Claims

1. A liposomal pharmaceutical preparation of mitoxantrone for use in a method for treating lymphoma~~, comprising administering to~~ in a subject in need thereof ~~a liposomal pharmaceutical preparation of mitoxantrone~~, wherein: the liposomal pharmaceutical preparation of mitoxantrone comprises mitoxantrone liposomes,

the mitoxantrone liposomes have a particle size of about 30-80 nm, and comprise mitoxantrone as an active ingredient, wherein mitoxantrone and the multivalent counter ion within the liposomes form a poorly soluble precipitate, the phospholipid bilayer of the liposomes comprises a phospholipid with a phase transition temperature (Tm) higher than body temperature, so that the phase transition temperature of liposomes is higher than the body temperature;

~~the lymphoma is preferably non-Hodgkin's lymphoma, further preferably aggressive non-Hodgkin's lymphoma, more preferably diffuse large B-cell lymphoma or peripheral T-cell lymphoma, and more further preferably relapsed or refractory diffuse large B-cell lymphoma or peripheral T-cell lymphoma; for example, the peripheral T-cell lymphoma is selected from non-specific peripheral T-cell lymphoma, angioimmunoblastic T-cell lymphoma, ALK+ systemic anaplastic large T-cell lymphoma, ALK-systemic anaplastic large T-cell lymphoma, extranodal NK/T-cell lymphoma, nasal-type, enteropathy-associated T-cell lymphoma, primary hepatosplenic γδ T-cell lymphoma, and subcutaneous panniculitis-like T-cell lymphoma.~~

the lymphoma is diffuse large B-cell lymphoma or peripheral T-cell lymphoma.

2. The ~~method of~~ liposomal pharmaceutical preparation of mitoxantrone for use according to claim 1, wherein the phospholipid with a Tm higher than body temperature is selected from phosphatidylcholine, hydrogenated soybean phosphatidylcholine, hydrogenated egg yolk phosphatidylcholine, dipalmitoyl phosphatidylcholine, distearoyl phosphatidylcholine and any combination thereof; and/or the liposomes have a particle size of about 35-75 nm, preferably 40-70 nm, further preferably 40-60 nm, particularly preferably 60 nm.

3. The ~~method of~~ liposomal pharmaceutical preparation of mitoxantrone for use according to claim 1 or 2, wherein the phospholipid bilayer contains hydrogenated soybean phosphatidylcholine, cholesterol, and polyethylene glycol 2000-modified distearoylphosphatidylethanolamine at a mass ratio of 3:1:1, and/or the liposomes have a particle size of about 60 nm, and/or the counter ion is sulfate ion.

4. The ~~method of~~ liposomal pharmaceutical preparation of mitoxantrone for use according to any one of claims 1 to 3, wherein the liposomal pharmaceutical preparation of mitoxantrone is administered as a single anti-tumor therapeutic agent without being combined with other anti-tumor agents.

5. The ~~method of~~ liposomal pharmaceutical preparation of mitoxantrone for use according to any one of claims 1 to 4, wherein the subject at least has received a first-line treatment, for example, the subject has diffuse large B-cell lymphoma and at least has received a first-line and/or second-line treatment, or for example the subject has peripheral T-cell lymphoma and at least has received a first-line treatment.

6. The ~~method of~~ liposomal pharmaceutical preparation of mitoxantrone for use according to any one of claims 1 to 5, wherein the liposomal pharmaceutical preparation of mitoxantrone is administered once per 1, 2, 3, 4, 5, 6, 7 or 8 weeks, preferably once per 3-6 weeks, further preferably once per 4 weeks; and/or

the liposomal pharmaceutical preparation of mitoxantrone is administered to the subject 1, 2, 3, 4, 5 or 6 times, for example 2, 3, 4 or 5 times; and/or the liposomal pharmaceutical preparation of mitoxantrone is administrated to the subject at a dosage of 6-30 mg/m^2, for example 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28 or 30 mg/m^2, preferably 14-24 mg/m^2.

7. The ~~method of~~ liposomal pharmaceutical preparation of mitoxantrone for use according to any one of claims 1 to 6, wherein the liposomal pharmaceutical preparation is administered to the subject via intravenous drip, and the administration period via drip is not less than 30, 40, 45, 50, 60, 70, 75, 80, 90, 100, 110 or 120 min, preferably 40-80 min, more preferably 60 min.

8. The ~~method of~~ liposomal pharmaceutical preparation of mitoxantrone for use according to any one of claims 1 to 7, wherein the total dosage of the liposomal pharmaceutical preparation administered to the subject is not more than 200 mg/m^2, for example not more than 120, 140, 160, 180 or 200 mg/m^2, preferably not more than 160 mg/m^2, and further preferably not more than 140 mg/m^2.

9. The ~~method of~~ liposomal pharmaceutical preparation of mitoxantrone for use according to any one of claims 1 to 8, wherein the route of administration is selected from oral administration, injection administration and local administration, preferably injection administration; further, the injection administration is selected from intravenous injection, subcutaneous injection and intramuscular injection, preferably intravenous injection; further, the intravenous injection is selected from intravenous drip and intravenous bolus injection, preferably intravenous drip.

10. The ~~method of~~ liposomal pharmaceutical preparation of mitoxantrone for use according to any one of claims 1 to 9, wherein the route of administration is intravenous drip, and the method comprises dissolving the mitoxantrone liposomes in sodium chloride injection or glucose injection, preferably in glucose injection, and then administering to the subject; wherein the concentration of sodium chloride injection is 0.5%-1%, preferably 0.9%; the concentration of glucose injection is 1%- 10%, preferably 5%.

11. The ~~method~~ liposomal pharmaceutical preparation of mitoxantrone for use according to any one of claims 1 to 10, ~~comprising~~wherein the method comprises formulating the mitoxantrone liposomes into a solution that can be directly infused before administering to the subject, wherein the concentration of the formulated solution of liposomes that can be directly infused is 0.05 mg/ml - 0.5 mg/ml, preferably 0.08 mg/ml - 0.4 mg/ml, more preferably 0.1 mg/ml - 0.3 mg/ml, more preferably 0.1 mg/ml, 0.15 mg/ml, 0.2 mg/ml, 0.25 mg/ml or 0.3 mg/ml.

12. The ~~method~~ liposomal pharmaceutical preparation of mitoxantrone for use according to any one of claims 1 to 11, ~~comprising~~wherein the method comprises administering to the subject the liposomal pharmaceutical preparation

of mitoxantrone 3 or more times for treatment, and the method achieves a higher overall remission rate (ORR) than the HDAC inhibitor used alone.

13. The ~~method~~liposomal pharmaceutical preparation of mitoxantrone for use according to claim 12, wherein the method comprises administering to the subject the liposomal pharmaceutical preparation of mitoxantrone 3 or more times for treatment, and the overall remission rate (ORR) of the method is at least 30%, preferably at least 40%; further, the overall remission rate is 30%-60%.