

CLAIMS

WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising an antibody or antigen binding fragment that binds to tumor necrosis factor-like protein 1A (anti-TL1A antibody or antigen binding fragment) at a concentration of (i) about 150 mg/mL to about 250 mg/mL; (ii) about 175 mg/mL to about 225 mg/mL; (iii) greater than about 150, 160, 165, 170, 175, 180, 185, 190, 195, 200, 205, 210, 215, 220, or 225 mg/mL; or (iv) about 150, 160, 165, 170, 175, 180, 185, 190, 195, 200, 205, 210, 215, 220, or 225 mg/mL.

~~2. A pharmaceutical composition comprising an antibody that binds to tumor necrosis factor like protein 1A (anti TL1A antibody) at a concentration greater than about 50 mg/mL.~~

~~3. The composition of claim 2, wherein the concentration is greater than about 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, or 145 mg/mL.~~

~~4. The composition of claim 2, wherein the concentration is about 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, or 145 mg/mL.~~

~~5. The composition of claim 1, wherein the concentration is greater than about 160, 165, 170, 175, 180, 185, 190, 195, 200, 205, 210, 215, 220, or 225 mg/mL.~~

~~6. The composition of claim 1, wherein the concentration is about 160, 165, 170, 175, 180, 185, 190, 195, 200, 205, 210, 215, 220, or 225 mg/mL.~~

~~7. The composition of claim 1, wherein the concentration is about 150 mg/mL to about 250 mg/mL.~~

~~8. The composition of claim 1, wherein the concentration is about 175 mg/mL to about 225 mg/mL.~~

~~9. A pharmaceutical composition for subcutaneous administration, the composition comprising an antibody that binds to tumor necrosis factor like protein 1A (anti-TL1A antibody), wherein about 150 mg to about 500 mg of the anti-TL1A antibody is present in the composition.~~

~~10. The composition of any one of claims 1-9, wherein the composition has a total volume of (i) less than or equal to about 2 mL, (ii) less than or equal to about 5 mL, or (iii) less than or equal to about 9 mL.~~

~~11. — A pharmaceutical composition comprising a therapeutically effective dose of an antibody that binds to tumor necrosis factor like protein 1A (anti-TL1A antibody), wherein the composition has a total volume of (i) less than or equal to about 2 mL, (ii) less than or equal to about 5 mL, or (iii) less than or equal to about 9 mL.~~

~~12. — The composition of claim 10 or claim 11, wherein the composition has a total volume less than or equal to about 9.0, 8.9, 8.8, 8.7, 8.6, 8.5, 8.4, 8.3, 8.2, 8.1, 8.0, 7.9, 7.8, 7.7, 7.6, 7.5, 7.4, 7.3, 7.2, 7.1, 7.0, 6.9, 6.8, 6.7, 6.6, 6.5, 6.4, 6.3, 6.2, 6.1, 6.0, 5.9, 5.8, 5.7, 5.6, 5.5, 5.4, 5.3, 5.2, 5.1, 5.0, 4.9, 4.8, 4.7, 4.6, 4.5, 4.4, 4.3, 4.2, 4.1, 4.0, 3.9, 3.8, 3.7, 3.6, 3.5, 3.4, 3.3, 3.2, 3.1, 3.0, 2.9, 2.8, 2.7, 2.6, 2.5, 2.4, 2.3, 2.2, 2.1, 2.0, 1.9, 1.8, 1.7, 1.6, 1.5, 1.4, 1.3, 1.2, 1.1, 1.0, 0.9, or 0.8 mL.~~

~~13.~~ 2. The composition of ~~any one of claims 9 to 12~~claim 1, wherein:
(i) the composition has a total volume of about 0.5 mL to about 1.5 mL;

~~14. — The composition of any one of claims 1 to 13, wherein~~
(ii) the composition has a viscosity of less than about 20 cP ~~or 10 cP~~;
or

~~15. — A pharmaceutical composition comprising a therapeutically effective dose of an antibody that binds to tumor necrosis factor like protein 1A (anti-TL1A antibody) in a pharmaceutical composition having a viscosity of less than about 20 cP or 10 cP.~~

~~16. — The composition of claim 14 or claim 15, wherein the composition has a viscosity of less than about 9, 8, 7, 6, or 5 cP.~~

~~17. — The composition of claim 14 or claim 15, wherein the composition has a viscosity of about 1 cP to about 7 cP, about 1 cP to about 2 cP, or about 10 cP to about 20 cP.~~

~~18. — A pharmaceutical composition comprising a therapeutically effective dose of an antibody that binds to tumor necrosis factor like protein 1A (anti-TL1A antibody), wherein~~

(iii) the composition has a percentage aggregation of anti-TL1A antibody or antigen binding fragment as measured by size exclusion chromatography of less than about ~~5~~2% of the total anti-TL1A antibody or antigen binding fragment in the composition.

~~19. — The composition of any one of claims 1 to 18, wherein the composition has a percentage aggregation of anti-TL1A antibody as measured by size-exclusion chromatography of less than about 5% of the total anti-TL1A antibody in the composition.~~

~~20. — The composition of claim 18 or claim 19, wherein the aggregation is less than about 4.5, 4, 3.5, 3, 2.5, 2, 1.5, 1, or 0.5%.~~

~~21~~3. The composition of ~~any one of claims 1 to 20~~claim 1 or 2, further comprising:

(i) a surfactant;

~~22. — The composition of any one of claims 1 to 21, comprising~~

(ii) a salt;

~~23. — The composition of any one of claims 1 to 22, comprising~~

(iii) a stabilizer;

~~24. — The composition of any one of claims 1 to 23, comprising~~

(iv) a buffering agent.

~~25. — The composition of any one of claims 1 to 24, such that the composition having~~has a pH of about 4.5 to about 8.0; or

(v) a combination of any of (i) to (iv).

~~26. — A pharmaceutical composition comprising an antibody that binds to tumor necrosis factor like protein 1A (anti-TL1A antibody) and a surfactant.~~

~~27. — A pharmaceutical composition comprising an antibody that binds to tumor necrosis factor like protein 1A (anti-TL1A antibody) and a salt.~~

~~28. — A pharmaceutical composition comprising an antibody that binds to tumor necrosis factor like protein 1A (anti-TL1A antibody) and a stabilizer.~~

~~29. — A pharmaceutical composition comprising an antibody that binds to tumor necrosis factor like protein 1A (anti-TL1A antibody) and a buffering agent.~~

~~30. — A pharmaceutical composition comprising an antibody that binds to tumor necrosis factor like protein 1A (anti-TL1A antibody), wherein the composition has a pH of about 4.5 to about 8.0.~~

~~31~~4. The composition of ~~any one of claims 21 to 26~~claim 3, wherein:

(i) the surfactant comprises a nonionic surfactant;

~~32. The composition of claim 31, wherein the nonionic surfactant~~

(ii) the surfactant comprises polysorbate-20;

~~33. The composition of any one of claims 21 to 26 and 31 to 32, wherein the~~

(iii) the surfactant is present at a concentration of about 0.005% to about 0.05% (v/v) of the composition;

~~34. The composition of claim 33, wherein the surfactant is present at a~~

~~concentration of about 0.01% to about 0.02% of the composition.~~

~~35. The composition of claim 33, wherein~~

(iv) the surfactant is present at a concentration of about 0.005%, about 0.006%, about 0.007%, about 0.008%, about 0.009%, about 0.01%, about 0.011%, about 0.012%, about 0.013%, about 0.014%, about 0.015%, about 0.016%, about 0.017%, about 0.018%, about 0.019%, about 0.02%, about 0.021%, about 0.022%, about 0.023%, about 0.024%, about 0.025%, about 0.026%, about 0.027%, about 0.028%, about 0.029%, or about 0.03% (v/v) of the composition;

~~36. The composition of any one of claims 22 to 25, 27, and 31 to 35, wherein~~

(v) the salt comprises sodium chloride, glycine, lysine-hydrochloride, arginine-hydrochloride, arginine glutamate, potassium chloride, magnesium chloride, or calcium chloride, or a combination thereof;

~~37. The composition of claim 36, wherein~~

(vi) the salt comprises sodium chloride;

~~38. The composition of claim 36 or 37, wherein the salt comprises lysine HCl.~~

~~39. The composition of any one of claims 22 to 25, 27, and 31 to 38, wherein the~~

(vii) the salt is present at a concentration of about 10 mM to about 100 mM in the composition;

~~40. The composition of claim 39, wherein the salt is present at a concentration of~~

~~about 25 mM in the composition.~~

~~41. The composition of claim 39, wherein~~

(viii) the salt is present at a concentration of about 40 mM in the composition;

~~42. The composition of any one of claims 23 to 25, 28, and 31 to 41, wherein~~
(ix) the stabilizer comprises a sugar, polyol, amino acid, or polymer,
cyclodextrin (e.g., HP-b-CD), or a combination thereof;-

~~43. The composition of claim 42, wherein~~
(x) the stabilizer comprises the sugar, wherein optionally the sugar
comprises sucrose, glucose, trehalose, maltose, or lactose, or a combination thereof;-

~~44. The composition of claim 43, wherein the sugar comprises sucrose, glucose,~~
~~trehalose, maltose, or lactose, or a combination thereof.~~

~~45. The composition of any one of claims 42 to 44, wherein~~
(xi) the stabilizer ~~sugar~~ comprises sucrose;-

~~46. The composition of claim 42, wherein the amino acid comprises glycine.~~

~~47. The composition of any one of claims 23 to 25, 28, and 31 to 46, wherein~~
(xii) the stabilizer is present at a concentration of about 50 mM to
about 300 mM in the composition-

~~48. The composition of claim 47, wherein the stabilizer is present at a~~
~~concentration of about 200 mM to about 280 mM.~~

~~49. The composition of claim 48, wherein the stabilizer is present at a~~
~~concentration of about 220 to about 240 mM.~~

~~50. The composition of claim 47, wherein~~
(xiii) the stabilizer is present at a concentration of about 150 mM,
about 160 mM, about 170 mM, about 180 mM, about 190 mM, about 200 mM, about 210
mM, about 220 mM, about 230 mM, about 240 mM, or about 250 mM-

~~51. The composition of claim 23 to 25, 28, and 31 to 50, wherein the stabilizer~~
~~comprises sucrose and glycine.~~

~~52. The composition of claim 51, wherein the sucrose is present at a concentration~~
~~of about 150 mM, about 160 mM, about 170 mM, about 180 mM, about 190 mM, about 200~~
~~mM, about 210 mM, about 220 mM, about 230 mM, about 240 mM, or about 250 mM.~~

~~53. The composition of claim 51 or 52, wherein the glycine is present at a~~
~~concentration of about 10 mM, about 15 mM, about 20 mM, about 25 mM, about 30 mM,~~
~~about 35 mM, about 40 mM, about 45 mM, about 50 mM, about 55 mM, about 60 mM, about~~

~~65 mM, about 70 mM, about 75 mM, about 80 mM, about 85 mM, about 90 mM, about 95 mM, about 100 mM, about 105 mM, about 110 mM, about 115 mM, or about 120 mM.~~

~~54. The composition of any one of claims 24 to 25, 29, and 31 to 53, wherein~~
(xiv) the buffering agent comprises acetate, phosphate, citrate,
glutamate, succinate, gluconate, histidine, glycylglycine, citric acid, Tris (tris
(hydroxymethyl) aminomethane), or diethanolamine, or a combination thereof;

~~55. The composition of claim 54, wherein~~
(xv) the buffering agent comprises acetate;

~~56. The composition of claim 54, wherein the buffering agent comprises~~
phosphate.

~~57. The composition of any one of claims 24 to 25, 29, and 31 to 56, wherein~~
(xvi) the buffering agent is present at a concentration of about 10 mM
to about 50 mM in the composition;

~~58. The composition of claim 57, wherein~~
(xvii) the composition comprises about 20 mM buffer;

~~59. The composition of any one of claims 25 and 30 to 58, wherein~~
(xviii) the composition has a pH of about 4.5 to about 7.5.

~~60. The composition of claim 59, wherein the composition has a pH of about 6 to~~
about 7.

~~61. The composition of claim 59, wherein the composition has a pH of about 6.5.~~

~~62. The composition of claim 59, wherein~~ optionally ~~the composition has a pH of~~
about 5 to about 5.5;

~~63. The composition of claim 59, wherein~~
(xix) the composition has a pH of about 5.3;
(xx) any combination of (i) to (xix); or
(xxi) the composition comprises 20 mM sodium acetate, 220 mM
sucrose, 40 mM NaCl, and 0.02% polysorbate-20, at pH 5.3.

;

~~645. Use of A method of treating an inflammatory disease in a subject, the method~~
~~comprising administering to the subject~~ an antibody or antigen binding fragment ~~that binds to~~

tumor necrosis factor-like protein 1A (anti-TL1A antibody or antigen binding fragment) in the manufacture of a medicament for the treatment of an inflammatory disease in a subject., wherein (i) the anti-TL1A antibody or antigen binding fragment is to be administered to the subject at a first dose up to about 1000 mg; (ii)-

~~65. — The method of claim 64, wherein the first dose is about 150 mg to about 1000 mg.~~

~~66. — The method of claim 65, wherein the first dose is about 500 mg to about 1000 mg.~~

~~67. — The method of claim 66, wherein the first dose is about 500 mg or about 800 mg.~~

~~68. — The method of any one of claims 64 to 67, wherein~~ the first dose is to be administered to the subject at a first time point, and a second dose is to be administered to the subject at a second time point.

~~69. — The method of claim 68, wherein the second time point is about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, or 31 days after the first time point.~~

~~70. — The method of claim 68, wherein and; and (iii)~~ the second time point is about 1, 2, 3, or 4 weeks after the first time point.

~~71. — The method of any one of claims 68 to 70, wherein the second dose comprises up to about 1000 mg anti-TL1A.~~

~~72. — The method of any one of claims 68 to 70, wherein the second dose comprises about 150 mg to about 1000 mg.~~

~~73. — The method of claim 72,~~ wherein the second dose comprises about 150 mg to about 600 mg.

~~74.~~ The ~~method of any one of claims 68 to 73~~use of claim 5, wherein:
(i) a third dose of anti-TL1A antibody or antigen binding fragment is to be administered to the subject at a third time point.

~~75. — The method of claim 74,~~ wherein the third time point is about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, or 31 days after the second time point.

~~76. — The method of claim 74, wherein the third time point is about 1, 2, 3, or 4 weeks after the second time point.~~

~~77. — The method of any one of claims 74 to 76, wherein the third dose comprises up to about 1000 mg anti-TL1A.~~

~~78. — The method of any one of claims 74 to 76, wherein the third dose comprises about 150 mg to about 1000 mg.~~

~~79. — The method of claim 78, wherein and the third dose comprises about 150 mg to about 600 mg; and/or.~~

~~80. — The method of any one of claims 74 to 79, wherein a fourth dose of anti-TL1A is administered to the subject at a fourth time point.~~

~~81. — The method of claim 80, wherein the fourth time point is about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, or 31 days after the third time point.~~

~~82. — The method of claim 80, wherein the fourth time point is about 1, 2, 3, or 4 weeks after the third time point.~~

~~83. — The method of any one of claims 80 to 82, wherein the fourth dose comprises up to about 1000 mg anti-TL1A.~~

~~84. — The method of any one of claims 80 to 82, wherein the fourth dose comprises about 150 mg to about 1000 mg.~~

~~85. — The method of claim 84, wherein the fourth dose comprises about 150 mg to about 600 mg.~~

~~86. — The method of any one of claims 80 to 85, wherein a fifth dose of anti-TL1A is administered to the subject at a fifth time point.~~

~~87. — The method of claim 86, wherein the fifth time point is about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, or 31 days after the fourth time point.~~

~~88. — The method of claim 86, wherein the fifth time point is about 1, 2, 3, or 4 weeks after the fourth time point.~~

~~89. — The method of any one of claims 86 to 88, wherein the fifth dose comprises up to about 1000 mg anti-TL1A.~~

~~90. — The method of any one of claims 86 to 88, wherein the fifth dose comprises about 150 mg to about 1000 mg.~~

~~91. — The method of claim 90, wherein the fifth dose comprises about 150 mg to about 600 mg.~~

~~92. — The method of any one of claims 86 to 91, wherein a sixth dose of anti-TL1A is administered to the subject at a sixth time point.~~

~~93. — The method of claim 92, wherein the sixth time point is about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, or 31 days after the fifth time point.~~

~~94. — The method of claim 92, wherein the sixth time point is about 1, 2, 3, or 4 weeks after the fifth time point.~~

~~95. — The method of any one of claims 92 to 94, wherein the sixth dose comprises up to about 1000 mg anti-TL1A.~~

~~96. — The method of any one of claims 92 to 94, wherein the sixth dose comprises about 150 mg to about 1000 mg.~~

~~97. — The method of claim 96, wherein the sixth dose comprises about 150 mg to about 600 mg.~~

~~98. — The method of any one of claims 64 to 97, wherein~~
~~_____ (ii) an additional dose of the anti-TL1A antibody or antigen binding fragment is to be administered to the subject at one or more additional time points, wherein optionally .~~

~~99. — The method of claim 98, wherein the one or more additional time points comprises about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, or 24 additional time points.~~

~~100. — The method of claim 98, wherein the composition is administered to the subject at about 12 additional time points.~~

~~101. — The method of any one of claims 98 to 100, wherein each additional time point is independently about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, or 31 days after a previous time point.~~

~~102.—The method of any one of claims 98 to 100, wherein, wherein each additional time point is independently about 1, 2, 3, or 4 weeks after a previous time point.~~

~~103.—The method of claim 102, wherein at least one of the additional time points is about 2 weeks after the previous time point.~~

~~104.—The method of any one of claims 98 to 103, wherein the additional dose comprises up to about 1000 mg anti-TL1A.~~

~~105.—The method of any one of claims 98 to 103, wherein and the additional dose comprises from about 150 mg to about 1000 mg anti-TL1A.~~

~~106.—The method of claim 105, wherein the additional dose is about 175 mg to about 300 mg anti-TL1A.~~

~~107.—The method of any one of claims 64 to 106, wherein the composition comprises the composition of any one of claims 1 to 63.~~

~~108.—An antibody or antigen binding fragment thereof that binds to tumor necrosis factor-like protein 1A (“TL1A,” and such antibody or antigen binding fragment thereof, “anti-TL1A antibody or antigen binding fragment”), wherein the antibody or antigen binding fragment binds to both monomeric TL1A and trimeric TL1A.~~

~~109.—The anti-TL1A antibody or antigen binding fragment of claim 108, wherein the antibody or antigen binding fragment blocks interaction of TL1A to Death Receptor 3 (“DR3”).~~

~~110.—The anti-TL1A antibody or antigen binding fragment of claim 108 or 109, wherein binding affinity of the antibody or antigen binding fragment to monomeric TL1A as measured by dissociation equilibrium constant ($K_{D\text{-monomer}}$) is comparable to binding affinity of the antibody or antigen binding fragment to trimeric TL1A as measured by dissociation equilibrium constant ($K_{D\text{-trimer}}$).~~

~~111.—The anti-TL1A antibody or antigen binding fragment of claim 110, wherein the $K_{D\text{-monomer}}$ is within 1.5, 2, 3, 4, 5, 6, 7, 8, 9, or 10 fold of the $K_{D\text{-trimer}}$.~~

~~112.—The anti-TL1A antibody or antigen binding fragment of claim 110 or 111, wherein the $K_{D\text{-monomer}}$ is no more than 0.06 nM.~~

~~113.—The anti-TL1A antibody or antigen binding fragment of claim 110 or 111, wherein the $K_{D-trimer}$ is no more than 0.06 nM.~~

~~114.—A method of neutralizing monomeric TL1A and trimeric TL1A in a subject comprising (a) administering an effective dose of anti-TL1A antibody or antigen binding fragment to the subject, wherein the antibody or antigen binding fragment binds to both monomeric TL1A and trimeric TL1A, and wherein the antibody or antigen binding fragment blocks interaction of TL1A to DR3.~~

~~115.—The method of claim 114, wherein the concentration of TL1A in a diseased tissue in the subject is reduced below the concentration of TL1A in a corresponding tissue in a control subject without IBD.~~

~~116.—The method of claim 114 or 115, wherein the subject has IBD.~~

~~117.—A method of reducing the concentration of TL1A in a diseased tissue in a subject with inflammatory bowel disease (“IBD”) comprising (a) administering an effective dose of anti-TL1A antibody or antigen binding fragment to the subject, —thereby reducing the concentration of TL1A in the diseased tissue in the subject below the concentration of TL1A in a corresponding tissue in a control subject without IBD.~~

~~1187. Use of~~ A method of treating IBD in a subject in need thereof comprising (a) administering an anti-TL1A antibody or antigen binding fragment in the manufacture of a medicament for treating IBD in a subject in need thereof~~to the subject,~~

wherein the anti-TL1A antibody or antigen binding fragment is ~~administered~~ to be used at an effective dose such that the concentration of TL1A in a diseased tissue in the subject after ~~step (a)~~ the use is below the concentration of TL1A in a corresponding tissue in a control subject without IBD,

wherein optionally the diseased tissue in the subject produces up to 20, 25, 30, 35, 40, 45, 50, 60, 70, 80, 90, 100, or more fold of TL1A compared to the corresponding tissue in the control subject during the induction regimen.

~~119.—A method of treating IBD in a subject in need thereof comprising —(a) administering an anti-TL1A antibody or antigen binding fragment to the subject at an effective dose, and~~

~~—(b) reducing the concentration of TL1A in a diseased tissue in the subject below the concentration of TL1A in a corresponding tissue in a control subject without IBD.~~

1208. The use method of ~~any one of claims 114 to 119~~claim 7, wherein:

(i) the effective dose comprises an induction regimen; or

~~121. The method of any one of claims 114 to 120, further comprising~~

~~—(c) maintaining TL1A in the diseased tissue in the subject at a concentration below the concentration of TL1A in the corresponding tissue in the control subject.~~

~~122. The method of claim 121, wherein~~

(ii) the effective dose comprises an induction regimen and a maintenance regimen after the induction regimen, wherein the TL1A in the diseased tissue in the subject is maintained with ~~a~~the maintenance regimen of the anti-TL1A antibody or antigen binding fragment.

~~123. The method of claim 122, wherein the induction regimen and the maintenance regimen are identical.~~

~~124. The method of claim 122, wherein the induction regimen and the maintenance regimen are different.~~

~~125. The method of any one of claims 122 to 124, wherein the maintenance regimen is administered after the induction regimen.~~

~~126. The method of any one of claims 115 to 125, wherein the diseased tissue in the subject produces up to 50, 60, 70, 80, 90, 100, or more fold of TL1A compared to the corresponding tissue in the control subject during the induction regimen.~~

~~127. The method of any one of claims 115 to 125, wherein the diseased tissue in the subject produces up to 50, 60, 70, 80, 90, 100, or more fold of TL1A compared to the corresponding tissue in the control subject within 1, 2, 3, 4, 5, or 6 weeks of start of the induction regimen.~~

~~128. The method of any one of claims 115 to 125, wherein the diseased tissue in the subject produces up to 50, 60, 70, 80, 90, 100, or more fold of TL1A compared to the corresponding tissue in the control subject.~~

~~1299.~~ The use of claim 8~~method of any one of claims 120 to 128~~, wherein:
(i) the induction regimen comprises a one-time administration of the anti-TL1A antibody or antigen binding fragment.

~~130.~~ ~~The method of claim 129,~~ wherein optionally the anti-TL1A antibody or antigen binding fragment is to be administered at 200 mg/dose, 250 mg/dose, 300 mg/dose, 350 mg/dose, 400 mg/dose, 450 mg/dose, 500 mg/dose, 550 mg/dose, 600 mg/dose, 650 mg/dose, 700 mg/dose, 750 mg/dose, 800 mg/dose, 850 mg/dose, 900 mg/dose, 950 mg/dose, 1000 mg/dose, 1100 mg/dose, 1200 mg/dose, 1250 mg/dose, 1300 mg/dose, 1400 mg/dose, 1500 mg/dose, 1600 mg/dose, 1700 mg/dose, 1750 mg/dose, 1800 mg/dose, 1900 mg/dose, or 2000 mg/dose;

~~131.~~ ~~The method of any one of claims 120 to 128~~, wherein
(ii) the induction regimen comprises multiple administrations of the anti-TL1A antibody or antigen binding fragment.

~~132.~~ ~~The method of any one of claims 120 to 128 and 131,~~ wherein optionally the induction regimen comprises administrations of

~~(i)~~ 1000 mg/dose on week 0, 1000 mg/dose on week 2, 1000 mg/dose on week 6, and 1000 mg/dose on week 10;

~~(ii)~~ 500 mg/dose on week 0, 500 mg/dose on week 2, 500 mg/dose on week 6, and 500 mg/dose on week 10;

~~(iii)~~ 1000 mg/dose on week 0, 1000 mg/dose on week 2, 1000 mg/dose on week 6, and 500 mg/dose on week 10;

~~(iv)~~ 1000 mg/dose on week 0, 1000 mg/dose on week 2, 500 mg/dose on week 6, and 500 mg/dose on week 10; or

~~(v)~~ 1000 mg/dose on week 0, 500 mg/dose on week 2, 500 mg/dose on week 6, and 500 mg/dose on week 10; or

~~133.~~ ~~The method of any one of claims 120 to 128 and 131~~, wherein
(iii) the induction regimen comprises administration of 2000, 1950, 1900, 1850, 1800, 1750, 1700, 1650, 1600, 1550, 1500, 1450, 1400, 1350, 1300, 1250, 1200, 1150, 1100, 1050, 1000, 950, 900, 850, 800, 750, 700, 650, 600, 550, 500, 450, 400, 350, 300, 250, or 200 mg/dose.

~~134. The method of any one of claims 120 to 128, 131, and 133, wherein~~
optionally the induction regimen comprises administration once every 2, 4, 6, or 8 weeks;

~~135. The method of any one of claims 120 to 128, 131, and 133, wherein~~ or the induction regimen comprises administration once every 2 or 4 weeks for the first 2 administrations and then once every 2, 4, 6, or 8 weeks for the remaining induction regimen.

~~136. The method of any one of claims 121 to 135, wherein the diseased tissue in the subject produces up to 10, 15, 20, 25, 30, 35, 40, 45, 50, or more fold of TL1A compared to the corresponding tissue in the control subject.~~

~~137. The method of any one of claims 121 to 132, wherein the diseased tissue in the subject produces up to 10, 15, 20, 25, 30, 35, 40, 45, 50, or more fold of TL1A compared to the corresponding tissue in the control subject during the maintenance regimen.~~

~~138. The method of any one of claims 121 to 132, wherein the diseased tissue in the subject produces up to 10, 15, 20, 25, 30, 35, 40, 45, 50, or more fold of TL1A compared to the corresponding tissue in the control subject within 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 16, 18, 20, 22, 24, 28, 32, 36, 40, 44, 48, or 52 weeks, or longer of start of the maintenance regimen.~~

~~139~~10. The use of claim 8 or 9~~method of any one of claims 122 to 138~~, wherein:
(i) the maintenance regimen comprises multiple administrations of the anti-TL1A antibody or antigen binding fragment;

~~140. The method of any one of claims 122 to 139, wherein~~
(ii) the maintenance regimen comprises administrations of the anti-TL1A antibody or antigen binding fragment at

- ~~—— (i) 500 mg/dose every 2 weeks,~~
- ~~—— (ii) 400 mg/dose every 2 weeks,~~
- ~~—— (iii) 300 mg/dose every 2 weeks,~~
- ~~—— (iv) 250 mg/dose every 2 weeks,~~
- ~~—— (v) 200 mg/dose every 2 weeks,~~
- ~~—— (vi) 150 mg/dose every 2 weeks,~~
- ~~—— (vii) 100 mg/dose every 2 weeks,~~
- ~~—— (viii) 50 mg/dose every 2 weeks,~~

~~143. The method of any one of claims 122 to 142, wherein~~
(v) the maintenance regimen comprises administrations of the anti-TL1A antibody or antigen binding fragment at 250 mg/dose every 4 weeks; ~~or~~;

~~144. The method of any one of claims 122 to 142, wherein the maintenance regimen comprises administrations of the anti-TL1A antibody or antigen binding fragment at 100 mg/dose every 4 weeks.~~

~~145. The method of any one of claims 122 to 144, wherein~~
(vi) the maintenance regimen continues for 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 40, 44, 48, or 52 weeks.

~~146. The method of any one of claims 117 to 145, wherein the antibody or antigen binding fragment binds to both monomeric TL1A and trimeric TL1A and wherein the antibody or antigen binding fragment blocks binding of TL1A to DR3.~~

~~147. The method of any one of claims 114 to 146, wherein at least 60%, 65%, 70%, 75%, 80%, 85%, 86%, 87%, 88%, 89%, 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, or 99% of the monomeric TL1A in the blood of the subject is occupied by the anti-TL1A antibody or antigen binding fragment.~~

~~148. The method of any one of claims 114 to 147, wherein at least 60%, 65%, 70%, 75%, 80%, 85%, 86%, 87%, 88%, 89%, 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, or 99% of the trimeric TL1A in the blood of the subject is occupied by the anti-TL1A antibody or antigen binding fragment.~~

~~149~~11. The use of any one of claims 7 to 10~~method of any one of claims 114 to 148,~~ wherein:

(i) binding affinity of the antibody or antigen binding fragment to monomeric TL1A as measured by dissociation equilibrium constant ($K_{D\text{-monomer}}$) is comparable to binding affinity of the antibody or antigen binding fragment to trimeric TL1A as measured by dissociation equilibrium constant ($K_{D\text{-trimer}}$);

~~150. The method of claim 149,~~ wherein optionally the $K_{D\text{-monomer}}$ is within 1.5, 2, 3, 4, 5, 6, 7, 8, 9, or 10 fold of the $K_{D\text{-trimer}}$; and wherein optionally

~~151. The method of claim 149 or 150, wherein the $K_{D\text{-monomer}}$ is no more than 0.06 nM;~~

~~152. The method of any one of claims 149 to 151, wherei andn the $K_{D\text{-trimer}}$ is no more than 0.06 nM;~~

~~153. The method of any one of claims 116 to 152, wherein~~
(ii) the IBD is Crohn's disease or ulcerative colitis; or

~~154. The method of any one of claims 115 to 153, wherein~~
(iii) the diseased tissue comprises any one or more selected from the group consisting of colon, small intestine, rectum, cecum, ileum, spleen, a fibrotic tissue from IBD, other tissues with IBD pathology, and other tissues of IBD pathogenesis.

~~155~~12. The use method of any one of claims ~~114~~8 to ~~154~~11, wherein:
(1) the effective dose or the induction regimen is determined by a dose determination method, wherein the dose determination method comprises:

(i) receiving a parameter of TL1A over-production in the diseased tissue comparing to TL1A production in a normal reference tissue;

~~—~~(ii) integrating the parameters received in (a) to an integrated whole-body physiologically based pharmacokinetic (PBPK) model or a population pharmacokinetic model (popPK); and

~~—~~(iii) determining the effective dose or the induction regimen such that the concentration of TL1A in diseased tissue in the subject after ~~step (a)~~the use is below the concentration of TL1A in a corresponding tissue in a control subject without IBD; and/or

~~156. The method of claim 155, wherein the parameter of TL1A over production is 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, or more fold over production comparing to TL1A production in the normal reference tissue.~~

~~157. The method of any one of claims 122 to 156, wherein~~
(2) the maintenance regimen is determined by a dose determination method, wherein the dose determination method comprises:

~~—~~(i) receiving a parameter of TL1A over-production in the diseased tissue comparing to TL1A production in a normal reference tissue;

——(ii) integrating the parameter received in (i) to an integrated whole-body physiologically based pharmacokinetic (PBPK) model or a population pharmacokinetic model (popPK); and

——(iii) determining the maintenance regimen such that the concentration of TL1A in diseased tissue in the subject after step (c) is below the concentration of TL1A in a corresponding tissue in a control subject without IBD.

~~158.—The method of claim 157, wherein the parameter of TL1A over production is 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, or more fold over production comparing to TL1A production in the normal reference tissue.~~

~~159.—The method of any one of claims 155 to 158, wherein the step (i) in the dose determination method further comprises receiving association rate of the antibody to TL1A ($k_{\text{on-mAb}}$), dissociation rate of the antibody from TL1A ($k_{\text{off-mAb}}$), synthesis rate of TL1A in normal tissue ($k_{\text{syn-normal}}$), synthesis rate of TL1A in diseased tissue ($k_{\text{syn-disease}}$), and/or degradation rate of TL1A ($k_{\text{deg-total TL1A}}$).~~

~~160.—The method of claim to 159, wherein the association rate of the antibody to TL1A ($k_{\text{on-mAb}}$) comprises the association rate of the antibody to monomeric TL1A ($k_{\text{on-monomer}}$) and association rate of the antibody to trimeric TL1A ($k_{\text{on-trimer}}$), wherein the dissociation rate of the antibody from TL1A ($k_{\text{off-mAb}}$) comprises the dissociation rate of the antibody from monomeric TL1A ($k_{\text{off-monomer}}$) and dissociation rate of the antibody from trimeric TL1A ($k_{\text{off-trimer}}$), and/or wherein the degradation rate of TL1A ($k_{\text{deg-total TL1A}}$) comprises degradation rate of monomeric TL1A ($k_{\text{deg-TL1A-monomer}}$) and degradation rate of trimeric TL1A ($k_{\text{deg-TL1A-trimer}}$).~~

~~161.—The method of any one of claims 155 to 160, wherein the step (i) in the dose determination method further comprises receiving association rate of the antibody to FeRn receptor ($k_{\text{on-mAb-FeRn}}$), dissociation rate of the antibody from FeRn ($k_{\text{off-mAb-FeRn}}$), association rate of the antibody TL1A complex to FeRn receptor ($k_{\text{on-(mAb-TL1A)-FeRn}}$), and/or dissociation rate of the antibody TL1A complex from FeRn ($k_{\text{off-(mAb-TL1A)-FeRn}}$).~~

~~162.—The method of claim 161, wherein the association rate of the antibody TL1A complex to FeRn receptor ($k_{\text{on-(mAb-TL1A)-FeRn}}$) comprises association rate of the antibody monomeric TL1A complex to FeRn receptor ($k_{\text{on-(mAb-monoTL1A)-FeRn}}$) and association rate of the antibody trimeric TL1A complex to FeRn receptor ($k_{\text{on-(mAb-triTL1A)-FeRn}}$), and/or wherein~~

~~the dissociation rate of the antibody-TL1A complex from FeRn ($k_{\text{off-(mAb-TL1A)-FeRn}}$) comprises dissociation rate of the antibody-monomeric TL1A complex from FeRn ($k_{\text{off-(mAb-monoTL1A)-FeRn}}$) and dissociation rate of the antibody-trimeric TL1A complex from FeRn ($k_{\text{off-(mAb-triTL1A)-FeRn}}$);~~

~~163.—The method of any one of claims 155 to 162, wherein the step (i) in the dose determination method further comprises receiving clearance rate of FeRn receptor bound by the antibody ($k_{\text{deg-mAb-FeRn}}$);~~

~~164.—The method of claim 163, wherein the clearance rate of FeRn receptor bound by the antibody ($k_{\text{deg-mAb-FeRn}}$) comprises clearance rate of the antibody to FeRn bound by the antibody-monomeric TL1A complex ($k_{\text{deg-(mAb-monoTL1A)-FeRn}}$) and clearance rate of FeRn receptor bound by the antibody-trimeric TL1A complex ($k_{\text{deg-(mAb-triTL1A)-FeRn}}$);~~

~~165.—The method of any one of claims 159 to 164, wherein in the dose determination method:~~

- ~~——(1) $k_{\text{on-monomer}}$ and $k_{\text{on-trimer}}$ are identical or different;~~
- ~~——(2) $k_{\text{off-monomer}}$ and $k_{\text{off-trimer}}$ are identical or different;~~
- ~~——(3) $k_{\text{deg-monomer}}$ and $k_{\text{deg-trimer}}$ are identical or different;~~
- ~~——(4) $k_{\text{on-(mAb-monoTL1A)-FeRn}}$ and $k_{\text{on-(mAb-triTL1A)-FeRn}}$ are identical or different;~~
- ~~——(5) $k_{\text{on-mAb-FeRn}}$ and $k_{\text{on-(mAb-monoTL1A)-FeRn}}$ are identical or different;~~
- ~~——(6) $k_{\text{on-mAb-FeRn}}$ and $k_{\text{on-(mAb-triTL1A)-FeRn}}$ are identical or different;~~
- ~~——(7) $k_{\text{off-(mAb-monoTL1A)-FeRn}}$ and $k_{\text{off-(mAb-triTL1A)-FeRn}}$ are identical or different;~~
- ~~——(8) $k_{\text{off-mAb-FeRn}}$ and $k_{\text{off-(mAb-monoTL1A)-FeRn}}$ are identical or different;~~
- ~~——(9) $k_{\text{off-mAb-FeRn}}$ and $k_{\text{off-(mAb-triTL1A)-FeRn}}$ are identical or different;~~
- ~~——(10) $k_{\text{deg-(mAb-monoTL1A)-FeRn}}$ and $k_{\text{deg-(mAb-triTL1A)-FeRn}}$ are identical or different;~~
- ~~——(11) $k_{\text{deg-mAb-FeRn}}$ and $k_{\text{deg-(mAb-triTL1A)-FeRn}}$ are identical or different;~~
- ~~——(12) $k_{\text{deg-mAb-FeRn}}$ and $k_{\text{deg-(mAb-monoTL1A)-FeRn}}$ are identical or different; or~~
- ~~——(13) any combination of (1) to (12);~~

~~166.—The method of any one of claims 155 to 165, wherein in the dose determination method:~~

- ~~—— $k_{\text{syn-disease}}$ is up to 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, or more fold of $k_{\text{syn-normal}}$;~~

~~167.—The method of any one of claims 155 to 166, wherein step (i) in the dose determination method further comprises receiving rate of TL1A trimerization ($k_{\text{on-TL1A-monomer-to-trimer}}$) and/or rate of TL1A monomerization ($k_{\text{off-TL1A-trimer-to-monomer}}$);~~

~~168.—A method of determining an effective dose regimen for administering an anti-TL1A antibody to a subject with IBD, wherein the method comprises:~~

~~——(a) receiving a parameter of TL1A over production in the diseased tissue comparing to TL1A production in a normal reference tissue;~~

~~——(b) integrating the parameter received in (a) to an integrated whole body physiologically based pharmacokinetic (PBPK) model; and~~

~~——(c) determining the effective dose regimen of the anti-TL1A antibody with the PBPK model from (b) such that after administration of the effective dose regimen the concentration of TL1A in a diseased tissue in the subject is below the concentration of TL1A in a corresponding tissue in a control subject without IBD.~~

~~169.—A method of determining an effective dose regimen for administering an anti-TL1A antibody to a subject with IBD, wherein the method comprises:~~

~~——(a) receiving a parameter of TL1A over production in the diseased tissue comparing to TL1A production in a normal reference tissue;~~

~~——(b) integrating the parameter received in (a) to a population pharmacokinetic (popPK) model; and~~

~~——(c) determining the effective dose regimen of the anti-TL1A antibody with the popPK model from (b) such that after administration of the effective dose regimen the concentration of TL1A in a diseased tissue in the subject is below the concentration of TL1A in a corresponding tissue in a control subject without IBD.~~

~~170.—The method of claim 168 or 169, wherein the parameter of TL1A over-production is 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200 or more fold over production comparing to TL1A production in the normal reference tissue.~~

~~171.—The method of any one of claims 168 to 170, wherein the step (a) further comprises receiving association rate of the antibody to TL1A ($k_{\text{on-mAb}}$), dissociation rate of the antibody from TL1A ($k_{\text{off-mAb}}$), synthesis rate of TL1A in normal tissue ($k_{\text{syn-normal}}$);~~

~~synthesis rate of TL1A in diseased tissue ($k_{\text{syn-disease}}$), and/or degradation rate of TL1A ($k_{\text{deg-total-TL1A}}$):~~

~~172.— The method of claim to 171, wherein the association rate of the antibody to TL1A ($k_{\text{on-mAb}}$) comprises the association rate of the antibody to monomeric TL1A ($k_{\text{on-monomer}}$) and association rate of the antibody to trimeric TL1A ($k_{\text{on-trimer}}$), wherein the dissociation rate of the antibody from TL1A ($k_{\text{off-mAb}}$) comprises the dissociation rate of the antibody from monomeric TL1A ($k_{\text{off-monomer}}$) and dissociation rate of the antibody from trimeric TL1A ($k_{\text{off-trimer}}$), and/or wherein the degradation rate of TL1A ($k_{\text{deg-total-TL1A}}$) comprises degradation rate of monomeric TL1A ($k_{\text{deg-TL1A-monomer}}$) and degradation rate of trimeric TL1A ($k_{\text{deg-TL1A-trimer}}$):~~

~~173.— The method of any one of claims 168 to 172, wherein the step (a) comprises receiving association rate of the antibody to FeRn receptor ($k_{\text{on-mAb-FeRn}}$), dissociation rate of the antibody from FeRn ($k_{\text{off-mAb-FeRn}}$), association rate of the antibody-TL1A complex to FeRn receptor ($k_{\text{on-(mAb-TL1A)-FeRn}}$), and/or dissociation rate of the antibody-TL1A complex from FeRn ($k_{\text{off-(mAb-TL1A)-FeRn}}$):~~

~~174.— The method of claim 173, wherein the association rate of the antibody-TL1A complex to FeRn receptor ($k_{\text{on-(mAb-TL1A)-FeRn}}$) comprises association rate of the antibody-monomeric TL1A complex to FeRn receptor ($k_{\text{on-(mAb-monoTL1A)-FeRn}}$) and association rate of the antibody-trimeric TL1A complex to FeRn receptor ($k_{\text{on-(mAb-triTL1A)-FeRn}}$), and/or wherein the dissociation rate of the antibody-TL1A complex from FeRn ($k_{\text{off-(mAb-TL1A)-FeRn}}$) comprises dissociation rate of the antibody-monomeric TL1A complex from FeRn ($k_{\text{off-(mAb-monoTL1A)-FeRn}}$) and dissociation rate of the antibody-trimeric TL1A complex from FeRn ($k_{\text{off-(mAb-triTL1A)-FeRn}}$):~~

~~175.— The method of any one of claims 168 to 174, wherein the step (a) further comprises receiving clearance rate of FeRn receptor bound by the antibody ($k_{\text{deg-mAb-FeRn}}$):~~

~~176.— The method of claim 175, wherein the clearance rate of FeRn receptor bound by the antibody ($k_{\text{deg-mAb-FeRn}}$) further comprises clearance rate of the antibody to FeRn bound by the antibody-monomeric TL1A complex ($k_{\text{deg-(mAb-monoTL1A)-FeRn}}$) and clearance rate of FeRn receptor bound by the antibody-trimeric TL1A complex ($k_{\text{deg-(mAb-triTL1A)-FeRn}}$):~~

~~177.—The method of any one of claims 168 to 176, wherein the diseased tissue comprises any one or more selected from the group consisting of colon, small intestine, rectum, cecum, ileum, spleen, a fibrotic tissue from IBD, other tissues with IBD pathology, and other tissues of IBD pathogenesis.~~

~~178.—The method of any one of claims 168 to 177, wherein:~~

- ~~——(1) $k_{\text{on-monomer}}$ and $k_{\text{on-trimer}}$ are identical or different;~~
- ~~——(2) $k_{\text{off-monomer}}$ and $k_{\text{off-trimer}}$ are identical or different;~~
- ~~——(3) $k_{\text{deg-monomer}}$ and $k_{\text{deg-trimer}}$ are identical or different;~~
- ~~——(4) $k_{\text{on-(mAb-monoTL1A)-FeRn}}$ and $k_{\text{on-(mAb-triTL1A)-FeRn}}$ are identical or different;~~
- ~~——(5) $k_{\text{on-mAb-FeRn}}$ and $k_{\text{on-(mAb-monoTL1A)-FeRn}}$ are identical or different;~~
- ~~——(6) $k_{\text{on-mAb-FeRn}}$ and $k_{\text{on-(mAb-triTL1A)-FeRn}}$ are identical or different;~~
- ~~——(7) $k_{\text{off-(mAb-monoTL1A)-FeRn}}$ and $k_{\text{off-(mAb-triTL1A)-FeRn}}$ are identical or different;~~
- ~~——(8) $k_{\text{off-mAb-FeRn}}$ and $k_{\text{off-(mAb-monoTL1A)-FeRn}}$ are identical or different;~~
- ~~——(9) $k_{\text{off-mAb-FeRn}}$ and $k_{\text{off-(mAb-triTL1A)-FeRn}}$ are identical or different;~~
- ~~——(10) $k_{\text{deg-(mAb-monoTL1A)-FeRn}}$ and $k_{\text{deg-(mAb-triTL1A)-FeRn}}$ are identical or different;~~
- ~~——(11) $k_{\text{deg-mAb-FeRn}}$ and $k_{\text{deg-(mAb-triTL1A)-FeRn}}$ are identical or different;~~
- ~~——(12) $k_{\text{deg-mAb-FeRn}}$ and $k_{\text{deg-(mAb-monoTL1A)-FeRn}}$ are identical or different; or~~
- ~~——(13) any combination of (1) to (12).~~

~~179.—The method of any one of claims 168 to 178, wherein:~~

- ~~—— $k_{\text{syn-disease}}$ is up to 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, or more fold of $k_{\text{syn-normal}}$;~~

~~180.—The method of any one of claims 168 to 179, wherein the effective dose regimen comprises an induction regimen of the anti-TL1A antibody or antigen binding fragment.~~

~~181.—The method of any one of claims 168 to 180, wherein the effective dose regimen comprises a maintenance regimen of the anti-TL1A antibody or antigen binding fragment.~~

~~182.—The method of claim 181, wherein the induction regimen and the maintenance regimen are identical.~~

~~183.—The method of claim 181, wherein the induction regimen and the maintenance regimen are different.~~

~~184.—The method of any one of claims 181 to 183, wherein the maintenance regimen is administered after the induction regimen.~~

~~185.—The method of any one of claims 180 to 184, wherein the diseased tissue in the subject produces up to 50, 60, 70, 80, 90, 100, or more fold of TL1A compared to the corresponding tissue in the control subject during the induction regimen.~~

~~186.—The method of any one of claims 180 to 185, wherein the diseased tissue in the subject produces up to 50, 60, 70, 80, 90, 100, or more fold of TL1A compared to the corresponding tissue in the control subject within 1, 2, 3, 4, 5, or 6 weeks of start of the induction regimen.~~

~~187.—The method of any one of claims 168 to 184, wherein the diseased tissue in the subject produces up to 50, 60, 70, 80, 90, 100, or more fold of TL1A compared to the corresponding tissue in the control subject.~~

~~188.—The method of any one of claims 180 to 187, wherein the induction regimen comprises a one time administration of the anti TL1A antibody or antigen binding fragment.~~

~~189.—The method of claim 188, wherein the anti TL1A antibody or antigen binding fragment is administered at 200 mg/dose, 250 mg/dose, 300 mg/dose, 350 mg/dose, 400 mg/dose, 450 mg/dose, 500 mg/dose, 550 mg/dose, 600 mg/dose, 650 mg/dose, 700 mg/dose, 750 mg/dose, 800 mg/dose, 850 mg/dose, 900 mg/dose, 950 mg/dose, 1000 mg/dose, 1100 mg/dose, 1200 mg/dose, 1250 mg/dose, 1300 mg/dose, 1400 mg/dose, 1500 mg/dose, 1600 mg/dose, 1700 mg/dose, 1750 mg/dose, 1800 mg/dose, 1900 mg/dose, or 2000 mg/dose.~~

~~190.—The method of any one of claims 180 to 187, wherein the induction regimen comprises multiple administrations of the anti TL1A antibody or antigen binding fragment.~~

~~191.—The method of any one of claims 180 to 187 and 190, wherein the induction regimen comprises administrations of~~

~~——(i) 1000 mg/dose on week 0, 1000 mg/dose on week 2, 1000 mg/dose on week 6, and 1000 mg/dose on week 10;~~

~~——(ii) 500 mg/dose on week 0, 500 mg/dose on week 2, 500 mg/dose on week 6, and~~

~~500 mg/dose on week 10;~~

~~—— (iii) 1000 mg/dose on week 0, 1000 mg/dose on week 2, 1000 mg/dose on week 6, and 500 mg/dose on week 10;~~

~~—— (iv) 1000 mg/dose on week 0, 1000 mg/dose on week 2, 500 mg/dose on week 6, and 500 mg/dose on week 10; or~~

~~—— (v) 1000 mg/dose on week 0, 500 mg/dose on week 2, 500 mg/dose on week 6, and 500 mg/dose on week 10.~~

~~192. — The method of any one of claims 180 to 187 and 190, wherein the induction regimen comprises administration of 2000, 1950, 1900, 1850, 1800, 1750, 1700, 1650, 1600, 1550, 1500, 1450, 1400, 1350, 1300, 1250, 1200, 1150, 1100, 1050, 1000, 950, 900, 850, 800, 750, 700, 650, 600, 550, 500, 450, 400, 350, 300, 250, or 200 mg/dose.~~

~~193. — The method of any one of claims 180 to 187, 190, and 192, wherein the induction regimen comprises administration once every 2, 4, 6, or 8 weeks.~~

~~194. — The method of any one of claims 180 to 187, 190, and 192, wherein the induction regimen comprises administration once every 2 or 4 weeks for the first 2 administrations and then once every 2, 4, 6, or 8 weeks for the remaining induction regimen.~~

~~195. — The method of any one of claims 168 to 184 and 188 to 194, wherein the diseased tissue in the subject produces up to 10, 15, 20, 25, 30, 35, 40, 45, 50, or more fold of TL1A compared to the corresponding tissue in the control subject.~~

~~196. — The method of any one of claims 181 to 195, wherein the diseased tissue in the subject produces up to 10, 15, 20, 25, 30, 35, 40, 45, 50, or more fold of TL1A compared to the corresponding tissue in the control subject during the maintenance regimen.~~

~~197. — The method of any one of claims 181 to 196, wherein the diseased tissue in the subject produces up to 10, 15, 20, 25, 30, 35, 40, 45, 50, or more fold of TL1A compared to the corresponding tissue in the control subject within 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 16, 18, 20, 22, 24, 28, 32, 36, 40, 44, 48, or 52 weeks, or longer of start of the maintenance regimen.~~

~~198.—The method of any one of claims 181 to 197, wherein the maintenance regimen comprises multiple administrations of the anti-TL1A antibody or antigen binding fragment.~~

~~199.—The method of any one of claims 181 to 198, wherein the maintenance regimen comprises administrations of the anti-TL1A antibody or antigen binding fragment at~~

- ~~——(i) 500 mg/dose every 2 weeks,~~
- ~~——(ii) 400 mg/dose every 2 weeks,~~
- ~~——(iii) 300 mg/dose every 2 weeks,~~
- ~~——(iv) 250 mg/dose every 2 weeks,~~
- ~~——(v) 200 mg/dose every 2 weeks,~~
- ~~——(vi) 150 mg/dose every 2 weeks,~~
- ~~——(vii) 100 mg/dose every 2 weeks,~~
- ~~——(viii) 50 mg/dose every 2 weeks,~~
- ~~——(ix) 500 mg/dose every 4 weeks,~~
- ~~——(x) 400 mg/dose every 4 weeks,~~
- ~~——(xi) 300 mg/dose every 4 weeks,~~
- ~~——(xii) 250 mg/dose every 4 weeks,~~
- ~~——(xiii) 200 mg/dose every 4 weeks,~~
- ~~——(xiv) 150 mg/dose every 4 weeks,~~
- ~~——(xv) 100 mg/dose every 4 weeks,~~
- ~~——(xvi) 50 mg/dose every 4 weeks,~~
- ~~——(xvii) 500 mg/dose every 6 weeks,~~
- ~~——(xviii) 400 mg/dose every 6 weeks,~~
- ~~——(xix) 300 mg/dose every 6 weeks,~~
- ~~——(xx) 250 mg/dose every 6 weeks,~~
- ~~——(xxi) 200 mg/dose every 6 weeks,~~
- ~~——(xxii) 150 mg/dose every 6 weeks,~~
- ~~——(xxiii) 100 mg/dose every 6 weeks,~~
- ~~——(xxiv) 50 mg/dose every 6 weeks,~~
- ~~——(xxv) 500 mg/dose every 8 weeks,~~
- ~~——(xxvi) 400 mg/dose every 8 weeks,~~
- ~~——(xxvii) 300 mg/dose every 8 weeks,~~
- ~~——(xxviii) 250 mg/dose every 8 weeks,~~

~~——(xxix) 200 mg/dose every 8 weeks,~~
~~——(xxx) 150 mg/dose every 8 weeks,~~
~~——(xxxi) 100 mg/dose every 8 weeks, or~~
~~——(xxxii) 50 mg/dose every 8 weeks.~~

~~200. —The method of any one of claims 181 to 198, wherein the maintenance regimen comprises administration of the anti-TL1A antibody or antigen binding fragment at 1000, 950, 900, 850, 800, 750, 700, 650, 600, 550, 500, 450, 400, 350, 300, 250, 200, 150, 100, or 50 mg/dose.~~

~~201. —The method of any one of claims 181 to 198 and 200, wherein the maintenance regimen comprises administration of the anti-TL1A antibody or antigen binding fragment once every 2, 4, 6, 8, 10, or 12 weeks.~~

~~202. —The method of any one of claims 181 to 201, wherein the maintenance regimen comprises administrations of the anti-TL1A antibody or antigen binding fragment at 250 mg/dose every 4 weeks.~~

~~203. —The method of any one of claims 181 to 202, wherein the maintenance regimen comprises administrations of the anti-TL1A antibody or antigen binding fragment at 100 mg/dose every 4 weeks.~~

~~204. —The method of any one of claims 181 to 203, wherein the maintenance regimen continues for 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 40, 44, 48, or 52 weeks.~~

~~205. —The method of any one of claims 168 to 204, wherein the effective dose regimen maintains the concentration of TL1A in diseased tissue in the subject below the concentration of TL1A in a corresponding tissue in a control subject without IBD for at least 4 weeks, 8 weeks, 12 weeks, 4 months, 5 months, 6 months, 7 months, 8 months, 9 months, 10 months, 11 months, 12 months, 2 years, and longer.~~

~~206. —The method of any one of claims 168 to 205, wherein at least 91%, at least 92%, at least 93%, at least 94%, at least 95%, at least 96%, at least 97%, at least 98%, or at least 99% of the monomeric TL1A in the blood of the subject is occupied by the anti-TL1A antibody or antigen binding fragment during the effective dose regimen.~~

~~207.—The method of any one of claims 168 to 206, wherein at least 91%, at least 92%, at least 93%, at least 94%, at least 95%, at least 96%, at least 97%, at least 98%, or at least 99% of the trimeric TL1A in the blood of the subject is occupied by the anti-TL1A antibody or antigen binding fragment during the effective dose regimen.~~

~~208.—The method of any one of claims 168 to 207, wherein step (a) further comprises receiving the rate of TL1A trimerization ($k_{\text{on-TL1A monomer-to-trimer}}$) and/or rate of TL1A monomerization ($k_{\text{off-TL1A trimer-to-monomer}}$).~~

~~209.—The method of any one of claims 115 to 208, wherein the concentration of TL1A is the concentration of free TL1A.~~

~~210~~13. The composition of any one of claims 1 to ~~63~~4, or the ~~antibody or antigen binding fragment~~use of any one of claims ~~108-5~~108-5 to ~~113-12~~113-12, ~~or the method of any one of claims 64 to 107 and 114 to 209~~, wherein the anti-TL1A antibody or antigen binding fragment comprises a heavy chain variable region comprising: an HCDR1 comprising an amino acid sequence set forth by SEQ ID NO: 1, an HCDR2 comprising an amino acid sequence set forth by any one of SEQ ID NOS: 2-5, and an HCDR3 comprising an amino acid sequence set forth by any one of SEQ ID NOS: 6-9; and a light chain variable region comprising an LCDR1 comprising an amino acid sequence set forth by SEQ ID NO: 10, an LCDR2 comprising an amino acid sequence set forth by SEQ ID NO: 11, an LCDR3 comprising an amino acid sequence set forth by any one of SEQ ID NOS: 12-15.

~~211~~14. The composition of any one of claims 1 to ~~63~~4, or the ~~antibody or antigen binding fragment~~use of any one of claims ~~108-5~~108-5 to ~~113-12~~113-12, ~~or the method of any one of claims 64 to 107 and 114 to 210~~, wherein:

(i) the anti-TL1A antibody or antigen binding fragment comprises a heavy chain variable framework region comprising a human IGHV1-46*02 framework or a modified human IGHV1-46*02 framework, and a light chain variable framework region comprising a human IGKV3-20 framework or a modified human IGKV3-20 framework; wherein the heavy chain variable framework region and the light chain variable framework region collectively comprise no or fewer than nine amino acid modification(s) from the human IGHV1-46*02 framework and the human IGKV3-20 framework.

~~212.—The composition of any one of claims 1 to 63, the antibody or antigen binding fragment of any one of claims 108 to 113, or the method of any one of claims 64 to 107 and~~

~~114 to 211, wherein:~~ or

(ii) the anti-TL1A antibody or antigen binding fragment comprises a heavy chain variable domain comprising an amino acid sequence at least ~~96~~97% identical to any one of SEQ ID NOS: 101-169, and a light chain variable domain comprising an amino acid sequence at least ~~96~~97% identical to any one of SEQ ID NOS: 201-220.

~~213~~15. The composition of any one of claims 1 to ~~63~~4, or the ~~antibody or antigen binding fragment~~use of any one of claims ~~108-5~~5 to ~~113~~12, ~~or the method of any one of claims 64 to 107 and 114 to 212,~~ wherein the anti-TL1A antibody or antigen binding fragment comprises a heavy chain variable region comprising SEQ ID NO: 301
X1VQLVQSGAEVKKPGASVKVSCKAS[HCDR1]WVX2QX3PGQGLEWX4G[HCDR2]
RX5TX6TX7DTSTSTX8YX9ELSSLRSEDFAVYYCAR[HCDR3]WGQGTTVTVSS, and a light chain variable region comprising SEQ ID NO: 303

EIVLTQSPGTLSPGERATLSC[LCDR1]WYQQKPGQAPRX10X11IY[LCDR2]GIPDR
FSGSGSGTDFLTISRLEPEDFAVYYC[LCDR3]FGGGTKLEIK, wherein each of X1-X11 is independently selected from A, R, N, D, C, Q, E, G, H, I, L, K, M, F, P, S, T, W, Y, or V, wherein HCDR1 comprises an amino acid sequence set forth by SEQ ID NO: 1, HCDR2 comprises an amino acid sequence set forth by any one of SEQ ID NOS: 2-5, HCDR3 comprises an amino acid sequence set forth by any one of SEQ ID NOS: 6-9, LCDR1 comprises an amino acid sequence set forth by SEQ ID NO: 10, LCDR2 comprises an amino acid sequence set forth by SEQ ID NO: 11, and LCDR3 comprises an amino acid sequence set forth by any one of SEQ ID NOS: 12 or 13.

16. An antibody or antigen binding fragment that binds to tumor necrosis factor-like protein 1A (anti-TL1A antibody or antigen binding fragment) for use in therapy.