

CLAIMS

1. Use of a bispecific antibody for the manufacture of a medicament for treating or managing an autoimmune disorder in a patient in need of such treatment or management, wherein the bispecific antibody binds to B-cell maturation antigen (BCMA) and an antigen that promotes activation of one or more T cells;

wherein the antigen that promotes activation of one or more T cells is CD3;

wherein the bispecific antibody is a trivalent bispecific antibody comprising two Fab fragments of an anti-BCMA antibody, one Fab fragment of an anti-CD3 antibody, and one Fc portion, wherein the bispecific antibody is in the format BCMA Fab - Fc - CD3 Fab - BCMA Fab;

wherein the anti-BCMA antibody has a variable region VH comprising an amino acid sequence that is identical to the amino acid sequence of SEQ ID NO:10 and a variable region VL comprising an amino acid sequence that is identical to the amino acid sequence of SEQ ID NO:14

wherein the anti-CD3 antibody comprises a variable region VH comprising an amino acid sequence that is identical to the amino acid sequence of SEQ ID NO:7 and a variable region VL comprising an amino acid sequence that is identical to the amino acid sequence of SEQ ID NO:8; and

wherein the autoimmune disorder is selected from the group consisting of IgA nephropathy, Membranous Nephropathy, Myasthenia gravis, Neuromyelitis optica, Pemphigus vulgaris, Anti-PAD4-activating rheumatoid arthritis, Sensitized / preformed antibodies in solid organ transplant, Guillain-Barre Syndrome (Acute inflammatory demyelinating polyneuropathy – AIDP), Chronic inflammatory demyelinating polyneuropathy (CIDP), Immune thrombocytopenic purpura, rheumatoid arthritis (RA) and anti-neutrophil cytoplasmic antibody ANCA-associated vasculitis (AAV).

2. The use according to claim 1, wherein the autoimmune disorder is AAV or RA.
3. The use according to claim 1 or claim 2, wherein the autoimmune disorder is AAV.

4. The use according to any one of claims 1 to 3, wherein the bispecific antibody comprises a heavy and light chain set consisting of polypeptides SEQ ID NO:48, SEQ ID NO:55, SEQ ID NO:56, and two copies of SEQ ID NO:57.

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5. The use according to any one of claims 1 to 4, wherein the AAV comprises diseases that are selected from the group consisting of granulomatosis with polyangiitis (GPA), eosinophilic granulomatosis with polyangiitis (EGPA), microscopic polyangiitis (MPA) and renal-limited ANCA-associated vasculitis.

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6. The use according to any one of claims 1 to 5, wherein the autoimmune disorder (e.g. AAV) is refractory or relapsed; and/or wherein the autoimmune disorder (e.g. AAV) is newly diagnosed.

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7. The use according to any one of claims 1 to 6, wherein the AAV is affecting one or more body parts of the patient selected from nervous system, eyes, nose, heart, kidneys, stomach, intestine, lungs, joints, muscles and skin.

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8. The use according to any one of claims 1 to 7, wherein the AAV is generalized with presence of life- or major organ-threatening manifestations.

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9. The use according to claim 8, wherein the patient has diffuse alveolar hemorrhage (DAH).

10. The use according to any one of claims 1 to 7, wherein the AAV is localized without organ-threatening manifestations.

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11. The use according to any one of claims 1 to 10, wherein:
 - (a) the patient is in need of plasmablast reduction;
 - (b) the patient is at risk of developing cytokine release syndrome;
 - (c) the patient is at risk of developing infection;
 - 5 (d) the patient is in need of induction of remission; and/or
 - (e) the patient is in need of maintenance of remission.

- 10 12. The use according to any one of claims 1 to 11, wherein the treatment or management results in:
 - (a) a reduction of plasmablasts in the patient by at least 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, at least 95%, or 100% relative to no treatment or a reference treatment;
 - (b) a lowered incidence of cytokine release syndrome in the patient by at least 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, at least 95%, or 100% relative to a reference treatment;
 - 15 (c) a lowered incidence of infection in the patient by at least 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, at least 95%, or 100% relative to a reference treatment;
 - 20 (d) a faster induction of remission in the patient by at least 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, at least 95%, or 100% relative to a reference treatment; and/or
 - (e) a longer maintenance of remission in the patient by at least 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, at least 95%, 25 or 100% relative to a reference treatment.

- 30 13. The use according to claim 12, wherein the reference treatment is treatment with steroids (e.g. glucocorticoids), cyclophosphamide, an anti-CD20 monoclonal antibody (e.g. rituximab), methotrexate, azathioprine, mycophenolate, mycophenolate mofetil, avacopan, anti-TNF agents (e.g. infliximab, adalimumab, golimumab, etanercept), anti-IL6R antibodies (e.g. tocilizumab, sarilumab), costimulatory blockade (e.g. abatacept), JAK inhibitors (e.g. tofacitinib, baricitinib) and/or belimumab, preferably wherein the reference treatment is treatment with steroids, cyclophosphamide or rituximab.

14. The use according to any one of claims 1 to 13, wherein the treatment or management is used for the induction of remission or the maintenance of remission.