

CLAIMS

1. Use of an anti-CD38 antibody in the manufacture of a medicament for treating a hematologic malignancy in a subject in need thereof, wherein a therapeutically effective amount of the anti-CD38 antibody is to be administered in combination with a corticosteroid for a time sufficient to treat the hematologic malignancy, and wherein the corticosteroid is to be administered in a dosing regimen that includes a reduction, elimination, or reduction followed by elimination, of corticosteroid administration to the subject.
2. The use of claim 1, wherein the corticosteroid to be administered to the subject is:
 - a) to be reduced to about 60% and then eliminated during a 28-day treatment cycle;
 - b) to be reduced to about 60% and then to about 30% and then eliminated during a 28-day treatment cycle; or
 - c) to be administered once and then eliminated during a 28-day treatment cycle.
3. The use of claim 1, wherein the anti-CD38 antibody is to be administered once weekly, every 2 weeks, or every 4 weeks during a 28-day cycle.
4. The use of claim 3, wherein the anti-CD38 antibody is to be administered once weekly during Cycle 1, every 2 weeks during Cycles 2-5, and every 4 weeks thereafter.
5. The use of claim 1, wherein a therapy is to be administered to the subject on a 28-day cycle, wherein the therapy comprises:
 - about 1,800 mg anti-CD38 antibody and about 30,000 U hyaluronidase to be administered on days 1, 8, 15 and 22;
 - about 100 mg pre-dose corticosteroid to be administered on day 1;
 - about 20 mg post-dose corticosteroid to be administered on days 1 and 2;
 - about 60 mg pre-dose corticosteroid to be administered on day 8;
 - about 20 mg post-dose corticosteroid to be administered on day 8;
 - about 30 mg pre-dose corticosteroid to be administered on day 15; and
 - about 20 mg post-dose corticosteroid to be administered on day 15, of the 28-day cycle.

6. The use of claim 5, wherein the therapy comprises:
 - about 1,800 mg daratumumab and about 30,000 U rHuPH20 recombinant hyaluronidase to be administered subcutaneously on days 1, 8, 15 and 22;
 - about 100 mg pre-dose methylprednisolone (MP) to be administered orally or intravenously on day 1;
 - about 20 mg post-dose MP to be administered orally on days 1 and 2;
 - about 60 mg pre-dose MP to be administered orally or intravenously on day 8;
 - about 20 mg post-dose MP to be administered orally on day 8;
 - about 30 mg pre-dose MP to be administered orally or intravenously on day 15;and
 - about 20 mg post-dose MP to be administered orally on day 15, of the 28-day cycle.
7. The use of claim 1, wherein a therapy is to be administered to the subject on a 28-day cycle, wherein the therapy comprises:
 - about 1,800 mg anti-CD38 antibody and about 30,000 U rHuPH20 hyaluronidase to be administered on days 1, 8, 15 and 22;
 - about 100 mg pre-dose corticosteroid to be administered on day 1;
 - about 20 mg post-dose corticosteroid to be administered on days 1 and 2;
 - about 60 mg pre-dose corticosteroid to be administered on day 8; and
 - about 20 mg post-dose corticosteroid to be administered on day 8, of the 28-day cycle.
8. The use of claim 7, wherein the therapy comprises:
 - about 1,800 mg daratumumab and about 30,000 U rHuPH20 recombinant hyaluronidase to be administered subcutaneously on days 1, 8, 15 and 22;
 - about 100 mg pre-dose methylprednisolone (MP) to be administered orally or intravenously on day 1;
 - about 20 mg post-dose MP to be administered orally on days 1 and 2;
 - about 60 mg pre-dose MP to be administered orally or intravenously on day 8;and
 - about 20 mg post-dose MP to be administered orally on day 8, of the 28-day cycle.

9. The use of claim 1, wherein a therapy is to be administered to the subject on a 28-day cycle, wherein the therapy comprises:
 - about 1,800 mg anti-CD38 antibody and about 30,000 U hyaluronidase to be administered subcutaneously on days 1, 8, 15 and 22; and
 - about 20 mg pre-dose corticosteroid to be administered intravenously on day 1, of the 28-day cycle.
10. The use of claim 9, wherein the therapy comprises:
 - a) about 1,800 mg of daratumumab and about 30,000 U rHuPH20 recombinant hyaluronidase to be administered subcutaneously on days 1, 8, 15 and 22; and
 - b) about 20 mg pre-dose dexamethasone to be administered intravenously on day 1, of the 28-day cycle.
11. The use of claim 1, wherein the corticosteroid comprises betamethasone, cortisol, cortisone, dexamethasone, glucocorticoid, hydrocortisone, methylprednisolone (MP), prednisolone, prednisone, triamcinolone, or a combination thereof.
12. The use of claim 11, wherein the corticosteroid comprises dexamethasone, methylprednisolone, prednisone, or a combination thereof.
13. The use of claim 1, wherein the hematologic malignancy is a CD38-positive hematologic malignancy.
14. The use of claim 1, wherein the anti-CD38 antibody comprises:
 - a) a heavy chain complementarity determining region 1 (HCDR1), HCDR2 and HCDR3 amino acid sequences of SEQ ID NOs:6, 7 and 8, respectively, and a light chain complementarity determining region 1 (LCDR1), LCDR2 and LCDR3 amino acid sequences of SEQ ID NOs:9, 10 and 11, respectively;
 - b) a heavy chain variable region (VH) sequence of SEQ ID NO:4, and a light chain variable region (VL) sequence of SEQ ID NO:5; or
 - c) a heavy chain sequence of SEQ ID NO:12, and a light chain sequence of SEQ ID NO:13, or
 a combination of the foregoing.

15. Use of an anti-CD38 antibody in the manufacture of a medicament for treating a hematologic malignancy in a subject in need thereof, wherein a therapeutically effective amount of the anti-CD38 antibody and a corticosteroid dose of < 0.05 mg/kg/day or equivalent are to be administered for a time sufficient to treat the hematologic malignancy.
16. The use of claim 15, wherein a corticosteroid dose of < 0.01 mg/kg/day or equivalent is to be administered.
17. The use of claim 15, wherein the corticosteroid comprises betamethasone, cortisol, cortisone, dexamethasone, glucocorticoid, hydrocortisone, methylprednisolone (MP), prednisolone, prednisone, triamcinolone, or a combination thereof.
18. Use of an anti-CD38 antibody in the manufacture of a medicament for treating a hematologic malignancy, wherein the anti-CD38 antibody is to be administered to a subject in need thereof for a time sufficient to treat the hematologic malignancy, and wherein disease control or complete remission is to be achieved and/or maintained at a corticosteroid dose of ≤ 0.05 mg/kg/day or equivalent.
19. The use of claim 18, wherein the disease control or complete remission is to be achieved and/or maintained at a corticosteroid dose of ≤ 0.01 mg/kg/day or equivalent.
20. The use of claim 18, wherein the disease control or complete remission is to be achieved and/or maintained without a corticosteroid.
21. The use of claim 1, wherein the anti-CD38 antibody is daratumumab.