

CLAIMS

1. Use of isatuximab for the manufacture of a medicament for the treatment of ~~A method of treating~~ a human individual having multiple myeloma, comprising:
 - administering isatuximab to the individual at a weekly dose of 10 mg/kg of a first one-month cycle;
 - administering the isatuximab at a dose of 10 mg/kg once every two weeks of a one-month cycle for at least 11 cycles following the first one-month cycle; and
 - administering the isatuximab at a monthly dose of 10 mg/kg for one or more additional one-month cycles following the at least 11 cycles.
2. Use of an anti-CD38 antibody for the manufacture of a medicament for the treatment of ~~A method of treating~~ a human individual having multiple myeloma, comprising:
 - administering an anti-CD38 antibody to the individual at a weekly dose of 10 mg/kg of a first one-month cycle;
 - administering the anti-CD38 antibody at a dose of 10 mg/kg once every two weeks of one or more one-month cycles after the first one-month cycle until the individual achieves a response of at least very good partial response (VGPR); and
 - administering the anti-CD38 antibody at a dose of 10 mg/kg once a month for one or more additional one-month cycles after the individual achieves the response of at least VGPR.
3. Use of an anti-CD38 antibody for the manufacture of a medicament for the treatment of a ~~A method of treating~~ human individuals having multiple myeloma, comprising:
 - administering an anti-CD38 antibody to the individuals at weekly dose of 10 mg/kg of a first one-month cycle;
 - administering the anti-CD38 antibody at a dose of 10 mg/kg on once every two weeks of one or more one-month cycles after the first one-month cycle;
 - measuring the individuals' responses to the treatment at one or more time points during the one or more one-month cycles after the first one-month cycle and selecting the individuals who have at least a Very Good Partial Response (VGPR); and
 - administering the anti-CD38 antibody at a dose of 10 mg/kg once a month for one or more additional one-month cycles to the selected individuals.
4. Use of an anti-CD38 antibody for the manufacture of a medicament for the treatment of ~~A method of treating~~ a human individual having multiple myeloma, comprising:

measuring the individual's serum and urine M-protein at a first time point prior to administration of an anti-CD38 antibody;

administering the anti-CD38 antibody to the individual at a weekly dose of 10 mg/kg of a first one-month cycle;

administering the anti-CD38 antibody at a dose of 10 mg/kg once every two weeks of one or more one-month cycles after the first one-month cycle;

measuring the individual's serum and/or urine M-protein at a second time point during the at least one or more one-month cycles after the first one-month cycle, and

administering the anti-CD38 antibody at a monthly dose of 10 mg/kg for one or more additional one-month cycles if (a) the individual's serum M-protein level at the second time point is reduced by at least 90% as compared to the individual's serum M-protein level at the first time point and (b) the individual's urine M-protein level at the second time point is less than 100 mg/24 hours.

5. Use of an anti-CD38 antibody for the manufacture of a medicament for the treatment of ~~A method of treating~~ a human individual having multiple myeloma, comprising:

measuring the individual's serum and/or urine M-protein level prior to administration of anti-CD38 antibody;

administering the anti-CD38 antibody to the individual at a weekly dose of 10 mg/kg of a first one-month cycle;

administering the anti-CD38 antibody isatuximab ~~isatuximab~~ at a dose of 10 mg/kg once every two weeks of one or more one-month cycles after the first one-month cycle until (a) the individual's serum M-protein level is reduced by at least 90% as compared to the serum M-protein level prior to the administration of the anti-CD38 antibody and (b) the individual's urine M-protein level is less than 100 mg/24 hours; and

administering the anti-CD38 antibody at a dose of 10 mg/kg once a month for one or more additional one-month cycles after (a) the individual's serum M-protein level is determined to be reduced by at least 90% as compared to the individual's serum M-protein level at the first time point and (b) the individual's urine M-protein level is determined to be less than 100 mg/24 hours.

6. The method ~~method~~ of claim 5, wherein (a) the reduction in the individual's serum M-protein level and (b) the individual's urine M-protein level of less than 100 mg/24 hours are maintained for at least about 12 months prior to administering the anti-CD38 antibody at a dose of 10 mg/kg once every 28-day cycle.

7. The ~~method~~-use of claim 2 or 3, wherein the response to treatment is measured by assessing M-protein level in the blood and/or urine of the individual or individuals.
8. The ~~method~~-use of any one of claims 5, 6, and 7, wherein the M-protein level in the blood and/or urine is assessed via immunofixation and/or electrophoresis.
9. The ~~method~~-use of any one of claims 2, 3, 7, and 8, wherein the response of at least VGPR is maintained for at least about 6 months prior to administering the anti-CD38 antibody once a month for one or more one-month cycles.
10. The ~~method~~-use of claim 9, wherein the response of at least VGPR is maintained for at least about 12 months prior to administering the anti-CD38 antibody once a month for one or more one-month cycles.
11. The ~~method~~-use of any one of claims 2-10, wherein the anti-CD38 antibody is administered at a dose of 10 mg/kg once every two weeks of the one or more one-month cycles for at least 11 cycles prior to administering the anti-CD38 antibody once a month for one or more additional one-month cycles.
12. The ~~method~~-use of any one of claims 1-11, wherein the anti-CD38 antibody is administered at a dose of 10 mg/kg once every other week of one or more one-month cycles for at least 23 cycles prior to administering the anti-CD38 antibody once a month for one or more additional one-month cycles
13. The ~~method~~-use of any one of claims 1-12, wherein the treatment extends the progression free survival (PFS) of the individual.
14. The ~~method~~-use of any one of claims 2-4 and 9-13 wherein the anti-CD38 antibody comprises (a) a heavy chain variable domain (VH) that comprises: a CDR-H1 comprising the amino acid sequence DYWMQ (SEQ ID NO: 1), a CDR-H2 comprising the amino acid sequence TIYPGDGDTGYAQKFQG (SEQ ID NO: 2), and a CDR-H3 comprising the amino acid sequence GDYYGSNSLDY (SEQ ID NO: 3), and (b) a light chain variable domain (VL) that comprises: a CDR-L1 comprising the amino acid sequence KASQDVSTVVA (SEQ ID NO: 4), a

CDR-L2 comprising the amino acid sequence SASYRYI (SEQ ID NO: 5), and a CDR-L3 comprising the amino acid sequence QQHYSPPYT (SEQ ID NO: 6).

15. The ~~method~~use of any one of claims 2-4 and 9-14, wherein the anti-CD38 antibody comprises a heavy chain variable region (VH) comprising an amino acid sequence of SEQ ID NO: 7 and a light chain variable region (VL) comprising an amino acid sequence of SEQ ID NO: 8 or SEQ ID NO: 9.

16. The ~~method~~use of any one of claims 2-4 and 9-15, wherein the anti-CD38 antibody is isatuximab.