CLAIMS

What is claimed is:

1. A pharmaceutical composition comprising Pralatrexate or a pharmaceutically acceptable salt, hydrate or ester thereof and a pharmaceutically acceptable excipient, wherein the pharmaceutical composition is formulated for subcutaneous administration.

2. The pharmaceutical composition of claim 1 comprising at least about 30 mg/ml of Pralatrexate and/or at most about 100 mg/ml Pralatrexate.

3. The pharmaceutical composition of claims 1 or 2, wherein the composition comprises from about 30 mg/ml to 90 mg/ml Pralatrexate, from about 30 mg/ml to about 80 mg/ml Pralatrexate, from about 30 mg/ml to about 70 mg/ml Pralatrexate, from about 35 mg/ml to 90 mg/ml Pralatrexate, from about 35 mg/ml to about 80 mg/ml Pralatrexate, from about 35 mg/ml to about 70 mg/ml Pralatrexate, from about 40 mg/ml to 90 mg/ml Pralatrexate, from about 40 mg/ml to about 80 mg/ml Pralatrexate, or from about 40 mg/ml to about 70 mg/ml Pralatrexate.

4. The pharmaceutical composition of any one of claims 1 to 3, wherein the composition comprises about 40 mg/ml Pralatrexate, about 50 mg/ml Pralatrexate, about 60 mg/ml Pralatrexate, about 70 mg/ml Pralatrexate, or about 80 mg/ml Pralatrexate.

5. The pharmaceutical composition of any one of claims 1-4, wherein the pharmaceutically acceptable excipient comprises a pharmaceutically acceptable alkalizer and/or solubilizer and/or surfactant and/or osmogen and/or one or more of a buffer, a pH stabilizer, an isotonicity agent, an antioxidant, a preservative, a solubility-enhancing agent, and a viscosity-enhancing agent.

6. The pharmaceutical composition of any one of claims 1-5, wherein the pharmaceutical composition includes an alkalizer and the alkalizer comprises lithium hydroxide, sodium hydroxide, potassium hydroxide or calcium hydroxide and/or wherein the pharmaceutical composition comprises a solubilizer and the solubilizer comprises one or more of propylene glycol, polyethylene glycol 300/400, glycerin, ethanol, polysorbate 80, Cremophor EL, N-methyl-2-pyrrolidone (NMP), or meglumine; and/or wherein the

pharmaceutical composition comprises a surfactant and the surfactant comprises Tween 80 or meglumine; and/or the pharmaceutical composition comprises an osmogen, and the osmogen comprises one or more of potassium chloride, sodium chloride, or mannitol.

7. The pharmaceutical composition of any one of claims 1-6, wherein the composition has an osmolarity of between about 250 mOsm to about 350 mOsm.

8. The pharmaceutical composition of any one of claims 1-7, wherein the composition has greater bioavailability of pralatrexate when administered to a subject as compared to an intravenous formulation of Pralatrexate.

9. The pharmaceutical composition of any one of claims 1-8, wherein a single dose subcutaneous administration of the composition to a subject provides at least one of:

a) a C_{max} of from 60 to 120 ng/mL,

b) an $AUC_{0\rightarrow\tau}$ of from 150 to 270 hr*ng/mL,

c) an $AUC_{0\rightarrow 24}$ of from 180 to 300 hr*ng/mL,

d) an $AUC_{0\rightarrow inf}$ of from 150 to 400 hr*ng/mL,

e) a T_{max} of from 0.5-1.5 hr,

f), a K_{el} of from 0.2-0.4 1/hr,

g) a $t_{1/2}$ of from 1.3-6.6 hr, and

h) a mean subcutaneous absolute bioavailability of from 1.7-2.1.

10. The pharmaceutical composition according to any one of claims 1-9, wherein said pharmaceutical composition comprises:

a) from about 30 mg/ml to about 110 mg/ml Pralatrexate;

b) a pH adjuster;

c) optionally from about 5 mg/ml to about 20 mg/ml alkalizer,

d) optionally from about 5 mg/ml to about 35 mg/ml buffer;

e) optionally from about 0.2 mg/ml to about 10 mg/ml osmogene or from about 6 to about 10 mg/ml non-inorganic salt osmogene; and

f) optionally from about 40 mg/ml to about 110 mg/ml surfactant.

11. The pharmaceutical composition according to any one of claims 1-10, wherein said pharmaceutical composition comprises:

a) from about 30 mg/ml to about 110 mg/ml Pralatrexate;

b) hydrochloric acid;

c) optionally from about 5 mg/ml to about 20 mg/ml sodium hydroxide,

d) optionally from about 5 mg/ml to about 35 mg/ml sodium bicarbonate, potassium dihydrogen phosphate, or a combination thereof;

e) optionally from about 0.2 mg/ml to about 10 mg/ml osmogen selected from sodium chloride, potassium chloride, mannitol or from about 6 to about 10 mg/ml mannitol; and

f) optionally from about 40 mg/ml to about 110 mg/ml surfactant of a surfactant selected from meglumine and Tween 80.

12. Use of the pharmaceutical composition according to any one of claims 1 to 11 in the manufacture of a medicament for the treatment of lymphoma in a subject in need thereof, wherein the pharmaceutical composition is to be administered subcutaneously to the subject.

13. The use according to claim 12, wherein the lymphoma is peripheral T-cell lymphoma (PTCL).

14. The use according to any one of claims 12-13, wherein the pharmaceutical composition is to be administered weekly and/or weekly for two weeks in a 21-day administration cycle.

15. The use according to any one of claims 12-14, wherein the subject is to be administered from about 10 mg/m^2 to 40 mg/m^2 Pralatrexate.