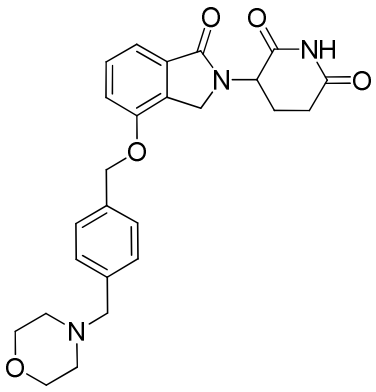
CLAIMS

What is claimed is:

1. Use of a compound in the manufacture of a medicament for treating or managing cancer, wherein (i) the compound is to be administered in combination with (ii) a proteasome inhibitor to a patient in need of such treatment or management, wherein the compound is Compound A



Compound A

or an enantiomer or mixture of enantiomers thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof; and wherein the compound is to be administered in an amount of about 1.0 mg, about 1.3 mg, or about 1.6 mg.

2. The use of claim 1, wherein the cancer is multiple myeloma.

3. The use of claim 2, wherein the multiple myeloma is relapsed or refractory multiple myeloma.

4. The use of any one of claims 1 to 3, wherein the patient has failed at least one prior therapy.

5. The use of claim 2, wherein the multiple myeloma is newly diagnosed.

6. The use of any one of claims 1 to 5, wherein the compound is to be
   (a) administered orally;
   (b) administered in an amount of about 1.0 mg per day; or
   (c) administered once daily for 21 days followed by 7 days of rest.

7. The use of any one of claims 1 to 6, wherein the proteasome inhibitor is bortezomib, or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof.

8. The use of claim 7, wherein the bortezomib or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be:

(a) administered in an amount of 1.3 mg/m^2;

(b) administered via subcutaneous administration; or

(c) administered once or twice weekly.

9. The use of claim 7 or 8, wherein:

(a) the compound is to be administered daily for 14 days followed by 7 days of rest in 21-day cycles; and

(b) the bortezomib or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be administered on days 1, 4, 8, and 11 in 21-day cycles at cycles 1 to 8 and on days 1 and 8 at cycle 9 and thereafter.

10. The use of claim 7 or 8, wherein:

(a) the compound is to be administered daily for 14 days followed by 7 days of rest in 21-day cycles at cycles 1 to 8 and then daily for 21 days followed by 7 days in 28-day cycles at cycle 9 and thereafter; and

(b) the bortezomib or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be administered on days 1, 4, 8, and 11 in 21-day cycles at cycles 1 to 8.

11. The use of claim 7 or 8, wherein:

(a) the compound is to be administered daily for 14 days followed by 7 days of rest in 21-day cycles; and

(b) the bortezomib or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be administered on days 1, 4, 8, and 11 in 21-day cycles at cycles 1 to 6.

12. The use of any one of claims 1 to 6, wherein the proteasome inhibitor is carfilzomib, or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof.

13. The use of claim 12, wherein the carfilzomib or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be:

(a) administered in an amount of 20 mg/m^2;

(b) administered via intravenous administration; or

(c) administered twice or once weekly.

14. The use of claim 12 or 13, wherein:

(a) the compound is to be administered daily for 21 days followed by 7 days in 28-day cycles; and

(b) the carfilzomib or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be:

(i) administered on day 1 in the first 28-day cycle and on days 1, 8, and 15 in the 28-day cycles thereafter; or

(ii) administered on days 1 and 2 in the first 28-day cycle and on days 1, 2, 8, 9, 15, and 16 of the 28-day cycles thereafter.

15. The use of any one of claims 1 to 6, wherein the proteasome inhibitor is marizomib (salinosporamide A), or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof.

16. The use of any one of claims 1 to 6, wherein the proteasome inhibitor is ixazomib, or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof.

17. The use of any one of claims 1 to 16, wherein dexamethasone, or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof is also to be administered.

18. The use of claim 17, wherein the dexamethasone, or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be:

(a) administered in an amount of 10 mg, 20 mg, or 40 mg;

(b) administered via oral administration; or

(c) administered once weekly.

19. The use of claim 17 or 18, wherein:

(a) the compound is to be administered daily for 14 days followed by 7 days of rest in 21-day cycles;

(b) the bortezomib or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be administered on days 1, 4, 8, and 11 in 21-day cycles at cycles 1 to 8 and on days 1 and 8 at cycle 9 and thereafter; and

(c) the dexamethasone, or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be administered on days 1, 8 and 15 in 21-day cycles.

20. The use of claim 17 or 18, wherein:

(a) the compound is to be administered daily for 14 days followed by 7 days of rest in 21-day cycles at cycles 1 to 8 and then daily for 21 days followed by 7 days in 28-day cycles at cycle 9 and thereafter;

(b) the bortezomib or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be administered on days 1, 4, 8, and 11 in 21-day cycles at cycles 1 to 8; and

(c) the dexamethasone, or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be administered on days 1, 2, 4, 5, 8, 9, 11 and 12 in 21-day cycles at cycles 1 to 8 and then on days 1, 8, 15, and 22 in 28-day cycles at cycle 9 and thereafter.

21. The use of claim 17 or 18, wherein

(a) the compound is to be administered daily for 14 days followed by 7 days of rest in 21-day cycles;

(b) the bortezomib or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be administered on days 1, 4, 8, and 11 in 21-day cycles at cycles 1 to 6; and

(c) the dexamethasone, or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be administered on days 1, 2, 4, 5, 8, 9, 11, and 12 in 21-day cycles at cycles 1 to 6.

22. The use of claim 17 or 18, wherein:

(a) the compound is to be administered daily for 21 days followed by 7 days in 28-day cycles;

(b) the carfilzomib or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be administered on day 1 in the first 28-day cycle and on days 1, 8, and 15 in the 28-day cycles; and

(c) the dexamethasone, or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be administered on days 1, 8, 15, and 22 in 28-day cycles.

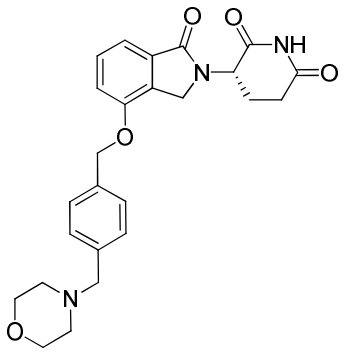
23. The use of claim 17 or 18, wherein:

(a) the compound is to be administered daily for 21 days followed by 7 days in 28-day cycles;

(b) the carfilzomib or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be administered on days 1 and 2 in the first 28-day cycle and on days 1, 2, 8, 9, 15, and 16 of the 28-day cycles; and

(c) the dexamethasone, or an enantiomer or a mixture of enantiomers thereof, or a pharmaceutically acceptable salt thereof is to be administered on days 1, 2, 8, 9, 15, 16, 22, and 23 in 28-day cycles.

24. The use of any one of claims 1 to 23, wherein the compound is Compound A-S



Compound A-S

or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof, wherein particularly the compound is a hydrochloride salt of Compound A-S.