

CLAIMS

What is claimed is

1. Use of a T Cell Immunoglobulin and Mucin Protein 3 (TIM-3) binding agent in the manufacture of a medicament for treating cancer in a human, wherein the TIM-3 binding agent is an antibody, an antibody conjugate, or an antigen binding fragment thereof, wherein the TIM-3 binding agent comprises a heavy chain variable region with three CDR sequences of SEQ ID NOs: 21 (HCDR1), 22 (HCDR2) and 23 (HCDR3), and a light chain variable region with three CDR sequences of SEQ ID NOs: 24 (LCDR1), 25 (LCDR2) and 26 (LCDR3), wherein the TIM-3 binding agent is to be administered at a flat dose of between 100 mg and 1500 mg.
2. The use of claim 1, wherein the TIM-3 binding agent is to be administered at a flat dose of about 100 mg, 300 mg or 900 mg.
3. The use of claim 1 or claim 2, wherein the TIM-3 binding agent is to be administered once every three weeks (Q3W).
4. The use of claim 3, wherein the TIM-3 binding agent is to be administered at a dose of about 300 mg once every three weeks (Q3W).
5. The use of any of the preceding claims, wherein the TIM-3 binding agent comprises an immunoglobulin heavy chain variable domain comprising an amino acid sequence having at least about 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99% or 100% sequence identity to SEQ ID NO:1 or SEQ ID NO:7 and/or an immunoglobulin light chain comprising an amino acid sequence having at least about 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99% or 100% sequence identity to SEQ ID NO:2 or SEQ ID NO:8.
6. The use of claim 5, wherein the TIM-3 binding agent is an immunoglobulin G4 (IgG4) humanized monoclonal antibody.
7. The use of claim 5 or claim 6, wherein the TIM-3 binding agent comprises an immunoglobulin heavy chain comprising an amino acid sequence having at least about 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99% or 100% sequence identity to SEQ ID NO:3 and/or an immunoglobulin light chain comprising an amino acid sequence having at least about 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99% or 100% sequence identity to SEQ ID NO:4.

8. The use of any of the preceding claims, wherein the TIM-3 binding agent is to be administered intravenously, optionally by intravenous infusion.
9. The use of any of the preceding claims, wherein the cancer is a solid tumour, optionally an advanced stage solid tumour.
10. The use of any of the preceding claims, wherein the cancer is:
 - i. a cancer associated with a high tumour mutation burden (TMB);
 - ii. a cancer that is microsatellite stable (MSS);
 - iii. a cancer that is characterized by microsatellite instability;
 - iv. a cancer that has a high microsatellite instability status (MSI-H);
 - v. a cancer that has a low microsatellite instability status (MSI-L);
 - vi. a cancer associated with high TMB and MSI-H;
 - vii. a cancer associated with high TMB and MSI-L or MSS;
 - viii. a cancer that has a defective DNA mismatch repair system;
 - ix. a cancer that has a defect in a DNA mismatch repair gene;
 - x. a hypermutated cancer;
 - xi. a cancer comprising a mutation in polymerase delta (POLD);
 - xii. a cancer comprising a mutation in polymerase epsilon (POLE);
 - xiii. a cancer that has homologous recombination repair deficiency/homologous repair deficiency (HRD).
 - xiv. adenocarcinoma, endometrial cancer, breast cancer, ovarian cancer, cervical cancer, fallopian tube cancer, testicular cancer, primary peritoneal cancer, colon cancer, colorectal cancer, stomach cancer, small intestine cancer, squamous cell carcinoma of the anus, squamous cell carcinoma of the penis, squamous cell carcinoma of the cervix, squamous cell carcinoma of the vagina, squamous cell carcinoma of the vulva, soft tissue sarcoma, melanoma, renal cell carcinoma, lung cancer, non-small cell lung cancer, adenocarcinoma of the lung, squamous cell carcinoma of the lung, stomach cancer, bladder cancer, gall bladder cancer, liver cancer, thyroid cancer, laryngeal cancer, salivary gland cancer, oesophageal cancer, head and neck cancer, squamous cell carcinoma of the head and neck, prostate cancer, pancreatic cancer, mesothelioma, Merkel cell carcinoma, sarcoma, glioblastoma, a haematological cancer, multiple myeloma, B-cell lymphoma, T-

cell lymphoma, Hodgkin's lymphoma/primary mediastinal B-cell lymphoma, chronic myelogenous leukaemia, acute myeloid leukaemia, non-Hodgkin's lymphoma, neuroblastoma, a CNS tumour, diffuse intrinsic pontine glioma (DIPG), Ewing's sarcoma, embryonal rhabdomyosarcoma, osteosarcoma, or Wilms tumour; or

- xv. a cancer of xiv) wherein the cancer is MSS or MSI-L, is characterized by microsatellite instability, is MSI-H, has high TMB, has high TMB and is MSS or MSI-L, has high TMB and is MSI-H, has a defective DNA mismatch repair system, has a defect in a DNA mismatch repair gene, is a hypermutated cancer, is an HRD cancer, comprises a mutation in polymerase delta (POLD), or comprises a mutation in polymerase epsilon (POLE).

11. The use of any of the preceding claims, wherein the human has been administered or is to be administered an immune checkpoint inhibitor or an agent that inhibits poly (ADP-ribose) polymerase (PARP).
12. The use of any of the preceding claims, wherein the human is resistant or refractory to treatment with a PD-1 inhibitor.
13. The use of any of the preceding claims, wherein the human has previously been treated with one or more different cancer modalities, optionally one or more of surgery, radiotherapy, chemotherapy, or immunotherapy.