

Claims:

1. An anti-idiotypic antibody fused to albumin or a functional fragment of albumin.

~~2. The anti-idiotypic antibody albumin fusion according to claim 1,~~ wherein the anti-idiotypic antibody is specific for an anti-CD38 antibody having a variable heavy ~~chain~~ domain comprising the amino acid sequence

~~QVQLVESGGGLVQPGGSLRLSCAASGFTFSSYMNWVRQAPGKGLEWVSGISGDPSTYYADSVKGRFTISRDN~~

~~SKNTLYLQMNSLRAEDTAVVYCARDLPLVYTGFAWGGTLTVSS~~ (of SEQ ID NO: 7), and a variable light chain domain comprising the amino acid sequence

~~DIELTQPPSVSVAPGQTARISCSGDNLRHYYVWYQQKPGQAPVLVIYGDSKRPSGIPERFSGNSGNTATLTISGT~~

~~QAEDEADYYCQTYTGASLVFGGGTKLTVLGQ~~ (of SEQ ID NO: 8), and

~~wherein the anti-idiotypic antibody is a Fab fragment.~~

~~32.~~ The anti-idiotypic antibody albumin fusion according to ~~any one of the preceding claims~~ claim 1,

wherein

said anti-idiotypic antibody comprises a variable heavy chain comprising

an HCDR1 of the amino acid sequence ~~YSFSNYWIS~~ (of SEQ ID NO: 18),

an HCDR2 of the amino acid sequence ~~WMGIIDPASSKTRYSPSFQG~~ (of SEQ ID NO: 19),

an HCDR3 of the amino acid sequence ~~SRGAGMDY~~ (of SEQ ID NO: 20), and

a variable light chain comprising

an LCDR1 of the amino acid sequence ~~TGSSSNIGAGYDVH~~ (of SEQ ID NO: 21),

an LCDR2 of the amino acid sequence ~~LLIYADNNRPS~~ (of SEQ ID NO: 22),

an LCDR3 of the amino acid sequence ~~GSYDESSNSM~~ (of SEQ ID NO: 23).

43. The anti-idiotypic antibody fused to albumin ~~fusion~~ according to any one of the preceding claims, wherein

said anti-idiotypic antibody comprises the variable heavy chain of the amino acid sequence

QVQLVQSGAEVKKPGESLKISCKGSGYSFSNYWISWVRQMPGKGLEWMGHDPASSKTRYSPSFQQGVTTISADKS

ISTAYLQWSSLKASDTAMYYCARSRGAGMDYWGGTGLTVSS (of SEQ ID NO: 16), and the variable light chain of the amino acid

sequence DIVLTQPPSVSGAPGQRVTISCTGSSSNIGAGYDVHWYQQLPGTAPKLLIYADNNRPSGVPDRFSGSKSGTSASLAITGLQSEADYYCGSYDESSNSMVFGGGTKLTVLGQ (of SEQ ID NO: 17).

54. The anti-idiotypic antibody fused to albumin ~~fusion~~ according any one of the preceding claims, wherein the comprising a

heavy chain ~~comprises~~ comprising the heavy chain amino acid sequence

QVQLVQSGAEVKKPGESLKISCKGSGYSFSNYWISWVRQMPGKGLEWMGHDPASSKTRYSPSFQQGVTTISADKS

ISTAYLQWSSLKASDTAMYYCARSRGAGMDYWGGTGLTVSSASTKGPSVFPLAPSSKSTSGGTAALGCLVKDYF

PEPVTISWNSGALTSGVHTFPAVLQSSGLYSLSSVVPSSSLGTQTYICNVNHKPSNTKVDKRVEPKSDIDAHKS

EVAHRFKDLGEENFKALVLIQFAQYLQQCPFEDHVKLNVETFAKTCVADESAENCDSLHTLFGDKLCTVATLR

ETYGEMADCCAKQEPERNECFQHKDDNPPLRLVRPEVDVMCTAFHDNEETFLKKYLYEIARRHPYFYAPELFF

FAKRYKAAFTTECCQAADKAAACLLPKLDELDEGKASSAKQRLKCASLQKFGERAFAKAWAVARLSQRFPKAEFAEV

SKLVTDLTQVHTECCHGDLLECADDRAADLAKYICENQDSISSKLKECCEKPLEKSHCIAEVENDEMPADLPDLAAD

FVESKDVCKNYAEAKDVFLGMFLYEYARRHPDYSVVLRLAKTYETTTLEKCCAAADPHECYAKVFDEFKPLVEEP

QNLIKQNCLEFEQLGEYKFQNALLVRYTKKVPQVSTPTLVEVSRNLGKVGSKCKHPEAKRMPCAEDYLSVVLNQ

LCVLHEKTPVSDRVTKCCTESLVNRRPCFSALEVDETYVPKEFNAETFTFHADICTLSEKERQIKKQTALVELVKHKP

KATKEQLKAVMDDFAAFEKCKADDKETCFEEGKKLVAAASQAALGLVNSRHHHHHH (of SEQ ID NO: 24),

and

wherein thea

light chain ~~comprises~~ comprising the light chain amino acid sequence

DIVLTQPPSVSGAPGQRVTISCTGSSSNIGAGYDVHWYQQLPGTAPKLLIYADNNRPSGVPDRFSGSKSGTSASLA

ITGLQSEDEADYYCGSYDESSNSMVFGGGTKLTVLGQPKAAPSVTLFPPSSEELQANKATLVCLISDFYPGAVTVA

WKADSSPVKAGVETTTPSKQSNNKYAASSYLSLTPEQWKSHRSYSCQVTHEGSTVEKTVAPTECS (of SEQ ID NO:

25).

5. The monoclonal anti-idiotypic antibody fused to albumin according to claim 1, wherein the anti-idiotypic antibody is an IgG1 isotype.

6. The monoclonal anti-idiotypic antibody fused to albumin according to claim 1, wherein the anti-idiotypic antibody is an IgM isotype.

7. The monoclonal anti-idiotypic antibody fused to album according to claim 1, wherein the albumin is a human albumin having the amino acid sequence of SEQ ID NO: 6.

68. The anti-idiotypic antibody fused to albumin ~~fusion~~ according any one of the preceding claims for use in evaluating a blood sample.

79. A nucleic acid encoding the anti-idiotypic antibody fused to albumin ~~fusion~~ according to any one of the preceding claims.

810. A method of evaluating a blood sample obtained from a patient undergoing treatment for multiple myeloma or other gammopathy comprising

a) obtaining a blood sample from said patient,
b) incubating the blood sample with an anti-idiotypic antibody fused to albumin ~~fusion~~ according to any one ~~of~~ claims 1-~~78~~,
c) performing immunofixation electrophoresis (IFE), and
d) reporting the results of the IFE,
where the sample is evaluated for total M-protein levels, and

-wherein the patient is undergoing treatment with the anti-CD38 antibody

having a variable heavy chain domain comprising the amino acid sequence

QVQLVESGGGLVQPGGSLRLSCAASGFTFSSYYMNWVRQAPGKGLEWVSGISGDPSENTYYADSVKGRFTISRDN

SKNTLYLQMNSLRAEDTAVVYCARDLPLVYTGFAYWGQGLTVTVSS (of SEQ ID NO: 7), and a variable light

chain domain comprising the amino acid sequence

DIELTQPPSVSVAPGQTARISCSGDNLRHYYVYVYQQKPGQAPVLVIYGDSKRPSGIPERFSGSNSGN

TATLTISGTQAEDEADYYCQTYTGASLVFGGGTKLTVLGQ (of SEQ ID NO: 8).

911. An anti-idiotypic antibody that is specific for an anti-CD38 antibody having a variable heavy chain domain comprising the amino acid sequence

QVQLVESGGGLVQPGGSLRLSCAASGFTFSSYYMNWVRQAPGKGLEWVSGISGDPSENTYYADSVKGRFTISRDN

SKNTLYLQMNSLRAEDTAVVYCARDLPLVYTGFAYWGQGLTVTVSS (of SEQ ID NO: 7), and a variable light

chain domain comprising the amino acid sequence

DIELTQPPSVSVAPGQTARISCSGDNLRHYYVYVYQQKPGQAPVLVIYGDSKRPSGIPERFSGSNSGN

TATLTISGTQAEDEADYYCQTYTGASLVFGGGTKLTVLGQ (of SEQ ID NO: 8),

~~10. A method of evaluating a blood sample obtained from a patient undergoing treatment for multiple myeloma or other gammopathy comprising~~

~~a) obtaining a blood sample from said patient,~~

~~b) incubating the blood sample with an anti-idiotypic antibody specific for the anti-CD38 antibody having a variable heavy domain comprising the amino acid sequence~~

~~QVQLVESGGGLVQPGGSLRLSCAASGFTFSSYYMNWVRQAPGKGLEWVSGISGDPSTNTYYADSVKGRFTISRDN SKNTLYLQMNSLRAEDTAVYYCARDLPLVYTGFAYWGQGTLLTVSS (SEQ ID NO: 7), and a variable light chain domain comprising the amino acid sequence~~

~~DIELTQPPSVSVAPGQTARISCSGDNLRHYVYVWYQQKPGQAPVLVIYGDSKRPSGIPERFSGSNSGNTATLTISGT QAEDEADYYCQTYTGGASLVFGGGTKLTVLGQ (SEQ ID NO: 8),~~

~~c) performing immunofixation electrophoresis (IFE), and~~

~~d) reporting the results of the IFE,~~

~~wherein the patient is undergoing treatment with the anti-CD38 antibody having a variable heavy domain comprising the amino acid sequence~~

~~QVQLVESGGGLVQPGGSLRLSCAASGFTFSSYYMNWVRQAPGKGLEWVSGISGDPSTNTYYADSVKGRFTISRDN SKNTLYLQMNSLRAEDTAVYYCARDLPLVYTGFAYWGQGTLLTVSS (SEQ ID NO: 7), and a variable light chain domain comprising the amino acid sequence~~

~~DIELTQPPSVSVAPGQTARISCSGDNLRHYVYVWYQQKPGQAPVLVIYGDSKRPSGIPERFSGSNSGNTATLTISGT QAEDEADYYCQTYTGGASLVFGGGTKLTVLGQ (SEQ ID NO: 8),~~

~~where the sample is evaluated for total M-protein levels.~~

~~11. The antibody according to claim 9 or method according to claim 10, and, wherein said anti-idiotypic~~

~~antibody comprises a variable heavy chain comprising~~

~~an HCDR1 of the amino acid sequence YSFSNYWIS (of SEQ ID NO: 18), 26~~

~~an HCDR2 of the amino acid sequence WMGIIDPASSKTRYSPSFQG (of SEQ ID NO: 19),~~

~~an HCDR3 of the amino acid sequence SRGAGMDY (of SEQ ID NO: 20), and~~

~~a variable light chain comprising~~

~~an LCDR1 of the amino acid sequence TGSSSNIGAGYDVH (of SEQ ID NO: 21),~~

~~an LCDR2 of the amino acid sequence LLIYADNNRPS (of SEQ ID NO: 22),~~

an LCDR3 of the amino acid sequence ~~GSYDESSNSM~~ (of SEQ ID NO: 23).