~~What is claimed is~~CLAIMS:

1. A composition comprising a ganglioside having the structure:

(A)x-[(P)y-(L)z]-(M)b;

wherein A is a ganglioside, or any portion thereof; x is an integer from 1 to 32; P is a heteroaryl; y is 1; L is a linker; z is an integer from 0 to 8; M is a core; and b is 0 or 1;

wherein P is optionally substituted with 1, 2, 3, 4, or 5 substituents independently selected from (1) hydrogen; (2) C_{1-7} acyl; (3) C_{1-20} alkyl; (4) amino; (5) C_{3-10} aryl; (6) hydroxy; (7) nitro; (8) C_{1-20} alkyl-amino; and (9) $-(CH_2)_qCONR^B$, where q is an integer from 0 to 4 and where R^B is selected from the group consisting of (a) hydrogen, (b) C_{1-6} alkyl, (c) C_{3-10} aryl, and (d) C_{1-6} alk-C_{6-10} aryl.

2. The composition of claim 1, wherein the heteroaryl is triazine or triazole.

3. The composition of claim 2, wherein

a) the triazine is 1, 3, 5 triazine; or

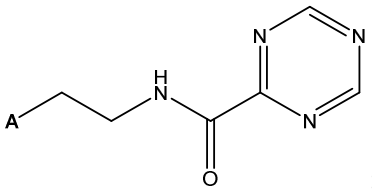
b) the triazole is 1, 2, 3 triazole or 1, 2, 4 triazole.

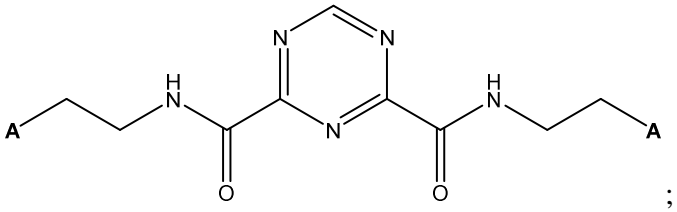
4. The composition of any one of claims 1-3, wherein the P is substituted with 1, 2, 3, 4, or 5 substituents independently selected from (1) hydrogen; (2) C_{1-20} alkyl-amino; and (3) $-(CH_2)_qCONR^B$, where q is an integer from 0 to 4 and where R^B is selected from the group consisting of (a) hydrogen, (b) C_{1-6} alkyl, (c) C_{3-10} aryl, and (d) C_{1-6} alk-C_{6-10} aryl.

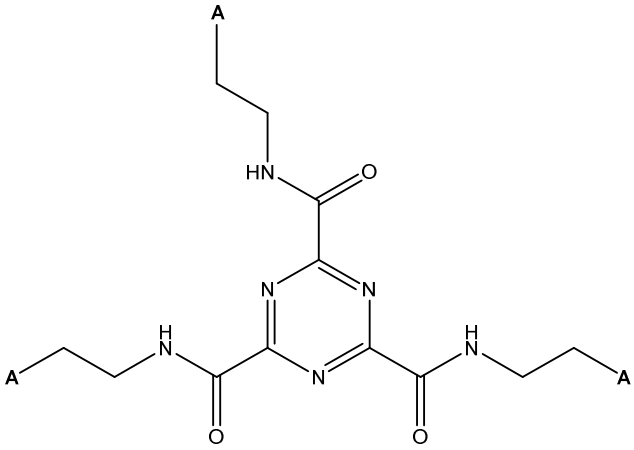
5. The composition of any one of claims 1-4, wherein the M is (1) amine or (2) polyamidoamine (PAMAM).

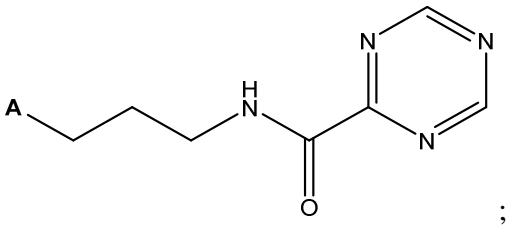
6. The composition of any one of claims 1-5, wherein x is 1, 2, 3, 4, 6, or 8.

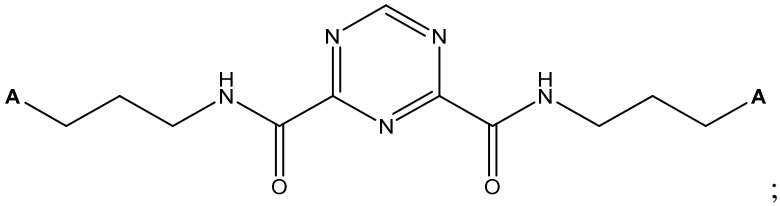
7. The composition of any one of claims 1-6, wherein the structure is selected from:

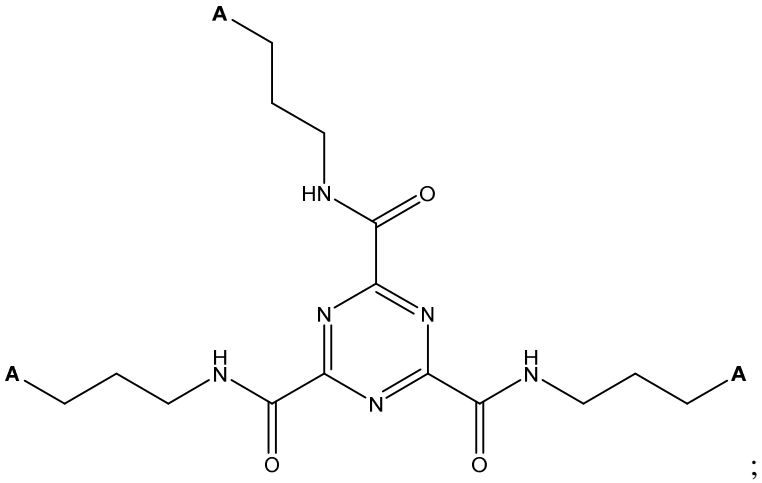

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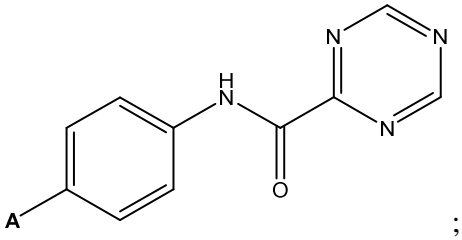

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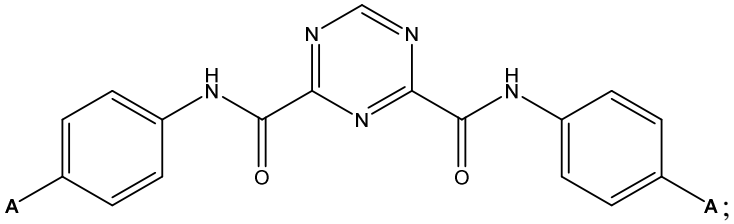

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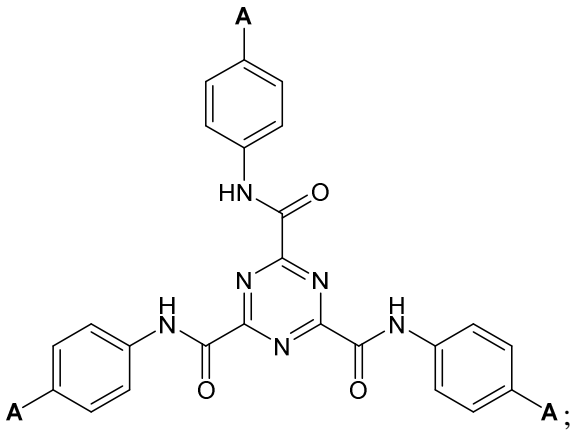

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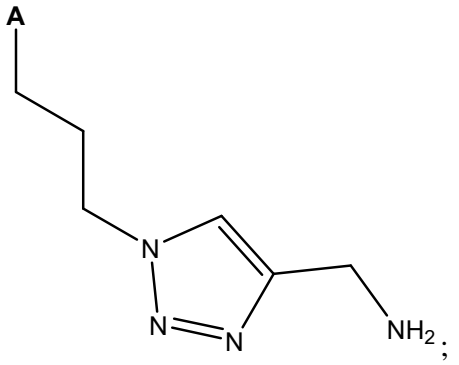

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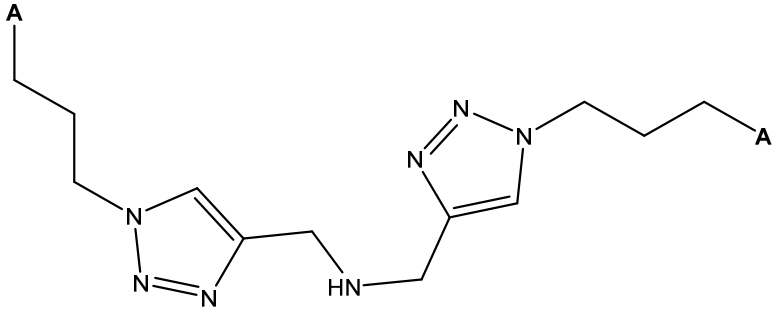

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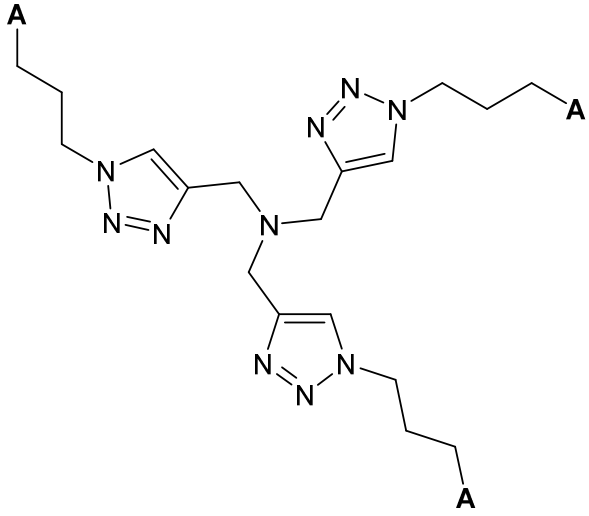

;



;



; and



;

wherein A is a ganglioside.

8. The composition of any one of claims 1-7, wherein the ganglioside is selected from GD2, GD3, GD1b, GT1b, fucosyl-GM1, GloboH, polysialic acid (PSA), GM2, GM3, sialyl-Lewis^X,

sialyl-Lewis^{Y}, sialyl-Lewis^{A}, sialyl-Lewis^{B}, and Lewis^{Y}, optionally wherein the ganglioside is GD2, GD3, GT1b, and GM2.

9. The composition of any one of claims 1-8, wherein the ganglioside is detectably labeled, optionally wherein the ganglioside is labeled with an enzyme, prosthetic group (e.g., streptavidin/biotin), fluorophore, luminescent tag, bioluminescent tag, and/or a radioisotope.

10. The composition of any one of claims 1-9, wherein the composition is a pharmaceutical composition.

11. Use of the composition of any one of claims 1-10, in the manufacture of a medicament for ~~A method of~~ inducing an immune response against a ganglioside in a subject~~, comprising administering to the subject the composition of any one of claims 1-10~~.

12. Use of the composition of any one of claims 1-10, in the manufacture of a medicament for ~~A method of~~ treating cancer in a subject ~~in need thereof, the method comprising administering to the subject the composition of any one of claims 1-10~~.

13. Use of the composition of any one of claims 1-10, in the manufacture of a medicament for treating~~The method of claim 11 or 12, wherein the subject is afflicted with a cancer or has~~ an infection (e.g., viral or bacterial infection) in a subject.

14. A method of producing an antibody ~~in a mammal~~, comprising:

(a) immunizing ~~the~~ a mammal with the composition of any one of claims 1-10, optionally further comprising an adjuvant; and

(b) isolating an antibody that binds to the ganglioside from the mammal, a cell from the mammal, or a hybridoma made using a cell from the mammal.

15. The method of claim 14, wherein the mammal is selected from a rabbit, a mouse, a goat, a camel, a dog, a sheep, or a rat.

16. A monoclonal antibody, or antigen-binding fragment thereof, wherein the monoclonal antibody specifically binds to the carbohydrate portion of a ganglioside.

~~17. The monoclonal antibody, or antigen-binding fragment thereof, of claim 16~~, wherein the ganglioside is (a) GD2, (b) GD3, or (c) GD2 and GD3.

~~18~~17. The monoclonal antibody or antigen-binding fragment thereof of claim 16 ~~or 17~~, wherein the monoclonal antibody or antigen-binding fragment thereof, comprises:

a) a combination of a heavy chain CDR1, CDR2, and CDR3 as set forth in Table 1, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity; and/or

b) a combination of a light chain CDR1, CDR2, and CDR3 as set forth in Table 1, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity.

~~19. The monoclonal antibody or antigen-binding fragment thereof of claim 16 or 17, wherein the monoclonal antibody, or antigen-binding fragment thereof, comprises:~~

~~a) a VH sequence as set forth in Table 2, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity; and/or~~

~~b) a VL sequence as set forth in Table 2, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity.~~

~~20. The monoclonal antibody or antigen-binding fragment thereof of claim 16 or 17, comprising six CDR amino acid sequences selected from:~~

~~a) SEQ ID NOs: 2, 4, 6, 8, 10, and 12 (clone 4), or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;~~

~~b) SEQ ID NOs: 14, 16, 18, 20, 22, and 24 (clone 6), or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;~~

c) SEQ ID NOs: 26 ,28, 30, 32, 34, and 36 (clone 7), or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;

d) SEQ ID NOs: 38, 40, 42, 44, 46, and 48 (clone 8), or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;

e) SEQ ID NOs: 50, 52, 54, 56, 58, and 60 (clone 9), or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;

f) SEQ ID NOs: 62, 64, 66, 68, 70, and 72 (clone 10), or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;

g) SEQ ID NOs: 74, 76, 78, 80, 82, and 84 (clone 13), or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;

h) SEQ ID NOs: 86, 88, 90, 92, 94, and 96 (clone 14), or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;

i) SEQ ID NOs: 98, 100, 102, 104, 106, and 108 (clone 15), or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;

j) SEQ ID NOs: 110, 112, 114, 116, 118, and 120 (clone 17), or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;

k) SEQ ID NOs: 122, 124, 126, 128, 130, and 132 (clone 18), or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity; and

l) SEQ ID NOs: 134, 136, 138, 140, 142, and 144 (clone 19), or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity.

21. The monoclonal antibody or antigen binding fragment thereof of claim 16 or 17, comprising the VH and VL amino acid sequences selected from:

~~a) SEQ ID NOs: 146 and 148, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;~~

~~b) SEQ ID NOs: 150 and 152, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;~~

~~c) SEQ ID NOs: 154 and 156, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;~~

~~d) SEQ ID NOs: 158 and 160, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;~~

~~e) SEQ ID NOs: 162 and 164, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;~~

~~f) SEQ ID NOs: 166 and 168, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;~~

~~g) SEQ ID NOs: 170 and 172, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;~~

~~h) SEQ ID NOs: 174 and 176, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;~~

~~i) SEQ ID NOs: 178 and 180, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;~~

~~j) SEQ ID NOs: 182 and 184, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity;~~

~~k) SEQ ID NOs: 186 and 188, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity; and~~

~~l) SEQ ID NOs: 190 and 192, or a variant sequence thereof which differs by only one or two amino acids, or which has at least or about 85% sequence identity.~~

~~22. The monoclonal antibody or antigen-binding fragment thereof, of any one of claims 16-21, wherein:~~

~~a) the monoclonal antibody or antigen-binding fragment thereof is chimeric, humanized, composite, murine, or human; and/or~~

~~b) the monoclonal antibody or antigen-binding fragment thereof comprises an immunoglobulin heavy chain constant domain selected from the group consisting of IgG, IgG1, IgG2, IgG2A, IgG2B, IgG3, IgG4, IgA, IgM, IgD, and IgE constant domains.~~

~~23. The monoclonal antibody or antigen-binding fragment thereof of any one of claims 16-22, wherein the monoclonal antibody or antigen-binding fragment thereof is detectably labeled or conjugated, comprises an effector domain, comprises an Fc domain, and/or is selected from the group consisting of Fv, F(ab')2, Fab', dsFv, scFv, sc(Fv)2, and diabodies fragments.~~

~~24. An immunoglobulin heavy and/or light chain selected from the immunoglobulin heavy and light chain sequences listed in Table 2.~~

~~25~~18. An isolated nucleic acid molecule that encodes:

a) a polypeptide comprising an amino acid sequence listed in Table 1 and/or Table 2;

b) a polypeptide comprising an amino acid sequence with at least or about 85% identity to an amino acid sequence listed in Table 1 and/or Table 2; and/or

c) the monoclonal antibody or antigen-binding fragment thereof, of ~~any one of~~ claim~~s~~ 16 or 17~~-23~~.

~~26. A vector comprising the isolated nucleic acid of claim 25.~~

~~27. A host cell which (a) comprises the isolated nucleic acid of claim 25, (b) comprises the vector of claim 26, and/or (c) expresses the antibody, or antigen-binding fragment thereof, of any one of claims 16-23.~~

~~28. A method of producing at least one monoclonal antibody or antigen-binding fragment thereof, according to any one of claims 16-23, wherein the method comprises the steps of: (i) culturing a host cell comprising a nucleic acid comprising a sequence encoding at least one monoclonal antibody, or antigen-binding fragment thereof, according to any one of claims 16-23 under conditions suitable to allow expression of said monoclonal antibody or antigen-binding~~

~~fragment thereof; and (ii) recovering the expressed monoclonal antibody or antigen-binding fragment thereof.~~

~~29. A device or kit comprising at least one monoclonal antibody or antigen-binding fragment thereof, according to any one of claims 16-23.~~

~~30. The device or kit of claim 29, further comprising:~~

~~(a) a label to detect the at least one monoclonal antibody or antigen-binding fragment thereof;~~

~~(b) a secondary antibody for detection of the primary antibody; and/or~~

~~(c) at least one reference antigen, optionally wherein the reference antigen is a ganglioside.~~

~~31. The device or kit of claim 30, wherein the reference antigen is selected from GD2, GD3, and a modified version of GD2 or GD3.~~

~~32. The device or kit of claim 30 or 31, wherein the reference antigen is selected from the ganglioside of any one of claims 1-9; thiophenyl GD2, thiophenyl GD3, GD2-O-aryl-NH_2, GD3-O-aryl-NH_2, p-amino phenyl ether GD2 (AP-GD2), p-amino phenyl ether GD3 (AP-GD3), triazine GD2 (e.g., 1, 3, 5-triazine-GD2, e.g., 2-Amino-4,6-dichloro-1,3,5-triazine-GD2), triazine GD3 (e.g., 1, 3, 5-triazine-GD3, e.g., 2-Amino-4,6-dichloro-1,3,5-triazine-GD3), a multimeric GD2 (e.g., PAMAM-GD2), and a multimeric GD3 (PAMAM-GD3).~~

~~33. A method of extracting lipids from a sample, the method comprising:~~

~~(a) obtaining the sample;~~

~~(b) adding to the sample about 2 to 5-fold volume of an organic solvent comprising $CHCl_3$:methanol:water at a ratio selected from (i) about 1:2:1, (ii) about 4:8:3, or (iii) about 2:4:1;~~

~~(c) shaking the combined mixture of (b); and~~

~~(d) separating the sample from the organic solvent, thereby extracting lipids from the sample.~~

~~34~~19. A method of purifying a ganglioside from a sample, the method comprising:

(a) obtaining the sample;

(b) adding to the sample about 2 to 5-fold volume of an organic solvent comprising $CHCl_3$:methanol:water at a ratio selected from (i) about 1:2:1, (ii) about 4:8:3, or (iii) about 2:4:1;

(c) shaking the combined mixture of (b); and

(d) separating the sample from the organic solvent, thereby extracting lipids from the sample.

~~35. The method of claim 33 or 34:~~

~~(i) wherein the sample is clarified by centrifugation prior to extraction with the organic solvent;~~

~~(ii) wherein the sample is from a mammal, optionally from a human;~~

~~(iii) wherein the sample is separated from the organic solvent by centrifugation;~~

~~(iv) wherein the sample is from a subject afflicted with a cancer or a cancer-free subject;~~

~~(v) wherein the sample comprises cells, serum, blood, peritumoral tissue, and/or intratumoral tissue;~~

~~(vi) further comprising repeating the steps of (b) (d) at least 1, 2, 3, 4, or 5 times; and/or~~

~~(vii) further comprising evaporating the residual organic solvent from the extracted sample of (d), optionally by centrifuging the solution under vacuum (e.g., speed vacuum).~~

~~36. A method of detecting the presence or level of at least one ganglioside (e.g., GD2 and/or GD3) comprising detecting said ganglioside in a sample using at least one monoclonal antibody or antigen-binding fragment thereof according to any one of claims 16-23, optionally wherein the sample is from a subject afflicted with a cancer or a cancer-free subject.~~

37. The method of claim 36, wherein the at least one monoclonal antibody or antigen-binding fragment thereof, forms a complex with a ganglioside (e.g., GD2 or GD3) and the complex is detected in an enzyme linked immunosorbent assay (ELISA), radioimmune assay (RIA), immunochemically (e.g., immunohistochemistry), or a flow cytometry.

38. The method of claim 37, wherein the complex is detected in an enzyme linked immunosorbent assay (ELISA).

39. The method of claim 37 or 38, wherein the complex is detected in sandwich ELISA.

40. The method of claim 39, wherein the complex is detected in sandwich ELISA using any two antibodies or antigen-binding fragments thereof, of any one of claims 16-23.

41. The method of claim 37 or 38, wherein the complex is detected in competitive ELISA.

42. The method of claim 41, wherein the competititve ELISA comprises a reference antigen that is selected from GD2, GD3, or a modified version of GD2 or GD3.

43. The method of claim 42, wherein the reference antigen is selected from the ganglioside of any one of claims 1-9, thiophenyl GD2, thiophenyl GD3, GD2-O-aryl-NH_2, GD3-O-aryl-NH_2, p-amino phenyl ether GD2 (AP-GD2), p-amino phenyl ether GD3 (AP-GD3), triazine GD2 (e.g., 1, 3, 5-triazine-GD2, e.g., 2-Amino-4,6-dichloro-1,3,5-triazine-GD2), triazine GD3 (e.g., 1, 3, 5-triazine-GD3, e.g., 2-Amino-4,6-dichloro-1,3,5-triazine-GD3), a multimeric GD2 (e.g., PAMAM-GD2), and a multimeric GD3 (PAMAM-GD3).

44. The method of claim 37, wherein the complex is detected in immunohistochemistry (IHC).

45. The method of detecting the presence, level, or lipid length of at least one ganglioside, the method comprising detecting said ganglioside in a sample using mass spectrometry (e.g.,

~~LC/MS or LC/MS/MS), optionally wherein the sample is from a subject afflicted with a cancer or a cancer-free subject.~~

~~46. The method of any one of claims 36-45, wherein the sample is prepared according to the method of any one of claims 33-35.~~

~~47~~20. ~~A method of~~Use of a monoclonal antibody according to claim 16 or 17, or antigen-binding fragment thereof, in diagnosing a cancer in a subject, the ~~method~~ use comprising:

a) determining the level of at least one ganglioside in a subject sample using ~~at least one~~the monoclonal antibody, or antigen-binding fragment thereof~~, optionally wherein the at least one monoclonal antibody, or antigen-binding fragment thereof is according to any one of claims 16-23~~; and

b) comparing said level of the at least one ganglioside to that in a control sample,

wherein a significantly higher level of the at least one ganglioside in the subject sample as compared to the level in the control sample indicates that the subject has a cancer.

21. The composition of any one of claims 1-10, for use in therapy.

~~48. A method of identifying a subject having a cancer, the method comprising:~~

~~a) determining the level of at least one ganglioside in a subject sample using at least one monoclonal antibody, or antigen-binding fragment thereof, optionally wherein the at least one monoclonal antibody, or antigen-binding fragment thereof is according to any one of claims 16-23; and~~

~~b) comparing said level of the at least one ganglioside to that in a control sample,~~

~~wherein a significantly higher level of the at least one ganglioside in the subject sample as compared to the level in the control sample identifies the subject as having a cancer.~~

~~49. A method of determining a grade of a cancer, the method comprising:~~

~~a) determining the level of at least one ganglioside in a subject sample using at least one monoclonal antibody, or antigen-binding fragment thereof, optionally wherein the at~~

~~least one monoclonal antibody, or antigen-binding fragment thereof is according to any one of claims 16-23; and~~

~~b) comparing said level of the at least one ganglioside to that in a control sample,~~

~~wherein at least 100% and no more than 200% increase in the level of the at least one ganglioside in the subject sample as compared to the level in the control sample indicates that the subject has a low-grade cancer; and/or~~

~~wherein at least 200% increase in the level of the at least one ganglioside in the subject sample as compared to the level in the control sample indicates that the subject has a high-grade cancer.~~

~~50. A method of determining a tumor burden of a cancer, the method comprising:~~

~~a) determining the level of at least one ganglioside in a subject sample using at least one monoclonal antibody, or antigen-binding fragment thereof, optionally wherein the at least one monoclonal antibody, or antigen-binding fragment thereof is according to any one of claims 16-23; and~~

~~b) comparing said level of the at least one ganglioside to that in a control sample,~~

~~wherein at least 100% and no more than 200% increase in the level of the at least one ganglioside in the subject sample as compared to the level in the control sample indicates that the subject has a low-tumor burden; and/or~~

~~wherein at least 200% increase in the level of the at least one ganglioside in the subject sample as compared to the level in the control sample indicates that the subject has a high-tumor burden.~~

~~51. A method of detecting a recurrence of a cancer in a subject, the method comprising:~~

~~a) obtaining or providing a sample from the subject whose cancer has regressed after receiving cancer treatment;~~

~~b) determining the level of at least one ganglioside in the subject sample using at least one monoclonal antibody, or antigen-binding fragment thereof, optionally wherein the at~~

least one monoclonal antibody, or antigen-binding fragment thereof is according to any one of claims 16-23; and

c) comparing said level of the at least one ganglioside to that in a control sample, wherein a significantly higher level of the at least one ganglioside in the subject sample as compared to the level in the control sample indicates a recurrence of a cancer in the subject.

52. A method of detecting a minimal residual disease in a subject, the method comprising:

a) obtaining or providing a sample from the subject in remission;

b) determining the level of at least one ganglioside in the subject sample using at least one monoclonal antibody, or antigen-binding fragment thereof, optionally wherein the at least one monoclonal antibody, or antigen-binding fragment thereof is according to any one of claims 16-23; and

c) comparing said level of the at least one ganglioside to that in a control sample, wherein a significantly higher level of the at least one ganglioside in the subject sample as compared to the level in the control sample indicates that the subject has a minimal residual disease.

53. A method of stratifying subjects afflicted with a cancer according to benefit from a cancer therapy, the method comprising:

a) determining the level of at least one ganglioside in a subject sample using at least one monoclonal antibody, or antigen-binding fragment thereof, optionally wherein the at least one monoclonal antibody, or antigen-binding fragment thereof is according to any one of claims 16-23;

b) determining the level of the at least one ganglioside in a control; and

c) comparing the level of the at least one ganglioside detected in steps a) and b);

wherein no significant change or a decrease in the level of the at least one ganglioside in the subject sample as compared to the level in the control is an indication that the subject afflicted with the cancer would benefit from the cancer therapy.

54. A method of determining whether a subject afflicted with a cancer would likely respond to a cancer therapy, the method comprising:

a) determining the level of at least one ganglioside in a subject sample using at least one monoclonal antibody, or antigen-binding fragment thereof, optionally wherein the at least one monoclonal antibody, or antigen-binding fragment thereof is according to any one of claims 16-23;

b) determining the level of the at least one ganglioside in a control; and

c) comparing the level of the at least one ganglioside detected in steps a) and b);

wherein a significantly higher level of the at least one ganglioside in the subject sample as compared to the level in the control is an indication that the subject afflicted with the cancer would not respond to the cancer therapy; and/or

wherein no significant change or a decrease in the level of the at least one ganglioside in the subject sample as compared to the level in the control is an indication that the subject afflicted with the cancer would respond to the cancer therapy.

55. A method for predicting the clinical outcome of a subject afflicted with a cancer, the method comprising:

a) determining the level of at least one ganglioside in a subject sample using at least one monoclonal antibody, or antigen-binding fragment thereof, optionally wherein the at least one monoclonal antibody, or antigen-binding fragment thereof is according to any one of claims 16-23;

b) determining the level of the at least one ganglioside in a control; and

c) comparing the level of the at least one ganglioside determined in steps a) and b);

wherein a significantly higher level of the at least one ganglioside in the subject sample as compared to the level in the control is an indication that the subject has a poor clinical outcome.

56. A method of monitoring the progression of a cancer in a subject, the method comprising:

a) detecting in a subject sample at a first point in time the level of at least one ganglioside using at least one monoclonal antibody, or antigen-binding fragment thereof, optionally wherein the at least one monoclonal antibody, or antigen-binding fragment thereof is according to any one of claims 16-23;

b) repeating step a) at a subsequent point in time; and

c) comparing the level of the at least one ganglioside detected in steps a) and b) to monitor the progression of the cancer in the subject, optionally wherein the subject is at risk for developing a cancer.

57. The method of claim 56, wherein between the first point in time and the subsequent point in time, the subject has received a cancer therapy.

58. A method of assessing the efficacy of a cancer therapy in a subject, the method comprising:

a) determining the level of at least one ganglioside using at least one monoclonal antibody, or antigen-binding fragment thereof, optionally wherein the at least one monoclonal antibody, or antigen-binding fragment thereof is according to any one of claims 16-23, in a first sample obtained from a subject;

b) repeating step a) during at least one subsequent point in time after administration of the cancer therapy; and

c) comparing the level of at least one ganglioside detected in steps a) and b),

wherein a significantly lower level of the at least one ganglioside in the at least one subsequent sample, relative to the first sample, is an indication that the therapy is efficacious to treat a cancer in the subject.

59. The method of any one of claims 56-58, wherein the first and/or at least one subsequent sample is a portion of a single sample or pooled samples obtained from the subject.

60. The method of any one of claims 47-59, wherein the at least one monoclonal antibody or antigen-binding fragment thereof, forms a complex with a ganglioside (e.g., GD2 or GD3) and the complex is detected in an enzyme-linked immunosorbent assay (ELISA),

~~radioimmune assay (RIA), immunochemically (e.g., immunohistochemistry), or a flow cytometry.~~

~~61. The method of claim 60, wherein the complex is detected in an enzyme linked immunosorbent assay (ELISA).~~

~~62. The method of claim 60 or 61, wherein the complex is detected in sandwich ELISA.~~

~~63. The method of claim 62, wherein the complex is detected in sandwich ELISA using any two antibodies of claims 16-23.~~

~~64. The method of claim 60 or 61, wherein the complex is detected in competitive ELISA.~~

~~65. The method of claim 64, wherein the competititve ELISA comprises a reference antigen that is selected from GD2, GD3, or a modified version of GD2 or GD3.~~

~~66. The method of claim 66 or 67, wherein the reference antigen is selected from the ganglioside of any one of claims 1-9, thiophenyl GD2, thiophenyl GD3, GD2-O-aryl NH_2, GD3-O-aryl NH_2, p-amino phenyl ether GD2 (AP-GD2), p-amino phenyl ether GD3 (AP-GD3), triazine GD2 (e.g., 1, 3, 5-triazine-GD2, e.g., 2-Amino-4,6-dichloro-1,3,5-triazine-GD2), triazine GD3 (e.g., 1, 3, 5-triazine-GD3, e.g., 2-Amino-4,6-dichloro-1,3,5-triazine-GD3), a multimeric GD2 (e.g., PAMAM-GD2), and a multimeric GD3 (PAMAM-GD3).~~

~~67. The method of claim 60, wherein the complex is detected in immunohistochemistry (IHC).~~

~~68. The method of any one of claims 47-66, wherein the sample is prepared according to the method of any one of claims 33-35.~~

69. A method of diagnosing a cancer in a subject, the method comprising:

a) determining the level of at least one ganglioside in a subject sample using mass spectrometry according to claim 45 or 46; and

b) comparing said level of the at least one ganglioside to that in a control sample,

wherein a significantly higher level of the at least one ganglioside in the subject sample as compared to the control sample indicates that the subject has a cancer.

70. A method of identifying a subject having a cancer, the method comprising:

a) determining the level of at least one ganglioside in a subject sample using mass spectrometry according to claim 45 or 46; and

b) comparing said level of the at least one ganglioside to that in a control sample,

wherein a significantly higher level of the at least one ganglioside in the subject sample as compared to the control sample identifies the subject as having a cancer.

71. A method of determining a grade of a cancer, the method comprising:

a) determining the level of at least one ganglioside in a subject sample using mass spectrometry according to claim 45 or 46; and

b) comparing said level of the at least one ganglioside to that in a control sample,

wherein at least 100% and no more than 200% increase in the level of the at least one ganglioside in the subject sample as compared to the level in the control sample indicates that the subject has low grade cancer; and/or

wherein at least 200% increase in the level of the at least one ganglioside in the subject sample as compared to the level in the control sample indicates that the subject has a high grade cancer.

72. A method of determining a tumor burden of a cancer, the method comprising:

a) determining the level of at least one ganglioside in a subject sample using mass spectrometry according to claim 45 or 46; and

b) comparing said level of the at least one ganglioside to that in a control sample,

wherein at least 100% and no more than 200% increase in the level of the at least one ganglioside in the subject sample as compared to the level in the control sample indicates that the subject has a low tumor burden; and/or

wherein at least 200% increase in the level of the at least one ganglioside in the subject sample as compared to the level in the control sample indicates that the subject has a high tumor burden.

73. A method of detecting a recurrence of a cancer in a subject, the method comprising:

a) obtaining or providing a sample from the subject whose cancer has regressed after receiving cancer treatment;

b) determining the level of at least one ganglioside in the subject sample using mass spectrometry according to claim 45 or 46; and

c) comparing said level of the at least one ganglioside to that in a control sample,

wherein a significantly higher level of the at least one ganglioside in the subject sample as compared to the level in the control sample indicates a recurrence of a cancer in the subject.

74. A method of detecting a minimal residual disease in a subject, the method comprising:

a) obtaining or providing a sample from the subject in remission;

b) determining the level of at least one ganglioside in the subject sample using mass spectrometry according to claim 45 or 46; and

c) comparing said level of the at least one ganglioside to that in a control sample,

wherein a significantly higher level of the at least one ganglioside in the subject sample as compared to the level in the control sample indicates that the subject has a minimal residual disease.

75. A method of stratifying subjects afflicted with a cancer according to benefit from a cancer therapy, the method comprising:

a) determining the level of at least one ganglioside in a subject sample using mass spectrometry according to claim 45 or 46;

b) determining the level of the at least one ganglioside in a control; and

c) comparing the level of the at least one ganglioside detected in steps a) and b);

wherein no significant change or a decrease in the level of the at least one ganglioside in the subject sample as compared to the level in the control is an indication that the subject afflicted with the cancer would benefit from the cancer therapy.

76. A method of determining whether a subject afflicted with a cancer would likely respond to a cancer therapy, the method comprising:

a) determining the level of at least one ganglioside in a subject sample using mass spectrometry according to claim 45 or 46;

b) determining the level of the at least one ganglioside in a control; and

c) comparing the level of the at least one ganglioside detected in steps a) and b);

wherein a significantly higher level of the at least one ganglioside in the subject sample as compared to the level in the control is an indication that the subject afflicted with the cancer would not respond to the cancer therapy; and/or

wherein no significant change or a decrease in the level of the at least one ganglioside in the subject sample as compared to the level in the control is an indication that the subject afflicted with the cancer would respond to the cancer therapy.

77. A method for predicting the clinical outcome of a subject afflicted with a cancer, the method comprising:

a) determining the level of at least one ganglioside in a subject sample using mass spectrometry according to claim 45 or 46;

b) determining the level of the at least one ganglioside in a control; and

c) comparing the level of the at least one ganglioside determined in steps a) and b);

wherein a significantly higher level of the at least one ganglioside in the subject sample as compared to the level in the control is an indication that the subject has a poor clinical outcome.

~~78. A method of monitoring the progression of a cancer in a subject, the method comprising:~~

~~a) detecting in a subject sample at a first point in time the level of at least one ganglioside using mass spectrometry according to claim 45 or 46;~~

~~b) repeating step a) at a subsequent point in time; and~~

~~c) comparing the level of the at least one ganglioside detected in steps a) and b) to monitor the progression of the cancer in the subject, optionally wherein the subject is at risk for developing a cancer.~~

~~79. The method of claim 78, wherein between the first point in time and the subsequent point in time, the subject has received a cancer therapy.~~

~~80. A method of assessing the efficacy of a cancer therapy in a subject, the method comprising:~~

~~a) determining the level of at least one ganglioside using mass spectrometry according to claim 45 or 46, in a first sample obtained from a subject;~~

~~b) repeating step a) during at least one subsequent point in time after administration of the cancer therapy; and~~

~~c) comparing the level of at least one ganglioside detected in steps a) and b),~~

~~wherein a significantly lower level of the at least one ganglioside in the at least one subsequent sample, relative to the first sample, is an indication that the therapy is efficacious to treat a cancer in the subject.~~

~~81. The method of any one of claims 78-80, wherein the first and/or at least one subsequent sample is a portion of a single sample or pooled samples obtained from the subject.~~

~~82. A method of diagnosing a cancer in a subject, the method comprising:~~

~~a) determining the lipid length of at least one ganglioside in a subject sample using mass spectrometry according to claim 45 or 46; and~~

b) comparing the said lipid length of the at least one ganglioside to that in a control sample,

wherein a significant change in heterogeneity of the lipid length of the at least one ganglioside in the subject sample as compared to the control sample indicates that the subject has a cancer.

83. A method of identifying a subject having a cancer, the method comprising:

a) determining the lipid length of at least one ganglioside in a subject sample using mass spectrometry according to claim 45 or 46; and

b) comparing the said lipid length of the at least one ganglioside to that in a control sample,

wherein a significant change in heterogeneity of the lipid length of the at least one ganglioside in the subject sample as compared to the control sample identifies the subject as having a cancer.

84. A method of determining a grade of a cancer, the method comprising:

a) determining the lipid length of at least one ganglioside in the subject sample using mass spectrometry according to claim 45 or 46; and

b) comparing the said lipid length of the at least one ganglioside to that in a control sample,

wherein at least 100% and no more than 200% change (e.g., increase or decrease) in heterogeneity of the lipid length of the at least one ganglioside in the subject sample as compared to that in the control sample indicates that the subject has a low grade cancer; and/or

wherein at least 200% change (e.g., increase or decrease) in heterogeneity of the lipid length of the at least one ganglioside in the subject sample as compared to that in the control sample indicates that the subject has a high grade cancer.

85. A method of determining a tumor burden of a cancer, the method comprising:

a) determining the lipid length of at least one ganglioside in the subject sample using mass spectrometry according to claim 45 or 46; and

b) comparing the said lipid length of the at least one ganglioside to that in a control sample,

wherein at least 100% and no more than 200% change (e.g., increase or decrease) in heterogeneity of the lipid length of the at least one ganglioside in the subject sample as compared to that in the control sample indicates that the subject has a low tumor burden; and/or

wherein at least 200% change (e.g., increase or decrease) in heterogeneity of the lipid length of the at least one ganglioside in the subject sample as compared to that in the control sample indicates that the subject has a high tumor burden.

86. A method of detecting a recurrence of a cancer in a subject, the method comprising:

a) obtaining or providing a sample from the subject whose cancer has regressed after receiving cancer treatment;

b) determining the lipid length of at least one ganglioside in the subject sample using mass spectrometry according to claim 45 or 46; and

c) comparing the said lipid length of the at least one ganglioside to that in a control sample,

wherein a significant change in heterogeneity of the lipid length of the at least one ganglioside in the subject sample as compared to that in the control sample indicates a recurrence of a cancer in a subject.

87. A method of detecting a minimal residual disease in a subject, the method comprising:

a) obtaining or providing a sample from the subject in remission;

b) determining the lipid length of at least one ganglioside in the subject sample using mass spectrometry according to claim 45 or 46; and

c) comparing the said lipid length of the at least one ganglioside to that in a control sample,

wherein a significant change in heterogeneity of the lipid length of the at least one ganglioside in the subject sample as compared to that in the control sample indicates that the subject has a minimal residual disease.

88. A method of stratifying subjects afflicted with a cancer according to benefit from a cancer therapy (e.g., immunotherapy), the method comprising:

a) determining the lipid length of at least one ganglioside in a subject sample using mass spectrometry according to claim 45 or 46;

b) determining the lipid length of the at least one ganglioside in a control; and

c) comparing the the lipid length of the at least one ganglioside detected in steps a) and b);

wherein no significant change in heterogeneity of the lipid length of the at least one ganglioside in the subject sample as compared to that in the control is an indication that the subject afflicted with the cancer would benefit from the cancer therapy.

89. A method of determining whether a subject afflicted with a cancer would likely respond to a cancer therapy (e.g., immunotherapy), the method comprising:

a) determining the lipid length of at least one ganglioside in a subject sample using mass spectrometry according to claim 45 or 46;

b) determining the lipid length of the at least one ganglioside in a control; and

c) comparing the lipid length of the at least one ganglioside detected in steps a) and b);

wherein a significant change in heterogeneity of the lipid length of the at least one ganglioside in the subject sample as compared to that in the control is an indication that the subject afflicted with the cancer would not respond to the cancer therapy; and/or

wherein no significant change in heterogeneity of the lipid length of the at least one ganglioside in the subject sample as compared to that in the control is an indication that the subject afflicted with the cancer would respond to the cancer therapy.

90. A method for predicting the clinical outcome of a subject afflicted with a cancer, the method comprising:

a) determining the lipid length of at least one ganglioside in a subject sample using mass spectrometry according to claim 45 or 46;

b) determining the lipid length of the at least one ganglioside in a control; and

c) comparing the lipid length of the at least one ganglioside determined in steps a) and b);

wherein a significant change in heterogeneity of the lipid length of the at least one ganglioside in the subject sample as compared to the control sample is an indication that the subject has a poor clinical outcome.

91. A method of monitoring the progression of a cancer in a subject, the method comprising:

a) detecting in a subject sample at a first point in time the lipid length of at least one ganglioside using mass spectrometry according to claim 45 or 46;

b) repeating step a) at a subsequent point in time; and

c) comparing heterogeneity of the lipid length of the at least one ganglioside detected in steps a) and b) to monitor the progression of the cancer in the subject, optionally wherein the subject is at risk for developing a cancer.

92. The method of claim 91, wherein between the first point in time and the subsequent point in time, the subject has received a cancer therapy.

93. A method of assessing the efficacy of a cancer therapy in a subject, the method comprising:

a) determining the lipid length of at least one ganglioside using mass spectrometry according to claim 45 or 46, in a first sample obtained from the subject;

b) repeating step a) during at least one subsequent point in time after administration of the cancer therapy; and

wherein a significant change in heterogeneity of the lipid length of the at least one ganglioside in the second sample, relative to the first sample, is an indication that the therapy is efficacious to treat a cancer in the subject.

94. The method of any one of claims 91-93, wherein the first and/or at least one subsequent sample is a portion of a single sample or pooled samples obtained from the subject.

95. The method of any one of claims 53, 54, 57, 58, 75, 76, 79, 80, 88, 89, 92, and 93, wherein the cancer therapy is a surgery, chemotherapy, cancer vaccines, chimeric antigen receptors, radiation therapy, immunotherapy, a modulator of expression of immune checkpoint inhibitory proteins or ligands, or any combination thereof.

96. The method of claim 95, wherein the immunotherapy is an immune checkpoint inhibition therapy.

97. The method of any one of claims 53, 54, 57, 58, 75, 76, 79, 80, 88, 89, 92, 93, 95, and 96, wherein the cancer therapy is avelumab, durvalumab, atezolizumab, BRAF/MEK inhibitor, pembrolizumab, nivolumab, ipilimumab, or a combination thereof.

98. The method of any one of claims 47-97, wherein the ganglioside is a tumor-associated ganglioside.

99. The method of claim 98, wherein the tumor-associated ganglioside is selected from GD2, GD3, GD1b, GT1b, fucosyl-GM1, GloboH, polysialic acid (PSA), GM2, GM3, sialyl Lewis^{X}, sialyl Lewis^{Y}, sialyl Lewis^{A}, sialyl Lewis^{B}, Lewis^{Y}, any portion thereof; optionally wherein the tumor-associated ganglioside is selected from GD1, GD2, GD3, GT1b, and GM2.

100. The method of any one of claims 13 and 35-99, wherein the cancer or tumor is selected from the group consisting of neuroblastoma, lymphoma, leukemia, melanoma, glioma, small cell lung cancer, breast carcinoma, ovarian cancer, soft tissue sarcomas, osteosarcoma, Ewing's sarcoma, desmoplastic round cell tumor, rhabdomyosarcoma, retinoblastoma, non-small

~~cell lung cancer, renal cell cancer, Wilms tumor, prostate cancer, gastric cancer, endometrial cancer, pancreatic cancer, and colon cancer.~~

~~101. The method of claim 100, wherein the cancer or tumor is selected from the group consisting of neuroblastoma, lymphoma, leukemia, melanoma, glioma, small cell lung cancer, breast carcinoma, ovarian cancer, soft tissue sarcomas, osteosarcoma, Ewing's sarcoma, desmoplastic round cell tumor, rhabdomyosarcoma, retinoblastoma.~~

~~102. The method of any one of claims 33-101, wherein the sample comprises cells, serum, blood, peritumoral tissue, and/or intratumoral tissue obtained from the subject.~~

~~103. The method of any one of claims 47-102, wherein said significantly higher level of at least one ganglioside comprises an at least twenty percent increase of the level of the at least one ganglioside.~~

~~104. The method of any one of claims 47-102, wherein the significantly lower level of at least one ganglioside comprises an at least twenty percent decrease of the level of the at least one ganglioside.~~

~~105. The method of any one of claims 82-102, wherein said significant change in heterogeneity of the lipid length comprises an at least twenty percent change (e.g., increase or decrease) in the subject sample relative to the control sample.~~

~~106. The method of any one of claims 47-105, wherein the control sample is a sample from a cancer-free subject.~~

~~107. The method of any one of claims 47-106, further comprising recommending, prescribing, and/or administering to the subject a cancer therapy.~~

~~108. The method of any one of claims 11-13 and 31-113, wherein the subject is a mammal.~~

~~109. The method of any one of claims 11-13 and 31-114, wherein the subject is an animal model of cancer or a human.~~

~~110. The method of any one of claims 11-13 and 31-115, wherein the subject is a human.~~