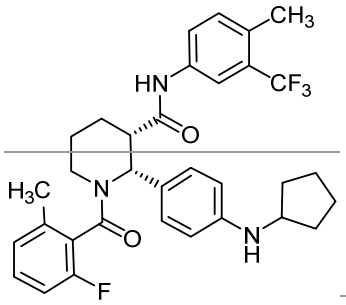
WHAT IS CLAIMED IS:

1. A solid solution capsule formulation comprising Compound 1 as a free base, in its neutral form or in the form of a pharmaceutically acceptable salt



(Compound 1)

and a vehicle comprising

at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10, and

at least one water-soluble solubilizer having a melting point at or above 37° C.

2. The solid solution capsule of claim **1**, wherein the vehicle comprises about 97 to 99% by weight of the total fill weight of said solid solution capsule.

3. The solid solution capsule of claim **1** wherein the vehicle comprises about 98% by weight of the total fill weight of said solid solution capsule.

4. The solid solution capsule of claim **1**, or claim **2**, comprising about 1 to 3% of Compound 1 by weight of the total fill weight of said solid solution capsule.

5. The solid solution capsule of claim **1**, claim **3**, comprising about 2% of Compound 1 by weight of the total fill weight of said solid solution capsule.

6. The solid solution capsule of any one of claims **1** to **5**, wherein the total weight of the vehicle comprises a 30:70 to 65:35 ratio of at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

7. The solid solution capsule of any one of claims **1** to **5**, wherein the total weight of the vehicle comprises a 35:65 to 65:35 ratio of at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

8. The solid solution capsule of any one of claims **1** to **5**, wherein the total weight of the vehicle comprises a 40:60 to 60:40 ratio of at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

9. The solid solution capsule of any one of claims **1** to **5**, wherein the total weight of the vehicle comprises a 45:55 to 55:45 ratio of at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

10. The solid solution capsule of any one of claims **1** to **5**, wherein the total weight of the vehicle comprises about a 50:50 ratio of at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

11. The solid solution capsule of any one of claims **1** to **10**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 comprises a polyoxyethylene derivative of a fatty acid containing from about 8 to 22 carbon atoms.

12. The solid solution capsule of any one of claims **1** to **10**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 comprises a polyoxyethylene derivative of a fatty acid, wherein the fatty acid is ricinoleic acid.

13. The solid solution capsule of any one of claims **1** to **10**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is a polyoxyethylene hydrogenated castor oil or a polyoxyethylene castor oil.

~~**14**. The solid solution capsule of any one of claims **1** to **10**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycol hydroxystearate or macrogolglycerol ricinoleate.~~

~~**15**. The solid solution capsule of any one of claims **1** to **10**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycol hydroxystearate.~~

~~**16**. The solid solution capsule of any one of claims **1** to **10**, wherein the at least one water-soluble solubilizer having a melting temperature at or above 37° C is selected from the group consisting of PEG-1000, PEG-1500, PEG-1540, PEG-2000, PEG-3000, PEG-3350, PEG-4000, PEG-6000, PEG-8000, PEG-10000, PEG-20000, poloxamer 188, poloxamer 237, poloxamer 338 and poloxamer 407.~~

~~**17**. The solid solution capsule of any one of claims **1** to **15**, wherein the at least one water-soluble solubilizer having a melting temperature at or above 37° C is selected from the group consisting of PEG-1540, PEG-2000, PEG-3000, PEG-3350, PEG-4000, PEG-6000.~~

~~**18**. The solid solution capsule of any one of claims **1** to **15**, wherein the at least one water-soluble solubilizer having a melting temperature at or above 37° C is PEG-4000.~~

~~**19**. The solid solution capsule of any one of claims **1** to **10**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycol hydroxystearate and the at least one water-soluble solubilizer having a melting temperature at or above 37° C is PEG-4000.~~

~~**20**. The solid solution capsule of any one of claims **1** to **19**, wherein the total fill weight of said solid solution capsule is from about 130 mg to 900 mg.~~

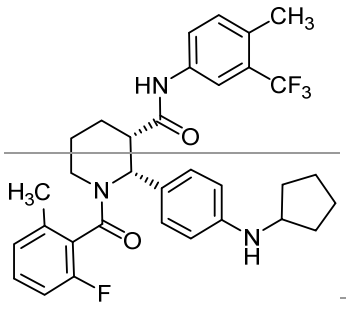
~~**21**. The solid solution capsule of any one of claims **1** to **19**, wherein the total fill weight of said solid solution capsule is about 500 mg.~~

22. The solid solution capsule of any one of claims **1** to **19**, wherein the capsule size is selected from the group consisting of #00, #0, #1, #2, #3, #4, or #5.

23. The solid solution capsule of any one of claims **1** to **19**, wherein the capsule size is #0.

24. The solid solution capsule of any one of claims **1** to **23**, wherein the capsule is a hard capsule.

25. A method of preparing a solid solution capsule comprising Compound 1 as a free base, in its neutral form or in the form of a pharmaceutically acceptable salt



(Compound 1)

and a vehicle comprising

at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10, and

at least one water-soluble solubilizer having a melting point at or above 37° C;

said method comprising

(a) melting the vehicle;

(b) combining the melted vehicle obtained in step (a) with Compound 1 to form a drug solution;

(c) encapsulating the drug solution in a capsule shell; and

(d) cooling the encapsulated drug solution to form a solid solution capsule comprising Compound 1.

26. The method of claim **25**, wherein step (a) comprises heating the vehicle to a temperature of about 50° to 85° C.

27. The method of claim **25**, wherein step (a) comprises

(i) heating at least one non-ionic surfactant having an HLB value of at least 10 to form a melted surfactant;

(ii) heating at least one water-soluble solubilizer to form a melted solubilizer; and

(iii) combining melted solubilizer with melted surfactant to form a melted vehicle.

28. The method of claim **27**, wherein step (i) comprises heating the at least one non-ionic surfactant having an HLB values of at least 10 to a temperature of about 50° to 70° C.

29. The method of claim **27** or claim **28**, wherein step (ii) comprises heating the at least one water-soluble solubilizer to a temperature of about 80 to 85 ° C.

30. The method of any one of claims **25** to **29** wherein the at least one non-ionic surfactant having an HLB value of at least 10 is a polyoxyethylene hydrogenated castor oil or a polyoxyethylene castor oil.

31. The method of any one of claims **25** to **29**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycol hydroxystearate or macrogolglycerol ricinoleate.

32. The method of any one of claims **25** to **29**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycol hydroxystearate.

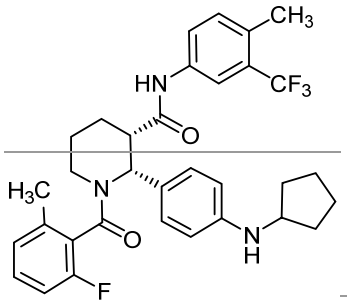
33. The method of any one of claims **25** to **29**, wherein the at least one water-soluble solubilizer having a melting temperature at or above 37° C is selected from the group consisting of PEG-1500, PEG-1540, PEG-2000, PEG-3000, PEG-3350, PEG-4000, PEG-6000, poloxamer 188, poloxamer 237, poloxamer 338 and poloxamer 407.

~~**34**. The method of any one of claims **25** to **29**, wherein the at least one water-soluble solubilizer having a melting temperature at or above 37° C is selected from the group consisting of PEG-1540, PEG-2000, PEG-3000, PEG-3350, PEG-4000, and PEG-6000.~~

~~**35**. The method of any one of claims **25** to **29**, wherein the at least one water-soluble solubilizer having a melting temperature at or above 37° C is PEG-4000.~~

~~**36**. The method of any one of claims **25** to **29**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycerol hydroxystearate and at least one water-soluble solubilizer polyethylene glycol 4000 (PEG-4000).~~

~~**37**. A solid solution capsule comprising Compound 1 as a free base, in its neutral form or in the form of a pharmaceutically acceptable salt~~



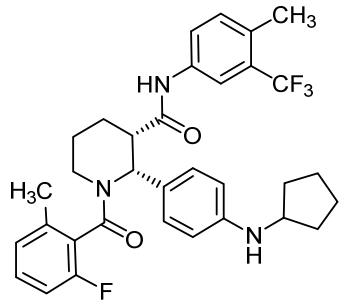
~~(Compound 1)~~

~~and a vehicle comprising~~

~~at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10, and~~

~~at least one water-soluble solubilizer having a melting point at or above 37° C;~~ ~~said solid solution capsule prepared according to the method of any one of claims **25** to **36**.~~

~~**38**~~**1**. Use of Compound 1 as a free base, in its neutral form or in the form of a pharmaceutically acceptable salt



(Compound 1)

and a vehicle comprising

at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10, and

at least one water-soluble solubilizer having a melting point at or above 37ºC,

in the preparation of a solution encapsulated in a capsule shell to form a solid solution capsule for ~~A method for~~ treating an individual suffering from or susceptible to a disease or disorder involving pathologic activation of C5a receptors~~, comprising administering to the individual an effective amount of a solid solution capsule of any one of claims **1** to **24**~~.

2. Use of claim 1, wherein:

(a) the vehicle comprises about 97 to 99% by weight of the total fill weight of said solid solution capsule, preferably wherein the vehicle comprises about 98% by weight of the total fill weight of said solid solution capsule or

(b) the solid solution capsule comprises about 1 to 3 % of Compound 1 by weight of the total fill weight of said solid solution capsule, preferably wherein the solid solution capsule comprises about 2% of Compound 1 by weight of the total fill weight of said solid solution capsule.

3. Use of claim **1** or **2**, wherein the total weight of the vehicle comprises a 30:70 to 65:35 ratio, preferably a 35:65 to 65:35 ratio of at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

4. Use of claim **1** or **2,** wherein the total weight of the vehicle comprises a 40:60 to 60:40 ratio, preferably a 45:55 to 55:45 ratio of at least one non-ionic surfactant having

a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

5. Use of claim **1** or **2,** wherein the total weight of the vehicle comprises about a 50:50 ratio, of at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

6. Use of any one of claims **1** to **5**, wherein:

(a) the at least one non-ionic surfactant having an HLB value of at least 10 comprises a polyoxyethylene derivative of a fatty acid containing from about 8 to 22 carbon atoms, preferably wherein the fatty acid is ricinoleic acid; or

(b) the at least one non-ionic surfactant having an HLB value of at least 10 is a polyoxyethylene hydrogenated castor oil or a polyoxyethylene castor oil; or

(c) the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycerol hydroxystearate or macrogolglycerol ricinoleate.

7. Use of any one of claims **1** to **5**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycerol hydroxystearate.

8. Use of any one of claims **1** to **7**, wherein:

(a) the at least one water-soluble solubilizer having a melting temperature at or above 37° C is selected from the group consisting of PEG-1000, PEG-1500, PEG-1540, PEG-2000, PEG-3000, PEG-3350, PEG-4000, PEG-6000, PEG-8000, PEG-10000, PEG-20000, poloxamer 188, poloxamer 237, poloxamer 338 and poloxamer 407, preferably selected from the group consisting of PEG-1540, PEG-2000, PEG-3000, PEG-3350, PEG-4000, PEG-6000.

9. Use of any one of claims **1** to **7**, wherein the at least one water-soluble solubilizer having a melting temperature at or above 37° C is PEG-4000.

10. Use of any one of claims **1** to **5**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycerol hydroxystearate and the at least one water-soluble solubilizer having a melting temperature at or above 37° C is PEG-4000.

11. Use of any one of claims **1** to **10**, wherein:

(a) the total fill weight of said solid solution capsule is from about 130 mg to 900 mg, preferably about 500 mg; or

(b) the capsule size is selected from the group consisting of #00, #0, #1, #2, #3, #4, or #5, preferably wherein the capsule size is #0; or

(c) the capsule is a hard capsule.

12. Use of any one of claims **1** to **11**, wherein Compound 1 is a free base, in its neutral form.

13~~9~~. The ~~method~~use of any one of claims ~~3~~**8**~~1~~ to **12**, wherein the disease or disorder is an inflammatory disease or disorder.

14~~0~~. The ~~method~~use of claim 1**3**~~9~~, wherein the disease or disorder is selected from the group consisting of neutropenia, sepsis, septic shock, Alzheimer's disease, multiple sclerosis, stroke, inflammatory bowel disease, age-related macular degeneration, chronic obstructive pulmonary disorder, inflammation associated with burns, lung injury, osteoarthritis, atopic dermatitis, chronic urticaria, ischemia-reperfusion injury, acute respiratory distress syndrome, systemic inflammatory response syndrome, multiple organ dysfunction syndrome, tissue graft rejection, cancer and hyperacute rejection of transplanted organs.

~~4~~**1**5. The ~~method~~use of any one of claims ~~3~~**8**~~1~~ to **12**, wherein the disease or disorder is a cardiovascular or cerebrovascular disorder.

~~42~~16. The ~~method~~uses of claim ~~4~~**1**5, wherein the disease or disorder is selected from the group consisting of myocardial infarction, coronary thrombosis, vascular occlusion,

post-surgical vascular reocclusion, artherosclerosis, traumatic central nervous system injury and ischemic heart disease.

~~43~~17. The ~~method~~use of any one of claims ~~38~~1 to 12, wherein the disease or disorder is an autoimmune disorder.

~~44~~18. The ~~method~~use of claim ~~43~~17, wherein the disease or disorder is selected from the group consisting of rheumatoid arthritis, C3 glomerulopathy (C3G), hidradenitis suppurativa (HS), systemic lupus erythematosus, Guillain-Barre syndrome, pancreatitis, lupus nephritis, lupus glomerulonephritis, psoriasis, immunoglobulin A (IgA) nephropathy, Crohn's disease, vasculitis, irritable bowel syndrome, dermatomyositis, multiple sclerosis, bronchial asthma, pemphigus, pemphigoid, scleroderma, myasthenia gravis, autoimmune hemolytic and thrombocytopenic states, Goodpasture's syndrome, immunovasculitis, tissue graft rejection and hyperacute rejection of transplanted organs.

~~45~~19. The ~~method~~use of any one of claims ~~38~~1 to 12, wherein the disease or disorder is a pathologic sequelae associated with the group consisting of insulin-dependent diabetes, mellitus, lupus nephropathy, Heyman nephritis, membranous nephritis, glomerulonephritis, contact sensitivity responses, and inflammation resulting from contact of blood with artificial surfaces.

~~46~~20. The ~~method~~use of any one of claims ~~38~~1 to 12, wherein the disease or disorder is selected from the group consisting of anti-neutrophil cytoplasmic antibody associate (ANCA) vasculitis, C3 glomerulopathy, hidradenitis suppurativa, and lupus nephritis.

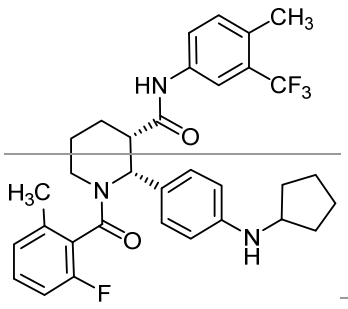
~~47. The method of claim 38, wherein the disease or disorder is anti-neutrophil cytoplasmic antibody associate (ANCA) vasculitis.~~

~~48. The method of claim 38, wherein the disease or disorder is C3 glomerulopathy.~~

~~49. The method of claim 38, wherein the disease or disorder is hidradenitis suppurativa.~~

50. The method of claim **38**, wherein the disease or disorder is lupus nephritis.

51. A single unit dosage capsule comprising about 2.6 mg to 25.2 mg of Compound 1 as a free base, in its neutral form



(Compound 1)

and a vehicle comprising

at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10, and

at least one water-soluble solubilizer having a melting point at or above 37° C.

52. The single unit dosage capsule of claim **51**, comprising about 2.6 mg to 18 mg of Compound 1 as a free base, in its neutral form.

53. The single unit dosage capsule of claim **51**, comprising about 10 mg of Compound 1 as a free base, in its neutral form.

54. The single unit dosage capsule any one of claims **51** to **53**, wherein the total fill weight of said solid solution capsule is from about 130 mg to 900 mg.

55. A kit comprising one or more solid solution capsules of any one of claims **1** to **24**, or one or more single dosage units of any one of claims **51** to **54**.