CLAIMS:

1. A composition, comprising immune globulin (IG) and a hyaluronidase, wherein:

the composition is formulated for subcutaneous administration;

the amount of IG in the composition is substantially the same as the amount when administered intravenously at the same dosing regime; and

the amount of hyaluronidase in the composition is sufficient to render the composition therapeutically effective.

2. The composition of claim 1, wherein the dosage regimen is a dosing frequency of no more than once monthly administration of IG.

3. The composition of any of claim 1 or claim 2, wherein the amount of a hyaluronidase in the composition is an amount that is sufficient to effect subcutaneous administration of the IG at a dosage administered no more than once a month.

4. The composition of any of claims 1-3, wherein the IG and a hyaluronidase in the composition are formulated for multiple dosage administration.

5. The composition of any of claims 1-3, wherein the immune globulin (IG) and a hyaluronidase in the composition are formulated for single dosage administration once a month.

6. The composition of claim 5, wherein the IG in the composition is or is about 5 grams (g), 10g, 15g, 20g, 21g, 22g, 23g, 24g, 25g, 26g, 27g, 28g, 29g, 30g, 31g, 32g, 33g, 34g, 35g, 36g, 37g, 38g, 39g or 40g.

7. The composition of claim 5 or claim 6, wherein the hyaluronidase in the composition is at or about 10 Units to 500,000 Units, 100 Units to 100,000 Units, 500 Units to 50,000 Units, 1000 Units to 10,000 Units, 5000 Units to 7500 Units, 5000 Units to 50,000 Units, or 1,000 Units to 10,000 Units.

8. The composition of any of claims 5-7, wherein the composition is a liquid and the volume of liquid is or is about 100 ml, 150 ml, 200 ml, 300 ml, 400 ml, 500 ml, 600 ml or 700 ml.

9. The composition of any of claims 5-8, wherein the hyaluronidase in the composition is in an amount that is at a ratio (units hyaluronidase/grams of IG) at or about 10 U/ gram (g), 20 U/g, 30 U/g, 35 U/g, 40 U/g, 50 U/g, 60 U/g, 70 U/g, 80 U/g, 90 U/g, 100 U/g, 150 U/g, or 300 U/g.

10. The composition of claim 9, wherein the hyaluronidase in the composition is administered at a ratio of or about 50 U/ gram IG.

11. The composition of any of claims 1-10, wherein the hyaluronidase in the composition is a PH20, or a truncated form thereof.

12. The composition of claim 11, wherein the PH20 is selected from an ovine, bovine or truncated human PH20.

13. The composition of claim 12, wherein the truncated human PH20 is selected from among polypeptides having a sequence of amino acids set forth in any of SEQ ID NOS:4-9, or allelic variants or other variants thereof.

14. The composition of any of claims 11-13, wherein the hyaluronidase is designated rHuPH20.

15. The composition of any of claims 1-14, wherein the IG in the composition is purified from human plasma.

16. The composition of claim 15, wherein the IG in the composition purified from human plasma is purified by alcohol fractionation.

17. The composition of claim 16, wherein the IG in the composition is further purified by any one or more of a chemical modification, incubation at pH 4.0 with or without pepsin, polyethylene glycol (PEG) precipitation, ion-exchange chromatography, enzymatic cleavage, solvent detergent treatment, diafiltration or ultrafiltration.

18. The composition of any of claims 1-17, wherein the IG in the composition contains IgG, IgA and IgM.

19. The composition of any of claims 1-18, wherein the IG in the composition contains greater than 95% IgG.

20. The composition of claim 19, wherein the IgG is monomeric.

21. The composition of any of claims 1-20, wherein the IG in the composition further contains protein-stabilizing excipients.

22. The composition of claim 21, wherein the protein-stabilizing excipient is selected from among one or more of glycine, maltose, a polyol, human serum albumin, mannitol, and non-ionic detergent.

23. The composition of any of claims 1-22, wherein the pH of the IG preparation in the composition is at or about 4.2 to 5.4, 4.6 to 5.1 or 4.8 to 5.0.

24. The composition of any of claims 1-23, wherein the IG in the composition has a protein concentration that is or is about 5 to 15% w/v, 6 to 15% w/v, or 8 to 12% w/v of IG composition.

25. The composition of claim 24, wherein the protein concentration is 10% w/v.

26. The composition of any of claims 1-25 that is a liquid.

27. The composition of any of claims 1-26, wherein the IG and a hyaluronidase are in a single composition .

28. The composition of any of claims 1-26, wherein the IG and a hyaluronidase are formulated separately.

29. A composition, comprising immune globulin (IG) and a hyaluronidase, wherein:

the composition is formulated for subcutaneous administration;

the amount of IG in the composition is substantially the same as the amount when administered intravenously for treatment of an IG-treatable disease or condition; and

the amount of hyaluronidase in the composition is sufficient to render the composition therapeutically effective.

30. The composition of claim 29, wherein the IG-treatable disease or condition is selected from among immunodeficiency; acquired hypogammaglobulinemia secondary to hematological malignancies; Kawasaki's disease; chronic inflammatory demyelinating polyneuropathy (CIDP); Guillain-Barre Syndrome; Idiopathic thrombocytopenic purpura; inflammatory myopathies; Lambert-Eaton myasthenic syndrome; multifocal motor neuropathy; Myasthenia Gravis; Moersch-Woltmann syndrome; secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency); specific antibody deficiency; Acute disseminated encephalomyelitis; ANCA-positive systemic necrotizing vasculitis; Autoimmune haemolytic anaemia; Bullous pemphigoid; Cicatricial pemphigoid; Evans syndrome (including autoimmune haemolytic anaemia with immune thrombocytopenia); Foeto-maternal/neonatal alloimmune thrombocytopenia (FMAIT/NAIT); Haemophagocytic syndrome; High-risk allogeneic haemopoietic stem cell transplantation; IgM paraproteinaemic neuropathy; kidney transplantation; multiple sclerosis; Opsoclonus myoclonus ataxia; Pemphigus foliaceus; Pemphigus

vulgaris; Post-transfusion purpura; Toxic epidermal necrolysis/Steven Johnson syndrome (TEN/SJS); Toxic shock syndrome; Alzheimer's Disease; Systemic lupus erythematosus; multiple myeloma; sepsis; B cell tumors; trauma; and a bacterial, viral or fungal infection.

31. The composition of claim 29 or claim 30, wherein the amount of IG in the composition is or is about 1 gram (g), 5g, 10g, 20g, 30g, 40g, 50g, 60g, 70g, 80g, 90g, 100g or 200g.

32. The composition of any of claims 29-30, wherein the amount of hyaluronidase in the composition is or is about 500 Units, 1000 Units, 2000 Units, 5000 Units, 10,000 Units, 30,000 Units, 40,000 Units,, 50,000 Units, 60,000 Units, 70,000 Units, 80,000 Units, 90,000 Units, 100,000 Units or more.

33. The composition of any of claims 29-32, wherein the amount of hyaluronidase in the composition is in an amount that is at a ratio (units hyaluronidase/grams of IG) that is or is about 10 U/g, 20 U/g, 30U/g, 40 U/g, 50 U/g, 60 U/g, 70 U/g, 80 U/g, 90 U/g, 100 U/g, 150 U/g, 200 U/g, 300 U/g, 400 U/g, 500 U/g or more.

34. The composition of any of claims 29-33, that is formulated for a dosage frequency of daily, weekly, biweekly, every 2-3 weeks, every 3-4 weeks or once a month.

35. The composition of any of claims 29-34 that is for single dosage administration.

36. The composition of any of claims 29-34 that is for multiple dosage administrations.

37. A composition, comprising immune globulin (IG) and a hyaluronidase, wherein:

the composition is formulated for subcutaneous administration;

the protein concentration of the IG in the composition is less than 16% w/v IG; and

the amount of hyaluronidase in the composition is sufficient to render the composition therapeutically effective.

38. The composition of claim 37, wherein the protein concentration of the IG is at or about 5 to 15% w/v, 6 to 15% w/v, or 8 to 12% w/v of IG.

39. The composition of claim 37 or claim 38, wherein the protein concentration of the IG is at or about 10% w/v.

40. The composition of any of claims 37-39, wherein the hyaluronidase in the composition is or is about 500 Units, 1000 Units, 2000 Units, 5000 Units, 10,000 Units, 30,000 Units, 40,000 Units,, 50,000 Units, 60,000 Units, 70,000 Units, 80,000 Units, 90,000 Units, 100,000 Units or more.

41. The composition of any of claims 37-40, wherein the IG and hyaluronidase are formulated as a single composition.

42. The composition of any of claims 37-40, wherein the IG and hyaluronidase are formulated separately.

43. Use of a composition of any of claims 1-42 for formulation of a medicament for treating an IG-treatable disease or condition in a subject.

44. The use of claim 43, wherein the IG-treatable disease or condition is selected from among immunodeficiency; acquired hypogammaglobulinemia secondary to hematological malignancies; Kawasaki's disease; chronic inflammatory demyelinating polyneuropathy (CIDP); Guillain-Barre Syndrome; Idiopathic thrombocytopenic purpura; inflammatory myopathies; Lambert-Eaton myasthenic syndrome; multifocal motor neuropathy; Myasthenia Gravis; Moersch-Woltmann syndrome; secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency); specific antibody deficiency; Acute disseminated encephalomyelitis; ANCA-positive systemic necrotizing vasculitis; Autoimmune haemolytic anaemia; Bullous pemphigoid; Cicatricial pemphigoid; Evans syndrome (including autoimmune haemolytic anaemia with immune thrombocytopenia); Foeto-maternal/neonatal alloimmune thrombocytopenia (FMAIT/NAIT); Haemophagocytic syndrome; High-risk allogeneic haemopoietic stem cell transplantation; IgM paraproteinaemic neuropathy; kidney transplantation; multiple sclerosis; Opsoclonus myoclonus ataxia; Pemphigus foliaceus; Pemphigus vulgaris; Post-transfusion purpura; Toxic epidermal necrolysis/Steven Johnson syndrome (TEN/SJS); Toxic shock syndrome; Alzheimer's Disease; Systemic lupus erythematosus; multiple myeloma; sepsis; B cell tumors; trauma; and a bacterial, viral or fungal infection.

45. The use of claim 44, wherein the IG-treatable disease or condition is an immunodeficiency and the immunodeficiency is selected from among common variable immunodeficiency (CVID), congenital agammaglobulinemia, Wiskott-

Aldrich syndrome, severe combined immunodeficiency (SCID), primary hypogammaglobulinemia, primary immunodeficiency diseases with antibody deficiency, X-linked agammaglobulinemia (XLA), hypogammaglobulinemia of infancy, and paraneoplastic cerebellar degeneration with no antibodies.

46. The use of claim 44, wherein the IG-treatable disease or condition is acquired hypogammaglobulinemia secondary to hematological malignancies and the hematological malignancy is selected from among chronic lymphocytic leukemia (CLL), multiple myeloma (MM) and non-Hodgkin's lymphoma (NHL).

47. The use of claim 44, wherein the IG-treatable disease or condition is an inflammatory myopathy and the inflammatory myopathy is selected from among polymyositis, dermatomyositis and inclusion body myositis.

48. The use of claim 44, wherein the IG-treatable disease or condition is a bacteria, viral or fungal condition and the bacterial, viral or fungal condition is selected from among *Haemophilus influenzae* type B, *Psuedomonas aeruginosa* types A and B, *Staphylococcus aureus*, Group B Streptococcus, *Streptococcus pneumoniae* types 1, 3, 4, 6, 7, 8, 9, 12, 14, 18, 19, and 23, Adenovirus types 2 and 5, Cytomegalovirus, Epstein Barr virus VCA, Hepatitis A virus, Hepatitis B virus, Herpes simplex virus-1, Herpes simplex virus-2, Influenza A, Measles, Parainfluenza types 1, 2 and 3, Polio, Varicella zoster virus, *Apergillus* and *Candida albicans*.

49. A pharmaceutical composition of any of claims 1-42 for use in treating an IG-treatable disease or condition in a subject.

50. The pharmaceutical composition of claim 49, wherein the IG-treatable disease or condition is selected from among immunodeficiency; acquired hypogammaglobulinemia secondary to hematological malignancies; Kawasaki's disease; chronic inflammatory demyelinating polyneuropathy (CIDP); Guillain-Barre Syndrome; Idiopathic thrombocytopenic purpura; inflammatory myopathies; Lambert-Eaton myasthenic syndrome; multifocal motor neuropathy; Myasthenia Gravis; Moersch-Woltmann syndrome; secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency); specific antibody deficiency; Acute disseminated encephalomyelitis; ANCA-positive systemic necrotizing vasculitis; Autoimmune haemolytic anaemia; Bullous pemphigoid; Cicatricial pemphigoid; Evans syndrome (including autoimmune haemolytic anaemia with immune thrombocytopenia); Foeto-maternal/neonatal alloimmune thrombocytopenia

(FMAIT/NAIT); Haemophagocytic syndrome; High-risk allogeneic haemopoietic stem cell transplantation; IgM paraproteinaemic neuropathy; kidney transplantation; multiple sclerosis; Opsoclonus myoclonus ataxia; Pemphigus foliaceus; Pemphigus vulgaris; Post-transfusion purpura; Toxic epidermal necrolysis/Steven Johnson syndrome (TEN/SJS); Toxic shock syndrome; Alzheimer's Disease; Systemic lupus erythematosus; multiple myeloma; sepsis; B cell tumors; trauma; and a bacterial, viral or fungal infection.

51. The pharmaceutical composition of claim 50, wherein the IG-treatable disease or condition is an immunodeficiency and the immunodeficiency is selected from among common variable immunodeficiency (CVID), congenital agammaglobulinemia, Wiskott-Aldrich syndrome, severe combined immunodeficiency (SCID), primary hypogammaglobulinemia, primary immunodeficiency diseases with antibody deficiency, X-linked agammaglobulinemia (XLA), hypogammaglobulinemia of infancy, and paraneoplastic cerebellar degeneration with no antibodies.

52. The pharmaceutical composition of claim 50, wherein the IG-treatable disease or condition is acquired hypogammaglobulinemia secondary to hematological malignancies and the hematological malignancy is selected from among chronic lymphocytic leukemia (CLL), multiple myeloma (MM) and non-Hodgkin's lymphoma (NHL).

53. The pharmaceutical composition of claim 50, wherein the IG-treatable disease or condition is an inflammatory myopathy and the inflammatory myopathy is selected from among polymyositis, dermatomyositis and inclusion body myositis.

54. The pharmaceutical composition of claim 50, wherein the IG-treatable disease or condition is a bacteria, viral or fungal condition and the bacterial, viral or fungal condition is selected from among *Haemophilus influenzae* type B, *Psuedomonas aeruginosa* types A and B, *Staphylococcus aureus*, Group B Streptococcus, *Streptococcus pneumoniae* types 1, 3, 4, 6, 7, 8, 9, 12, 14, 18, 19, and 23, Adenovirus types 2 and 5, Cytomegalovirus, Epstein Barr virus VCA, Hepatitis A virus, Hepatitis B virus, Herpes simplex virus-1, Herpes simplex virus-2, Influenza A, Measles, Parainfluenza types 1, 2 and 3, Polio, Varicella zoster virus, *Apergillus* and *Candida albicans*.

a first composition comprising IG formulated for subcutaneous single dosage administration in an amount for treatment of an IG-treatable disease no more than once per month; and

a second composition comprising a soluble hyaluronidase formulated for single dosage administration in combination with the IG for the treatment no more than once per month.

56. The combination of claim 55, wherein the compositions are in a dual chamber container or in single container separated from each other.

57. The combination of claim 56, wherein the hyaluronidase is positioned in the container to be administered before the IG.

58. The combination of claim 56 or claim 57, wherein the container is a syringe, tube or bottle.

59. The combination of claim 58, wherein the container further comprises a needle for injection.

60. The combination of any of claims 55-59, wherein the soluble hyaluronidase is a PH20, or a truncated form thereof.

61. The combination of claim 60, wherein the PH20 is selected from an ovine, bovine or truncated human PH20.

62. The combination of claim 61, wherein the truncated human PH20 is selected from among polypeptides having a sequence of amino acids set forth in any of SEQ ID NOS:4-9, or allelic variants or other variants thereof.

63. The combination of any of claims 55-62, wherein the soluble hyaluronidase is designated rHuPH20.

64. The combination of any of claims 55-63, wherein the IG is purified from human plasma.

65. The combination of any of claims 55-64, wherein the IG is lyophilized or is provided in a liquid.

66. The combination of claim 65, wherein the volume of liquid is or is about 100 ml, 150 ml, 200 ml, 300 ml, 400 ml, 500 ml, 600 ml or 700 ml.

67. The combination of any of claims 55-66, wherein the IG has a protein concentration that is or is about 5 to 15% w/v, 6 to 15% w/v, or 8 to 12% w/v of IG composition.

68. The combination of claim 67, wherein the protein concentration is 10% w/v.

69. The combination of any of claims 55-68, wherein the IG in the composition is or is about 5 grams (g), 10g, 15g, 20g, 21g, 22g, 23g, 24g, 25g, 26g, 27g, 28g, 29g, 30g, 31g, 32g, 33g, 34g, 35g, 36g, 37g, 38g, 39g or 40g.

70. The combination of any of claims 55-69, wherein the hyaluronidase is provided in a liquid.

71. The combination of claim 70, wherein the volume of liquid is or is about 1 ml, 2 ml, 3 ml, 4 ml, 5 ml, 6 ml, 7 ml, 8 ml, 9 ml, 10 ml, 20 ml or 30 ml.

72. The combination of any of claims 55-71, wherein the hyaluronidase is at or about 10 Units to 500,000 Units, 100 Units to 100,000 Units, 500 Units to 50,000 Units, 1000 Units to 10,000 Units, 5000 Units to 7500 Units, 5000 Units to 50,000 Units, or 1,000 Units to 10,000 Units.

73. A combination of compositions, comprising:

a first composition comprising IG formulated for subcutaneous administration at a protein concentration of the IG in the composition that is less than 16% w/v IG; and

a second composition comprising a soluble hyaluronidase formulated in combination with the IG in an amount sufficient to render the composition of IG therapeutically effective.

74. The combination of claim 73, wherein the compositions are formulated for single dosage administration or for multiple dosage administration.

75. The combination of claim 73 or claim 74, wherein the amount of IG in the composition is substantially the same as the amount in a single dosage administration when administered intravenously for treatment of an IG-treatable disease or condition.

76. The combination of any of claims 73-75, wherein the first composition and second composition are formulated in an amount for administration daily, weekly, biweekly, every 2-3 weeks, every 3-4 weeks or monthly.

77. The combination of any of claims 73-76, wherein the amount of IG in the first composition is or is about 1 gram (g), 5g, 10g, 20g, 30g, 40g, 50g, 60g, 70g, 80g, 90g, 100g or 200g.

78. The combination of any of claims 73-77, wherein the amount of hyaluronidase in the composition is or is about 500 Units, 1000 Units, 2000 Units, 5000 Units, 10,000 Units, 30,000 Units, 40,000 Units, 50,000 Units, 60,000 Units, 70,000 Units, 80,000 Units, 90,000 Units, 100,000 Units or more.

79. The combination of any of claims 73-78, wherein the amount of hyaluronidase in the composition is in an amount that is at a ratio (units hyaluronidase/grams of IG) that is or is about 10 U/g, 20 U/g, 30U/g, 40 U/g, 50 U/g, 60 U/g, 70 U/g, 80 U/g, 90 U/g, 100 U/g, 150 U/g, 200 U/g, 300 U/g, 400 U/g, 500 U/g or more.

80. A kit, comprising the combination of any of claims 55-79 or the composition of any of claims 1-42, and optionally instructions for use in treatment of an IG-treatable disease or condition.

81. A method for treating an IG-treatable disease or condition in a subject, comprising:

subcutaneously administering to the subject a soluble hyaluronidase and an immune globulin (IG) for treating the disease or condition, wherein administration of the IG is effected such that the amount administered and frequency of administration is substantially the same as for IV (intravenous) administration of the same amount via IV for the same disease or condition.

82. A method for treating an IG-treatable disease or condition in a subject in need of such treatment, comprising:

subcutaneously administering to the subject a soluble hyaluronidase and an amount of immune globulin (IG) effective for treating the disease or condition, wherein the administration is carried out using a dosage regimen in which

(a) a quantity of IG; and

(b) a dosing frequency for successive administrations of IG to the subject

are selected such that the therapeutic effect of the subcutaneous IG administration upon the subject is at least substantially equivalent to intravenous administration of the IG to the subject using the same dosing regimen.

83. The method of claim 81 or claim 82, wherein bioavailability of the subcutaneously administered IG is at least about 90% of the bioavailability of the same dosage administered via IV administration.

84. The method of claim 81 or claim 82, wherein the amount of soluble hyaluronidase is sufficient to render the administered IG therapeutically effective.

85. The method of claim 81 or claim 82, wherein the amount of soluble hyaluronidase is sufficient to effect subcutaneous administration of the IG at a dosage administered no more than once a month.

86. The method of claim 81 or claim 82, wherein the frequency of the dosage regimen comprises no more than once monthly administration of IG.

87. The method of claim 81 or claim 82, wherein the frequency of the dosage regimen is daily, weekly, biweekly, every 2-3 weeks, every 3-4 weeks or monthly.

88. The method of any of claims 81-87, wherein the soluble hyaluronidase is a PH20, or a truncated form thereof.

89. The method of claim 88, wherein the PH20 is selected from an ovine, bovine or truncated human PH20.

90. The method of claim 89, wherein the truncated human PH20 is selected from among polypeptides having a sequence of amino acids set forth in any of SEQ ID NOS:4-9, or allelic variants or other variants thereof.

91. The method of any of claims 81-90, wherein the soluble hyaluronidase is rHuPH20.

92. The method of any of claims 81-91, wherein the IG is purified from human plasma.

93. The method of claim 92, wherein the IG purified from human plasma is purified by alcohol fractionation.

94. The method of claim 93, wherein the IG is further purified by any one or more of a chemical modification, incubation at pH 4.0 with or without pepsin, polyethylene glycol (PEG) precipitation, ion-exchange chromatography, enzymatic cleavage, solvent detergent treatment, diafiltration or ultrafiltration.

95. The method of any of claims 81-94, wherein the IG contains IgG, IgA and IgM.

96. The method of claim 95, wherein the IG contains greater than 95% IgG.

97. The method of claim 96, wherein the IgG is monomeric.

98. The method of any of claims 81-97, wherein the IG further contains protein-stabilizing excipients.

99. The method of claim 98, wherein the protein-stabilizing excipient is selected from among one or more of glycine, maltose, a polyol, human serum albumin, mannitol, and non-ionic detergent.

100. The method of any of claims 81-99, wherein the pH of the IG preparation is at or about 4.2 to 5.4, 4.6 to 5.1 or 4.8 to 5.0.

101. The method of claim any of claims 81-100, wherein the IG has a protein concentration that is or is about 5 to 15% w/v, 6 to 15% w/v, or 8 to 12% w/v of IG composition.

102. The method of claim 101, wherein the protein concentration is 10% w/v.

103. The method of any of claims 81-102, wherein the IG is infused at a rate of 10 ml/hr to 300 ml/hr.

104. The method of claim 103, wherein the rate is selected from among at or about 10 ml/hr, 20 ml/hr, 30 ml/hr, 40 ml/hr, 50 ml/hr, 60 ml/hr, 70 ml/hr, 80 ml/hr, 90 ml/hr, 100 ml/hr, 150 ml/hr, 200 ml/hr, 250 ml/hr and 300 ml/hr.

105. The method of claim 103 or claim 104, wherein the rate is controlled by a pump.

106. The method of claim 103 or claim 104, wherein the rate is controlled by gravity.

107. The method of any of claims 81-106, wherein the IG and hyaluronidase are administered separately.

108. The method of claim 107, wherein the IG and hyaluronidase are administered simultaneously or intermittently.

109. The method of any of claims 81-108, wherein the hyaluronidase is administered prior to administration of IG.

110. The method of claim 109, wherein hyaluronidase is administered 0.5 minutes, 1 minute, 2 minutes, 3 minutes, 4 minutes, 5 minutes, 6 minutes, 7 minutes, 8 minutes, 9 minutes, 10 minutes, 20 minutes or 30 minutes prior to administration of IG.

111. The method of any of claims 81-110, wherein the IG and hyaluronidase are in a single composition.

112. The method of any of claims 81-111, wherein about or 5 grams (g), 10g, 15g, 20g, 21g, 22g, 23g, 24g, 25g, 26g, 27g, 28g, 29g, 30g, 31g, 32g, 33g, 34g, 35g, 36g, 37g, 38g, 39g or 40g of IG is administered

113. The method of any of claims 81-112, wherein the hyaluronidase is administered at a ratio (units hyaluronidase/grams of IG) at or about 10 U/ gram (g), 20 U/g, 30 U/g, 35 U/g, 40 U/g, 50 U/g, 60 U/g, 70 U/g, 80 U/g, 90 U/g, 100 U/g, 150 U/g, or 300 U/g.

114. The method of claim 113, wherein the hyaluronidase is administered at a ratio of or about 50 U/ gram IG.

115. The method of any of claims 81-114, wherein the IG-treatable disease or condition is selected from among immunodeficiency; acquired hypogammaglobulinemia secondary to hematological malignancies; Kawasaki's disease; chronic inflammatory demyelinating polyneuropathy (CIDP); Guillain-Barre Syndrome; Idiopathic thrombocytopenic purpura; inflammatory myopathies; Lambert-Eaton myasthenic syndrome; multifocal motor neuropathy; Myasthenia Gravis; Moersch-Woltmann syndrome; secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency); specific antibody deficiency; Acute disseminated encephalomyelitis; ANCA-positive systemic necrotizing vasculitis; Autoimmune haemolytic anaemia; Bullous pemphigoid; Cicatricial pemphigoid; Evans syndrome (including autoimmune haemolytic anaemia with immune thrombocytopenia); Foeto-maternal/neonatal alloimmune thrombocytopenia (FMAIT/NAIT); Haemophagocytic syndrome; High-risk allogeneic haemopoietic stem cell transplantation; IgM paraproteinaemic neuropathy; kidney transplantation; multiple sclerosis; Opsoclonus myoclonus ataxia; Pemphigus foliaceus; Pemphigus vulgaris; Post-transfusion purpura; Toxic epidermal necrolysis/Steven Johnson syndrome (TEN/SJS); Toxic shock syndrome; Alzheimer's Disease; Systemic lupus erythrematosus; multiple myeloma; sepsis; B cell tumors; trauma; and a bacterial viral or fugal infection.

116. The method of claim 115, wherein the IG-treatable disease or condition is an immunodeficiency and the immunodeficiency is selected from among common variable immunodeficiency (CVID), congenital agammaglobulinemia, Wiskott-Aldrich syndrome, severe combined immunodeficiency (SCID), primary hypogammaglobulemia, primary immunodeficiency diseases with antibody

deficiency, X-linked agammaglobulinemia (XLA), hypogammglobulinemia of infancy, and paraneoplastic cerebellar degeneration with no antibodies.

117. The method of claim 115, wherein the IG-treatable disease or condition is acquired hypogammaglobulinemia secondary to hematological malignancies and the hematological malignancy is selected from among chronic lymphocytic leukemia (CLL), multiple myeloma (MM) and non-Hodgkin's lymphoma (NHL).

118. The method of claim 115, wherein the IG-treatable disease or condition is an inflammatory myopathy and the inflammatory myopathy is selected from among polymyositis, dermatomyositis and inclusion body myositis.

119 The method of claim 115, wherein the IG-treatable disease or condition is a bacteria, viral or fungal condition and the bacterial, viral or fungal condition is selected from among *Haemophilus influenzae* type B, *Psuedomonas aeruginosa* types A and B, *Staphylococcus aureus*, Group B Streptococcus, *Streptococcus pneumoniae* types 1, 3, 4, 6, 7, 8, 9, 12, 14, 18, 19, and 23, Adenovirus types 2 and 5, Cytomegalovirus, Epstein Barr virus VCA, Hepatitis A virus, Hepatitis B virus, Herpes simplex virus-1, Herpes simplex virus-2, Influenza A, Measles, Parainfluenza types 1, 2 and 3, Polio, Varicella zoster virus, *Apergillus* and *Candida albicans*.

Claims:

1. A combination for use in increasing the bioavailability of subcutaneously administered immune globulin (IG) for the treatment of an IG-treatable disease or condition in a subject, comprising:

a first composition comprising IG formulated for subcutaneous single dosage administration of 0.5 grams (g) to 70 g, wherein:

the concentration of IG is 5 to 15% w/v

the IG is formulated in a volume of liquid that is 50 mL to 700 mL; and

a second composition, comprising a soluble hyaluronidase, formulated for direct subcutaneous single dosage administration in an amount that is at a ratio of 10-500 Units (U) hyaluronidase per gram (g) of the IG, wherein:

the soluble hyaluronidase is formulated in a volume of liquid that is 5 to 30 mL;

the hyaluronidase is formulated separately from the IG for administration prior to administration of the IG and at the same site as the IG; and

the amount of hyaluronidase effects increased bioavailability of the IG when administered in combination with the IG to at least 90% of the bioavailability of the same single dosage of IG administered via intravenous administration for treatment of the same IG-treatable disease or condition.

2. Use of a combination for formulation of a medicament for increasing the bioavailability of subcutaneously administered immune globulin (IG) to at least 90% of the bioavailability of the same single dosage of IG administered via intravenous administration for treating an IG-treatable disease or condition in a subject, wherein the combination comprises:

a first composition comprising IG formulated for subcutaneous single dosage administration of 0.5 grams (g) to 70 g, wherein the concentration of IG is 5 to 15% w/v; and

a second composition comprising a soluble hyaluronidase formulated for subcutaneous single dosage administration prior to administration of, and at the same site

as, the IG in a volume that is 5 to 30 mL and in an amount that is a ratio of 10-500 Units (U) hyaluronidase per gram (g) of the IG; wherein:

the soluble hyaluronidase is formulated separately from the IG for administration prior to administration of the IG and at the same site as the IG; and

the hyaluronidase effects increased bioavailability of the IG when administered in combination with the IG to at least 90% of the bioavailability of the same single dosage of IG administered via intravenous administration for treatment of the same IG-treatable disease or condition.

3. The composition or use of claim 1 or claim 2, wherein the IG in the composition is between 20 to 30 grams (g), 21 g to 42 g, 27 g to 61 g or 25.5 g to 61.2 g of IG.

4. The composition or use of any of claims 1-3, wherein the amount of hyaluronidase in the formulation is between 1000 Units to 10,000 Units or 5000 Units to 7500 Units.

5. The composition or use of any of claims 1-4, wherein the soluble hyaluronidase is a PH20, or a PH20 lacking all or a portion of the GPI anchor attachment signal sequence, such that upon expression, the hyaluronidase is soluble.

6. The composition or use of claim 5, wherein the PH20 is selected from an ovine PH20, bovine PH20 or human PH20, wherein the human PH20 lacks all or a portion of the GPI anchor attachment signal sequence, such that upon expression, the hyaluronidase is soluble.

7. The composition or use of claim 6, wherein the PH20 is a human PH20 selected from among polypeptides having the sequence of amino acids set forth in any of SEQ ID NOS:4-9, or a sequence of amino acids that exhibits at least 91% sequence identity to the sequence of amino acids set forth in any of SEQ ID NOS:4-9.

8. The composition or use of any of claims 5-7, wherein the soluble hyaluronidase is designated rHuPH20.

9. The combination or use of any of claims 1-8, wherein the IG has a protein concentration that is 6 to 15% w/v, or 8 to 12% w/v of IG composition.

10. The combination or use of any of claims 1-9, wherein the soluble hyaluronidase is designated rHuPH20.

11. The combination of any of claims 1-10, wherein the IG-treatable disease or condition is selected from among immunodeficiency; acquired hypogammaglobulinemia secondary to hematological malignancies; Kawasaki's disease; chronic inflammatory demyelinating polyneuropathy (CIDP); Guillain-Barre Syndrome; Idiopathic thrombocytopenic purpura; inflammatory myopathies; Lambert-Eaton myasthenic syndrome; multifocal motor neuropathy; Myasthenia Gravis; Moersch-Woltmann syndrome; secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency); specific antibody deficiency; Acute disseminated encephalomyelitis; ANCA-positive systemic necrotizing vasculitis; Autoimmune haemolytic anaemia; Bullous pemphigoid; Cicatricial pemphigoid; Evans syndrome (including autoimmune haemolytic anaemia with immune thrombocytopenia); Foeto-maternal/neonatal alloimmune thrombocytopenia (FMAIT/NAIT); Haemophagocytic syndrome; High-risk allogeneic haemopoietic stem cell transplantation; IgM paraproteinaemic neuropathy; kidney transplantation; multiple sclerosis; Opsoclonus myoclonus ataxia; Pemphigus foliaceus; Pemphigus vulgaris; Post-transfusion purpura; Toxic epidermal necrolysis/Steven Johnson syndrome (TEN/SJS); Toxic shock syndrome; Alzheimer's Disease; Systemic lupus erythematosus; multiple myeloma; sepsis; B cell tumors; trauma; and a bacterial, viral or fungal infection.

12. The combination or use of claim 11, wherein the IG-treatable disease or condition is an immunodeficiency and the immunodeficiency is selected from among common variable immunodeficiency (CVID), congenital agammaglobulinemia, Wiskott-Aldrich syndrome, severe combined immunodeficiency (SCID), primary hypogammaglobulinemia, primary immunodeficiency diseases with antibody deficiency, X-linked agammaglobulinemia (XLA), hypogammaglobulinemia of infancy, and paraneoplastic cerebellar degeneration with no antibodies.

13. The combination or use of claim 11, wherein the IG-treatable disease or condition is acquired hypogammaglobulinemia secondary to hematological malignancies and the hematological malignancy is selected from among chronic lymphocytic leukemia (CLL), multiple myeloma (MM) and non-Hodgkin's lymphoma (NHL).

14. The combination of claim 11, wherein the IG-treatable disease or condition is an inflammatory myopathy and the inflammatory myopathy is selected from among polymyositis, dermatomyositis and inclusion body myositis.

15. The combination of claim 11, wherein the IG-treatable disease or condition is a bacteria, viral or fungal condition and the bacterial, viral or fungal condition is selected from among *Haemophilus influenzae* type B, *Psuedomonas aeruginosa* types A and B, *Staphylococcus aureus*, Group B Streptococcus, *Streptococcus pneumoniae* types 1, 3, 4, 6, 7, 8, 9, 12, 14, 18, 19, and 23, Adenovirus types 2 and 5, Cytomegalovirus, Epstein Barr virus VCA, Hepatitis A virus, Hepatitis B virus, Herpes simplex virus-1, Herpes simplex virus-2, Influenza A, Measles, Parainfluenza types 1, 2 and 3, Polio, Varicella zoster virus, *Apergillus* and *Candida albicans.*