Claims

1 A monoclonal antibody or antigen-binding fragment thereof that specifically binds to CD20 comprising:
(i) 1) the heavy chain variable domain comprises an amino acid sequence shown in SEQ ID NO: 2; and
2) the light chain variable domain comprises an amino acid sequence shown in SEQ ID NO: 4; or
(ii) 1) the heavy chain variable domain comprises an amino acid sequence shown in SEQ ID NO: 6; and
2) the light chain variable domain comprises an amino acid sequence shown in SEQ ID NO: 8.

2 The monoclonal antibody according to Claim 1 comprising:
(i) 1) a heavy chain comprising an amino acid sequence shown in SEQ ID NO: 1; and
2) a light chain comprising an amino acid sequence shown in SEQ ID NO: 3; or
(ii) 1) a heavy chain comprising an amino acid sequence shown in SEQ ID NO: 5; and
2) a light chain comprising an amino acid sequence shown in SEQ ID NO: 7.

3 The monoclonal antibody according to Claim 1, wherein the antibody that specifically binds to CD20 is a full-length IgG antibody.

4 The monoclonal antibody according to Claim 3, wherein the full-length IgG antibody relates to human IgG1, IgG2, IgG3, IgG4 isotype.

5 The monoclonal antibody according to Claim 4, wherein the full IgG antibody relates to human IgG1 isotype.

6 A nucleic acid encoding the monoclonal antibody or antigen-binding fragment thereof according to any of Claims 1-5.

7 The nucleic acid according to Claim 6, wherein the nucleic acid is DNA.

8 An expression vector comprising the nucleic acid according to any of Claims 6-7.

9 A method for production of a host cell for production of the monoclonal antibody or antigen-binding fragment thereof according to any of Claims 1-5 comprising transformation of a cell with the expression vector according to Claim 8.

10 A host cell for production of the monoclonal antibody or antigen-binding fragment thereof according to any of Claims 1-5 comprising the nucleic acid according to any of Claims 6-7.

11 A method for production of the monoclonal antibody or antigen-binding fragment thereof according to any of Claims 1-5 comprising culturing of a host cell according to Claim 10 in a culture medium under conditions sufficient to produce said antibody or antigen-binding fragment thereof, if necessary, followed by isolation and purification of the produced antibody or antigen-binding fragment thereof.

12 A pharmaceutical composition comprising the monoclonal antibody or antigen-binding fragment thereof according to any of Claims 1-5 in combination with one or more pharmaceutically acceptable excipients.

13 A monoclonal antibody or antigen-binding fragment thereof according to any of Claims 1-5 or a pharmaceutical composition according to claim 12 for the treatment of a disease or disorder mediated by CD20, wherein the disease or disorder is selected from:

a) an oncological disease or disorder

wherein the oncological disease or disorder is selected from the group consisting of: B cell lymphoma or leukemia; or

b) an autoimmune disease or disorder;

wherein the autoimmune disease or disorder is selected from the group consisting of: rheumatoid arthritis, juvenile rheumatoid arthritis (Still's disease), systemic lupus erythematosus (SLE), lupus nephritis, ulcerative colitis, Wegener's disease, inflammatory bowel disease, idiopathic thrombocytopenic purpura (ITP), thrombotic throbocytopenic purpura (TTP), autoimmune thrombocytopenia, multiple sclerosis, psoriasis, IgA nephropathy, IgM polyneuropathies, myasthenia gravis, vasculitis, ANCA vasculitis, rejection of graft of parenchymatous organs, graft-versus-host disease (GvHD), diabetes mellitus, Raynaud's syndrome, Sjorgen's syndrome and glomerulonephritis.

14 A monoclonal antibody or antigen-binding fragment thereof according to any of Claims 1-5 or a pharmaceutical composition according to claim 12 for the treatment according to Claim 13, wherein the B cell lymphoma is selected from: non-Hodgkin lymphoma (NHL) or Hodgkin’s disease (Hodgkin’s lymphoma); or

wherein the leukemia is selected from: chronic

lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

15 A pharmaceutical combination comprising the monoclonal antibody or antigen-binding fragment thereof according to any of Claims 1-5 and at least one different therapeutically active compound.

16 The pharmaceutical combination according to Claim 15, wherein the different therapeutically active antitumour compound is selected from a chemotherapeutic agent, antibody or anti-hormonal agent.

17 The pharmaceutical combination according to claim 15 for the treatment of a disease or disorder mediated by CD20; wherein the disease or disorder is selected from:

a) an oncological disease or disorder;

wherein the oncological disease or disorder is selected from the group consisting of: B cell lymphoma or leukemia; or

b) an autoimmune disease or disorder;

wherein the autoimmune disease or disorder is selected from the group consisting of: rheumatoid arthritis, juvenile rheumatoid arthritis (Still's disease), systemic lupus erythematosus (SLE), lupus nephritis, ulcerative colitis, Wegener's disease, inflammatory bowel disease, idiopathic thrombocytopenic purpura (ITP), thrombotic throbocytopenic purpura (TTP), autoimmune thrombocytopenia, multiple sclerosis, psoriasis, IgA nephropathy, IgM polyneuropathies, myasthenia gravis, vasculitis, ANCA vasculitis, rejection of graft of parenchymatous organs, graft-versus-host disease (GvHD), diabetes mellitus, Raynaud's syndrome, Sjorgen's syndrome and glomerulonephritis.

18 The pharmaceutical combination according to claim 15 for the treatment according to Claim 17, wherein the B cell lymphoma is selected from: non-Hodgkin lymphoma (NHL) or Hodgkin’s disease (Hodgkin’s lymphoma); or

wherein the leukemia is selected from: chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

19 Use of the monoclonal antibody or antigen-binding fragment thereof according to any of Claims 1-5 or the pharmaceutical composition according to Claim 12 in the manufacture of a medicament for the treatment of a disease or disorder mediated by CD20;

wherein the disease or disorder is selected from:

a) an oncological disease or disorder,

wherein the oncological disease or disorder is selected from the group consisting of: B cell lymphoma or leukemia; or

b) an autoimmune disease or disorder,

wherein the autoimmune disease or disorder is selected from the group consisting of: rheumatoid arthritis, juvenile rheumatoid arthritis (Still's disease), systemic lupus erythematosus (SLE), lupus nephritis, ulcerative colitis, Wegener's disease, inflammatory bowel disease, idiopathic thrombocytopenic purpura (ITP), thrombotic throbocytopenic purpura (TTP), autoimmune thrombocytopenia, multiple sclerosis, psoriasis, IgA nephropathy, IgM polyneuropathies, myasthenia gravis, vasculitis, ANCA vasculitis, rejection of graft of parenchymatous organs, graft-versus-host disease (GvHD), diabetes mellitus, Raynaud's syndrome, Sjorgen's syndrome and glomerulonephritis.

20 The use according to Claim 19, wherein the B cell lymphoma is selected from: non-Hodgkin lymphoma (NHL) or Hodgkin’s disease (Hodgkin’s lymphoma); or

wherein the leukemia is selected from: chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).