CLAIMS

What is claimed is:

1. A monoclonal antibody or an antigen-binding portion thereof that binds to human programmed death-ligand 1 ("PD-L1") ("anti-PD-L1 antibody") which comprises the CDR1, CDR2, and CDR3 regions in a heavy chain variable region comprising consecutively linked amino acids having the sequence set forth in SEQ ID NO: 35, and the CDR1, CDR2 and CDR3 regions in a light chain variable region comprising consecutively linked amino acids having the sequence set forth in SEQ ID NO: 36.

2. The monoclonal antibody or antigen-binding portion thereof of claim 1, where the antibody or antigen-binding portion thereof comprises a heavy chain variable region comprising consecutively linked amino acids having the sequence set forth in SEQ ID NO: 35, and a light chain variable region comprising consecutively linked amino acids having the sequence set forth in SEQ ID NO: 36.

3. A kit comprising: (i) the antibody or antigen-binding portion thereof of claim 1 or 2, and (ii) instructions for detecting PD-L1 expression in a tissue sample obtained from a subject using the antibody or antigen-binding portion thereof.

4. The kit of claim 3, further comprising an antibody or antigen-binding portion thereof that specifically binds to human programmed death 1 ("PD-1") ("an anti-PD-1 antibody") or an anti-PD-L1 antibody and instructions to administer the anti-PD-1 antibody or the anti-PD-L1 antibody to a subject identified as having positive PD-L1 expression.

5. A method of measuring membranous PD-L1 on isolated tumor cells, comprising performing an immunohistochemistry assay using the antibody or antigen-binding portion thereof of claim 1 or 2.

6. Use of an anti-PD-1 antibody or an anti-PD-L1 antibody in the manufacture of a medicament for treatment a human subject afflicted with a cancer, wherein the subject is identified as being suitable for an immunotherapy by having the expression of PD-L1 polypeptide detected by the antibody or antigen-binding portion thereof of claim 1 or 2.

7. The use of claim 6, wherein a subject having PD-L1 expression is identified as suitable for an immunotherapy.

8. The use of claim 6 or 7, wherein the subject identified as suitable for an immunotherapy is to be administered a composition comprising a therapeutically effective amount of an anti-PD-1 antibody or an anti-PD-L1 antibody.

9. The use of any one of claims 6 to 8, wherein the PD-L1 expression is detected by an immunohistochemical assay of the test tissue sample.

10. The use of any one of claims 6 to 9, wherein the cancer is a hematologic malignancy selected from multiple myeloma, B-cell lymphoma, Hodgkin lymphoma/primary mediastinal B-cell lymphoma, non-Hodgkin's lymphomas, acute myeloid lymphoma, chronic myelogenous leukemia, chronic lymphoid leukemia, lymphocytic lymphoma, follicular lymphoma, diffuse large B-cell lymphoma, Burkitt's lymphoma, immunoblastic large cell lymphoma, precursor B-lymphoblastic lymphoma, mantle cell lymphoma, acute lymphoblastic leukemia, mycosis fungoides, anaplastic large cell lymphoma, T -cell lymphoma, and precursor T -lymphoblastic lymphoma.

11. The use of any one of claims 6 to 10, wherein the cancer is an advanced, recurring, metastatic, and/or refractory cancer.

12. The use of any one of claims 6 to 11, wherein the cancer is melanoma, renal cell carcinoma, NSCLC, castration-resistant prostate cancer (CRPC), or colorectal cancer (CRC).

13. A method of identifying a subject suitable for an immunotherapy, comprising measuring PD-L1 expression in a test tissue sample obtained from the subject with the antibody or antigen-binding portion thereof of claim 1 or 2, wherein the subject is afflicted with a cancer.

14. The use of claim 9, wherein the immunohistochemical assay is an automated immunohistochemical assay.

15. The use of any one of claims 6 to 12, wherein the test tissue sample is a formalin-fixed paraffin-embedded (FFPE) tissue sample.

16. The use of any one of claims 6 to 12 and 14 to 15, wherein at least 1% of tumor cells express cell surface PD-L1.

17. The use of any one of claims 6 to 12 and 14 to 16, wherein at least 5% of tumor cells express cell surface PD-L1.

18. The monoclonal antibody or antigen-binding portion thereof of claim 1 for use in therapy.

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