[0024] In another example, provided herein is a method of treating a disease or disorder in a subject comprising administering an effective amount of the formulation described herein to the subject, wherein the disease or disorder is selected from the group consisting of infection, cancer, and inflammatory disease.

[0024a] In one aspect, the present disclosure refers to use of a stable aqueous pharmaceutical formulation in the manufacture of a medicament for treating cancer in a subject, said formulation comprising an anti-PDL1 monoclonal antibody in a concentration of 40 mg/ml to 125 mg/ml, histidine acetate or sodium acetate in a concentration of 15 mM to 25 mM, sucrose in a concentration of 60 mM to 240 mM, polysorbate in a concentration of 0.005% (w/v) to 0.06% (w/v), and pH 5.0 to 6.3, wherein said monoclonal antibody comprises:

a light chain variable region comprising the amino acid sequence of SEQ ID NO:7,

a heavy chain variable region comprising the amino acid sequence of SEQ ID NO:32,

wherein said monoclonal antibody is an IgG1, an IgG2, an IgG3 or an IgG4 antibody, and

wherein the cancer is selected from the group consisting of a solid tumor, a hematologic cancer, bladder cancer, brain cancer, breast cancer, colon cancer, colorectal cancer, gastric cancer, glioma, head cancer, leukemia, liver cancer, lung cancer, lymphoma, myeloma, neck cancer, ovarian cancer, melanoma, pancreatic cancer, renal cancer, salivary cancer, stomach cancer, thymic epithelial cancer, thyroid cancer, and squamous cell carcinoma of the head and neck.

[0025] It is to be understood that one, some, or all of the properties of the various examples described herein may be combined to form other examples of the present disclosure. These and other aspects of the disclosure will become apparent to one of skill in the art. These and other examples of the disclosure are further described by the detailed description that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] **FIG. 1** is a series of graphs showing statistical analysis of stability data of α-PDL1 formulations at 40°C by ICIEF using JMP software. **A)** Average main peak rate loss from fractional factorial design of experiments (DOE). **B)** Main peak analysis from fractional factorial DOE. Main peak contains α-PDL1 charged species with the same pH as the pI (isoelectric point) of the molecule.

[0027] **FIG. 2** is a series of graphs showing statistical analysis of stability data of α-PDL1 formulations at 25°C by ICIEF using JMP software. **A)** Average main peak rate loss from fractional factorial design of experiments (DOE). **B)** Main peak analysis from fractional factorial DOE. Main peak contains α-PDL1 charged species with the same pH as the pI (isoelectric point) of the molecule.

[0028] **FIG. 3** is a series of graphs showing statistical analysis of stability data of α-PDL1 formulations at 40°C by SE-HPLC using JMP software. **A)** Average main peak rate loss from fractional factorial design of experiments (DOE). **B)** Main peak analysis from fractional factorial DOE. Main peak contains α-PDL1 monomer.

[0029] **FIG. 4** is a series of graphs showing statistical analysis of stability data of α-PDL1 formulations at 25°C by SE-HPLC using JMP software. **A)** Average main peak rate loss from fractional factorial design of experiments (DOE). **B)** Main peak analysis from fractional factorial DOE. Main peak contains α-PDL1 monomer.

[0030] **FIG. 5** is a graph showing lack of significant PS20 degradation of various α-PDL1 formulations stored at various temperatures and time. Graph of percent (%) PS20 remaining in the formulation as detected by evaporative light scattering detector (ELSD) in F1 through

CLAIMS

WHAT IS CLAIMED IS:

1. Use of a stable aqueous pharmaceutical formulation in the manufacture of a medicament for treating cancer in a subject, said formulation comprising an anti-PDL1 monoclonal antibody in a concentration of 40 mg/ml to 125 mg/ml, histidine acetate or sodium acetate in a concentration of 15 mM to 25 mM, sucrose in a concentration of 60 mM to 240 mM, polysorbate in a concentration of 0.005% (w/v) to 0.06% (w/v), and pH 5.0 to 6.3, wherein said monoclonal antibody comprises:

a light chain variable region comprising the amino acid sequence of SEQ ID NO:7,

a heavy chain variable region comprising the amino acid sequence of SEQ ID NO:32,

wherein said monoclonal antibody is an IgG1, an IgG2, an IgG3 or an IgG4 antibody, and

wherein the cancer is selected from the group consisting of a solid tumor, a hematologic cancer, bladder cancer, brain cancer, breast cancer, colon cancer, colorectal cancer, gastric cancer, glioma, head cancer, leukemia, liver cancer, lung cancer, lymphoma, myeloma, neck cancer, ovarian cancer, melanoma, pancreatic cancer, renal cancer, salivary cancer, stomach cancer, thymic epithelial cancer, thyroid cancer, and squamous cell carcinoma of the head and neck.

2. The use of claim 1, wherein said monoclonal antibody is in a concentration of 60 mg/ml, sucrose is in a concentration of 120 mM, and pH is 5.8.

3. The use of claim 1, wherein said monoclonal antibody is in a concentration of 125 mg/ml, sucrose is in a concentration of 240 mM, and pH is 5.5.

4. The use of any one of claims 1-3, wherein said monoclonal antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO:9, and a heavy chain comprising the amino acid sequence of SEQ ID NO:10.

5. The use of claim 1, wherein said monoclonal antibody is in a concentration of 60 mg/mL, said histidine acetate is in a concentration of 20 mM, said sucrose is in a concentration of 120 mM,

and said polysorbate is polysorbate 20 in a concentration of 0.04% (w/v), and said formulation has a pH of 5.8.

6. The use of claim 5, wherein said monoclonal antibody comprises a light chain variable region comprising the amino acid sequence of SEQ ID NO:7, and a heavy chain variable region comprising the amino acid sequence of SEQ ID NO:32.

7. The use of claim 5, wherein said monoclonal antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO:9, and a heavy chain comprising the amino acid sequence of SEQ ID NO:10.

8. The use of claim 1, wherein said monoclonal antibody is in a concentration of 125 mg/mL, said histidine acetate is in a concentration of 20 mM, said sucrose is in a concentration of 240 mM, and said polysorbate is polysorbate 20 in a concentration of 0.02%, and said formulation has a pH of 5.5.

9. The use of claim 8, wherein said monoclonal antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO:9, and a heavy chain comprising the amino acid sequence of SEQ ID NO:10.

10. The use of any one of claims 1-3, 5-6, and 8, wherein said monoclonal antibody is a humanized antibody.

11. The use of any one of claims 1-3, 5-6, 8, and 10, wherein said monoclonal antibody comprises a N297A or D265A/N297A substitution in the constant region, wherein numbering of the residue is that of the EU index as in Kabat.

12. The use of any one of claims 1-11, wherein the formulation is for intravenous (IV) administration.

13. The use of any one of claims 1-12, wherein the cancer is locally advanced or metastatic.

14. The use of any one of claims 1-13, wherein the cancer is bladder cancer.

15. The use of any one of claims 1-13, wherein the cancer is lung cancer.

16. The use of claim 15, wherein the lung is non-small cell lung cancer.

17. The use of any one of claims 1-13, wherein the cancer is breast cancer.

18. The use of any one of claims 1-17, wherein the subject has PDL1 positive cancer.

19. The use of any one of claims 1-18, wherein the formulation is to be administered in conjunction with another therapeutic agent to the subject.

20. The use of claim 19, wherein the therapeutic agent is a chemotherapeutic agent or an antibody treatment.