Claims

1. A proliposomal powder dispersion formulated for intravesical administration, consisting of
    A. paclitaxel,
    B. dimyristoyl phosphatidylcholine (DMPC), and
    C. dimyrsitoyl phosphatidyl glycerol sodium (DMPG)

    wherein the weight/weight (w/w) ratios (A) : (B) : (C) are (1) : (1-2) : (0.2-0.7).

2. The proliposomal powder dispersion according to claim 1, wherein the (w/w) ratios (A) : (B) : (C) are (1) : (1.4) : (0.6).

3. A composition, comprising an admixture of a proliposomal powder dispersion according to claim 1, and at least one pharmaceutically acceptable excipient.

4. The composition according to claim 3, wherein the at least one pharmaceutically acceptable excipient is mannitol.

5. The composition according to claim 4, wherein the w/w ratio of the (proliposomal powder dispersion) : (mannitol) is (1) : (0.15-0.8).

6. Use of a hydrated form of the proliposomal powder dispersion according to claim 1, in the manufacture of a medicament for the treatment of bladder cancer or an upper tract urothelial carcinoma (UTUC) in a patient, whereby the medicament is to be introduced into the patient *via* intravesical administration.

7. The use according to claim 6, wherein bladder cancer is treated, and the bladder cancer is a non-muscle invasive bladder cancer.

8. The use according to claim 6, wherein the paclitaxel does not precipitate in the bladder at pH from 4.5-8.

9. The use according to claim 6, wherein UTUC is treated, and intravesical administration comprises delivery of the hydrated dispersion into the ureter or renal pelvis, or both.

10. A method of preparing a liposomal paclitaxel formulation for intravesical administration comprising the steps of:

(i) dispersing a first lipid and a second lipid in an aqueous vehicle by stirring, mixing, and/or homogenizing to form a dispersion;

(ii) adding paclitaxel to the dispersion of the first lipid and the second lipid;

(iii) homogenizing the dispersion of the first lipid, the second lipid, and the paclitaxel to obtain liposomes that incorporate the paclitaxel;

(iv) homogenizing the liposomes to obtain nanosized liposomal particles in the dispersion; and

(v) adding a lyoprotectant or cryoprotectant

wherein the first and second lipids are DMPC and DMPG and the weight/weight (w/w) ratios of paclitaxel: DMPC:DMPG are 1:1-2:0.2-0.7.

11. The method according to claim 10, wherein the method further comprises step

(vi) lyophilizing the dispersion to form a proliposomal powder dispersion.

12. The method of claim 10, wherein step (iii) is performed at a high pressure, or at a temperature higher than the Tc/Tg of the lipids, or both.

13. The composition according to claim 5, wherein the (w/w) ratios (A) : (B) : (C) are (1) : (1.4) : (0.6).

14. A liposomal suspension comprising a composition according to claim 13, wherein the composition is hydrated in sterile water or a pharmaceutically-acceptable aqueous solution.

15. The proliposomal powder dispersion according to claim 1, wherein the (w/w) ratios (A) : (B) : (C) are (1) : (1.43) : (0.57).

16. The composition according to claim 5, wherein the (w/w) ratios (A) : (B) : (C) are (1) : (1.43) : (0.57).

17. A hydrated form of the proliposomal powder dispersion according to claim 1, for use in the treatment of bladder cancer or an upper tract urothelial carcinoma (UTUC) in a patient *via* intravesical administration.