## Claims

1. A monoclonal antibody or antigen-binding fragment thereof that specifically binds to the TRBV5-1 segment of the human T cell receptor beta-chain variable domain, comprising:

(i) (a) a light chain variable domain comprising:

CDR1 with the amino acid sequence of SEQ ID NO: 1,

CDR2 with the amino acid sequence of SEQ ID NO: 4 and

CDR3 with the amino acid sequence of SEQ ID NO: 8; and

(b) a heavy chain variable domain comprising:

CDR1 with the amino acid sequence of SEQ ID NO: 12,

CDR2 with the amino acid sequence of SEQ ID NO: 13 and

CDR3 with the amino acid sequence of SEQ ID NO: 18; or

(ii) (a) a light chain variable domain comprising:

CDR1 with the amino acid sequence of SEQ ID NO: 2,

CDR2 with the amino acid sequence of SEQ ID NO: 5 and

CDR3 with the amino acid sequence of SEQ ID NO: 9; and

(b) a heavy chain variable domain comprising:

CDR1 with the amino acid sequence of SEQ ID NO: 12,

CDR2 with the amino acid sequence of SEQ ID NO: 13 and

CDR3 with the amino acid sequence of SEQ ID NO: 18; or

(iii) (a) a light chain variable domain comprising:

CDR1 with the amino acid sequence of SEQ ID NO: 1,

CDR2 with the amino acid sequence of SEQ ID NO: 5 and

CDR3 with the amino acid sequence of SEQ ID NO: 8; and

(b) a heavy chain variable domain comprising:

CDR1 with the amino acid sequence of SEQ ID NO: 12,

CDR2 with the amino acid sequence of SEQ ID NO: 14 and

CDR3 with the amino acid sequence of SEQ ID NO: 18; or

(iv) (a) a light chain variable domain comprising:

CDR1 with the amino acid sequence of SEQ ID NO: 2,

CDR2 with the amino acid sequence of SEQ ID NO: 4 and

CDR3 with the amino acid sequence of SEQ ID NO: 9; and

(b) a heavy chain variable domain comprising:

CDR1 with the amino acid sequence of SEQ ID NO: 12,

CDR2 with the amino acid sequence of SEQ ID NO: 14 and

CDR3 with the amino acid sequence of SEQ ID NO: 18; or

(v) (a) a light chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 2,
CDR2 with the amino acid sequence of SEQ ID NO: 6 and
CDR3 with the amino acid sequence of SEQ ID NO: 8; and
(b) a heavy chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 12,
CDR2 with the amino acid sequence of SEQ ID NO: 14 and
CDR3 with the amino acid sequence of SEQ ID NO: 18; or
(vi) (a) a light chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 2,
CDR2 with the amino acid sequence of SEQ ID NO: 6 and
CDR3 with the amino acid sequence of SEQ ID NO: 8; and
(b) a heavy chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 12,
CDR2 with the amino acid sequence of SEQ ID NO: 13 and
CDR3 with the amino acid sequence of SEQ ID NO: 18; or
(vii) (a) a light chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 1,
CDR2 with the amino acid sequence of SEQ ID NO: 4 and
CDR3 with the amino acid sequence of SEQ ID NO: 8; and
(b) a heavy chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 12,
CDR2 with the amino acid sequence of SEQ ID NO: 15 and
CDR3 with the amino acid sequence of SEQ ID NO: 18; or
(viii) (a) a light chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 2,
CDR2 with the amino acid sequence of SEQ ID NO: 4 and
CDR3 with the amino acid sequence of SEQ ID NO: 9; and
(b) a heavy chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 12,
CDR2 with the amino acid sequence of SEQ ID NO: 15 and
CDR3 with the amino acid sequence of SEQ ID NO: 18; or
(ix) (a) a light chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 1,
CDR2 with the amino acid sequence of SEQ ID NO: 6 and

CDR3 with the amino acid sequence of SEQ ID NO: 9; and
(b) a heavy chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 12,
CDR2 with the amino acid sequence of SEQ ID NO: 15 and
CDR3 with the amino acid sequence of SEQ ID NO: 18; or
(x) (a) a light chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 2,
CDR2 with the amino acid sequence of SEQ ID NO: 6 and
CDR3 with the amino acid sequence of SEQ ID NO: 11; and
(b) a heavy chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 12,
CDR2 with the amino acid sequence of SEQ ID NO: 15 and
CDR3 with the amino acid sequence of SEQ ID NO: 18; or
(xi) (a) a light chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 1,
CDR2 with the amino acid sequence of SEQ ID NO: 5 and
CDR3 with the amino acid sequence of SEQ ID NO: 8; and
(b) a heavy chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 12,
CDR2 with the amino acid sequence of SEQ ID NO: 16 and
CDR3 with the amino acid sequence of SEQ ID NO: 18; or
(xii) (a) a light chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 1,
CDR2 with the amino acid sequence of SEQ ID NO: 4 and
CDR3 with the amino acid sequence of SEQ ID NO: 8; and
(b) a heavy chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 12,
CDR2 with the amino acid sequence of SEQ ID NO: 16 and
CDR3 with the amino acid sequence of SEQ ID NO: 18; or
(xiii) (a) a light chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 3,
CDR2 with the amino acid sequence of SEQ ID NO: 7 and
CDR3 with the amino acid sequence of SEQ ID NO: 10; and
(b) a heavy chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 12,

CDR2 with the amino acid sequence of SEQ ID NO: 17 and
CDR3 with the amino acid sequence of SEQ ID NO: 18; or
(xiv) (a) a light chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 2,
CDR2 with the amino acid sequence of SEQ ID NO: 5 and
CDR3 with the amino acid sequence of SEQ ID NO: 9; and
(b) a heavy chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 12,
CDR2 with the amino acid sequence of SEQ ID NO: 16 and
CDR3 with the amino acid sequence of SEQ ID NO: 18; or
(xv) (a) a light chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 2,
CDR2 with the amino acid sequence of SEQ ID NO: 4 and
CDR3 with the amino acid sequence of SEQ ID NO: 9; and
(b) a heavy chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 12,
CDR2 with the amino acid sequence of SEQ ID NO: 16 and
CDR3 with the amino acid sequence of SEQ ID NO: 18; or
(xvi) (a) a light chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 1,
CDR2 with the amino acid sequence of SEQ ID NO: 6 and
CDR3 with the amino acid sequence of SEQ ID NO: 9; and
(b) a heavy chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 12,
CDR2 with the amino acid sequence of SEQ ID NO: 16 and
CDR3 with the amino acid sequence of SEQ ID NO: 18; or
(xvii) (a) a light chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 2,
CDR2 with the amino acid sequence of SEQ ID NO: 6 and
CDR3 with the amino acid sequence of SEQ ID NO: 11; and
(b) a heavy chain variable domain comprising:
CDR1 with the amino acid sequence of SEQ ID NO: 12,
CDR2 with the amino acid sequence of SEQ ID NO: 16 and
CDR3 with the amino acid sequence of SEQ ID NO: 18; or
(xviii) (a) a light chain variable domain comprising:

CDR1 with the amino acid sequence of SEQ ID NO: 2,

CDR2 with the amino acid sequence of SEQ ID NO: 6 and

CDR3 with the amino acid sequence of SEQ ID NO: 8; and

(b) a heavy chain variable domain comprising:

CDR1 with the amino acid sequence of SEQ ID NO: 12,

CDR2 with the amino acid sequence of SEQ ID NO: 16 and

CDR3 with the amino acid sequence of SEQ ID NO: 18; or

(ixx) (a) a light chain variable domain comprising:

CDR1 with the amino acid sequence of SEQ ID NO: 2,

CDR2 with the amino acid sequence of SEQ ID NO: 6 and

CDR3 with the amino acid sequence of SEQ ID NO: 10; and

(b) a heavy chain variable domain comprising:

CDR1 with the amino acid sequence of SEQ ID NO: 12,

CDR2 with the amino acid sequence of SEQ ID NO: 17 and

CDR3 with the amino acid sequence of SEQ ID NO: 18; or

(xx) (a) a light chain variable domain comprising:

CDR1 with the amino acid sequence of SEQ ID NO: 2,

CDR2 with the amino acid sequence of SEQ ID NO: 7 and

CDR3 with the amino acid sequence of SEQ ID NO: 9; and

(b) a heavy chain variable domain comprising:

CDR1 with the amino acid sequence of SEQ ID NO: 12,

CDR2 with the amino acid sequence of SEQ ID NO: 17 and

CDR3 with the amino acid sequence of SEQ ID NO: 18.

2. The monoclonal antibody or antigen-binding fragment thereof according to claim 1, wherein:

(i) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 19 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 29; or

(ii) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 20 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 29; or

(iii) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 21 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 30; or

(iv) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 22 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 30; or

(v) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 23 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 30; or

(vi) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 23 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 31; or

(vii) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 19 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 32; or

(viii) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 22 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 32; or

(ix) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 24 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 32; or

(x) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 26 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 32; or

(xi) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 21 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 33; or

(xii) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 19 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 33; or

(xiii) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 25 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 34; or

(xiv) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 20 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 33; or

(xv) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 22 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 33; or

(xvi) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 24 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 33; or

(xvii) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 26 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 33; or

(xviii) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 23 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 33; or

(ixx) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 27 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 34; or

(xx) (a) the light chain variable domain comprises the amino acid sequence of SEQ ID NO: 28 and

(b) the heavy chain variable domain comprises the amino acid sequence of SEQ ID NO: 34.

3. The monoclonal antibody according to claim 1, wherein the antibody that specifically binds to the TRBV5-1 segment of the human T cell receptor beta-chain variable domain is a full-length IgG antibody.

4. The monoclonal antibody according to claim 3, wherein the full-length IgG antibody is of human IgG1, IgG2, IgG3 or IgG4 isotype.

5. The monoclonal antibody according to claim 4, wherein the antibody comprises:

i) 446G and 447K deletion according to the EU numbering scheme for amino acids of antibodies in the CH3 region; or

ii) S239D and I332E mutations according to the EU numbering scheme for amino acids of antibodies; or

iii) G236A, S239D and I332E mutations according to the EU numbering scheme for amino acids of antibodies.

6. The monoclonal antibody according to claim 1, comprising:

(i) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 35, and

(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 45; or

(ii) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 36, and

(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 46; or

(iii) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 37, and

(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 47; or

(iv) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 38, and

(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 47; or

(v) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 39, and

(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 48; or

(vi) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 39, and

(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 49; or

(vii) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 35, and

(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 50; or

(viii) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 38, and

(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 50; or

(ix) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 40, and

(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 50; or

(x) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 42, and

(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 50; or

(xi) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 37, and
(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 51; or
(xii) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 35, and
(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 51; or
(xiii) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 41, and
(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 52; or
(xiv) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 36, and
(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 51; or
(xv) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 38, and
(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 51; or
(xvi) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 40, and
(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 51; or
(xvii) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 42, and
(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 51; or
(xviii) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 39, and
(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 51; or
(ixx) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 43, and
(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 52; or
(xx) (a) a light chain comprising the amino acid sequence of SEQ ID NO: 44, and
(b) a heavy chain comprising the amino acid sequence of SEQ ID NO: 52.

7. The nucleic acid that encodes the antibody or antigen-binding fragment thereof according to any one of claims 1–6.

8. An expression vector comprising the nucleic acid according to claim 7.

9. A host cell for producing the antibody or antigen-binding fragment thereof according to any one of claims 1–6, comprising the nucleic acid according to claim 7.

10. A method for producing the antibody or antigen-binding fragment thereof according to any one of claims 1–6, comprising culturing the host cell according to claim 9 in a growth medium under conditions sufficient to produce said antibody, followed by isolation and purification of the resulting antibody.

11. A pharmaceutical composition, comprising the antibody or antigen-binding fragment thereof according to any one of claims 1–6 in a therapeutically effective amount in combination with one or more pharmaceutically acceptable excipients.

12. The pharmaceutical composition, comprising the antibody or antigen-binding fragment thereof according to any one of claims 1–6 and at least one other therapeutically active compound.

13. The pharmaceutical composition according to claim 12, wherein the other therapeutically active compound is an antibody, insulin preparations, a small molecule, a hormone therapy agent or any combination thereof.

14. The pharmaceutical composition according to any one of claims 11 or 12, intended for treatment or prophylaxis of a disease or disorder mediated by the TRBV5-1 segment of the human T cell receptor beta-chain variable domain.

15. The pharmaceutical composition according to claim 14, wherein the disease or disorder mediated by the TRBV5-1 segment of the human T cell receptor beta-chain variable domain is selected from the group: type I diabetes mellitus, delayed progression of stage 2 to stage 3 type I diabetes mellitus, high blood glucose, impaired glucose tolerance, prediabetes, rejection of nickel implants or prostheses, sarcoidosis, berylliosis, celiac disease or dermatitis herpetiformis.