

Claims

1. An isolated monoclonal antibody or antigen-binding fragment thereof that specifically binds to GD2 (ganglioside GD2), comprising:

(a) a heavy chain variable domain comprising:

CDR1 with an amino acid sequence of SEQ ID NO: 2,

CDR2 with the amino acid sequence of SEQ ID NO: 3,

CDR3 with an amino acid sequence of SEQ ID NO: 5; and

(b) a light chain variable domain comprising:

CDR1 with an amino acid sequence of SEQ ID NO: 9,

CDR2 with an amino acid sequence of SEQ ID NO: 11,

CDR3 with an amino acid sequence of SEQ ID NO: 12.

2. The isolated monoclonal antibody or antigen-binding fragment thereof according to claim 1, wherein:

(a) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 17;

(b) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 21.

3. The isolated monoclonal antibody according to any of claims 1-2, wherein the antibody that specifically binds to GD2 is a full-length IgG antibody.

4. The isolated monoclonal antibody according to claim 3, wherein the full-length IgG antibody belongs to the human IgG1, IgG2, IgG3 or IgG4 isotype.

5. The isolated monoclonal antibody according to claim 1, including:

(a) a heavy chain comprising the amino acid sequence of SEQ ID NO: 33, and

(b) a light chain comprising the amino acid sequence of SEQ ID NO: 41.

6. An isolated nucleic acid that encodes the antibody or antigen-binding fragment thereof according to claim 1.

7. The isolated nucleic acid according to claim 6, wherein the nucleic acid is DNA.

8. An expression vector comprising the nucleic acid according to claim 6.

9. A host cell for obtaining the antibody or antigen-binding fragment thereof according to claim 1, comprising the nucleic acid according to claim 6.

10. A method for obtaining the antibody or antigen-binding fragment thereof according to claim 1, comprising culturing the host cell according to claim 9 in a growth medium under conditions sufficient to produce said antibody, if necessary, followed by isolation and purification of the resulting antibody.

11. A pharmaceutical composition comprising the antibody or antigen-binding fragment thereof according to claim 1 in combination with one or more pharmaceutically acceptable excipients.

12. The pharmaceutical composition according to claim 11 for treating a disease or disorder mediated by GD2.

13. The pharmaceutical composition according to claim 12, wherein the disease or disorder mediated by GD2 is selected from the group of brain tumor, neuroblastoma, glioblastoma, medulloblastoma, retinoblastoma, astrocytoma, melanoma, B-cell lymphoma, small cell lung cancer, renal carcinoma, desmoplastic small round cell fibroma, osteosarcoma, Ewing's sarcoma, breast cancer, rhabdomyosarcoma, leiomyosarcoma, liposarcoma, fibrosarcoma, or soft tissue sarcoma.

14. A pharmaceutical composition comprising the antibody or antigen-binding fragment thereof according to claim 1 and at least one other therapeutically active compound.

15. The pharmaceutical composition according to claim 14 for treating a disease or disorder mediated by GD2.

16. The pharmaceutical composition according to claim 15, wherein the disease or disorder mediated by GD2 is selected from the group of brain tumor, neuroblastoma, glioblastoma, medulloblastoma, retinoblastoma, astrocytoma, melanoma, B-cell lymphoma, small cell lung cancer, renal carcinoma, desmoplastic small round cell fibroma, osteosarcoma, Ewing's sarcoma, breast cancer, rhabdomyosarcoma, leiomyosarcoma, liposarcoma, fibrosarcoma, or soft tissue sarcoma.

17. The pharmaceutical composition according to claim 14, wherein the other therapeutically active compound is an antibody, chemotherapeutic agent, hormone therapy agent or an immune checkpoint inhibitor, or the other therapeutically active compound is selected from the group of IL-2, GM-CSF, isotretinoin, one or more other cytokines, or any combination of therapeutically active compounds from this group.

18. The pharmaceutical composition according to claim 17, wherein the immune checkpoint inhibitor is selected from a PD-1 inhibitor, PD-L1 inhibitor or CTLA-4 inhibitor.

19. The pharmaceutical composition according to claim 18, wherein the PD-1 inhibitor is an antibody that specifically binds to PD-1.

20. The pharmaceutical composition according to claim 19, wherein the antibody that specifically binds to PD-1 is selected from the group of prolgolimab, pembrolizumab, nivolumab.

21. The pharmaceutical composition according to claim 18, wherein the CTLA-4 inhibitor is an antibody that specifically binds to CTLA-4.

22. The pharmaceutical composition according to claim 21, wherein the antibody that specifically binds to CTLA-4 is ipilimumab or nurulimab.

23. The pharmaceutical composition according to claim 18, wherein the PD-L1 inhibitor is an antibody that specifically binds to PD-L1.

24. The pharmaceutical composition according to claim 23, wherein the antibody that specifically binds to PD-L1 is selected from the group of durvalumab, avelumab, atezolizumab, manelimab.