Claims

1. A ~~kit of parts~~vaccine/inhibitor combination comprising:

(i) as vaccine an RNA vaccine comprising ~~an~~ at least one RNA, wherein the at least one RNA is an mRNA comprising at least one open reading frame (ORF) coding for at least one antigen~~;~~ and

(ii) as inhibitor a composition comprising a PD-1 pathway inhibitor~~; for use in medicine.~~,

wherein the PD-1 pathway inhibitor is an antagonistic antibody, which is directed against PD-1.

2. ~~Use~~ The combination according to claim 1, wherein the antibody directed against PD-1 is BMS-936558/MDX1106, CT-011 or MK-3475.

3. The combination according to claim 1 or 2, wherein the at least one RNA of the RNA vaccine is an isolated RNA.

4. The combination according to any one of ~~a kit~~claims 1-3, wherein the at least one RNA of ~~parts~~the RNA vaccine is a stabilized RNA.

5. The combination according to any one of claims 1-4, wherein the at least one RNA of the RNA vaccine is at least partially G/C modified.

6. The combination according to any one of claims 1-5, wherein the at least one RNA of the RNA vaccine comprises a codon-optimized region.

7. The combination according to any one of claims 1-6, wherein the at least one RNA of the RNA vaccine is complexed with a carrier.

8. The combination according to claim 7, wherein the carrier is a cationic or polycationic compound or a polymeric carrier.

9. A pharmaceutical composition comprising:

(i) an RNA vaccine comprising at least one RNA comprising at least one open reading frame coding for at least one antigen as defined in any one of the preceding claims and

(ii) a PD-1 pathway inhibitor as defined in any one of the preceding claims.

10. A kit of parts comprising:

(i) an RNA vaccine comprising an at least one RNA comprising at least one open reading frame coding for at least one antigen~~,~~ as defined in any one of the preceding claims and

(ii) a composition comprising a PD-~~1~~1 pathway inhibitor~~,~~ as defined in any one of the preceding claims.

11. The combination according to any one of claims 1-8, the pharmaceutical composition according to claim 9, the kit of parts according to claim 10 for medical use.

12. Use of the combination according to any one of claims 1-8, the pharmaceutical composition according to claim 9, the kit of parts according to claim 10 in the manufacture of a medicament for preventing or treating a tumor or cancer disease or an infectious disease.

~~3~~13. The combination or kit of parts according to claim ~~1~~11 or ~~the use according to claim 2~~12, wherein the PD-1 pathway inhibitor and the RNA vaccine are to be administered to a patient in need thereof sequentially.

~~4.~~14. The combination or kit of parts according to claim ~~1~~11 or ~~the use according to claim 2~~12, wherein the PD-1 pathway inhibitor and the RNA vaccine are to be administered to a subject in need thereof concurrently.

~~5~~15. The combination or kit of parts ~~or the use~~ according to any ~~one~~ of claims ~~1~~11 to ~~4~~14, wherein the PD-1 pathway inhibitor and the RNA vaccine are to be administered to a subject in need thereof via different administration routes.

16. A PD-1 pathway inhibitor as defined in any one of the preceding claims for use in therapy in combination with an RNA vaccine as defined in any one of the preceding claims.

17. An RNA vaccine as defined in any one of the preceding claims for use in therapy in combination with a PD-1 pathway inhibitor as defined in any one of the preceding claims.