

WHAT IS CLAIMED IS:

- Claim 1. A pharmaceutical composition comprising:
- a) about 5 mg/mL to about 200 mg/mL enoblituzumab;
 - b) acetate;
 - c) sucrose;
 - d) polysorbate 80 ("PS80"); and
 - e) water.
- Claim 2. The pharmaceutical composition of claim 1, wherein said acetate comprises sodium acetate and is present at a concentration of about 5 mM to about 30 mM.
- Claim 3. The pharmaceutical composition of any one of claims 1-2, wherein said composition comprises:
- a) about 5 mM to about 30 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 6.0; or
 - b) about 8 mM to about 24 mM acetate, about 72 mg/mL to about 108 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 4.4 to about 5.6; or
 - c) about 16 mM to about 24 mM acetate, about 72 mg/mL to about 108 mg/mL of sucrose, about 0.05 mg/mL to about 0.2 mg/mL of PS80, and water, wherein the composition has a pH of about 4.3 to about 5.3; or
 - d) about 8 mM to about 12 mM acetate, about 72 mg/mL to about 108 mg/mL of sucrose, about 0.05 mg/mL to about 0.2 mg/mL of PS80, and water, wherein the composition has a pH of about 4.5 to about 5.5; or
 - e) about 10 mM acetate, about 90 mg/mL of sucrose, about 0.1 mg/mL of PS80, and water, wherein the composition has a pH of about 4.6 to about 5.5; or
 - f) about 20 mM acetate, about 90 mg/mL of sucrose, about 0.1 mg/mL of PS80, and water, wherein the composition has a pH of about 4.4 to about 5.2.
- Claim 4. The pharmaceutical composition of any one of claims 1-3, wherein said acetate comprises glacial acetic acid at a concentration of about 0.1 mg/mL to about

0.65 mg/mL and sodium acetate trihydrate at a concentration of about 0.6 mg/mL to about 1.8 mg/mL.

- Claim 5. The pharmaceutical composition of any one of claims 1-4, wherein said composition has a pH of about 4.6 to about 5.5.
- Claim 6. The pharmaceutical composition of any one of claims 1-5, wherein said composition comprises about 25 mg/mL of enoblituzumab, 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 4.7 to about 5.5.
- Claim 7. The pharmaceutical composition of any one of claims 1-5, wherein said composition comprises about 25 mg/mL of enoblituzumab, about 0.27 mg/mL of glacial acetic acid, about 0.74 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 4.6 to about 5.4.
- Claim 8. The pharmaceutical composition of any one of claims 1-5, wherein said composition comprises about 120 mg/mL of enoblituzumab, about 0.52 mg/mL of glacial acetic acid, about 1.5 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 4.4 to about 5.2.
- Claim 9. The pharmaceutical composition of any one of claims 1-8, wherein said composition does not comprise an antioxidant.
- Claim 10. The pharmaceutical composition of any one of claims 1-8, wherein said composition has a shelf-life of at least about 18 months at about 2°C to about 8°C.
- Claim 11. The pharmaceutical composition of any one of claims 1-10, wherein said composition has an osmolality of about 200 to about 400 mOsm/kg H₂O.

- Claim 12. The pharmaceutical composition of any one of claims 1-11, wherein said composition maintains monomeric purity of said enoblituzumab for at least about 3 months at about 25°C.
- Claim 13. The pharmaceutical composition of any one of claims 1-12, wherein said composition maintains the heterogeneity profile of said enoblituzumab for about for at least about 3 months at 25°C.
- Claim 14. A container comprising the pharmaceutical composition of any one of claims 1-13.
- Claim 15. The container of claim 14, wherein said container comprises about 10 mL volume of said pharmaceutical composition, wherein volume comprises:
- a) about 250 mg enoblituzumab;
 - b) about 10 mM sodium acetate
 - c) about 900 mg sucrose;
 - d) about 1 mg PS80; and
 - e) water; and
- wherein said composition has a pH of about 4.6 to about 5.5.
- Claim 16. The container of claim 14, wherein said container comprises about 10 mL volume of said pharmaceutical composition, wherein said volume comprises:
- a) about 250 mg enoblituzumab;
 - b) about 1.8 mg glacial acetic acid
 - c) about 9.5 mg sodium acetate trihydrate;
 - d) about 900 mg sucrose;
 - e) about 1 mg PS80; and
 - f) water; and
- wherein said composition has a pH of about 4.7 to about 5.5.
- Claim 17. The container of claim 14, wherein said container comprises about 17 mL volume of said pharmaceutical composition, wherein said volume comprises:
- a) about 425 mg enoblituzumab;
 - b) about 10 mM sodium acetate;
 - c) about 1530 mg sucrose;
 - d) about 1.7 mg PS80; and

e) water; and

wherein said composition has a pH of about 4.6 to about 5.4.

Claim 18. The container of claim 14, wherein said container comprises about 17 mL volume of said pharmaceutical composition, wherein said volume comprises:

- a) about 425 mg enoblituzumab;
- b) about 3.06 mg glacial acetic acid
- c) about 16.15 mg sodium acetate trihydrate;
- d) about 1530 mg sucrose;
- e) about 1.7 mg PS80; and
- f) water; and

wherein said composition has a pH of about 4.7 to about 5.5.

Claim 19. A kit comprising the pharmaceutical composition of any one of claims 1-13, or the container of any one of claims 14-18, and optionally further comprising instructions for administration of the pharmaceutical composition to a subject in need thereof.

Claim 20. Use of the pharmaceutical composition according to any one of claims 1-13, the container of any one of claims 14-18, or the kit of claim 19 in the manufacture of a medicament for the treatment of cancer in a subject in need thereof.

Claim 21. The use of claim 20, wherein said use comprises:

- a) diluting the pharmaceutical composition in a container comprising 0.9% sodium chloride or D5W, to obtain a dosing solution, wherein the container is an IV bag or a syringe;
- b) inverting the container to mix the diluted solution; and
- c) attaching the container containing the dosing solution to a device for administration to said subject.

Claim 22. The use of any one of claims 20-21, wherein said dosing solution maintains monomeric purity of said enoblituzumab for about 6 hours at about 25°C or for about 24 hours at about 2°C to about 8°C.

Claim 23. The use of any one of claims 20-22, wherein the medicament is to be administered by IV infusion for at least about 30 minutes.

- Claim 24. The use of any one of claims 20-23, wherein said pharmaceutical composition is diluted to obtain a weight-based treatment dose of about 6 mg/kg to about 15 mg/kg.
- Claim 25. The use of any one of claims 21-24, wherein said administration of the dosing solution is once every 3 weeks.
- Claim 26. The use of any one of claims 20-25, wherein said cancer expresses B7-H3.
- Claim 27. The use of any one of claims 20-26, wherein said 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, 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, POLE exonuclease domain mutation positive endometrial cancer, Ewing's sarcoma, extraskeletal myxoid chondrosarcoma, gallbladder cancer, bile duct cancer, cholangiocarcinoma bile duct cancer, gastric cancer, gastroesophageal junction (GEJ) cancer, gestational trophoblastic disease, germ cell tumor, 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, 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, Merkel cell carcinoma, 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), posterior uveal melanoma, renal metastatic cancer, rhabdoid tumor, rhabdomyosarcoma, sarcoma, skin cancer, 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 28. The use of any one of claims 26 or 27, wherein said cancer is anal cancer, bladder cancer, breast cancer, bile duct cancer, cervical cancer, colorectal cancer, endometrial cancer, gastric cancer, GEJ cancer, head and neck cancer, liver cancer, lung cancer, lymphoma, ovarian cancer, prostate cancer, skin cancer, and urothelial cancer.

Claim 29. The use of any one of claims 27 or 28, wherein said prostate cancer is mCRPC.