

CLAIMS

~~171.~~ A fusion protein comprising:

(a) _____

(i) _____ a spike protein from 2019-nCoV having at least 90% identity with SEQ ID NO: 1;
; or

(ii) _____ a polypeptide having at least 90% identity to an immunogenic fragment of SEQ ID NO: 1, wherein ~~or a fragment thereof, that has a common antigenic cross-reactivity with said spike protein, wherein optionally~~ said fragment comprises or consists of receptor-binding domain (RBD) of the 2019-nCoV spike protein, preferably having at least 90% identity with SEQ ID NO: 15; and

~~18.~~ The fusion protein of claim 17, which further comprises:

(b) _____

(ai) the Hepatitis B surface antigen, ~~or a fragment thereof that has a common antigenic cross-reactivity with said Hepatitis B surface antigen;~~

(bii) the HPV 18 L1 protein, ~~or a fragment thereof that has a common antigenic cross-reactivity with said HPV 18 L1 protein;~~

(ciii) the Hepatitis E P239 protein, ~~or a fragment thereof that has a common antigenic cross-reactivity with said Hepatitis E P239 protein;~~ and/or

(div) the HPV 16 L1 protein, ~~or a fragment thereof that has a common antigenic cross-reactivity with said HPV 16 L1 protein;~~
wherein optionally:

2. The fusion protein of claim 1, wherein:

(ia) the fusion protein is encoded by a polynucleotide which comprises or consists of a nucleic acid sequence having at least 90% identity with any one of SEQ ID NO: 3, 5, 6, 8, 26, 27, 29, 30, or 32; and/or

(ib) the fusion protein comprises or consists of an amino acid sequence having at least 90% identity with any one of SEQ ID NO: 9, 10, 11, 12, 28, 31, or 33.

~~193.~~ A virus-like particle (VLP) comprising:

(a) _____ a spike protein from 2019-nCoV having at least 90% identity with SEQ ID NO: 1;

(b) a polypeptide having at least 90% identity to an immunogenic fragment of SEQ ID NO: 1, wherein or a fragment thereof, that has a common antigenic cross-reactivity with said spike protein, wherein optionally said fragment comprises or consists of receptor-binding domain (RBD) of the 2019-nCoV spike protein, preferably optionally having at least 90% identity with SEQ ID NO: 15;

wherein optionally said VLP comprises or consists of a fusion protein as defined in claim ~~17~~1 or ~~18~~2.

~~14.~~ An isolated polynucleotide encoding:

~~(a)~~ a spike protein from 2019-nCoV having at least 90% identity with SEQ ID NO: 1, or

(b) a polypeptide having at least 90% identity to an immunogenic fragment thereof of SEQ ID NO: 1, wherein said fragment that comprises or consists of receptor-binding domain (RBD) of the 2019-nCoV spike protein, optionally having at least 90% identity with SEQ ID NO: 15; and has a common antigenic cross-reactivity with said spike protein,
wherein said polynucleotide is optimised for recombinant expression.

~~25.~~ The polynucleotide of claim ~~14~~4, which:

(a) is optimised for expression in a host cell selected from:

(ai) *Escherichia coli*;

(bii) yeast, preferably *Komagataella* or *Saccharomyces*; and/or

(ciii) mammalian cells, preferably human cells; and/or

(b)

~~5.~~ ~~The polynucleotide of any one of claims 1 to 4, which~~ has a codon adaptation index (CAI) of at least about 0.80, preferably at least about 0.9, more preferably at least about 0.93.

~~36.~~ The polynucleotide of claim ~~14~~4 or ~~5~~2, wherein one or more cis-acting sequence motif is omitted, said one or more cis-acting sequence motif being independently selected from:

(a) an internal TATA-box;

(b) a chi-site;

(c) a ribosomal entry site;

(d) an AT-rich and/or GC-rich stretch of sequence;

- (e) an RNA instability motif;
- (f) a repeat sequence and/or an RNA secondary structure;
- (g) a cryptic splice donor site;
- (h) a cryptic splice acceptance site; and/or
- (i) any combination of (a) to (i).

47. The polynucleotide of any one of claims ~~1-4~~ to 63, wherein the polynucleotide integrates into the host cell genome.

~~68~~. The polynucleotide of any one of claims ~~1-4~~ to 57, which comprises or consists of a nucleic acid sequence having:

- (a) at least 90% identity to SEQ ID NO: 2;
- (b) at least 90% identity to SEQ ID NO: 3;
- (c) at least 90% identity to SEQ ID NO: 4;
- (d) at least 90% identity to SEQ ID NO: 5;
- (e) at least 90% identity to SEQ ID NO: 6;
- (f) at least 90% identity to SEQ ID NO: 7;
- (g) at least 90% identity to SEQ ID NO: 8
- (h) at least 90% identity to SEQ ID NO: 13
- (i) at least 90% ~~sequence~~ identity to SEQ ID NO: 14
- (j) at least 90% identity to SEQ ID NO: 26
- (k) at least 90% identity to SEQ ID NO: 27
- (l) at least 90% identity to SEQ ID NO: 29;
- (m) at least 90% identity to SEQ ID NO: 30; or
- (n) at least 90% identity to SEQ ID NO: 32.

79. The polynucleotide of any one of claims ~~1-4~~ to ~~68~~, wherein the encoded spike protein, or fragment thereof:

- (a) retains the conformational epitopes present in the native 2019-nCoV spike protein; and/or
- (b) results in the production of neutralising antibodies specific for the spike protein or fragment thereof when the nucleic acid or the encoded spike protein or fragment thereof is administered to a subject; ~~and/or~~

~~(c) comprises or consists of receptor-binding domain (RBD) of the 2019-nCoV spike protein, preferably having at least 90% identity with SEQ ID NO: 15.~~

~~810.~~ An expression construct comprising polynucleotide of any one of claims ~~1-4~~ to ~~79~~, operably linked to a promoter.

~~911.~~ A vaccine composition comprising:

~~(a) a spike protein from 2019-nCoV having at least 90% identity with SEQ ID NO: 1;~~ or

~~(b) a polypeptide having at least 90% identity to an immunogenic fragment of SEQ ID NO: 1, wherein a fragment thereof, that has a common antigenic cross-reactivity with said spike protein, wherein optionally said fragment comprises or consists of receptor-binding domain (RBD) of the 2019-nCoV spike protein, preferably optionally having at least 90% identity with SEQ ID NO: 15; optionally~~

~~10.~~ ~~The composition of claim 9, which wherein the composition~~ results in the production of neutralising antibodies specific for the spike protein or fragment thereof when administered to a subject.

~~1112.~~ A viral vector, RNA vaccine or DNA plasmid that:

~~(a) expresses a spike protein from 2019-nCoV having at least 90% identity with SEQ ID NO: 1;~~ or

~~(b) expresses a polypeptide having at least 90% identity to an immunogenic fragment thereof of SEQ ID NO: 1 or a fragment thereof, that has a common antigenic cross-reactivity with said spike protein, wherein optionally said fragment comprises or consists of receptor-binding domain (RBD) of the 2019-nCoV spike protein, preferably having at least 90% identity with SEQ ID NO: 15.~~

~~1213.~~ The viral vector, RNA vaccine or DNA plasmid of claim ~~12~~4, which expresses the spike protein or fragment thereof, further comprising a signal peptide; optionally

~~13.~~ ~~The viral vector, RNA vaccine or DNA plasmid of claim 12,~~ wherein the signal peptide directs secretion from human cells.

14. The viral vector, RNA vaccine or DNA plasmid of ~~any one of claims 11-12 or 13 to 13,~~ wherein the viral vector, RNA vaccine or DNA plasmid further expresses one or more additional antigen or a fragment thereof, preferably one or more additional antigen from 2019-nCoV, or a fragment thereof; optionally

~~15. The viral vector, RNA vaccine or DNA plasmid of claim 14,~~ wherein the spike protein or fragment thereof and the one or more additional antigen or fragment thereof are expressed:

- (a) as a fusion protein; or
- (b) in separate viral vectors, RNA vaccines or DNA plasmids for use in combination.

~~16~~15. The viral vector, RNA vaccine or DNA plasmid of any one of claims ~~11-12~~ to ~~15~~14, which comprises one or more polynucleotide as defined in any one of claims ~~1-4~~ to ~~7-9~~ or an expression construct of claim ~~8~~10.

~~20. An antibody, or binding fragment thereof, that specifically binds to a 2091-nCoV spike protein antigen, or fragment thereof, as defined in claim 1.~~

~~21. The antibody, or binding fragment thereof, of claim 20, wherein the antibody is a monoclonal or polyclonal antibody.~~

~~22. The antibody, or binding fragment thereof, of claim 20 or 21, wherein the antibody is an Fab, F(ab')₂, Fv, scFv, Fd or dAb.~~

~~23. An oligonucleotide aptamer that specifically binds to a 2019-nCoV spike protein or fragment thereof as defined in any claim 1.~~

~~24~~16. A vaccine composition comprising the viral vector, and/or RNA vaccine and/or DNA plasmid of any one of claims ~~11-12~~ to ~~16~~15.

~~25~~17. The polynucleotide of any one of claims ~~1-4~~ to ~~7~~9, and/or the expression construct of claim ~~8~~10, and/or vaccine composition of any one of claims ~~9, 10~~11 and/or ~~24~~16, and/or the viral vector and/or RNA vaccine and/or DNA plasmid of any one of claims ~~11-12~~ to ~~16~~15, and/or the virus-

like particle of claim ~~19~~3, and/or the fusion protein of claim ~~17~~1 or ~~18~~2, and/or the antibody of any one of claims ~~20 to 22~~ and/or the aptamer of claim ~~23~~ for use in the treatment and/or prevention of 2019-nCoV infection.

~~26~~18. Use of the polynucleotide of any one of claims ~~1~~4 to ~~7~~9, and/or the expression construct of claim ~~8~~10, and/or vaccine composition of any one of claims ~~9, 10~~11 and/or ~~24~~16, and/or the viral vector and/or RNA vaccine and/or DNA plasmid of any one of claims ~~11~~12 to ~~16~~15, and/or the virus-like particle of claim ~~19~~3, and/or the fusion protein of claim ~~17~~1 or ~~18~~2, and/or the antibody of any one of claims ~~20 to 22~~ and/or the aptamer of claim ~~23~~ in the manufacture of a medicament for the prevention and/or treatment of 2019-nCoV infection.

~~27~~19. A method of producing a spike protein from 2019-nCoV having at least 90% identity with SEQ ID NO: 1, or a fragment thereof, comprising expressing a polynucleotide as defined in any one of claims ~~1~~4 to ~~7~~9 in a host cell, and optionally purifying the spike protein or fragment.

~~28~~20. The method of claim ~~27~~19, which further comprises formulating said spike protein or fragment thereof with a pharmaceutically acceptable carrier or diluent.