

We claim:

1. An aqueous pharmaceutical formulation comprising:
161-274 mg/ml antibody or antigen-binding fragment thereof that binds specifically to complement factor 5, wherein the antibody or antigen-binding fragment thereof comprises heavy chain complementarity determining regions (CDRs) (HCDR1, HCDR2, and HCDR3) of a heavy chain variable region (HCVR) comprising the amino acid sequence set forth in SEQ ID NO: 98, and light chain CDRs (LCDR1, LCDR2, and LCDR3) of a light chain variable region (LCVR) comprising the amino acid sequence set forth in SEQ ID NO: 106; and a pharmaceutically acceptable carrier comprising a buffer and 50-100 mM L-arginine; wherein the formulation has a pH of 5.5-6.1.
2. The pharmaceutical formulation of claim 1, wherein the antibody or antigen-binding fragment thereof is an antibody.
3. The pharmaceutical formulation of any one of claims 1-2, wherein the concentration of antibody or antigen-binding fragment thereof is about 200 mg/ml.
4. The pharmaceutical formulation of any one of claims 1-3, wherein the L-arginine is L-arginine-hydrochloride.
5. The pharmaceutical formulation of any one of claims 1-4, wherein the concentration of L-arginine is about 100 mM.
6. The pharmaceutical formulation of any one of claims 1-5, comprising sucrose, mannitol, dextrose, glycerol, TMAO (trimethylamine N-oxide), trehalose, ethylene glycol, glycine betaine, xylitol or sorbitol.
7. The pharmaceutical formulation of any one of claims 1-6, comprising an oligosaccharide, wherein the oligosaccharide is sucrose.

8. The pharmaceutical formulation of any one of claims 6-7, comprising an oligosaccharide, wherein the concentration of oligosaccharide is about 2% (w/v).
9. The pharmaceutical formulation of any one of claims 1-8, wherein the antibody is pozelimab.
10. The pharmaceutical formulation of any one of claims 1-9, wherein the buffer is phosphate buffer, acetate buffer, citrate buffer, histidine buffer, or imidazole buffer.
11. The pharmaceutical formulation of claim 10, wherein the buffer is histidine buffer.
12. The pharmaceutical formulation of any one of claims 1-11, wherein the concentration of buffer is about 20 mM.
13. The pharmaceutical formulation of any one of claims 1-12, comprising a non-ionic detergent, wherein the non-ionic detergent is polyoxyethylene-based detergent or glycosidic compound-based detergent, polysorbate-20, polysorbate-80 or tween-20.
14. The pharmaceutical formulation of claim 13, wherein the non-ionic detergent is polysorbate-80.
15. The pharmaceutical formulation of any one of claims 1-14, comprising a non-ionic detergent, wherein the concentration of non-ionic detergent is about 0.15% (w/v).
16. A pharmaceutical formulation comprising:
 - 180-210 mg/ml pozelimab;
 - about 20 ± 4 mM buffer;
 - about 100 ± 20 mM L-arginine;
 - about 2 ± 0.4 % (w/v) oligosaccharide;
 - about 0.15 ± 0.075 % (w/v) non-ionic detergent; and
 - water,
 - at pH 5.8 ± 0.3 .

17. A pharmaceutical formulation comprising:

about 200 mg/ml pozelimab;
about 20 ± 4 mM histidine buffer;
about 100 ± 20 mM L-arginine;
about 2 ± 0.4 % (w/v) sucrose;
about 0.15 ± 0.075 % (w/v) polysorbate-80; and
water,
at pH 5.8 ± 0.3 .

18. The pharmaceutical formulation of any one of claims 1-17 for use in combination with a further therapeutic agent.

19. The pharmaceutical formulation of claim 18, wherein the further therapeutic agent is an oligonucleotide, anti-coagulant, warfarin, aspirin, heparin, phenindione, fondaparinux, idraparinux, a thrombin inhibitor, argatroban, lepirudin, bivalirudin, dabigatran, an anti-inflammatory drug, a corticosteroid, a non-steroidal anti-inflammatory drug (NSAID), an antihypertensive, an angiotensin-converting enzyme inhibitor, an immunosuppressive agent, vincristine, cyclosporine A, or methotrexate, a fibrinolytic agent ancrod, E-aminocaproic acid, antiplasmin-a1, prostacyclin, defibrotide, a lipid-lowering agent, an inhibitor of hydroxymethylglutaryl CoA reductase, an anti-CD20 agent, rituximab, an anti-TNFalpha agent, infliximab, an anti-seizure agent, magnesium sulfate, a C3 inhibitor and/or an anti-thrombotic agent.

20. The pharmaceutical formulation of claim 19, wherein the further therapeutic agent is an oligonucleotide which is:

- a DNA oligonucleotide,
- an RNA oligonucleotide,
- a single stranded DNA oligonucleotide,
- a single stranded RNA oligonucleotide,
- a double stranded DNA oligonucleotide, or
- a double stranded RNA oligonucleotide;

optionally, wherein the oligonucleotide is conjugated to a sugar and the oligonucleotide is formulated separately from the pharmaceutical formulation.

21. A method for making the pharmaceutical formulation of any one of claims 1-20, comprising admixing the antibody or antigen-binding fragment thereof and the carrier.

22. An intravenous formulation comprising a pharmaceutical formulation of any one of claims 1-20 in an aqueous intravenous solution.

23. The intravenous formulation of claim 22, wherein the aqueous intravenous solution has a volume of about 250 ml, 500 ml, 750 ml or 1000 ml.

24. The intravenous formulation of claim 22 or 23, comprising one or more selected from the group consisting of sodium chloride, dextrose, potassium salt, potassium chloride, calcium salt, calcium chloride, sodium lactate and lactate salt.

25. The intravenous formulation of any one of claims 22-24, wherein the aqueous intravenous solution comprises 0.9% Normal Saline, Lactated Ringers, 5% dextrose in water; 0.45% Normal Saline; 0.33% NaCl; 0.225% NaCl; 2.5% dextrose in water; 3% NaCl; 5% NaCl; 5% dextrose in 0.45% NaCl; 5% dextrose and 0.45% NaCl; 5% dextrose in 0.9% NaCl; 5% dextrose in Lactated Ringer's; Lactated Ringers that contains 0.6% NaCl; 10% dextrose in water; 20% dextrose in water; or 50% dextrose in water.

26. The intravenous formulation of any one of claims 22-25, which contains an amount of said pharmaceutical formulation for use at a dose of 1, 3, 10, 15 or 30 mg/kg body weight of a subject.

27. An intravenous glass or plastic bag or glass or plastic bottle comprising the intravenous formulation of any one of claims 22-26.

28. The intravenous formulation, bag or bottle of any one of claims 22-27 which is sterile.

29. A method for making the intravenous formulation of any one of claims 22-26 and 28, comprising introducing said pharmaceutical formulation into the aqueous intravenous solution.
30. A vessel or injection device comprising the formulation of any one of claims 1-20, 22-26, and 28.
31. A method for reducing the viscosity of a composition comprising 161-274 mg/ml pozelimab comprising combining said pozelimab with arginine to produce a composition having a final concentration of arginine of 50-100 mM.
32. The method of claim 31, wherein the final concentration of arginine in the composition is about 50 mM or about 100 mM.
33. The method of any one of claims 31-32, wherein the final concentration of pozelimab in the composition is about 161 mg/ml, about 175 mg/ml, about 177 mg/ml, about 190 mg/ml, about 198 mg/ml, about 200 mg/ml, about 205 mg/ml, about 211 mg/ml, about 220 mg/ml, about 221 mg/ml, about 240 mg/ml, about 242 mg/ml or about 274 mg/ml.
34. The method of any one of claims 31-33, wherein viscosity, measured as cP at 20°C, is reduced by about 30% or 30-42%.
35. A method for administering the pharmaceutical formulation or intravenous formulation of any one of claims 1-20, 22-26, and 28 to a subject comprising introducing the formulation and, optionally, a further therapeutic agent, into the body of the subject.
36. The method of claim 35, wherein the pharmaceutical formulation or intravenous formulation is introduced into the body of the subject separately from the further therapeutic agent.
37. The method of any one of claims 35-36, wherein the pharmaceutical formulation or intravenous formulation, and the further therapeutic agent are to be administered parenterally.

38. The method of claim 37, wherein parenterally is intravenously, intramuscularly, or subcutaneously.

39. Use of the pharmaceutical formulation and/or intravenous formulation of any one of claims 1-20, 22-26, and 28 for treating or preventing a C5-associated disease in a subject, optionally in combination with a further therapeutic agent;

wherein the C5-associated disease is selected from the group consisting of: adult respiratory distress syndrome; age-related macular degeneration (AMD); allergy; Alport's syndrome; Alzheimer's disease; antiphospholipid syndrome (APS); asthma; atherosclerosis; atypical hemolytic uremic syndrome (aHUS); an autoimmune disease; autoimmune hemolytic anemia (AIHA); balloon angioplasty; bronchoconstriction; bullous pemphigoid; a burn; C3 glomerulopathy; capillary leak syndrome; cardiovascular disorder; catastrophic antiphospholipid syndrome (CAPS); cerebrovascular disorder; CHAPLE disease; chemical injury; chronic obstructive pulmonary disease (COPD); cold agglutinin disease (CAD); corneal and/or retinal tissue; Crohn's disease; Degos disease; dense deposit disease (DDD); dermatomyositis; diabetes; diabetic angiopathy; diabetic macular edema (DME); diabetic nephropathy; diabetic retinopathy; dilated cardiomyopathy; disorder of inappropriate or undesirable complement activation; dyspnea; emphysema; epidermolysis bullosa; epilepsy; fibrogenic dust disease; frostbite; geographic atrophy (GA); glomerulonephritis; glomerulopathy; Goodpasture's Syndrome; Graves' disease; Guillain Barre Syndrome; Hashimoto's thyroiditis; a hemodialysis complication; hemolysis-elevated liver enzymes-and low platelets (HELLP) syndrome; hemolytic anemia; hemoptysis; Henoch-Schonlein purpura nephritis; hereditary angioedema; hyperacute allograft rejection; hypersensitivity pneumonitis; idiopathic thrombocytopenic purpura (ITP); IgA nephropathy; an immune complex disorder; immune complex vasculitis; immune complex-associated inflammation; infectious disease; inflammation caused by an autoimmune disease; an inflammatory disorder; inherited CD59 deficiency; injury due to inert dusts and/or minerals; interleukin-2 induced toxicity during IL-2 therapy; ischemia-reperfusion injury; Kawasaki's disease; lung disease or disorder; lupus nephritis; membranoproliferative glomerulonephritis; membranoproliferative nephritis; mesenteric artery reperfusion after aortic reconstruction; mesenteric/enteric vascular disorder; multifocal motor neuropathy (MMN); multiple sclerosis; myasthenia gravis; myocardial infarction; myocarditis; neurological disorder; neuromyelitis optica; obesity; ocular angiogenesis; choroidal neovascularization; an organic dust disease; a parasitic disease;

Parkinson's disease; paroxysmal nocturnal hemoglobinuria (PNH); Pauci-immune vasculitis; pemphigus; percutaneous transluminal coronary angioplasty (PTCA); peripheral vascular disorder; pneumonia; a post-ischemic reperfusion condition; post-pump syndrome in cardiopulmonary bypass; post-pump syndrome in renal bypass; progressive kidney failure; proliferative nephritis; a proteinuric kidney disease; psoriasis; a pulmonary embolism; pulmonary fibrosis; a pulmonary infarction; pulmonary vasculitis; recurrent fetal loss; renal disorder; renal ischemia; renal ischemia-reperfusion injury; renovascular disorder; restenosis following stent placement; rheumatoid arthritis; rotational atherectomy; schizophrenia; sepsis; septic shock; SLE nephritis; smoke injury; spinal cord injury; spontaneous fetal loss; stroke; systemic inflammatory response to sepsis; systemic lupus erythematosus (SLE); systemic lupus erythematosus-associated vasculitis; Takayasu's disease; a thermal injury; thrombotic thrombocytopenic purpura (TTP); traumatic brain injury; type I diabetes; typical hemolytic uremic syndrome; uveitis; vasculitis; vasculitis associated with rheumatoid arthritis; venous gas embolus (VGE); and xenograft rejection.

40. The use of claim 39, wherein said pharmaceutical formulation and/or intravenous formulation is to be administered separately from the further therapeutic agent.

41. The use of any one of claims 39-40, wherein the C5-associated disease is selected from the group consisting of: atypical hemolytic uremic syndrome (aHUS), paroxysmal nocturnal hemoglobinuria (PNH), myasthenia gravis and CHAPLE disease.

42. Use of the pharmaceutical formulation and/or intravenous formulation of any one of claims 1-20, 22-26, and 28 for reducing complement activity in the body of a subject in need thereof, optionally in combination with a further therapeutic agent.

43. The use of claim 42, wherein the pharmaceutical formulation and/or intravenous formulation is to be administered separately from the further therapeutic agent.

44. Use of the pharmaceutical formulation and/or intravenous formulation of any one of claims 1-20, 22-26, and 28 for use in treating a C5-associated disease in a subject, optionally in combination with a further therapeutic agent, wherein the subject has ceased receiving a first therapeutic agent that is different from the anti-C5 antibody or antigen-binding fragment

thereof in the pharmaceutical formulation or intravenous formulation and is useful for treating the C5-associated disease;

wherein the C5-associated disease is selected from the group consisting of: adult respiratory distress syndrome; age-related macular degeneration (AMD); allergy; Alport's syndrome; Alzheimer's disease; antiphospholipid syndrome (APS); asthma; atherosclerosis; atypical hemolytic uremic syndrome (aHUS); an autoimmune disease; autoimmune hemolytic anemia (AIHA); balloon angioplasty; bronchoconstriction; bullous pemphigoid; a burn; C3 glomerulopathy; capillary leak syndrome; cardiovascular disorder; catastrophic antiphospholipid syndrome (CAPS); cerebrovascular disorder; CHAPLE disease; chemical injury; chronic obstructive pulmonary disease (COPD); cold agglutinin disease (CAD); corneal and/or retinal tissue; Crohn's disease; Degos disease; dense deposit disease (DDD); dermatomyositis; diabetes; diabetic angiopathy; diabetic macular edema (DME); diabetic nephropathy; diabetic retinopathy; dilated cardiomyopathy; disorder of inappropriate or undesirable complement activation; dyspnea; emphysema; epidermolysis bullosa; epilepsy; fibrogenic dust disease; frostbite; geographic atrophy (GA); glomerulonephritis; glomerulopathy; Goodpasture's Syndrome; Graves' disease; Guillain Barre Syndrome; Hashimoto's thyroiditis; a hemodialysis complication; hemolysis-elevated liver enzymes-and low platelets (HELLP) syndrome; hemolytic anemia; hemoptysis; Henoch-Schonlein purpura nephritis; hereditary angioedema; hyperacute allograft rejection; hypersensitivity pneumonitis; idiopathic thrombocytopenic purpura (ITP); IgA nephropathy; an immune complex disorder; immune complex vasculitis; immune complex-associated inflammation; infectious disease; inflammation caused by an autoimmune disease; an inflammatory disorder; inherited CD59 deficiency; injury due to inert dusts and/or minerals; interleukin-2 induced toxicity during IL-2 therapy; ischemia-reperfusion injury; Kawasaki's disease; lung disease or disorder; lupus nephritis; membranoproliferative glomerulonephritis; membranoproliferative nephritis; mesenteric artery reperfusion after aortic reconstruction; mesenteric/enteric vascular disorder; multifocal motor neuropathy (MMN); multiple sclerosis; myasthenia gravis; myocardial infarction; myocarditis; neurological disorder; neuromyelitis optica; obesity; ocular angiogenesis; choroidal neovascularization; an organic dust disease; a parasitic disease; Parkinson's disease; paroxysmal nocturnal hemoglobinuria (PNH); Pauci-immune vasculitis; pemphigus; percutaneous transluminal coronary angioplasty (PTCA); peripheral vascular disorder; pneumonia; a post-ischemic reperfusion condition; post-pump syndrome in cardiopulmonary bypass; post-pump syndrome in renal bypass; progressive kidney failure;

proliferative nephritis; a proteinuric kidney disease; psoriasis; a pulmonary embolism; pulmonary fibrosis; a pulmonary infarction; pulmonary vasculitis; recurrent fetal loss; renal disorder; renal ischemia; renal ischemia-reperfusion injury; renovascular disorder; restenosis following stent placement; rheumatoid arthritis; rotational atherectomy; schizophrenia; sepsis; septic shock; SLE nephritis; smoke injury; spinal cord injury; spontaneous fetal loss; stroke; systemic inflammatory response to sepsis; systemic lupus erythematosus (SLE); systemic lupus erythematosus-associated vasculitis; Takayasu's disease; a thermal injury; thrombotic thrombocytopenic purpura (TTP); traumatic brain injury; type I diabetes; typical hemolytic uremic syndrome; uveitis; vasculitis; vasculitis associated with rheumatoid arthritis; venous gas embolus (VGE); and xenograft rejection.

45. The use of claim 44, wherein the pharmaceutical formulation and/or intravenous formulation is to be administered separately from the further therapeutic agent.

46. The use of any one of claims 44-45, wherein the first therapeutic agent is tesidolumab, crovalimab, eculizumab, or ravulizumab.