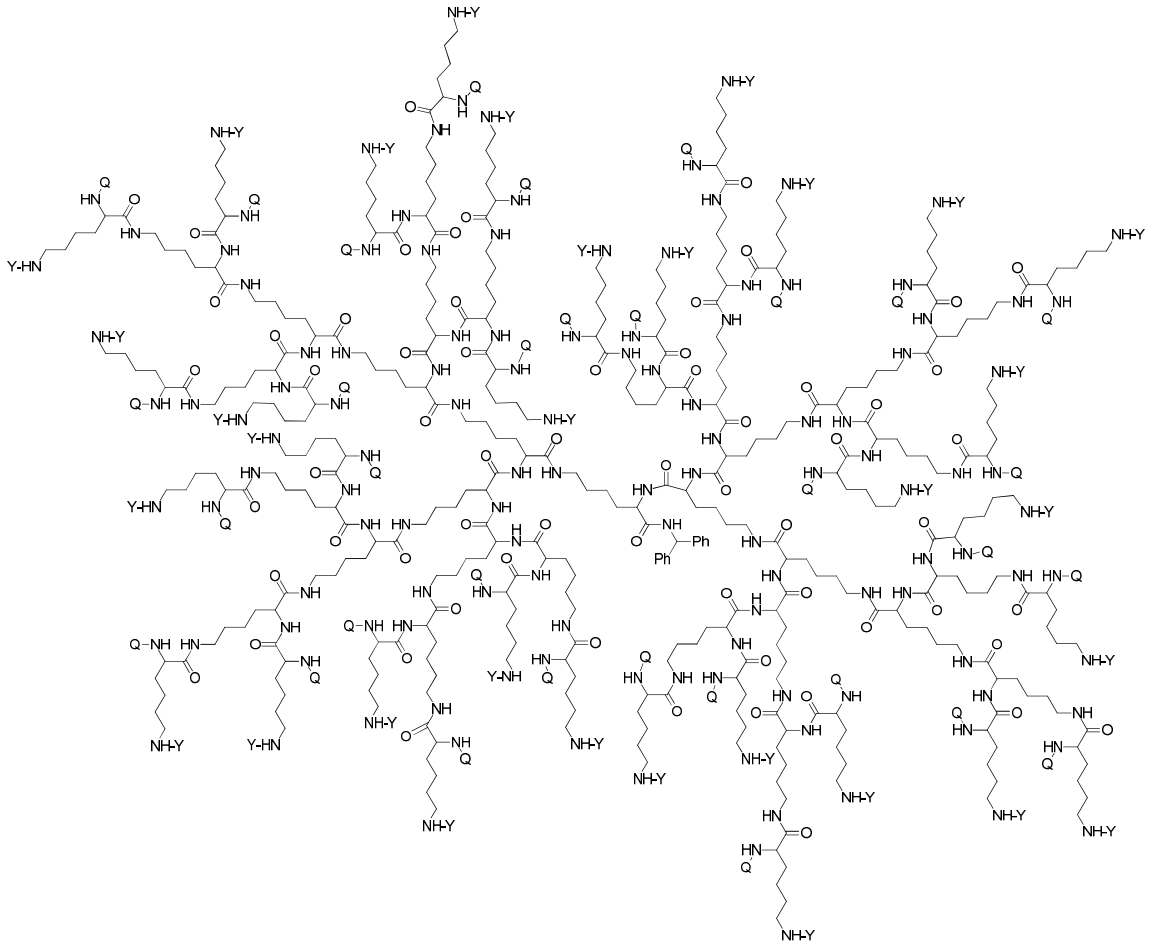
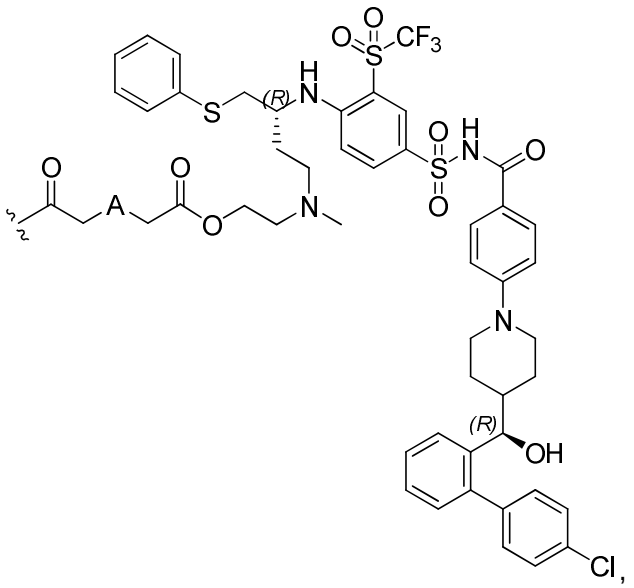
CLAIMS

1. A pharmaceutical composition comprising a lyophilized dendrimer of formula (IV):



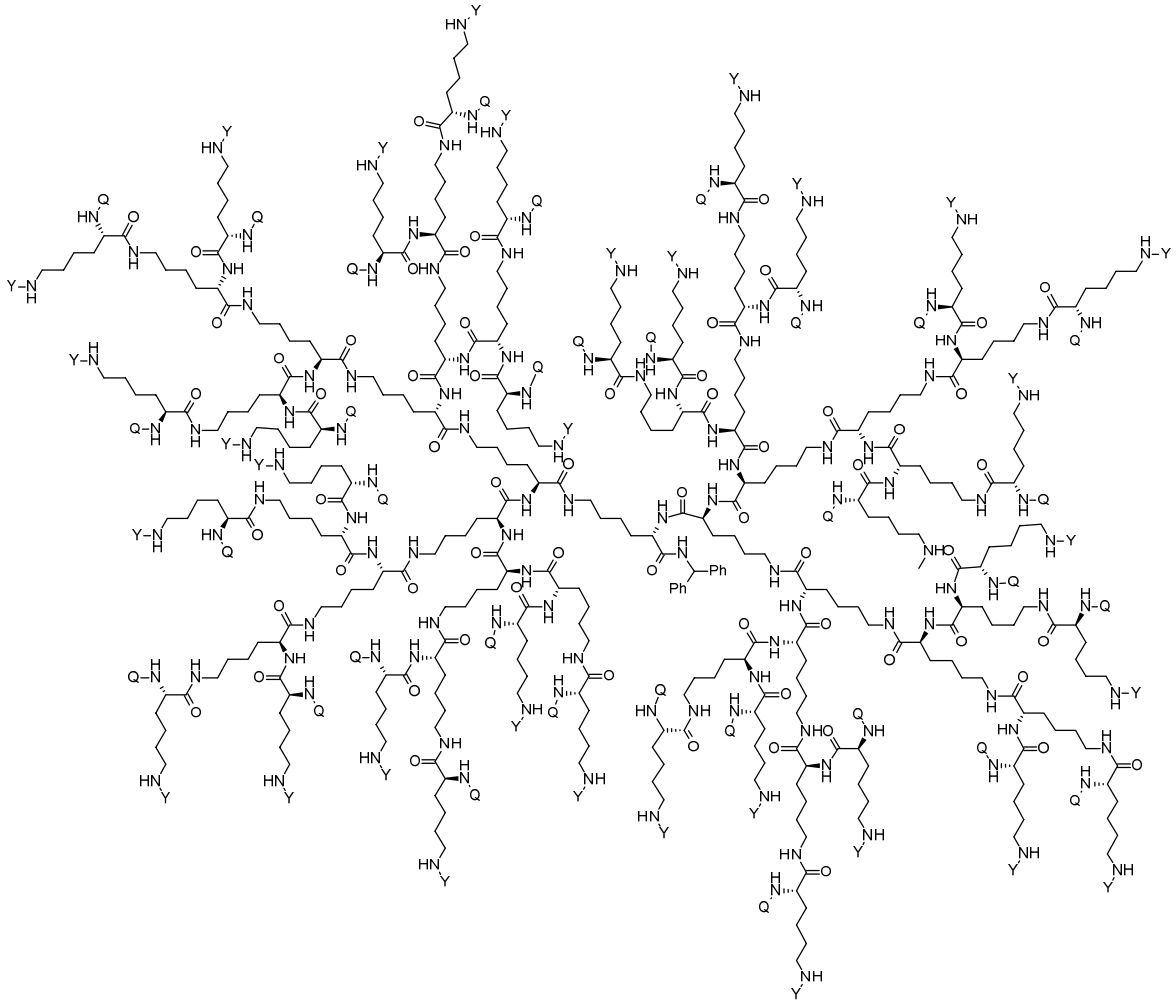
(IV),

or a pharmaceutically acceptable salt thereof, wherein Y is $PEG_{1800-2400}$ or H; Q is H or L-AA, in which L-AA has the structure:



A is –S- or –N(CH_3), provided that if the sum of $PEG_{1800\text{-}2400}$ and L-AA is less than 64, the remaining Q and Y moieties are H, and provided that at least one Q is L-AA.

2. A pharmaceutical composition comprising a lyophilized dendrimer of formula (V):

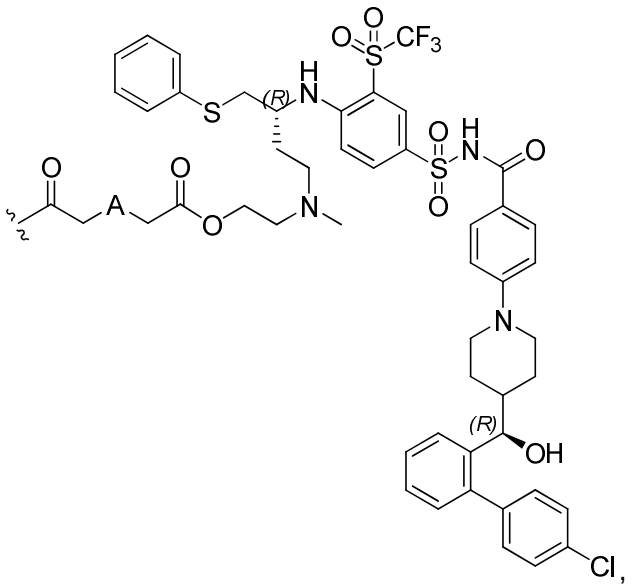


(V)

or a pharmaceutically acceptable salt thereof, wherein

Y is $PEG_{1800-2400}$ or H;

Q is H or L-AA, wherein L-AA has the structure:



A is –S- or –N(CH_3), provided that if the sum of $PEG_{1800-2400}$ and L-AA is less than 64, the remaining Q and Y moieties are H, and provided that at least one Q is L-AA.

3. The pharmaceutical composition of claim 1 or 2, wherein A is –N(CH_3).

4. The pharmaceutical composition of any one of claims 1-3, wherein the sum of $PEG_{1800-2400}$ and L-AA is an integer between 50 and 64; or an integer between 58 and 64.

5. The pharmaceutical composition of any one of claims 1-4, wherein the dendrimer has between 25 and 32 $PEG_{1800-2400}$; or between 29 and 32 $PEG_{1800-2400}$.

6. The pharmaceutical composition of any one of claims 1-5, wherein the dendrimer has between 25 and 32 L-AA; or between 29 and 32 L-AA.

7. The pharmaceutical composition of any one of claims 1-6, wherein the dendrimer has between 0 and 14 hydrogens at the Q and/or Y positions; or between 0 and 6 hydrogens at the Q and/or Y positions.

8. The pharmaceutical composition of any one of claims 1-7, wherein the PEG has an average molecular weight of between about 2000 and 2200 Da.

9. The pharmaceutical composition of any one of claims 1-8, wherein the PEG has a PDI of between about 1.00 and 1.10; or a PDI of about 1.05.

10. The pharmaceutical composition of any one of claims 1-9, wherein the dendrimer has a molecular weight of between about 90 and 120 kDa; or a molecular weight of between about 103 and 107 kDa.

11. The pharmaceutical composition of any one of claims 1-10, wherein the pH of the pharmaceutical composition is between about 4.0 and about 6.0; or between about 4.8 to about 5.6.

12. The pharmaceutical composition of any one of claims 1-11, wherein the pharmaceutical composition comprises between about 90-110% of the dendrimer of formula (I), (II), (III), (IV) or (V), when assayed against a reference standard of known purity.

13. The pharmaceutical composition of any one of claims 1-12, wherein the purity of the pharmaceutical composition is not less than 85% as measured by SEC-UV.

14. The pharmaceutical composition of any one of claims 1-13, wherein the pharmaceutical composition comprises less than about 3% w/w total impurities; or comprises ≤1.0% w/w free Compound A; or comprises ≤0.5% w/w any single unspecified impurity; or comprises ≤1.2% w/w total free impurities; or comprises not more than 1.5% w/w acetic acid.

15. The pharmaceutical composition of any one of claims 1-14, wherein the pharmaceutical composition has an average particle size determined by DLS of between about 15 and about 25 d.nm; or an a PDI as determined by DLS of between about 0.20 and about 0.30.

16. The pharmaceutical composition of any one of claims 1-15, wherein the pharmaceutical composition comprises not more than about 6000 particulates of greater than or equal to about 10 μm per 50 mL container upon reconstitution in a pharmaceutically acceptable diluent or solvent; not more than about 600 particulates of greater than or equal to about 25 μm per 50 mL container upon reconstitution in a pharmaceutically acceptable diluent or solvent.

17. The pharmaceutical composition of any one of claims 1-16, wherein the osmolality of the pharmaceutical composition is between about 200 and about 400 mOsmol/kg upon reconstitution in a pharmaceutically acceptable diluent or solvent.

18. A pharmaceutical composition comprising a lyophilized compound of formula (IV) or (V) prepared by the process comprising the steps of dissolving the compound of formula (IV) or (V) in glacial acetic acid to form a solution, freeze drying the solution and subliming the acetic acid at reduced pressure.

19. A pharmaceutical composition of any one of claims 1-18 for use in treating cancer.

20. Use of a pharmaceutical composition of any one of claims 1-18 in the manufacture of a medicament for treating cancer.