a one-shot vaccine for the prevention or treatment of chikungunya virus infection.~~, wherein the composition comprises or consists of i) CHIKV-Δ5nsP3 which expresses an E2 protein as defined by SEQ ID NO: 2, a CHIKV-Δ5nsP3 which expresses an E2 protein as defined by SEQ ID NO: 3 or a mixture thereof; and ii) one or~~

~~more pharmaceutically acceptable excipients, wherein said composition is administered to a subject at a dose of about 10^3 to 5 x 10^4 $TCID_{50}$/dose, preferably about 10^3 to 2 x 10^4 $TCID_{50}$/dose~~.

~~7. The pharmaceutical composition of any one of claims 1 to 6, wherein said composition is a liquid frozen composition.~~

~~8. The pharmaceutical composition of any one of claims 1 to 6, wherein said composition is a lyophilized composition.~~

~~9. The pharmaceutical composition of any one of claims 1 to 8, wherein the pharmaceutically acceptable excipients essentially consist of sucrose, potassium phosphate and sodium citrate and, optionally, magnesium chloride, D-sorbitol, L-methionine and recombinant human serum albumin rHSA.~~

~~10. The pharmaceutical composition according to any one of claims 1 to 9, wherein said pharmaceutically acceptable excipients essentially consist of about 5% (w/v) sucrose, about 10 mM potassium phosphate, about 25 mM sodium citrate and about 0.01% (w/v) recombinant human serum albumin (rHSA).~~

~~11. The pharmaceutical composition according to any one of claims 1 to 9, wherein said pharmaceutically acceptable excipients essentially consist of about 5% (w/v) sucrose; about 5 mM potassium phosphate; about 25 mM sodium citrate; about 5 mM $MgCl_2$; about 0.5 % (w/v) D-sorbitol; about 10 mM L-methionine; and about 0.01% (w/v) recombinant human serum albumin(rHSA).~~

6~~12~~. The pharmaceutical composition according to~~of~~ any one of claims 1 to 4~~11~~, wherein said composition is able to increase serum antibody titers to said virus in a human by at least 1 log relative to a control within about 14 days from primary immunization.

7~~13~~. The pharmaceutical composition according to~~of~~ any one of claims 1 to 4~~11~~, wherein said composition is able to increase serum antibody titers to said virus in a human by at least 1 log relative to a control within about 7 days from primary immunization.

8~~14~~. The pharmaceutical composition according to~~of~~ any one of claims 1 to 4, 6 or 7~~13~~, wherein said composition is able to stimulate seroconversion in at least 25%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, at least 90%, at least 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99%, up to 100% of vaccinated subjects within 7 days of vaccination, wherein seroconversion is defined as reaching a neutralizing CHIKV antibody titer of at least 10, preferably at least 20.

9~~15~~. The pharmaceutical composition according to~~of~~ any one of ~~claims 1 to 13~~claims 1 to 4, 6 or 7, wherein said composition is able to stimulate seroconversion in at least 25%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, at least 90%, at least 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99%, up to 100% of vaccinated subjects within 14 days of vaccination, wherein seroconversion is defined as reaching a neutralizing CHIKV antibody titer of at least 10, preferably at least 20.

10~~16~~.The pharmaceutical composition according to~~of~~ any one of claims 1 to 4 or 6 to 9 ~~15~~, wherein the protective immune response lasts for at least 6 months.

11~~17~~.The pharmaceutical composition according to~~of~~ any one of claims 1 to 4 or 6 to 9~~to 15~~, wherein the protective immune response lasts for at least 12 months.

12~~18~~.The pharmaceutical composition according to~~of~~ any one of claims 1 to 4 or 6 to 9~~to 15~~, wherein the protective immune response lasts for at least 24 months.

13~~19~~.The pharmaceutical composition according to~~of~~ any one of claims 1 to 4 or 6 to 9~~15~~, wherein the protective immune response confers life-long protection against CHIK virus disease.

14~~20~~. Use of a pharmaceutical composition according to any one of claims 1 to 13 in the manufacture of a medicament ~~The pharmaceutical composition of any one of claims 1 to 19, for use in a method of~~ for treating or preventing a Chikungunya virus infection.