

CLAIMS

What is claimed is:

1. An aqueous formulation comprising ~~about~~ 100-300 mg/mL of ~~an isolated~~ neonatal Fc receptor (FcRn) antagonist in 20-60 mM histidine/histidine HCl, 0-70 mM sucrose, 0-150 mM NaCl, 0-250 mM arginine HCl, 0%-0.05% (w/v) polysorbate 20 or polysorbate 80, 0-15 mM L-methionine, pH 6.0-6.5, wherein the ~~isolated~~ FcRn antagonist consists of a variant Fc region, and wherein ~~the said~~ variant Fc region consists of two Fc domains which form a homodimer, wherein the amino acid sequence of each of the Fc domains consists of the amino acid sequence set forth in SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 2, wherein the aqueous formulation is a sterile aqueous formulation³.
2. The aqueous formulation according to claim 1, comprising ~~about~~ 100-200 mg/mL of the ~~isolated neonatal Fc receptor (FcRn)~~ antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.02%-0.04% (w/v) polysorbate 20 or polysorbate 80, pH 6.0, ~~wherein the amino acid sequence of each of the Fc domains consists of SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 3.~~
3. The aqueous formulation according to claim 1, comprising 150 mg/mL of the FcRn antagonist ARGX-113 in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein ~~ARGX-113 is the isolated FcRn antagonist,~~ wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.
4. The aqueous formulation according to claim 1, comprising about 175 mg/mL of ARGX-113 ~~in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein ARGX-113 is the isolated FcRn antagonist, wherein the amino acid sequence of each of the Fc domains consists of SEQ ID NO: 1.~~
5. ~~The aqueous formulation according to claim 1, comprising 200 mg/mL ARGX-113 in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate~~

20, pH 6.0, wherein ~~ARGX-113 is the isolated FcRn antagonist, wherein the amino acid~~ sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

5. The aqueous formulation according to claim 1, comprising 175 mg/mL of the FcRn antagonist in in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

6. The aqueous formulation according to claim 1, comprising about 100-200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

7. The aqueous formulation according to claim 1, comprising 200 mg/mL of the FcRn antagonist in in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

8. The aqueous formulation according to claim 1, comprising 100-200 mg/mL of the FcRn~~isolated neonatal Fe receptor (FcRn)~~ antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.02%-0.04% (w/v) polysorbate 20 or polysorbate 80, pH 6.0, wherein the amino acid sequence of each of the Fc domains consists of SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 3.

97. The aqueous formulation according to claim 1, comprising about 165 mg/mL of the~~isolated neonatal Fe receptor (FcRn)~~ antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains consists of SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 3.

108. The aqueous formulation according to claim 1, comprising about 175 mg/mL of the FcRn antagonist ARGX-113 in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein ~~ARGX-113~~ is the isolated FcRn antagonist, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

119. The aqueous formulation according to claim 1, comprising 175-200 mg/mL of the FcRn antagonist ARGX-113 in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein ~~ARGX-113~~ is the isolated FcRn antagonist, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

1240. The aqueous formulation according to claim 1, comprising about 100-200 mg/mL of the isolated neonatal Fc receptor (FcRn) antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

13. The aqueous formulation according to claim 1, comprising 200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

14. The aqueous formulation according to claim 1, comprising 100-200 mg/mL of the FcRn) antagonist in 50 mM histidine/histidine HCl, 60 mM sucrose, 150 mM arginine HCl, and 0.02%-0.04% (w/v) polysorbate 20 or polysorbate 80, pH 6.0, ~~wherein the amino acid sequence of each of the Fc domains consists of SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 3.~~

1544. The aqueous formulation according to claim 1, comprising about 100-200 mg/mL of the isolated neonatal Fc receptor (FcRn) antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM arginine HCl, 10 mM L-methionine, and 0.02%-0.04% (w/v)

polysorbate 20 or polysorbate 80, pH 6.0, wherein the amino acid sequence of each of the Fc domains consists of SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 3.

~~16.~~ ~~The~~ ~~12.~~ ~~An~~ aqueous formulation according to claim 1, comprising 175 mg/mL of the FcRn antagonist ~~ARGX-113~~ in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM arginine HCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein ~~ARGX-113~~ is the isolated FcRn antagonist, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

~~17~~ ~~13.~~ The aqueous formulation according to claim 1, comprising 200 mg/mL of the FcRn antagonist ~~ARGX-113~~ in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM arginine HCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein ~~ARGX-113~~ is the isolated FcRn antagonist, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

~~18~~ ~~14.~~ The aqueous formulation according to claim 1, comprising ~~about~~ 100-300 mg/mL of the isolated neonatal Fc receptor (FcRn) antagonist in 50 mM histidine/histidine HCl, 200 mM arginine HCl, pH 6.5.

19. An aqueous formulation comprising 100-200 mg/mL of an FcRn antagonist in 20 mM L-histidine/L-histidine HCl, 100 mM NaCl, 60 mM sucrose, 10 mM L-methionine, and 0.04% (w/v) polysorbate 20, pH 6.0-6.5, wherein the FcRn antagonist consists of a variant Fc region, and wherein the variant Fc region consists of two Fc domains which form a homodimer, wherein the amino acid sequence of each of the Fc domains consists of the amino acid sequence set forth in SEQ ID NO: 1, ~~SEQ ID NO: 2,~~ or SEQ ID NO: 2, wherein the aqueous formulation is a sterile aqueous formulation~~3~~.

20. The aqueous formulation according to claim 19, wherein the amino acid sequence of each of the Fc domains consists of the amino acid sequence set forth in SEQ ID NO: 1.

21. The aqueous formulation according to claim 19 or 20, wherein the aqueous formulation comprises 180 mg/mL of the FcRn antagonist.

22+5. A packaged pharmaceutical product comprising a sterile container comprising a therapeutically effective amount of the aqueous formulation of any one of claims 1 to 21+4.

23. The packaged pharmaceutical product according to claim 22, wherein the packaged pharmaceutical product is presented as a single-use vial, a multi-use vial, or a pre-filled syringe.

24. The packaged pharmaceutical product according to claim 22 or 23, wherein the packaged pharmaceutical product is presented as a single-use vial.

25+6. A device comprising a therapeutically effective amount of the aqueous formulation of any one of claims 1 to 21+4.

26+7. The device according to claim 25+6, wherein the device comprises or consists of a syringe comprising the aqueous formulation.

27. The device according to claim 26, wherein the syringe is a pre-filled syringe.

28. A packaged pharmaceutical product comprising a sterile container comprising a therapeutically effective amount of an aqueous formulation comprising 100-300 mg/mL of an FcRn antagonist in 20-60 mM histidine/histidine HCl, 0-70 mM sucrose, 0-150 mM NaCl, 0-250 mM arginine HCl, 0%-0.05% (w/v) polysorbate 20 or polysorbate 80, 0-15 mM L-methionine, pH 6.0-6.5, wherein the FcRn antagonist consists of a variant Fc region, and wherein the variant Fc region consists of two Fc domains which form a homodimer, wherein the amino acid sequence of each of the Fc domains consists of the amino acid sequence set forth in SEQ ID NO: 1 or SEQ ID NO: 2.

29. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises 100-200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.02%-0.04% (w/v) polysorbate 20 or polysorbate 80, pH 6.0.

30. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises 150 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

31. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises about 175 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

32. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises 175 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

33. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises about 200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

34. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises 200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein the amino

acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

35. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises 100-200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.02%-0.04% (w/v) polysorbate 20 or polysorbate 80, pH 6.0.

36. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises about 165 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.04% (w/v) polysorbate 20, pH 6.0.

37. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises about 175 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

38. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises 175 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

39. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises about 200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

40. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises 200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

41. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises 100-200 mg/mL of the FcRn antagonist in 50 mM histidine/histidine HCl, 60 mM sucrose, 150 mM arginine HCl, and 0.02%-0.04% (w/v) polysorbate 20 or polysorbate 80, pH 6.0.

42. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises 100-200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM arginine HCl, 10 mM L-methionine, and 0.02%-0.04% (w/v) polysorbate 20 or polysorbate 80, pH 6.0.

43. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises 175 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM arginine HCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

44. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises 200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM arginine HCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

45. The packaged pharmaceutical product according to claim 28, wherein the aqueous formulation comprises 100-300 mg/mL of the FcRn antagonist in 50 mM histidine/histidine HCl, 200 mM arginine HCl, pH 6.5.

46. A packaged pharmaceutical product comprising a sterile container comprising a therapeutically effective amount of an aqueous formulation comprising 100-200 mg/mL of an FcRn antagonist in 20 mM L-histidine/L-histidine HCl, 100 mM NaCl, 60 mM sucrose, 10 mM L-methionine, and 0.04% (w/v) polysorbate 20, pH 6.0-6.5, wherein the FcRn antagonist consists of a variant Fc region, and wherein the variant Fc region consists of two Fc domains which form a homodimer, wherein the amino acid sequence of each of the Fc domains consists of the amino acid sequence set forth in SEQ ID NO: 1 or SEQ ID NO: 2.

47. The packaged pharmaceutical product according to claim 46, wherein the amino acid sequence of each of the Fc domains consists of the amino acid sequence set forth in SEQ ID NO: 1.

48. The packaged pharmaceutical product according to claim 46 or 47, wherein the aqueous formulation comprises 180 mg/mL of the FcRn antagonist.

49. The packaged pharmaceutical product according to any one of claims 28 to 48, wherein the packaged pharmaceutical product is presented as a single-use vial, a multi-use vial, or a pre-filled syringe.

50. The packaged pharmaceutical product according to any one of claims 28 to 49, wherein the packaged pharmaceutical product is presented as a single-use vial.

51. A device comprising a therapeutically effective amount of an aqueous formulation comprising 100-300 mg/mL of an FcRn antagonist in 20-60 mM histidine/histidine HCl, 0-70 mM sucrose, 0-150 mM NaCl, 0-250 mM arginine HCl, 0%-0.05% (w/v) polysorbate 20 or polysorbate 80, 0-15 mM L-methionine, pH 6.0-6.5, wherein the FcRn antagonist consists of a variant Fc region, and wherein the variant Fc region consists of two Fc domains which form a homodimer, wherein the amino acid sequence of each of the Fc domains consists of the amino acid sequence set forth in SEQ ID NO: 1 or SEQ ID NO: 2.

52. The device according to claim 51, wherein the aqueous formulation comprises 100-200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.02%-0.04% (w/v) polysorbate 20 or polysorbate 80, pH 6.0.

53. The device according to claim 51, wherein the aqueous formulation comprises 150 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

54. The device according to claim 51, wherein the aqueous formulation comprises about 175 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

55. The device according to claim 51, wherein the aqueous formulation comprises 175 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

56. The device according to claim 51, wherein the aqueous formulation comprises about 200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

57. The device according to claim 51, wherein the aqueous formulation comprises 200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, and 0.04% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the

Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

58. The device according to claim 51, wherein the aqueous formulation comprises 100-200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.02%-0.04% (w/v) polysorbate 20 or polysorbate 80, pH 6.0.

59. The device according to claim 51, wherein the aqueous formulation comprises about 165 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.04% (w/v) polysorbate 20, pH 6.0.

60. The device according to claim 51, wherein the aqueous formulation comprises about 175 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

61. The device according to claim 51, wherein the aqueous formulation comprises 175 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

62. The device according to claim 51, wherein the aqueous formulation comprises about 200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

63. The device according to claim 51, wherein the aqueous formulation comprises 200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM NaCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein the amino

acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

64. The device according to claim 51, wherein the aqueous formulation comprises 100-200 mg/mL of the FcRn antagonist in 50 mM histidine/histidine HCl, 60 mM sucrose, 150 mM arginine HCl, and 0.02%-0.04% (w/v) polysorbate 20 or polysorbate 80, pH 6.0.

65. The device according to claim 51, wherein the aqueous formulation comprises 100-200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM arginine HCl, 10 mM L-methionine, and 0.02%-0.04% (w/v) polysorbate 20 or polysorbate 80, pH 6.0.

66. The device according to claim 51, wherein the aqueous formulation comprises 175 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM arginine HCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

67. The device according to claim 51, wherein the aqueous formulation comprises 200 mg/mL of the FcRn antagonist in 20 mM histidine/histidine HCl, 60 mM sucrose, 100 mM arginine HCl, 10 mM L-methionine, and 0.03% (w/v) polysorbate 20, pH 6.0, wherein the amino acid sequence of each of the Fc domains of the FcRn antagonist consists of the amino acid sequence set forth in SEQ ID NO: 1.

68. The device according to claim 51, wherein the aqueous formulation comprises 100-300 mg/mL of the FcRn antagonist in 50 mM histidine/histidine HCl, 200 mM arginine HCl, pH 6.5.

69. A device comprising a therapeutically effective amount of an aqueous formulation comprising 100-200 mg/mL of an FcRn antagonist in 20 mM L-histidine/L-histidine HCl, 100 mM NaCl, 60 mM sucrose, 10 mM L-methionine, and 0.04% (w/v) polysorbate 20, pH 6.0-6.5, wherein the FcRn antagonist consists of a variant Fc region, and wherein the variant Fc region consists of two Fc domains which form a homodimer, wherein the amino acid

sequence of each of the Fc domains consists of the amino acid sequence set forth in SEQ ID NO: 1 or SEQ ID NO: 2.

70. The device according to claim 69, wherein the amino acid sequence of each of the Fc domains consists of the amino acid sequence set forth in SEQ ID NO: 1.

71. The device according to claim 69 or 70, wherein the aqueous formulation comprises 180 mg/mL of the FcRn antagonist.

72. The device according to any one of claims 51-71, wherein the device comprises or consists of a syringe comprising the aqueous formulation.

73. The device according to claim 72, wherein the syringe is a pre-filled syringe.