

CLAIMS

1. A pharmaceutical combination comprising a synergistic combination of:

(A) an anti-BST1 antibody, or an antigen-binding portion thereof, said antibody or portion comprising:

a) a heavy chain variable region comprising:

i) a first vhCDR comprising SEQ ID NO: 10;

ii) a second vhCDR comprising a sequence selected from SEQ ID NO: 12 and SEQ ID NO: 51; and

iii) a third vhCDR comprising SEQ ID NO: 14; and

b) a light chain variable region comprising:

i) a first vlCDR comprising SEQ ID NO: 16;

ii) a second vlCDR comprising SEQ ID NO: 18; and

iii) a third vlCDR comprising SEQ ID NO: 20; wherein the anti-BST1 antibody is capable of inducing antibody-dependent cell-mediated cytotoxicity (ADCC);

and

(B) a cytidine analogue, wherein the cytidine analogue is 5-aza-cytidine or 5-aza-2'-deoxycytidine, or a pharmaceutically-acceptable salt thereof,

wherein the pharmaceutical combination is in the form of a combined preparation for simultaneous, separate or sequential use.

2. The pharmaceutical combination as claimed in claim 1, wherein the anti-BST1 antibody or the antigen-binding portion thereof comprises:

(a) a heavy chain variable region having at least 80%, 85%, 90%, 95%, 99% or 100% amino acid sequence identity to SEQ ID NO: 2 or SEQ ID NO: 46, and

(b) a light chain variable region having at least 80%, 85%, 90%, 95%, 99% or 100% amino acid sequence identity to SEQ ID NO: 4 or SEQ ID NO: 49.

3. The pharmaceutical combination as claimed in claim 1 or claim 2, wherein the anti-BST1 antibody comprises:

(a) a heavy chain having at least 80%, 85%, 90%, 95%, 99% or 100% amino acid sequence identity to SEQ ID NO: 74, and

(b) a light chain having at least 80%, 85%, 90%, 95%, 99% or 100% amino acid sequence identity to SEQ ID NO: 76.

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4. The pharmaceutical combination as claimed in any one of claims 1 to 3, wherein the anti-BST1 antibody is a human IgG1 monoclonal antibody.

10 5. The pharmaceutical combination as claimed in any one of claims 1 to 4, wherein the anti-BST1 antibody is an engineered antibody having increased binding to Fc receptors, preferably wherein the antibody is afucosylated or defucosylated.

15 6. The pharmaceutical combination as claimed in any one of claims 1 to 5, wherein the anti-BST1 antibody is a bispecific antibody or multi-specific antibody which specifically binds to a first antigen comprising BST1 and a second antigen selected from the group consisting of the CD3 antigen and the CD5 antigen.

20 7. The pharmaceutical combination according to any one of claims 1 to 6, wherein (A) and/or (B) additionally comprise one or more pharmaceutically-acceptable diluents, excipients or carriers.

8. A kit comprising:

(i) the anti-BST1 antibody or antigen-binding portion thereof as defined in any one of claims 1 to 3; and

25 (ii) a cytidine analogue, wherein the cytidine analogue is 5-aza-cytidine or 5-aza-2'-deoxycytidine, or a pharmaceutically-acceptable salt thereof.

9. A pharmaceutical combination according to any one of claims 1 to 7, for use in the treatment of cancer, wherein components (A) and (B) are simultaneously, separately or sequentially administered to the patient for the treatment of the cancer.

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10. The pharmaceutical combination for use according to claim 9, wherein the anti-BST1 antibody or antigen-binding portion is afucosylated or defucosylated.

35 11. The pharmaceutical combination for use according to claim 9 or claim 10, wherein the cancer is acute myeloid leukemia (AML), B-cell chronic lymphocytic leukemia, breast cancer, colorectal

cancer, kidney cancer, head and neck cancer, lung cancer, ovarian cancer or pancreatic cancer, preferably acute myeloid leukemia (AML).

12. Use of components (A) and (B) of the pharmaceutical combination as defined in any one of claims 1 to 7 in the manufacture of a pharmaceutical combination for simultaneous, separate or sequential use for the treatment of cancer.

13. The use according to claim 12, wherein the anti-BST1 antibody or antigen-binding portion is afucosylated or defucosylated.

14. The use according to claim 12 or claim 13, wherein the cancer is acute myeloid leukemia (AML), B-cell chronic lymphocytic leukemia, breast cancer, colorectal cancer, kidney cancer, head and neck cancer, lung cancer, ovarian cancer or pancreatic cancer, preferably acute myeloid leukemia (AML).

15. A pharmaceutical combination according to any one of claims 1 to 7 for use in therapy or for use as a medicament.