

We Claim:

1. A stable lyophilized pharmaceutical formulation, the formulation comprising an anti-CD19 antibody in a concentration of 20 mg/ml to 125 mg/ml, a buffer, polysorbate in a concentration of 0.005% (w/v) to 0.06% (w/v), and pH of 6.0, wherein the formulation further comprises

a) trehalose in a concentration of 180 mM to 240 mM or

b) mannitol in a concentration of 180 mM to 240 mM and sucrose in a concentration of 10 mM to 50mM,

and wherein said anti-CD19 antibody comprises a heavy chain constant domain of the sequence

ASTKGPSVFPLAPSSKSTSGGTAALGCLVKDYFPEPVTVSWNSGALTSGVHTFPAVLQSSG
LYSLSSVVTVPSSSLGTQTYICNVNHKPSNTKVDKKVEPKSCDKTHTCPPCPAPELLGGPDV
FLFPPKPKDTLMISRTPEVTCVVDVSHEDPEVQFNWYVDGVEVHNAKTKPREEQFNSTFR
VSVLTVVHQDWLNGKEYKCKVSNKALPAPEEKTISKTKGQPREPQVYTLPPSREEMTKNQ
VSLTCLVKGFYPSDIAVEWESNGQPENNYKTTTPMLDSDGSFFLYSKLTVDKSRWQQGNVF
SCSVMHEALHNHYTQKSLSLSPGK (SEQ ID NO: 8) and a light chain constant domain of the sequence

RTVAAPSVFIFPPSDEQLKSGTASVVCLLNNFYPREAKVQWKVDNALQSGNSQESVTEQDS
KDSTYLSLSSTLTLSKADYEKHKVYACEVTHQGLSSPVTKSFNRGEC (SEQ ID NO: 9).

2. The formulation of claim 1, wherein said anti-CD19 antibody in the formulation is 40 mg/ml.

3. The formulation of any one of claims 1 or 2, wherein said buffer is citrate buffer or phosphate buffer.

4. The formulation of claim 3, wherein said citrate buffer or phosphate buffer are in a concentration of between 20 and 50mM.

5. The formulation of claim 4, wherein said citrate buffer or phosphate buffer are in a concentration of 25mM.

6. The formulation of any one of claims 1-5, wherein said trehalose in the formulation is 200 mM.

7. The formulation of any one of claims 1-5, wherein said mannitol in the formulation is 219 mM and said sucrose in the formulation is 29 mM.

8. The formulation of any one of claims 1-7 wherein said polysorbate in the formulation is polysorbate 20.

9. The formulation of any one of claims 1-8, wherein said polysorbate in the formulation is 0.02%.

10. The formulation of any one of claims 1-9, wherein said anti-CD19 antibody further comprises a HCDR1 region of sequence SYVMH (SEQ ID NO: 1), an HCDR2 region of sequence NPYNDG (SEQ ID NO: 2), an HCDR3 region of sequence GTYYYGTRVFDY (SEQ ID NO: 3), an LCDR1 region of sequence RSSKSLQNVNGNTYLY (SEQ ID NO: 4), an LCDR2 region of sequence RMSNLNS (SEQ ID NO: 5), and an LCDR3 region of sequence MQHLEYPIT (SEQ ID NO: 6).

11. The formulation of any one of claims 1-9, wherein said anti-CD19 antibody further comprises a variable heavy chain of the sequence

EVQLVESGGGLVKPGGSLKLSAASGYTFTSYVMHWVRQAPGKGLEWIGYINPYNDGTTY
NEKFQGRVTISDKSISTAYMELSSLRSEDTAMYYCARGTYYYGTRVFDYWGQGTLVTVSS
(SEQ ID NO: 10) and a variable light chain of the sequence

DIVMTQSPATLSLSPGERATLSCRSSKSLQNVNGNTYLYWFQQKPGQSPQLLIYRMSNLNS
GVPDRFSGSGSGTEFTLTISLEPEDFAVYYCMQHLEYPITFGAGTKLEIK (SEQ ID NO: 11).

12. The formulation of any one of claims 1-11, wherein the formulation is stable at 2-8°C for at least 6 months, at least 12 months, at least 18 months, at least 24 months or at least 36 months.

13. The formulation of any one of claims 1-5, 10, or 11, wherein said anti-CD19 antibody is in an amount of 40 mg/mL, said citrate buffer in a concentration of 25 mM, said trehalose in a concentration of 200 mM, polysorbate in a concentration of 0.02% (w/v) and said formulation has a pH of 6.0.

14. The formulation of any one of claims 1-5, 10, or 11, wherein said anti-CD19 antibody is in an amount of 40 mg/mL, said citrate buffer in a concentration of 25 mM, said mannitol in a concentration of 219 mM and said sucrose in a concentration of 29mM, polysorbate in a concentration of 0.02% (w/v) and said formulation has a pH of 6.0.

15. A container holding the stable lyophilized pharmaceutical formulation of any one of claims 1-14.

16. A solution for administration to a patient, which is reconstituted from the stable lyophilized pharmaceutical formulation of claim 1 and which solution comprises said anti-CD19 antibody in a concentration of 20 mg/ml to 125 mg/ml, a buffer, polysorbate in a concentration of 0.005% (w/v) to 0.06% (w/v), and has a pH of 6.0, wherein the formulation further comprises

a) trehalose in a concentration of 180 mM to 240 mM or

b) mannitol in a concentration of 180 mM to 240 mM and sucrose in a concentration of 10 mM to 50mM.

17. The solution of claim 16, wherein the solution comprises said anti-CD19 antibody in an amount of 40 mg/mL, citrate buffer in a concentration of 25 mM, trehalose in a concentration of 200 mM, polysorbate in a concentration of 0.02% (w/v), and has a pH of 6.0.

18. The solution of claim 16 or 17, wherein said anti-CD19 antibody comprises a variable heavy chain of the sequence

EVQLVESGGGLVKPGGSLKLSCAASGYTFTSYVMHWVRQAPGKGLEWIGYINPYNDGTTY
NEKFQGRVTISSDKSISTAYMELSSLRSEDTAMYYCARGTYYYGTRVFDYWGQGTLVTVSS

(SEQ ID NO: 10) and a variable light chain of the sequence

DIVMTQSPATLSLSPGERATLSCRSSKSLQNVNGNTYLYWFQQKPGQSPQLLIYRMSNLNS
GVPDRFSGSGSGTEFTLTISILEPEDFAVYYCMQHLEYPITFGAGTKLEIK (SEQ ID NO: 11).

19. The solution of any one of claims 16 to 18 for use in treating a disease or disorder in a subject, the treatment comprising administering an effective amount of the solution to the subject, wherein the disease or disorder is cancer.

20. The solution for use according to claim 19, wherein the disease or disorder is non-Hodgkin's lymphoma, chronic lymphocytic leukemia or acute lymphoblastic leukemia.

21. The solution for use according to claim 20, wherein the non-Hodgkin's lymphoma is selected from the group consisting of follicular lymphoma, small lymphocytic lymphoma, mucosa-associated lymphoid tissue lymphoma, marginal zone lymphoma, diffuse large B cell lymphoma, Burkitt's lymphoma, and mantle cell lymphoma.

22. The solution for use according to claim 20, wherein the non-Hodgkin's lymphoma is diffuse large B cell lymphoma.