WHAT IS CLAIMED IS:

Claim 1. A pharmaceutical composition comprising:

(a) about 10 mg/mL to about 100 mg/mL retifanlimab;

(b) acetate;

(c) sucrose;

(d) polysorbate 80 ("PS80"); and

(e) water.

Claim 2. The pharmaceutical composition of claim 1, wherein the acetate:

(a) is present at a concentration of about 5 mM to about 30 mM; and/or

(b) comprises sodium acetate.

Claim 3. The pharmaceutical composition of claim 1 or 2, wherein the composition comprises:

(a) about 5 mM to about 30 mM acetate, about 50 mg/mL to about 130 mg/mL of sucrose, about 0.02 mg/mL to about 0.6 mg/mL of PS80, and water, wherein the composition has a pH of about 4.0 to about 6.5;

(b) about 7.5 mM to about 20 mM acetate, about 50 mg/mL to about 130 mg/mL of sucrose, about 0.05 mg/mL to about 0.6 mg/mL of PS80, and water, wherein the composition has a pH of about 4.0 to about 6.5;

(c) about 9 mM to about 11 mM acetate, about 76 mg/mL to about 104 mg/mL of sucrose, about 0.08 mg/mL to about 0.53 mg/mL of PS80, and water, wherein the composition has a pH of about 4.5 to about 5.7; or

(d) about 9 mM to about 11 mM acetate, about 80 mg/mL to about 100 mg/mL of sucrose, about 0.08 mg/mL to about 0.15 mg/mL of PS80, and water, wherein the composition has a pH of about 4.5 to about 5.7**.**

Claim 4. The pharmaceutical composition of any one of claims 1-3, wherein the retifanlimab:

(a) is present at a concentration of about 20 mg/mL to about 30 mg/mL; or

(b) is present at a concentration of about 25 mg/mL.

Claim 5. The pharmaceutical composition of any one of claims 1-4, wherein the acetate comprises:

(a) glacial acetic acid at a concentration of about 0.05 mg/mL to about 0.35 mg/mL and sodium acetate trihydrate at a concentration of about 0.80 mg/mL to about 2.0 mg/mL; or

(b) glacial acetic acid at a concentration of about 0.18 mg/mL and sodium acetate trihydrate at a concentration of about 0.95 mg/mL.

Claim 6. The pharmaceutical composition of any one of claims 1-5, wherein the sucrose:

(a) is present at a concentration of about 80 mg/mL to about 100 mg/mL; or

(b) is present at a concentration of about 90 mg/mL.

Claim 7. The pharmaceutical composition of any one of claims 1-6, wherein the PS80:

(a) is present at a concentration of about 0.08 mg/mL to about 0.15 mg/mL; or

(b) is present at a concentration of about 0.1 mg/mL.

Claim 8. The pharmaceutical composition of any one of claims 1-7, wherein:

(a) the composition has a pH of about 4.5 to about 5.7; or

(b) the composition has a pH of about 5.1.

Claim 9. The pharmaceutical composition of any one of claims 1-8, wherein the composition comprises about 25 mg/mL of retifanlimab, about 0.18 mg/mL of glacial acetic acid, about 0.95 mg/mL of sodium acetate trihydrate, about 90 mg/mL of sucrose, about 0.1 mg/mL of PS80, and water, wherein the composition has a pH of about 4.8 to about 5.4.

Claim 10. The pharmaceutical composition of any one of claims 1-9, wherein the composition has a shelf-life of at least about 18 months, about 24 months, about 36 months, about 48 months, or about 60 months, at about 2^{o}C to about 8^{o}C.

Claim 11. The pharmaceutical composition of any one of claims 1-16, wherein the composition has an osmolality of about 200 to about 400 mOsm/kg H_2O, about 225 to about 400 mOsm/kg H_2O, about 250 to about 375 mOsm/kg H_2O, or about 260 to about 340 mOsm/kg H_2O.

Claim 12. The pharmaceutical composition of any one of claims 1-11, wherein the composition maintains:

(a) monomeric purity of the retifanlimab for at least about 3 months at 25°C, or for at least about 18 months at 2°C to about 8°C; and/or

(b) heterogeneity profile of the retifanlimab for at least about 3 months at 25°C, or for at least about 18 months at about 2°C to about 8°C.

Claim 13. The pharmaceutical composition of any of claims 1-12, wherein said the water is sterile, nonpyrogenic, distilled water.

Claim 14. The pharmaceutical composition of any one of claims 1-13, wherein the composition is sterile.

Claim 15. A container comprising the pharmaceutical composition of any one of claims 1-14, wherein the container comprises:

(a) about 10 mL volume of the pharmaceutical composition, wherein the about 10 mL volume of the pharmaceutical composition comprises:

(i) about 250 mg retifanlimab;

(ii) about 1.8 mg glacial acetic acid;

(iii) about 9.5 mg sodium acetate trihydrate;

(iv) about 900 mg sucrose;

(v) about 1 mg PS80; and

(vi) water; and

wherein the composition has a pH of about 4.8 to about 5.4;

(b) about 15 mL volume of the pharmaceutical composition, wherein the about 15 mL volume of the pharmaceutical composition comprises:

(i) about 375 mg retifanlimab;

(ii) about 2.7 mg glacial acetic acid;

(iii) about 14.25 mg sodium acetate trihydrate;

(iv) about 1350 mg sucrose;

(v) about 1.5 mg PS80; and

(vi) water; and

wherein the composition has a pH of about 4.8 to about 5.4;

(c) about 20 mL volume of the pharmaceutical composition, wherein the about 20 mL volume of the pharmaceutical composition comprises:

(i) about 500 mg retifanlimab;

(ii) about 3.6 mg glacial acetic acid;

(iii) about 19 mg sodium acetate trihydrate;

(iv) about 1800 mg sucrose;

(v) about 2 mg PS80; and

(vi) water; and

wherein the composition has a pH of about 4.8 to about 5.4.

Claim 16. A kit comprising the pharmaceutical composition of any one of claims 1-14, or the container of claim 15, and optionally further comprising instructions for administration of the pharmaceutical composition to a subject in need thereof.

Claim 17. A kit comprising a container comprising a pharmaceutical composition, the composition comprising:

(a) about 21 mg/mL to about 29 mg/mL of retifanlimab, about 0.16 mg/mL to about 0.20 mg/mL of glacial acetic acid, about 0.86 mg/mL to about 1.1 mg/mL of sodium acetate trihydrate, about 76 mg/mL to about 104 mg/mL of sucrose, about 0.08 mg/mL to about 0.53 mg/mL of PS80, and water, wherein the composition has a pH of about 4.5 to about 5.7; or

(b) about 22.5 mg/mL to about 27.5 mg/mL of retifanlimab, about 0.16 mg/mL to about 0.20 mg/mL of glacial acetic acid, about 0.86 mg/mL to about 1.1 mg/mL of sodium acetate trihydrate, about 76 mg/mL to about 104 mg/mL of sucrose, about 0.08 mg/mL to about 0.53 mg/mL of PS80, and water, wherein the composition has a pH of about 4.5 to about 5.7; or

(c) about 250 mg retifanlimab, about 1.8 mg glacial acetic acid, about 9.5 mg sodium acetate trihydrate, about 900 mg sucrose, about 1 mg PS80, and wherein said composition has a pH of about 4.8 to about 5.4; or

(d) about 375 mg retifanlimab, about 2.7 mg glacial acetic acid, about 14.25 mg sodium acetate trihydrate, about 1350 mg sucrose, about 1.5 mg PS80, and wherein said composition has a pH of about 4.8 to about 5.4; or

(e) about 500 mg retifanlimab, about 3.6 mg glacial acetic acid, about 19 mg sodium acetate trihydrate, about 1800 mg sucrose, about 2 mg PS80, and wherein said composition has a pH of about 4.8 to about 5.4; and

optionally further comprising instructions for administration of the pharmaceutical composition to a subject in need thereof.

Claim 18. The kit of claim 16 or 17, wherein the composition comprises about 25 mg/mL of retifanlimab, about 0.18 mg/mL of glacial acetic acid, about 0.95 mg/mL of sodium acetate trihydrate, about 90 mg/mL of sucrose, about 0.1 mg/mL of PS80, and water, wherein the composition has a pH of about 4.8 to about 5.4.

Claim 19. The kit of claim 16 or 17, wherein the composition comprises about 250 mg retifanlimab, about 1.8 mg glacial acetic acid, about 9.5 mg sodium acetate trihydrate, about 900 mg sucrose, about 1 mg PS80, and wherein said composition has a pH of about 4.8 to about 5.4.

Claim 20. The kit of claim 16 or 17, wherein the composition comprises about 375 mg retifanlimab, about 2.7 mg glacial acetic acid, about 14.25 mg sodium acetate

trihydrate, about 1350 mg sucrose, about 1.5 mg PS80, and wherein said composition has a pH of about 4.8 to about 5.4.

Claim 21. The kit of claim 16 or 17, wherein the composition about 500 mg retifanlimab, about 3.6 mg glacial acetic acid, about 19 mg sodium acetate trihydrate, about 1800 mg sucrose, about 2 mg PS80, and wherein said composition has a pH of about 4.8 to about 5.4.

Claim 22. Use of the pharmaceutical composition of any one of claims 1-15, for the production of a medicament for the treatment of cancer in a subject in need thereof.

Claim 23. Use of the pharmaceutical composition according to any one of claims 1-15, the container of claim 16, the kit of any one of claims 17-21, in the manufacture of a medicament for the treatment of cancer in a subject in need thereof.

Claim 24. The use of claim 22 or 23, wherein the use comprises:

(a) diluting the pharmaceutical composition in a container in 0.9% sodium chloride to obtain a dosing solution;

(b) inverting the container to mix the diluted solution; and

(c) attaching the container containing the dosing solution to a device for administration to the subject.

Claim 25. The use of claim 24, wherein the container is an IV bag containing 0.9% sodium chloride.

Claim 26. The use of claim 22 or 23, wherein the use comprises:

a) diluting the pharmaceutical composition in a container in 5% dextrose in water (D5W) to obtain a dosing solution;

b) inverting the container to mix the diluted solution; and

c) attaching the container containing the dosing solution to a device for administration to the subject.

Claim 27. The use of claim 26, wherein the container is an IV bag containing D5W.

Claim 28. The use of any one of claims 22-27, wherein said dosing solution maintains monomeric purity of said retifanlimab for about 6 hours at 25°C or for about 24 hours at about 2°C to about 8°C.

Claim 29. The use of any one of claims 22-28, wherein said administration is by IV infusion for at least about 30 minutes or at least about 60 minutes.

Claim 30. The use of any one of claims 22-29, wherein the pharmaceutical composition is diluted to obtain a flat dose of about 375 mg, or about 500 mg.

Claim 31. The use of any one of claims 22-30, wherein administration of the dosing solution is once every 2 weeks, once every 3 weeks, or once every 4 weeks.

Claim 32. The use of any one of claims 22-31, wherein the cancer expresses PD-L1.

Claim 33. The use of any one of claims 22-32, wherein the cancer is selected from the group consisting of: adrenal gland cancer, AIDS-associated cancer, alveolar soft part sarcoma, anal cancer, squamous cell carcinoma of the anal canal (SCAC), bladder cancer, bone cancer, brain and spinal cord cancer, breast cancer, HER2+ breast cancer or Triple-Negative Breast Cancer (TNBC), carotid body tumor, cervical cancer, HPV-related cervical cancer, chondrosarcoma, chordoma, chromophobe renal cell carcinoma, clear cell carcinoma, colon cancer, colorectal cancer, desmoplastic small round cell tumor, ependymoma, endometrial cancer, unselected endometrial cancer, MSI-high endometrial cancer, dMMR endometrial cancer, DNA polymerase ε (POLE) exonuclease domain mutation positive endometrial cancer, Ewing's sarcoma, extraskeletal myxoid chondrosarcoma, gallbladder or bile duct cancer, cholangiocarcinoma bile duct cancer, gastric cancer, gastroesophageal junction (GEJ) cancer, gestational trophoblastic disease, germ cell tumor, glioma, glioblastoma, head and neck cancer, squamous cell carcinoma of head and neck (SCCHN), a hematological malignancy, a hepatocellular carcinoma, islet cell tumor, Kaposi's Sarcoma, kidney cancer, renal cell carcinomas (RCC), clear cell RRC, papillary RCC and chromophobe RCC, leukemia, acute myeloid leukemia, liposarcoma/malignant lipomatous tumor, liver cancer, hepatocellular carcinoma liver cancer (HCC), lymphoma, diffuse large

B-cell lymphoma (DLBCL), non-Hodgkin's lymphoma (NHL), lung cancer, small cell lung cancer (SCLC), non-small cell lung cancer (NSCLC), medulloblastoma, melanoma, uveal melanoma, meningioma, mesothelioma, mesothelial pharyngeal cancer, multiple endocrine neoplasia, multiple myeloma, myelodysplastic syndrome, neuroblastoma, neuroendocrine tumors, ovarian cancer, pancreatic cancer, papillary thyroid carcinoma, parathyroid tumor, pediatric cancer, peripheral nerve sheath tumor, pharyngeal cancer, pheochromocytoma, pituitary tumor, prostate cancer, metastatic castration resistant prostate cancer (mCRPC), posterious uveal melanoma, renal metastatic cancer, rhabdoid tumor, rhabdomyosarcoma, sarcoma, skin cancer, Merkel cell carcinoma, a small round blue cell tumor of childhood, neuroblastoma, rhabdomyosarcoma, soft-tissue sarcoma, squamous cell cancer, stomach cancer, synovial sarcoma, testicular cancer, thymic carcinoma, thymoma, thyroid cancer, urothelial cancer, and uterine cancer.

Claim 34. The use of claim 33, wherein the cancer is anal cancer, breast cancer, colorectal cancer, endometrial cancer, gastric cancer, GEJ cancer, head and neck cancer, kidney cancer, liver cancer, lung cancer, lymphoma, melanoma, multiple myeloma, ovarian cancer, pancreatic cancer, prostate cancer, and skin cancer, and urothelial cancer.

Claim 35. The use of any one of claims 33-34, wherein the cancer is SCAC.

Claim 36. The use of any one of claims 33-34, wherein the lung cancer is NSCLC.

Claim 37. The use of any one of claims 33-39, wherein the endometrial cancer, is MSI-high endometrial cancer, dMMR endometrial cancer, or POLE exonuclease domain mutation positive endometrial cancer.

Claim 38. The use of any one of claims 33-39, wherein the skin cancer is melanoma, or Merkel cell carcinoma.

Claim 39. The use of any one of claims 33-34, wherein said head and neck cancer is SCCHN.

Claim 40. The use of any one of claims 33-34, wherein the prostate cancer is mCRPC.

Claim 41. The use of any one of claims 33-34, wherein the kidney cancer is RCC or clear cell RCC.

Claim 42. The use of any one of claims 33-34, wherein the cancer is urothelial cancer.

Claim 43. The use of any one of claims 22-42, wherein the subject is a human subject.