

Claims

1 A monoclonal antibody or antigen-binding fragment thereof that specifically binds to CD20 comprising:

- ~~1) a heavy chain variable domain comprising an amino acid sequence shown in SEQ ID NO: 2 or SEQ ID NO: 6;~~
- ~~2) a light chain variable domain comprising an amino acid sequence shown in SEQ ID NO: 4 or SEQ ID NO: 8.~~

~~2 A monoclonal antibody or antigen-binding fragment thereof according to Claim 1, wherein~~

- ~~(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.~~

~~3 A monoclonal antibody or antigen-binding fragment thereof according to Claim 1, wherein~~

- ~~(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.~~

~~4 A monoclonal antibody according to Claim 1 comprising:~~

- ~~1) a heavy chain comprising an amino acid sequence shown in SEQ ID NO: 1 or SEQ ID NO: 5;~~
- ~~2) a light chain comprising an amino acid sequence shown in SEQ ID NO: 3 or SEQ ID NO: 7.~~

~~5—2 A—The~~ monoclonal antibody according to Claim ~~4—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.~~

~~6 A monoclonal antibody according to Claim 4 comprising:~~

- ~~(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.~~

~~7—3 A—The~~ monoclonal antibody according to Claim 1, wherein the antibody that specifically binds to CD20 is a full-length IgG antibody.

~~8—4 A—The~~ monoclonal antibody according to Claim ~~7—3~~, wherein the full-length IgG antibody relates to human IgG1, IgG2, IgG3, IgG4 isotype.

~~9—5~~ A—The monoclonal antibody according to Claim ~~8~~4,
wherein the full IgG antibody relates to human IgG1 isotype.

~~10—6~~ A nucleic acid encoding an antibody or antigen-
binding fragment thereof according to any of Claims 1-~~9~~5.

~~11—7~~ A—The nucleic acid according to Claim ~~10~~6, wherein
the nucleic acid is DNA.

~~12—8~~ An expression vector comprising a—the nucleic acid
according to any of Claims ~~10~~6-117.

~~13—9~~ A method for production of a host cell for production
of an antibody or antigen-binding fragment thereof according
to any of Claims 1-~~9~~5 comprising transformation of a cell
with a—the expression vector according to Claim ~~12~~8.

~~14—10~~ A host cell for production of an antibody or
antigen-binding fragment thereof according to any of Claims
1-~~9~~5 comprising a—the nucleic acid according to any of
Claims ~~10~~6-117.

~~15—11~~ A method for production of an antibody or antigen-
binding fragment thereof according to any of Claims 1-~~9~~5
comprising culturing of a host cell according to Claim ~~14~~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.

~~16—12~~ A pharmaceutical composition for prophylaxis or
~~treatment of a disease or disorder mediated by CD20~~
comprising an antibody or antigen-binding fragment thereof
according to any of Claims 1-~~9~~5 in combination with one or
more pharmaceutically acceptable excipients.

13 An 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

~~17—A pharmaceutical composition for prophylaxis or~~
~~treatment according to Claim 16,~~ wherein the disease or
disorder is selected from:

- a) an oncological disease or disorder ~~or~~
- b) ~~an autoimmune disease or disorder.~~

~~18—A pharmaceutical composition according to Claim 17,~~
wherein the oncological disease or disorder is selected from
the group comprising: B cell lymphoma or leukemia; ~~or—~~

- b) an autoimmune disease or disorder;

wherein the autoimmune disease or disorder is selected from the group comprising: 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 thrombocytopenic 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.

~~19—14~~ An antibody or antigen-binding fragment thereof according to any of Claims 1-5 or a pharmaceutical composition according to claim 12 for the treatment A ~~pharmaceutical composition according to Claim 18~~13, wherein the B cell lymphoma is selected from: non-Hodgkin lymphoma (NHL) or Hodgkin's disease (Hodgkin's lymphoma); ~~or~~.

~~20—A pharmaceutical composition according to Claim 18,~~ wherein the leukemia is selected from: chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

~~21—A pharmaceutical composition according to Claim 17, wherein the autoimmune disease or disorder is selected from the group comprising: 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 thrombocytopenic 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.~~

~~22—15~~ A pharmaceutical combination for prophylaxis or treatment of a disease or disorder mediated by CD20 comprising an antibody or antigen-binding fragment thereof according to any of Claims 1-95 and at least one different therapeutically active compound.

~~23—16~~ A ~~The~~ pharmaceutical combination according to Claim ~~22~~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;

~~24 A method for inhibition of biological activity of CD20 in a subject in need of such inhibition comprising administration of an effective amount of an antibody or antigen-binding fragment thereof according to any of Claims 1-9.~~

~~25 A method for treatment of a disease or disorder mediated by CD20 comprising administration in a subject in need of such treatment of an antibody or antigen-binding fragment thereof according to any of Claims 1-9 or a pharmaceutical composition according to Claim 16 in a therapeutically effective amount.~~

~~26 A method for treatment of a disease or disorder according to Claim 25, 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 comprising: B cell lymphoma or leukemia; or~~

~~b) an autoimmune disease or disorder;-
wherein the autoimmune disease or disorder is selected from the group comprising: 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 thrombocytopenic 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.~~

~~27 A method for treatment of a disease or disorder according to Claim 26, wherein the oncological disease or disorder is selected from the group comprising: B cell lymphoma or leukemia.~~

~~28—18 The pharmaceutical combination according to claim 15 for the treatment A method for treatment of a disease or disorder according to Claim 27~~¹⁷, wherein the B cell lymphoma is selected from: non-Hodgkin lymphoma (NHL) or Hodgkin's disease (Hodgkin's lymphoma); or-

~~29 A method for treatment of a disease or disorder according to Claim 27, wherein the leukemia is selected from: chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).~~

~~30—A method for treatment of a disease or disorder according to Claim 26, wherein the autoimmune disease or disorder is selected from the group comprising: 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 thrombocytopenic 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.~~

~~31—19 Use of an antibody or antigen-binding fragment thereof according to any of Claims 1-9-5 or a pharmaceutical composition according to Claim 16-12 in the manufacture of a medicament for the treatment in a subject in need of such treatment of a disease or disorder mediated by CD20;~~

~~32—Use of an antibody or antigen-binding fragment thereof according to Claim 27, 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 comprising: B cell lymphoma or leukemia; or
b) an autoimmune disease or disorder,
wherein the autoimmune disease or disorder is selected from the group comprising: 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 thrombocytopenic 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.~~

~~33—The use of an antibody or antigen-binding fragment thereof according to Claim 32, wherein the oncological disease or disorder is selected from the group comprising: B cell lymphoma or leukemia.~~

~~34—20 The use of an antibody or antigen-binding fragment thereof according to Claim 33-19, wherein the B cell lymphoma is selected from: non-Hodgkin lymphoma (NHL) or Hodgkin's disease (Hodgkin's lymphoma); or—~~

35—The use of an antibody or antigen-binding fragment thereof according to Claim 33, wherein the leukemia is selected from: chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

36—The use of an antibody or antigen-binding fragment thereof according to Claim 32, wherein the autoimmune disease or disorder is selected from the group comprising: 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 thrombocytopenic 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.