significant difference was determined by performing a Dunnett's multiple comparison test. The results are shown in FIG. 3 and Table 1.

[0120]

[Table 1]

Treatment	Dose	Thoracic tumor			Pleural effusion		
		Incidence	Mass (mg)		Incidence	Volume (μL)	
			Median	Range		Median	Range
Control	DW	8/8	550	380 - 650	3/8	0	0 - 300
MNC	1×10^6 cells	8/8	590	380 - 640	2/8	0	0 - 200
GM2A b	10 μg	7/8	360*	0 - 590	1/8	0	0 - 250
GM2A b + MNC	10, 1×10^6 cells	4/8	< 10*	0 - 510	1/8	0	0 - 150

[0121]

As a result, the incidence of thoracic tumor, and the average tumor mass were significantly smaller in the anti-GM2 antibody-administered mice than in the antibody non-administered mice and the human MNC only administered mice. The incidence of pleural effusion accumulation was also lowered.

[0122]

The mice administered with both the anti-GM2 antibody and the human MNC had lower incidences of thoracic tumor, and smaller average tumor masses than mice administered with the human MNC or the anti-GM2 antibody. The result that anti-tumor effect was not observed in the sole administration of the human MNC suggested that the human MNC enhanced the anti-tumor effect of the anti-GM2 antibody, and improved efficacy.

[0123]

These results suggested the potential effectiveness of the anti-GM2 antibody for malignant mesothelioma patients.

[0124]

[Example 4] GM2 expression in SCID mouse malignant mesothelioma cell line MSTO-211H orthotopic graft model

A tumor block was removed from the chest region of the human malignant mesothelioma cell line MSTO-211H-grafted mice, and embedded in an OCT compound. The embedded block was cut into about a 6-μm slices, and frozen tissue slices were produced. Then immunohistochemical staining was performed as follows.

[0125]

CLAIMS

1. A therapeutic or diagnostic agent for mesothelioma, comprising, as an active ingredient, an antibody or a fragment thereof that binds to a ganglioside GM2.

2. The therapeutic or diagnostic agent according to claim 1, wherein the mesothelioma is one selected from pleural mesothelioma, peritoneal mesothelioma and pericardial mesothelioma.

3. The therapeutic or diagnostic agent according to claim 2, wherein the pleural mesothelioma or the peritoneal mesothelioma is malignant pleural mesothelioma or malignant peritoneal mesothelioma.

4. The therapeutic or diagnostic agent according to any one of claims 1 to 3, wherein the antibody is an antibody that binds to the α2-3 linked sialic acid (SA) of GM2.

5. The therapeutic or diagnostic agent according to any one of claims 1 to 4, wherein the antibody is a monoclonal antibody.

6. The therapeutic or diagnostic agent according to any one of claims 1 to 5, wherein the antibody is a recombinant antibody.

7. The therapeutic or diagnostic agent according to claim 6, wherein the recombinant antibody is one selected from a chimeric antibody, a humanized antibody, and a human antibody.

8. The therapeutic or diagnostic agent according to any one of claims 1 to 7, wherein the antibody is an antibody that comprises heavy chain (hereinafter, "H chain") complementarity determining regions (CDRs; hereinafter, abbreviated to "CDRs") 1 to 3 having the amino acid sequences of SEQ ID NOS: 1 to 3, respectively, and light chain (hereinafter, "L chain") CDRs 1 to 3 having the amino acid sequences of SEQ ID NOS: 4 to 6, respectively.

9. The therapeutic or diagnostic agent according to any one of claims 1 to 8, wherein the antibody is one selected from:

an antibody that comprises an H-chain variable region (hereinafter, referred to as "VH") having the amino acid sequence of SEQ ID NO: 7 and an L-chain variable region (hereinafter, referred to as "VL") having the amino acid sequence of SEQ ID NO: 8;

an antibody that comprises a VH having the amino acid sequence of SEQ ID NO: 7 and a VL having the amino acid sequence of SEQ ID NO: 9;

an antibody that comprises a VH having the amino acid sequence of SEQ ID NO: 10 and a VL having the amino acid sequence of SEQ ID NO: 8; and

an antibody that comprises a VH having the amino acid sequence of SEQ ID NO: 10 and a VL having the amino acid sequence of SEQ ID NO: 11.

10. The therapeutic or diagnostic agent according to any one of claims 1 to 9, comprising at least one combination drug.

11. The therapeutic or diagnostic agent according to claim 10, wherein the combination drug is at least one selected from a chemotherapeutic agent and a protein drug.

12. A treating method or diagnosing method for mesothelioma, using as an active ingredient an antibody or a fragment thereof that binds to a ganglioside GM2.

13. Use of an antibody or a fragment thereof that binds to a ganglioside GM2 for the manufacture of a therapeutic agent for mesothelioma.

significant difference was determined by performing a Dunnett's multiple comparison test. The results are shown in FIG. 3 and Table 1.

[0120]

[Table 1]

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[0125]

CLAIMS

1. The use of an antibody or a fragment thereof that binds to a ganglioside GM2 in the manufacture of a therapeutic or diagnostic agent for the treatment of mesothelioma.

2. The use according to claim 1, wherein the mesothelioma is one selected from pleural mesothelioma, peritoneal mesothelioma and pericardial mesothelioma.

3. The use according to claim 2, wherein the pleural mesothelioma or the peritoneal mesothelioma is malignant pleural mesothelioma or malignant peritoneal mesothelioma.

4. The use according to any one of claims 1 to 3, wherein the antibody is an antibody that binds to the α2-3 linked sialic acid (SA) of GM2.

5. The use according to any one of claims 1 to 4, wherein the antibody is a monoclonal antibody.

6. The use according to any one of claims 1 to 5, wherein the antibody is a recombinant antibody.

7. The use according to claim 6, wherein the recombinant antibody is one selected from a chimeric antibody, a humanized antibody, and a human antibody.

8. The use according to any one of claims 1 to 7, wherein the antibody is an antibody that comprises heavy chain (hereinafter, "H chain") complementarity determining regions (CDRs; hereinafter, abbreviated to "CDRs") 1 to 3 having the amino acid sequences of SEQ ID NOS: 1 to 3, respectively, and light chain (hereinafter, "L chain") CDRs 1 to 3 having the amino acid sequences of SEQ ID NOS: 4 to 6, respectively.

9. The use according to any one of claims 1 to 8, wherein the antibody is one selected from:

an antibody that comprises an H-chain variable region (hereinafter, referred to as "VH") having the amino acid sequence of SEQ ID NO: 7 and an L-chain variable region (hereinafter, referred to as "VL") having the amino acid sequence of SEQ ID NO: 8;

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an antibody that comprises a VH having the amino acid sequence of SEQ ID NO: 10 and a VL having the amino acid sequence of SEQ ID NO: 11.

10. The use according to any one of claims 1 to 9, comprising at least one combination drug.

11. The use according to claim 10, wherein the combination drug is at least one selected from a chemotherapeutic agent and a protein drug.