CLAIMS

What is claimed is:

1. ~~A method of treating a solid tumor in a human patient, the method comprising administering to the patient an effective amount of each of:~~
~~(a) an anti-LAG-3 antibody comprising CDR1, CDR2 and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:3, and CDR1, CDR2 and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:5,~~
~~(b) an anti-PD-1 antibody comprising CDR1, CDR2 and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:19, and CDR1, CDR2 and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:21,~~
~~wherein the method comprises at least one administration cycle, wherein the cycle is a period of eight weeks, wherein for each of the at least one cycles, four doses of the anti-LAG-3 antibody are administered at a dose of 3, 20, 80, or 240 mg and four doses of the anti-PD-1 antibody are administered at a dose of 80 or 240 mg.~~

~~2. The method of claim 1, wherein the anti-LAG-3 antibody and anti-PD-1 antibody are administered at the following doses:~~
~~(a) 3 mg anti-LAG-3 antibody and 80 mg of anti-PD-1 antibody;~~
~~(b) 3 mg anti-LAG-3 antibody and 240 mg of anti-PD-1 antibody;~~
~~(c) 20 mg anti-LAG-3 antibody and 240 mg of anti-PD-1 antibody;~~
~~(d) 80 mg anti-LAG-3 antibody and 240 mg of anti-PD-1 antibody; or~~
~~(e) 240 mg anti-LAG-3 antibody and 240 mg of anti-PD-1 antibody.~~

~~3. The method of claim 1, wherein the anti-PD-1 and anti-LAG-3 antibodies are formulated for intravenous administration.~~

~~4. The method of claim 1, wherein the anti-PD-1 and anti-LAG-3 antibodies are formulated together.~~

~~5. The method of claim 1, wherein the anti-PD-1 and anti-LAG-3 antibodies are formulated separately.~~

6. The method of claim 1, wherein the treatment consists of up to 12 cycles.

7. The method of claim 1, wherein anti-PD-1 antibody is administered on Days 1, 15, 29, and 43 of each cycle.

8. The method of claim 1, wherein anti-LAG-3 antibody is administered on Days 1, 15, 29, and 43 of each cycle.

9. The method of claim 1, wherein the anti-PD-1 antibody is administered prior to administration of the anti-LAG-3 antibody.

10. The method of claim 9, wherein the anti-LAG-3 antibody is administered within about 30 minutes prior to administration of the anti-PD-1 antibody.

11. The method of claim 1, wherein the anti-PD-1 antibody is administered after administration of the anti-LAG-3 antibody.

12. The method of claim 1, wherein the anti-PD-1 antibody is administered concurrently with the anti-LAG-3 antibody.

13. The method of claim 1, wherein the treatment produces at least one therapeutic effect chosen from a reduction in size of a tumor, reduction in number of metastasic lesions over time, complete response, partial response, and stable disease.

14. The method of claim 1, wherein the solid tumor is chosen from melanoma, non-small cell lung cancer (NSCLC), human papilloma virus (HPV)-related tumor, and gastric adenocarcinoma.

15. The method of claim 1, wherein the anti-LAG-3 antibody comprises
(a) a heavy chain variable region CDR1 comprising the sequence set forth in SEQ ID NO:7;
(b) a heavy chain variable region CDR2 comprising the sequence set forth in SEQ ID NO:8;

~~(c) a heavy chain variable region CDR3 comprising the sequence set forth in SEQ ID NO:9;~~

~~(d) a light chain variable region CDR1 comprising the sequence set forth in SEQ ID NO:10;~~

~~(e) a light chain variable region CDR2 comprising the sequence set forth in SEQ ID NO:11; and~~

~~(f) a light chain variable region CDR3 comprising the sequence set forth in SEQ ID NO:12.~~

~~16. The method of claim 1, wherein the anti-LAG-3 antibody comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:3 and 5, respectively.~~

~~17. The method of claim 1, wherein the anti-LAG-3 antibody comprises heavy and light chains comprising the sequences set forth in SEQ ID NOs:1 and 2, respectively.~~

~~18. The method of claim 1, wherein the anti-PD-1 antibody comprises~~

~~(a) a heavy chain variable region CDR1 comprising the sequence set forth in SEQ ID NO:23;~~

~~(b) a heavy chain variable region CDR2 comprising the sequence set forth in SEQ ID NO:24;~~

~~(c) a heavy chain variable region CDR3 comprising the sequence set forth in SEQ ID NO:25;~~

~~(d) a light chain variable region CDR1 comprising the sequence set forth in SEQ ID NO:26;~~

~~(e) a light chain variable region CDR2 comprising the sequence set forth in SEQ ID NO:27; and~~

~~(f) a light chain variable region CDR3 comprising the sequence set forth in SEQ ID NO:28.~~

~~19. The method of claim 1, wherein the anti-PD-1 antibody comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:19 and 21, respectively.~~

~~20. The method of claim 1, wherein the anti-PD-1 antibody comprises heavy and light chains comprising the sequences as set forth in SEQ ID NOs:17 and 18, respectively.~~

~~21. A kit for treating a solid tumor in a human patient, the kit comprising:~~
~~(a) a dose of an anti-LAG-3 antibody comprising CDR1, CDR2 and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:3, and CDR1, CDR2 and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:5;~~
~~(b) a dose of an anti-PD-1 antibody comprising CDR1, CDR2 and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:19, and CDR1, CDR2 and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:21; and~~
~~(c) instructions for using the anti-LAG-3 antibody and anti-PD-1 antibody in the method of claim 1.~~

~~22.~~ A pharmaceutical composition comprising an~~n~~ anti-LAG-3 antibody and an anti-PD-1 antibody, wherein the pharmaceutical composition comprises a pharmaceutically-acceptable carrier, 80 mg of an anti-LAG-3 antibody and 240 mg of an anti-PD-1 antibody; wherein the anti-PD-1 antibody comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:19 and 21, respectively; and the anti-LAG-3 antibody comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:3 and 5, respectively~~comprising CDR1, CDR2 and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:3, and CDR1, CDR2 and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:5, for co-administration with an anti-PD-1 antibody comprising CDR1, CDR2 and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:19, and CDR1, CDR2 and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:21, in at least one cycle, wherein for each cycle four doses of the anti-LAG-3 antibody are administered at a dose of 3, 20, 80, or 240 mg and four doses of the anti-PD-1 antibody are administered at a dose of 80 or 240 mg~~.

2. The pharmaceutical composition according to claim 1, wherein the anti-LAG-3 antibody is a human antibody.

3. The pharmaceutical composition according to claim 1 or 2, wherein the anti-PD-1 antibody is a human antibody.

4. The pharmaceutical composition according to any one of claims 1-3, wherein the anti-LAG-3 antibody is an IgG1, IgG2, IgG3, IgG4, IgM, IgAl, IgA2, IgAsec, IgD, or IgE isotype.

5. The pharmaceutical composition according to any one of claims 1-4, wherein the anti-PD-1 antibody is an IgG1, IgG2, IgG3, IgG4, IgM, IgAl, IgA2, IgAsec, IgD, or IgE isotype.

6. The pharmaceutical composition according to any one of claims 1-5, wherein the anti-LAG-3 antibody and anti-PD-1 antibody are human, IgG4 isotype antibodies.

7. The pharmaceutical composition according to any one of claims 1-6, wherein the anti-LAG-3 antibody comprises heavy and light chains comprising the sequences set forth in SEQ ID NOs:1 and 2, respectively.

8. The pharmaceutical composition according to any one of any one of claims 1-7, wherein the anti-PD-1 antibody comprises heavy and light chains comprising the sequences as set forth in SEQ ID NOs:17 and 18, respectively.

9. The pharmaceutical composition according to any one of claims 1-8, which is formulated for parenteral administration.

10. The pharmaceutical composition according to any one of claims 1-9, which is formulated for injection or infusion.

11. The pharmaceutical composition according to any one of claims 1-10, which is formulated for intravenous administration.

12. The pharmaceutical composition of any one of claims 1-11, wherein the pharmaceutically-acceptable carrier is a sterile liquid.

13. The pharmaceutical composition of any one of claims 1-12, wherein the pharmaceutically-acceptable carrier is water, an oil, aqueous solution saline, aqueous dextrose, or a glycerol solution.~~23. An anti-LAG-3 antibody comprising CDR1, CDR2 and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:3, and CDR1, CDR2 and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:5, for co-administration with an anti-PD-1 antibody comprising CDR1, CDR2 and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:19, and CDR1, CDR2 and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:21, in at least one cycle, wherein for each cycle four doses of the anti-LAG-3 antibody are administered at a dose of 3, 20, 80, or 240 mg/kg and four doses of the anti-PD-1 antibody are administered at a dose of 80 or 240 mg/kg.~~