

WHAT IS CLAIMED:

1. A method of treating a human subject diagnosed with diabetic retinopathy (DR), comprising administering to the subretinal space in the eye of said human subject an expression vector encoding an anti-human vascular endothelial growth factor (hVEGF) antibody, wherein the expression vector is administered via subretinal delivery in a single dose about 1.6×10^{11} GC/eye at a concentration of 6.2×10^{11} GC/mL or about 2.5×10^{11} GC/eye at a concentration of 1.0×10^{12} GC/mL, wherein the anti-hVEGF antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO. 2 or SEQ ID NO. 4, and a light chain comprising the amino acid sequence of SEQ ID NO. 1, or SEQ ID NO. 3; and wherein the expression vector is an AAV8 vector.
2. The method of claim 1, wherein the administering is by injecting the expression vector into the subretinal space using a subretinal drug delivery device.
3. The method of any one of claims 1-2, wherein the administering delivers a therapeutically effective amount of the anti-hVEGF antibody to the retina of said human subject.
4. The method of claim 3, wherein the therapeutically effective amount of the anti-hVEGF antibody is produced by human retinal cells of said human subject.
5. The method of claim 4, wherein the therapeutically effective amount of the anti-hVEGF antibody is produced by human photoreceptor cells, horizontal cells, bipolar cells, amacrine cells, retina ganglion cells, and/or retinal pigment epithelial cells in the external limiting membrane of said human subject.
6. The method of claim 5, wherein the human photoreceptor cells are cone cells and/or rod cells.
7. The method of claim 6, wherein the retina ganglion cells are midget cells, parasol cells, bistratified cells, giant retina ganglion cells, photosensitive ganglion cells, and/or Müller glia.
8. The method of any one of claims 1-7, wherein the expression vector comprises the CB7 promoter.
9. The method of claim 8, wherein the expression vector is Construct II.
10. A single dose composition comprising 1.6×10^{11} GC at a concentration of 6.2×10^{11} GC/mL or 2.5×10^{11} GC at a concentration of 1.0×10^{12} GC/mL of an expression vector encoding an anti-human vascular endothelial growth factor (hVEGF) antibody in a formulation

buffer (pH=7.4), wherein the formulation buffer comprises Dulbecco's phosphate buffered saline and 0.001% Pluronic F68, wherein the anti-hVEGF antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO. 2 or SEQ ID NO. 4, and a light chain comprising the amino acid sequence of SEQ ID NO. 1, or SEQ ID NO. 3; and wherein the wherein the expression vector is an AAV8 vector.

11. The composition of claim 10, wherein the expression vector is Construct II.

12. The method of any one of claims 1-9, which further comprises, after the administering step, a step of monitoring the post ocular injection thermal profile of the injected material in the eye using an infrared thermal camera.

13. The method of claim 12, wherein the infrared thermal camera is a FLIR T530 infrared thermal camera.

14. A method of treating a human subject diagnosed with DR, comprising administering to the subretinal space in the eye of said human subject an expression vector encoding an anti-human vascular endothelial growth factor (hVEGF) antibody, wherein about 2.5×10^{11} genome copies per eye of the expression vector are administered by double suprachoroidal injections, wherein the anti-hVEGF antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO. 2 or SEQ ID NO. 4, and a light chain comprising the amino acid sequence of SEQ ID NO. 1, or SEQ ID NO. 3; and wherein the expression vector is an AAV8 vector.

15. A method of treating a human subject diagnosed with DR, comprising administering to the subretinal space in the eye of said human subject an expression vector encoding an anti-human vascular endothelial growth factor (hVEGF) antibody, wherein about 5.0×10^{11} genome copies per eye of the expression vector are administered by double suprachoroidal injections, wherein the anti-hVEGF antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO. 2 or SEQ ID NO. 4, and a light chain comprising the amino acid sequence of SEQ ID NO. 1, or SEQ ID NO. 3; and wherein the expression vector is an AAV8 vector.

16. The method of any one of claims 14-15, wherein the administering delivers a therapeutically effective amount of the anti-hVEGF antibody to the retina of said human subject.

17. The method of claim 16, wherein the therapeutically effective amount of the anti-hVEGF antibody is produced by human retinal cells of said human subject.

18. The method of claim 17, wherein the therapeutically effective amount of the anti-hVEGF antibody is produced by human photoreceptor cells, horizontal cells, bipolar cells, amacrine cells, retina ganglion cells, and/or retinal pigment epithelial cells in the external limiting membrane of said human subject.

19. The method of claim 18, wherein the human photoreceptor cells are cone cells and/or rod cells.

20. The method of claim 19, wherein the retina ganglion cells are midget cells, parasol cells, bistratified cells, giant retina ganglion cells, photosensitive ganglion cells, and/or Müller glia.

21. The method of any one of claims 14-20, wherein the expression vector comprises the CB7 promoter.

22. The method of claim 21, wherein the expression vector is Construct II.

23. The method of any one of claims 14-22, which further comprises, after the administering step, a step of monitoring the post ocular injection thermal profile of the injected material in the eye using an infrared thermal camera.

24. The method of claim 23, wherein the infrared thermal camera is a FLIR T530 infrared thermal camera.

25. A single dose composition comprising about 6.0×10^{10} genome copies per eye, 1.6×10^{11} genome copies per eye, 2.5×10^{11} genome copies per eye, 5.0×10^{11} genome copies per eye, or 3.0×10^{12} genome copies per eye of an expression vector encoding an anti-human vascular endothelial growth factor (hVEGF) antibody in a formulation buffer (pH=7.4), wherein the formulation buffer comprises Dulbecco's phosphate buffered saline and 0.0001% Pluronic F68, wherein the anti-hVEGF antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO. 2 or SEQ ID NO. 4, and a light chain comprising the amino acid sequence of SEQ ID NO. 1, or SEQ ID NO. 3; and wherein the expression vector is an AAV8 vector.

26. The composition of claim 25, wherein the expression vector is Construct II.

27. The method of any one of claims 1-9 and 12-24, wherein the method does not result in shedding of the expression vector.

28. The method of any one of claims 1-9 and 12-24, wherein less than 1000, less than 500, less than 100, less than 50 or less than 10 expression vector gene copies/5 μ L are detectable

by quantitative polymerase chain reaction in a biological fluid at any point after administration.

29. The method of any one of claims 1-9 and 12-24, wherein 210 expression vector gene copies/5 μ L or less are detectable by quantitative polymerase chain reaction in a biological fluid at any point after administration.

30. The method of any one of claims 1-9 and 12-24, wherein less than 1000, less than 500, less than 100, less than 50 or less than 10 vector gene copies/5 μ L are detectable by quantitative polymerase chain reaction in a biological fluid by 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13 or 14 weeks after administration.

31. The method of any one of claims 1-9 and 12-24, wherein no vector gene copies are detectable in a biological fluid by week 14 after administration of the vector.

32. The method of any one of claims 28-31, wherein the biological fluid is tears, serum or urine.