

CLAIMS

1. Use of an anti-CD30 antibody-drug conjugate in the manufacture of a medicament for treating cancer in a combinatorial therapy, wherein the cancer is a solid tumor selected from the group consisting of non-small cell lung cancer (NSCLC), melanoma, head and neck cancer, renal cell carcinoma, microsatellite instability-high or mismatch repair deficient cancer, bladder cancer, colon cancer, rectal cancer, gastric cancer, gastroesophageal junction carcinoma, esophageal cancer, cervical cancer, hepatocellular carcinoma, endometrial carcinoma, Merkel cell carcinoma, cutaneous squamous cell carcinoma, breast cancer, and tumor mutational burden-high cancer, and the medicament is to be administered to a subject in combination with an anti-PD-1 antibody or an antigen-binding fragment thereof, wherein the anti-PD-1 antibody or antigen-binding fragment thereof comprises a heavy chain variable region and a light chain variable region, wherein the heavy chain variable region comprises:
 - (i) a CDR-H1 comprising the amino acid sequence of SEQ ID NO:17;
 - (ii) a CDR-H2 comprising the amino acid sequence of SEQ ID NO:18; and
 - (iii) a CDR-H3 comprising the amino acid sequence of SEQ ID NO:19; andwherein the light chain variable region comprises:
 - (i) a CDR-L1 comprising the amino acid sequence of SEQ ID NO:20;
 - (ii) a CDR-L2 comprising the amino acid sequence of SEQ ID NO:21; and
 - (iii) a CDR-L3 comprising the amino acid sequence of SEQ ID NO:22.
2. The use of claim 1, wherein the anti-PD-1 antibody or antigen-binding fragment thereof inhibits the activity of PD-1.
3. The use of claim 1 or claim 2, wherein the anti-PD-1 antibody or antigen-binding fragment thereof comprises a heavy chain variable region comprising the amino acid sequence of SEQ ID NO:31 and a light chain variable region comprising the amino acid sequence of SEQ ID NO:32.
4. The use of any one of claims 1-3, wherein the anti-PD-1 antibody or antigen-binding fragment thereof is pembrolizumab or a biosimilar thereof.

5. The use of any one of claims 1-4, wherein the anti-CD30 antibody-drug conjugate comprises an anti-CD30 antibody or antigen-binding fragment thereof conjugated to a therapeutic agent.
6. The use of claim 5, wherein the anti-CD30 antibody or antigen-binding fragment thereof of the anti-CD30 antibody drug conjugate comprises a heavy chain variable region and a light chain variable region, wherein the heavy chain variable region comprises:
- (i) a CDR-H1 comprising the amino acid sequence of SEQ ID NO:1;
 - (ii) a CDR-H2 comprising the amino acid sequence of SEQ ID NO:2; and
 - (iii) a CDR-H3 comprising the amino acid sequence of SEQ ID NO:3; and
- wherein the light chain variable region comprises:
- (i) a CDR-L1 comprising the amino acid sequence of SEQ ID NO:4;
 - (ii) a CDR-L2 comprising the amino acid sequence of SEQ ID NO:5; and
 - (iii) a CDR-L3 comprising the amino acid sequence of SEQ ID NO:6.
7. The use of claim 5 or claim 6, wherein the anti-CD30 antibody or antigen-binding fragment thereof of the anti-CD30 antibody drug conjugate comprises a heavy chain variable region comprising the amino acid sequence of SEQ ID NO:7 and a light chain variable region comprising the amino acid sequence of SEQ ID NO:8.
8. The use of any one of claims 5-7, wherein the anti-CD30 antibody or antigen-binding fragment thereof of the anti-CD30 antibody drug conjugate is cAC10 or a biosimilar thereof.
9. The use of any one of claims 1-8, wherein the anti-CD30 antibody-drug conjugate is brentuximab vedotin or a biosimilar thereof.
10. The use of any one of claims 1-9, wherein the anti-PD-1 antibody or antigen-binding fragment thereof is to be administered at a flat dose ranging from about 50 mg to about 500 mg.
11. The use of any one of claims 1-10, wherein the anti-PD-1 antibody or antigen-binding fragment thereof is to be administered once about every 1 week, once about every 2 weeks, once about every 3 weeks, once about every 4 weeks, once about every 5 weeks, or once about every 6 weeks.

12. The use of any one of claims 1-11, wherein the anti-CD30 antibody-drug conjugate is to be administered at a dose of about 1.8 mg/kg of the subject's body weight.
13. The use of claim 12, wherein the anti-CD30 antibody-drug conjugate is to be administered once about every 3 weeks.
14. The use of any one of claims 1-13, wherein the subject has not been previously treated for the cancer.
15. The use of any one of claims 1-14, wherein the subject has been previously treated for the cancer and the subject failed treatment, did not respond to treatment, progressed on treatment, or relapsed after first-line treatment.
16. The use of claim 15, wherein the subject failed treatment, did not respond to treatment, progressed on treatment, or relapsed after treatment with an anti-PD-1 monoclonal antibody.
17. The use of claim 16, wherein the subject was on a PD-1 checkpoint inhibitor therapy as the last previous line of therapy within 90 days of being administered the combination of the anti-PD-1 antibody or an antigen-binding fragment thereof and the anti-CD30 antibody-drug conjugate.
18. The use of claim 16, wherein the subject was previously treated for the cancer with surgery.
19. The use of any one of claims 1-18, wherein the cancer is metastatic.
20. The use of any one of claims 1-19, wherein the cancer is NSCLC.
21. The use of claim 20, wherein the subject progressed after having developed a prior objective response of complete response or partial response (CR/PR) for at least 3 months or stable disease for at least 6 months.

22. The use of claim 20 or 21, wherein the subject does not have a known targetable EGFR, ALK, ROS1, or BRAF mutation.

23. The use of any one of claims 1-19, wherein the cancer is melanoma.

24. The use of claim 23, wherein the subject does not have a targetable gene mutation.

25. The use of claim 23, wherein the subject is a BRAF-V660E/V600K subject who failed targeted therapy.

26. The use of any one of claims 1-25, wherein the subject has not been previously treated with the anti-CD30 antibody-drug conjugate.

27. The use of any one of claims 1-26, wherein the subject does not have known active central nervous system metastases and/or carcinomatous meningitis.

28. The use of any one of claims 1-27, wherein the anti-PD-1 antibody or antigen-binding fragment thereof and the anti-CD30 antibody-drug conjugate are to be administered sequentially.

29. The use of any one of claims 1-28, wherein the anti-PD-1 antibody or antigen-binding fragment thereof and the anti-CD30 antibody-drug conjugate are to be administered simultaneously.

30. The use of any one of claims 1-29, wherein at least about 0.1%, at least about 1%, at least about 2%, at least about 3%, at least about 4%, at least about 5%, at least about 6%, at least about 7%, at least about 8%, at least about 9%, at least about 10%, at least about 15%, at least about 20%, at least about 25%, at least about 30%, at least about 35%, at least about 40%, at least about 45%, at least about 50%, at least about 60%, at least about 70%, or at least about 80% of cancer cells from the subject express PD-L1.

31. The use of any one of claims 1-30, wherein less than about 0.1%, less than about 0.5%, less than about 1%, less than about 2%, less than about 3%, less than about 4%, or less than about 5% of cancer cells from the subject express CD30.

32. The use of any one of claims 1-30, wherein the cancer cells from the subject do not express CD30.