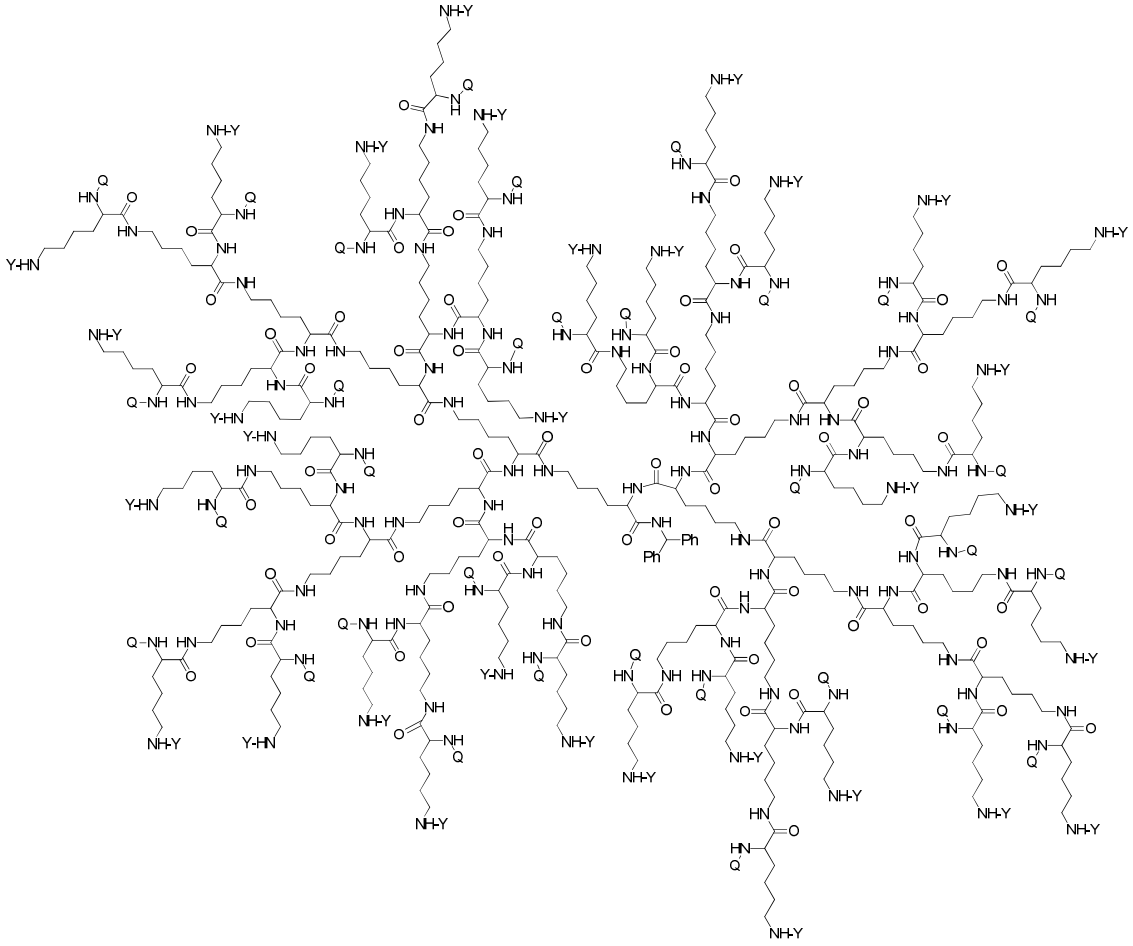
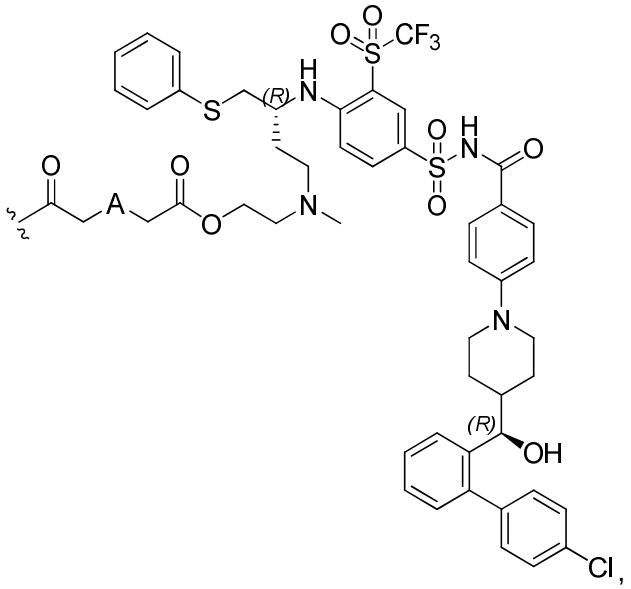
Claims

1. Use of a 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:

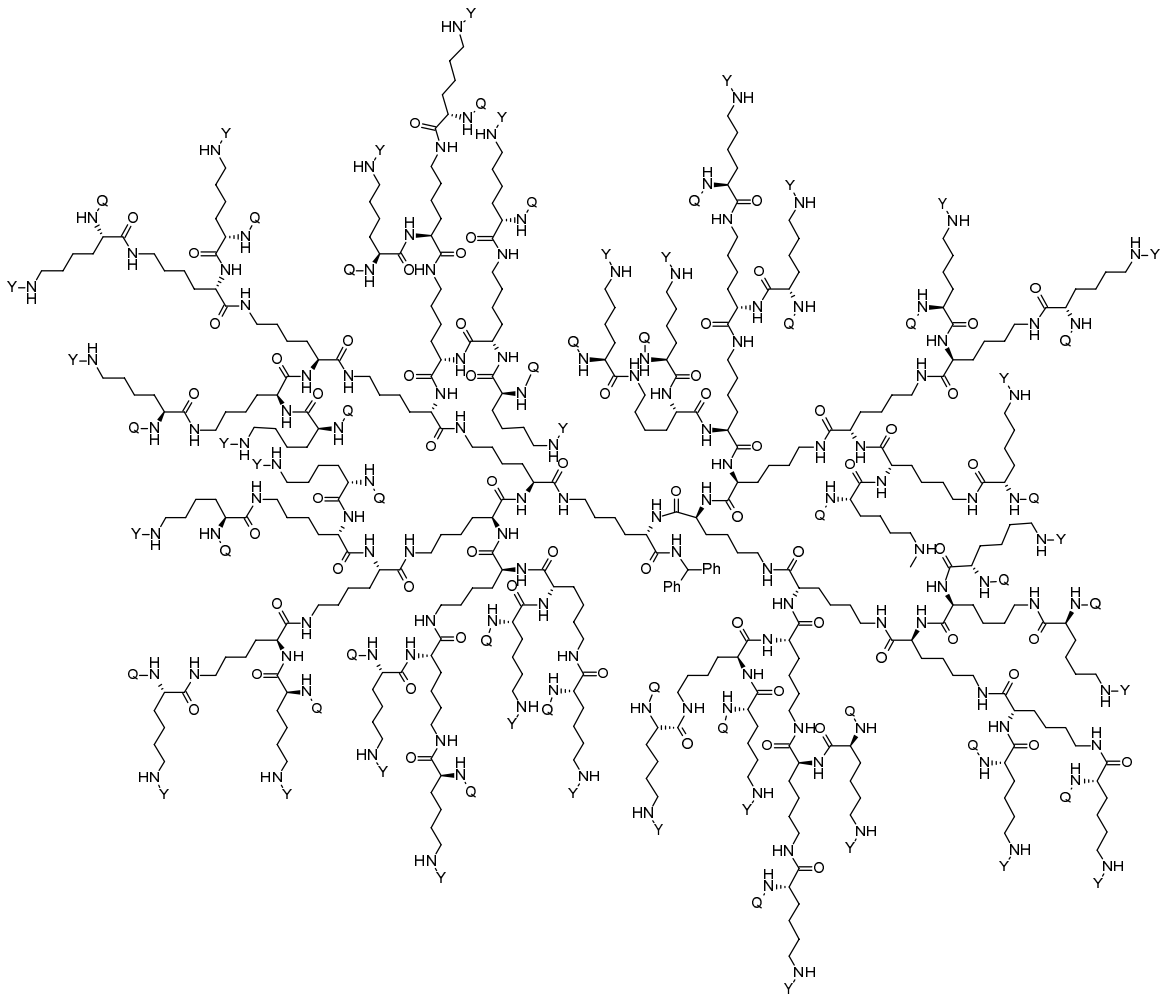


A is–N(CH_3), provided that if the sum of $PEG_{1800-2400}$ and L-AA is less than 64, the remaining Q and Y moieties are H, and provided that at least one Q is L-AA;

in the manufacture of a medicament for the treatment of cancer related to Bcl-2 and/or Bcl-XL;

wherein the cancer is a hematological or solid malignancy selected from lymphomas, leukemia, acute lymphoblastic lymphoma (ALL), acute myelogenous leukemia (AML), chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), chronic myelogenous leukemia (CML), acute monocytic leukemia (AMoL), multiple myeloma, mantle cell lymphoma, diffuse large B cell lymphoma (DLBCL), Burkitt's lymphoma, Non-Hodgkin's lymphoma, follicular lymphoma, non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), breast cancer, neuroblastoma, prostate cancer, melanoma, pancreatic cancer, uterine cancer, endometrial cancer, and colon cancer.

2. Use of a dendrimer of formula (V):

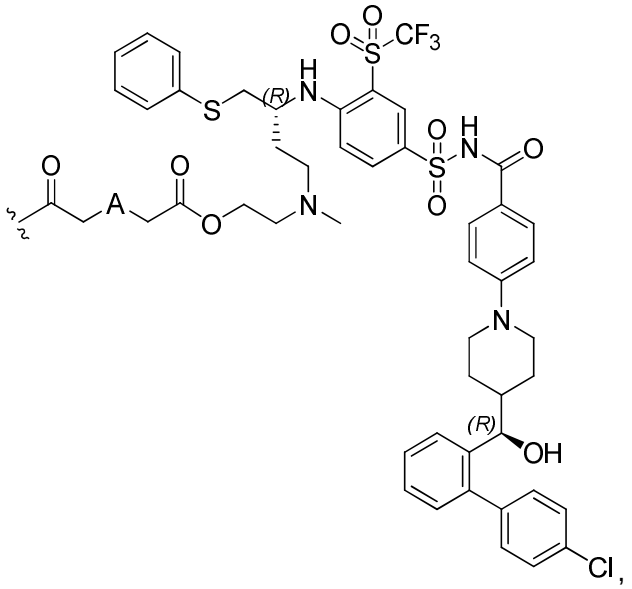


(V)

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 –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;

in the manufacture of a medicament for the treatment of cancer related to Bcl-2 and/or Bcl-XL;

wherein the cancer is a hematological or solid malignancy selected from lymphomas, leukemia, acute lymphoblastic lymphoma (ALL), acute myelogenous leukemia (AML), chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), chronic myelogenous leukemia (CML), acute monocytic leukemia (AMoL), multiple myeloma, mantle cell lymphoma, diffuse large B cell lymphoma (DLBCL), Burkitt's lymphoma, Non-Hodgkin's lymphoma, follicular lymphoma, non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), breast cancer, neuroblastoma, prostate cancer, melanoma, pancreatic cancer, uterine cancer, endometrial cancer, and colon cancer.

3. The use of claim 1 or 2, wherein the sum of $PEG_{1800-2400}$ and L-AA is an integer between 50 and 64.

4. The use of claim 3, wherein the sum of $PEG_{1800-2400}$ and L-AA is an integer between 58 and 64.

5. The use of any one of claims 2-4, wherein the dendrimer has between 25 and 32 $PEG_{1800-2400}$.

6. The use of claim 5, wherein the dendrimer has between 29 and 32 $PEG_{1800-2400}$.

7. The use of any one of claims 2-6, wherein the dendrimer has between 25 and 32 L-AA.

8. The use of claim 7, wherein the dendrimer has between 29 and 32 L-AA.

9. The use of any one of claim 2-8, wherein the dendrimer has between 0 and 14 hydrogens at the Q and/or Y positions.

10. The use of claim 9, wherein the dendrimer has between 0 and 6 hydrogens at the Q and/or Y positions.

11. The use of any one of claims 2-10, wherein the PEG has an average molecular weight of between about 2000 and 2200 Da.

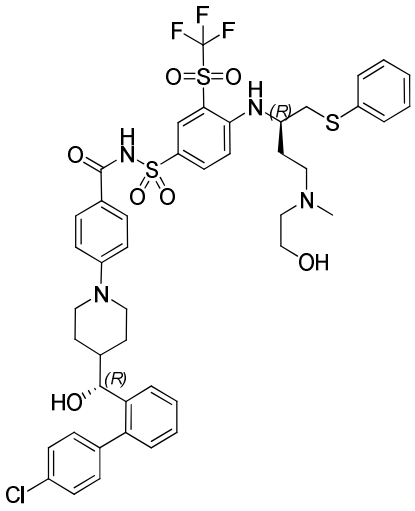
12. The use of any one of claims 1-11, wherein the PEG has a PDI of between about 1.00 and 1.10.

13. The use of claim 12, wherein the PEG has a PDI of about 1.05.

14. The use of any one of claims 1-13, wherein the dendrimer has a molecular weight of between about 90 and 120 kDa.

15. The use of claim 14, wherein the dendrimer has a molecular weight of between about 103 and 107 kDa.

16. The use of any one of claims 1-15, wherein AA is Compound A:



(Compound A).

17. The use of any one of claims 1-16, wherein the dendrimer is to be administered as a reconstituted lyophilized pharmaceutical composition.

18. The use of claim 17, wherein the lyophilized pharmaceutical composition is lyophilized from acetic acid.

19. The use of claim 17 or 18, wherein the pH of the pharmaceutical composition is between about 4.0 and about 6.0.

20. The use of claim 19, wherein the pH of the pharmaceutical composition is between about 4.8 to about 5.6.

21. The use of any one of claims 17-20, wherein the lyophilized 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.

22. The use of any one of claims 17-21, wherein the purity of the pharmaceutical composition is not less than 85% as measured by SEC-UV.

23. The use of any one of claims 17-22, wherein the pharmaceutical composition comprises less than about 3% w/w total impurities.

24. The use of claim 23, wherein the pharmaceutical composition comprises ≤1.0% w/w free Compound A.

25. The use of claim 24, wherein the pharmaceutical composition comprises ≤0.5% w/w any single unspecified impurity.

26. The use of claim 25, wherein the pharmaceutical composition comprises ≤1.2% w/w total free impurities.

27. The use of any one of claims 17-26, wherein the pharmaceutical composition comprises not more than about 1.5% w/w acetic acid.

28. The use of any one of claims 17-27, wherein the pharmaceutical composition has an average particle size determined by DLS of between about 15 and about 25 d.nm.

29. The use of any one of claims 17-28, wherein the pharmaceutical composition has an a PDI as determined by DLS of between about 0.20 and about 0.30.

30. The use of any one of claims 17-29, wherein the pharmaceutical composition comprises not more than about 6000 particulates of greater than or equal to about 10 μm per 50 mL container.

31. The use of any one of claims 17-30, wherein the pharmaceutical composition comprises not more than about 600 particulates of greater than or equal to about 25 μm per 50 mL container.

32. The use of any one of claims 17-31, wherein the osmolality of the pharmaceutical composition is between about 200 and about 400 mOsmol/kg.

33. The use of any one of claims 17-32, wherein the pharmaceutical composition is no more than about 0.06 EU/mg.

34. The use of any one of claims 17-33, wherein the pharmaceutical composition is prepared by the process comprising the steps of dissolving the compound of formula (I), (II),

(III), (IV) or (V) in glacial acetic acid to form a solution, freeze drying the solution and subliming the acetic acid at reduced pressure.

35. The use of any one of claim 17-34, wherein the lyophilized pharmaceutical composition is reconstituted in a pharmaceutically acceptable diluent selected from a citrate buffer or an acetate buffer.

36. The use of any one of claims 17-35, wherein the lyophilized pharmaceutical composition has an acetic acid not more than about 5%.

37. The use of claim 36, wherein the acetic acid has a water content of less than about 500 ppm.