CLAIMS

1. A pharmaceutical preparation comprising melphalan flufenamide, or a salt thereof, and γ-cyclodextrin or a pharmaceutically acceptable derivative of γ-cyclodextrin.

2. A pharmaceutical preparation according to Claim 1, in which the weight ratio (w/w) between the γ-cyclodextrin or a pharmaceutically acceptable derivative of γ-cyclodextrin and melphalan flufenamide is 1:1 to 100:1, 4:1 to 80:1, 5:1 to 25:1, or 10:1 to 25:1.

3. A pharmaceutical preparation according to Claim 1 or 2, in which the pharmaceutical preparation is a lyophilized powder.

4. A pharmaceutical preparation according to Claim 3, in which the pharmaceutical preparation comprises 1 mg to 30 mg melphalan flufenamide (excluding the mass of any counterion).

5. A pharmaceutical preparation according to Claim 4, comprising sucrose.

6. A pharmaceutical preparation according to Claim 5, in which the weight ratio (w/w) of sucrose to melphalan flufenamide is 25:1 to 75:1, for example 50:1.

7. A pharmaceutical preparation according to any preceding claim, which is substantially free from organic solvent.

8. A pharmaceutical preparation according to Claim 1 or 2, in which the pharmaceutical preparation is a liquid formulation comprising propylene glycol.

9. A pharmaceutical preparation according to Claim 8, in which the melphalan flufenamide, or salt thereof, is at a concentration of about 10 mg/mL to about 50 mg/mL (excluding the mass of any counterion).

10. A pharmaceutical preparation according to Claim 9, in which the melphalan flufenamide, or salt thereof, is at a concentration of about 15 mg/mL to about 25 mg/mL (excluding the mass of any counterion).

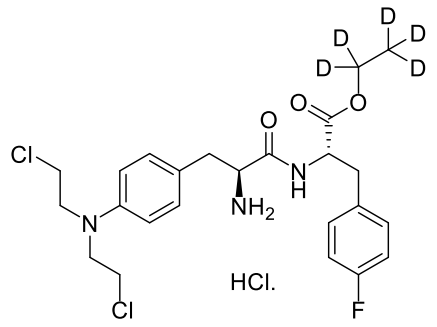
11. A pharmaceutical preparation according to any preceding claim, comprising one or more additional therapeutic agent(s) selected from the group consisting of a protease inhibitor (PI), an immunomodulatory drug (IMiD), an alkylator and a monoclonal antibody (for example an anti-CD38 antibody or an anti-SLAMF7 antibody).

12. A pharmaceutical preparation according to any of Claims 3 to 7, in which the pharmaceutical preparation consists essentially of melphalan flufenamide, or a salt thereof, γ-cyclodextrin or a pharmaceutically acceptable derivative of γ-cyclodextrin, and sucrose.

13. A pharmaceutical preparation according to Claim 8, 9 or 10, in which the pharmaceutical preparation consists essentially of melphalan flufenamide, or a salt thereof; γ-cyclodextrin or a pharmaceutically acceptable derivative of γ-cyclodextrin; and propylene glycol and/or PEG.

14. A pharmaceutical preparation according to any preceding claim, in which the melphalan flufenamide is in the form of its hydrochloride salt.

15. A pharmaceutical preparation according to any preceding claim, in which the melphalan flufenamide is deuterated melphalan flufenamide, preferably the deuterated melphalan flufenamide has the structure



16. A pharmaceutical preparation according to any preceding claim, in which the pharmaceutically acceptable derivative of γ-cyclodextrin is selected from the group consisting of hydroxypropyl-γ-cyclodextrin, succinyl-γ-cyclodextrin, sulfobutyl ether-γ-cyclodextrin, γ-cyclodextrin phosphate sodium salt, γ-cyclodextrin sulphate sodium salt, 2-carboxyethyl-γ-cyclodextrin, acetylated-γ-cyclodextrin, and sugammadex; and preferably in which the pharmaceutically acceptable derivative of γ-cyclodextrin is hydroxypropyl-γ-cyclodextrin.

17. A pharmaceutical preparation according to any preceding claim, in which the weight ratio (w/w) between the γ-cyclodextrin or a pharmaceutically acceptable derivative of γ-cyclodextrin and melphalan flufenamide is 15:1 to 25:1, for example 20:1 to 25:1.

18. A composition comprising a pharmaceutical preparation according to any preceding claim and a physiologically acceptable aqueous solvent or diluent.

19. A composition comprising melphalan flufenamide, or a salt thereof, γ-cyclodextrin or a pharmaceutically acceptable derivative of γ-cyclodextrin, and a physiologically acceptable aqueous solvent.

20. A composition according to Claim 18 or 19, in which the physiologically acceptable aqueous solvent is a glucose solution, a saline solution, or a mixture thereof.

21. A kit comprising a pharmaceutical preparation according to any of Claims 1 to 17 and a physiologically acceptable aqueous solvent or diluent.

22. A kit comprising melphalan flufenamide, or a salt(s) thereof, γCD or a pharmaceutically acceptable derivative of γ-cyclodextrin, and optionally one or more physiologically acceptable aqueous solvent or diluent.

23. A kit according to any preceding Claim 21, in which the melphalan flufenamide, or a salt(s) thereof, is provided as a lyophilised preparation comprising (or consisting essentially of) melphalan flufenamide and sucrose, or provided as a liquid pharmaceutical formulation comprising (or consisting essentially of) melphalan flufenamide and propylene glycol and/or polyethylene glycol.

24. A pharmaceutical preparation according to any of Claims 1 to 17, or a composition according to Claim 18, 19 or 20, or a kit according to Claim 21, 22 or 23, for use as a medicament.

25. A pharmaceutical preparation according to any of Claims 1 to 17, or a composition according to Claim 18, 19 or 20, or a kit according to Claim 21, 22 or 23, for use in treatment or prophylaxis of a disease or condition that may be treated with conventional chemotherapy agents, for example, with an alkylator (e.g. melphalan, cyclophosphamide and bendamustine).

26. A pharmaceutical preparation according to any of Claims 1 to 17, or a composition according to Claim 18, 19 or 20, or a kit according to Claim 21, 22 or 23, for use in the treatment or prophylaxis of cancer or for use in the treatment or prophylaxis of amyloidosis.

27. A pharmaceutical preparation according to any of Claims 1 to 17, or a composition according to Claim 18, 19 or 20, or a kit according to Claim 21, 22 or 23, for use in the treatment or prophylaxis of cancer, in which the cancer is selected from the group consisting

of multiple myeloma, breast cancer, lung cancer, ovarian cancer, glioblastoma, leukaemias and lymphomas.

28. Use of a pharmaceutical preparation according to any of Claims 1 to 17 or a composition according to Claim 18, 19 or 20 in the preparation of a medicament for the treatment of a patient, in which the pharmaceutical preparation or the composition is to be administered to a subject in need thereof.

29. Use of a pharmaceutical preparation according to any of Claims 1 to 17, or a composition according to Claim 18, 19 or 20 in the preparation of a medicament for the treatment or prophylaxis of cancer, in which the pharmaceutical preparation or composition is to be administered to a subject in need thereof.