

CLAIMS

- 1.** A humanized antibody capable of binding to human Tim-3, comprising:
a heavy chain variable region (VH) comprising a VH-CDR1 amino acid sequence of SEQ ID NO 3, a VH-CDR2 amino acid sequence of SEQ ID NO 26 and a VH-CDR3 amino acid sequence of SEQ ID NO 5; and a light chain variable region (VL) comprising a VL-CDR1 amino acid sequence of SEQ ID NO 6, a VL-CDR2 amino acid sequence of SEQ ID NO 7 and a VL-CDR3 amino acid sequence of SEQ ID NO 27.
- 2.** The antibody of Claim 1, comprising:
a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO 28, and a light chain variable domain having the amino acid sequence of SEQ ID NO 36.
- 3.** The antibody of Claim 1 or 2, wherein the antibody is a Fab, F(ab')₂, Fv, or a single chain Fv (ScFv).
- 4.** The antibody of Claim 1 or 2, wherein the antibody comprises a heavy chain constant region of the subclass of IgG1, IgG2, IgG3, or IgG4 or a variant thereof, and a light chain constant region of the type of kappa or lambda or a variant thereof.
- 5.** The antibody of Claim 4, wherein the antibody comprises a variant heavy chain constant region of the subclass of IgG1, IgG2, IgG3, or IgG4, wherein the variant heavy chain constant region provides a reduced or eliminated effector function.
- 6.** The antibody of Claim 5, wherein the effector function is antibody-dependent cell-mediated cytotoxicity (ADCC) or complement-dependent cytotoxicity (CDC).
- 7.** The antibody of Claim 4, wherein the antibody comprises a heavy chain constant region of human IgG1 or a variant thereof.
- 8.** The antibody of Claim 7, wherein the variant heavy chain constant region of human IgG1 comprises one or more mutations selected from a group consisting of E₂₃₃P, L₂₃₄A, L₂₃₅A, L₂₃₆Δ and P₃₂₉A.
- 9.** The antibody of Claim 8, wherein the variant human IgG1 heavy chain constant region comprising the amino sequence of SEQ ID NO 21, and a human kappa light chain constant region.
- 10.** A pharmaceutical composition, comprising the antibody of any one of Claims 1-9, and a pharmaceutically acceptable excipient.
- 11.** The antibody according to any one of Claims 1-9 for use in medicine.

- 12.** Use of an antibody according to any one of Claims 1 to 9 in the preparation of a pharmaceutical composition for treating a cancer or a tumor, wherein the antibody is to be administered in combination with a second therapeutic agent wherein the second therapeutic agent is selected from a chemotherapy, a targeted therapy, an oncolytic drug, a cytotoxic agent, an immune-based therapy, a cytokine, an activator of a costimulatory molecule, an inhibitor of an inhibitory molecule, a vaccine, or a cellular immunotherapy.
- 13.** The use according to Claim 12, wherein the cancer is selected from a lung cancer, a liver cancer, a stomach cancer, a cervical cancer, a melanoma, a renal cancer, a breast cancer, a colorectal cancer, a leukemia, a lymphoma, an ovarian cancer, a head and neck cancer or a metastatic lesion of the cancer.
- 14.** The use of Claim 12 or 13, wherein the antibody is to be administered in combination with an inhibitor of an immune checkpoint molecule selected from PD-1, PD-L1, PD-L2, CTLA-4, LAG-3, CEACAM-1, CEACAM-5, VISTA, BTLA, TIGIT, LAIR1, CD160, 2B4 or TGFR.
- 15.** The use of Claim 12 or 13, wherein the antibody is to be administered in combination with an anti-PD-1 mAb 317-4B6, or 317-4B6/IgG4mt10.
- 16.** Use of an antibody according to any one of Claims 1 to 9 in the preparation of a pharmaceutical composition for treating an infectious disease.
- 17.** The use of Claim 12, wherein the infectious disease is a chronic viral infection.