

WHAT IS CLAIMED IS:

1. Use of an anti-PD-1 antagonist and an indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor in the manufacture of a medicament for the treatment of cancer in a human subject, wherein the medicament is to be administered to the subject,

wherein the subject is identified as exhibiting a combined biomarker comprising (a) a high *IFN* γ inflammatory signature score and (b) a low tryptophan 2,3-dioxygenase 2 (*TDO2*) gene expression score prior to the medicament is to be administered;

wherein the *IFN* γ inflammatory signature score is determined by measuring the expression of a panel of inflammatory genes comprising interferon gamma (*IFN* γ) related genes ("*IFN* γ inflammatory gene panel") in a sample obtained from the subject.

2. Use of an anti-PD-1 antagonist and an IDO1 inhibitor in the manufacture of a medicament for the treatment of cancer in a human subject, wherein

(i) the subject is identified as exhibiting a combined biomarker comprising (a) a high *IFN* γ inflammatory signature score and (b) a low *TDO2* gene expression score; and,

(ii) the medicament is to be administered to the subject;

wherein the *IFN* γ inflammatory signature score is determined by measuring the expression of an *IFN* γ inflammatory gene panel in a sample obtained from the subject.

3. Use of an anti-PD-1 antagonist and an IDO1 inhibitor in the manufacture of a medicament for the treatment of cancer in a human subject, wherein the subject is identified as suitable for treatment with the medicament by measuring an *IFN* γ inflammatory signature score and *TDO2* gene expression in a sample obtained from the subject and;

wherein the *IFN* γ inflammatory signature score is determined by measuring the expression of an *IFN* γ inflammatory gene panel in a sample obtained from the subject.

4. The use of claim 3, wherein the subject exhibits a combined biomarker comprising (a) a high *IFN* γ inflammatory signature score and (b) a low *TDO2* gene expression score.

5. The use of claim 4, wherein the medicament is to be administered to the subject.

6. An IDO1 inhibitor for use in treating a cancer in combination with an anti-PD-1 antagonist in a human subject in need thereof, wherein the subject is identified as exhibiting a

combined biomarker comprising (a) a high *IFN* γ inflammatory signature score and (b) a low *TDO2* gene expression score prior to the IDO1 inhibitor is to be administered; and,

wherein the *IFN* γ inflammatory signature score is determined by measuring the expression of an *IFN* γ inflammatory gene panel in a sample obtained from the subject.

7. An combined biomarker for use in identifying a human subject afflicted with a cancer suitable for treatment with an IDO1 inhibitor in combination with an anti-PD-1 antagonist, wherein the combined biomarker comprises (i) an *IFN* γ inflammatory signature score and (ii) a *TDO2* gene expression measured in a sample obtained from the subject; and,

wherein the *IFN* γ inflammatory signature score is determined by measuring the expression of an *IFN* γ inflammatory gene panel in a sample obtained from the subject.

8. The combined biomarker for use of claim 7, wherein the subject exhibits a combined biomarker comprising (a) a high *IFN* γ inflammatory signature score and (b) a low *TDO2* gene expression score.

9. The use of any one of claims 1 to 5, IDO1 inhibitor for use of claim 6, or combined biomarker for use of claim 7 or 8, wherein the *IFN* γ inflammatory gene panel consists essentially of 1 inflammatory gene, 2 inflammatory genes, 3 inflammatory genes, 4 inflammatory genes, 5 inflammatory genes, 6 inflammatory genes, 7 inflammatory genes, 8 inflammatory genes, 9 inflammatory genes, 10 inflammatory genes, 11 inflammatory genes, 12 inflammatory genes, 13 inflammatory genes, 14 inflammatory genes, 15 inflammatory genes, 16 inflammatory genes, 17 inflammatory genes, 18 inflammatory genes, 19 inflammatory genes, 20 inflammatory genes, 21 inflammatory genes, 22 inflammatory genes, 23 inflammatory genes, 24 inflammatory genes, 25 inflammatory genes, 26 inflammatory genes, 27 inflammatory genes, or 28 inflammatory genes.

10. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 9 wherein the inflammatory genes are selected from the group consisting of *IFN* γ , *CXCL10*, *HLA-DRA*, *CXCR6*, *TIGIT*, *CD274 (PD-L1)*, *PDCD1LG2 (PD-L2)*, *LAG3*, *NKG7*, *PSMB10*, *CMKLR1*, *CD8A*, *IDO1*, *CCL5*, *CXCL9*, *HLA.DQA1*, *CD276*, *HLA.DRB1*, *STAT1*, *HLA.E*, *CCR5*, *CXCL11*, *GZMA*, *PRF1*, *IR2RG*, *CD3D*, *CD2*, *ITGAL*, *TAGAP*, *CIITA*, *PTPRC*, *CD3E*, *GZMK*, *GZMB*, *PDCD1*, *SLAMF6*, *CXCL13*, and any combination thereof.

11. The use of any one of claims 1 to 5, 9 and 10, the IDO1 inhibitor for use of any one of claims 6 and 9 to 10, or combined biomarker for use of any one of claims 7 to 10, wherein the *IFN* γ inflammatory gene panel consists of or consists essentially of

- (i) *IFN* γ , *CXCL10*, *CXCL9*, *HLA-DRA*, *IDO1*, and *STAT1*;
- (ii) *IFN* γ , *CXCL10*, *CXCL9*, *HLA-DRA*, *IDO1*, *STAT1*, *CCR5*, *CXCL11*, *GZMA*, and *PRF1*;
- (iii) *CXCR6*, *TIGIT*, *CD274 (PD-L1)*, *PDCD1LG2 (PD-L2)*, *LAG3*, *NKG7*, *PSMB10*, *CMKLR1*, *CD8A*, *IDO1*, *CCL5*, *CXCL9*, *HLA.DQA1*, *CD276*, *HLA.DRB1*, *STAT1*, *HLA.E*, and *TDO2*;
- (iv) *IFN* γ , *IR2RG*, *CXCR6*, *CD3D*, *CD2*, *ITGAL*, *TAGAP*, *CIITA*, *HLA-DRA*, *PTPRC*, *CXCL9*, *CCL5*, *NKG7*, *GZMA*, *PRF1*, *CCR5*, *CD3E*, *GZMK*, *HLA-E*, *GZMB*, *PDCD1*, *SLAMF6*, *CXCL13*, *CXCL10*, *IDO1*, *LAG3*, *STAT1*, *CXCL11* or,
- (v) any combination thereof.

12. The use of any one of claims 1 to 5 and 9 to 11, the IDO1 inhibitor for use of any one of claims 6 and 9 to 11, or combined biomarker for use of any one of claims 7 to 11, wherein the high *IFN* γ inflammatory signature score is characterized by an *IFN* γ inflammatory signature score that is greater than an average *IFN* γ inflammatory signature score, wherein the average *IFN* γ inflammatory signature score is determined by averaging the expression the genes of the *IFN* γ inflammatory gene panel in cancer samples obtained from a population of subjects afflicted with the cancer.

13. The use of any one of claims 1 to 5 and 9 to 12, IDO1 inhibitor for use of any one of claims 6 and 9 to 12, or combined biomarker for use of any one of claims 7 to 12, wherein the average *IFN* γ inflammatory signature score is determined by averaging the expression of the *IFN* γ inflammatory gene panel genes in cancer samples obtained from the population of subjects.

14. The use of any one of claims 1 to 5 and 9 to 13, IDO1 inhibitor for use of any one of claims 6 and 9 to 13, or combined biomarker for use of any one of claims 7 to 13, wherein the high *IFN* γ inflammatory signature score is characterized by an *IFN* γ inflammatory signature score that is higher than the average *IFN* γ inflammatory signature score of a reference sample.

15. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 14, wherein the reference sample comprises a non-tumor tissue of the subject, a corresponding non-tumor tissue of the subject, or the corresponding tissue of subjects without a tumor.

16. The use of any one of claims 1 to 5 and 9 to 15, IDO1 inhibitor for use of any one of claims 6 and 9 to 15, or combined biomarker for use of any one of claims 7 to 15, wherein the high *IFN* γ inflammatory signature score is characterized by an *IFN* γ inflammatory signature score that is at least about 25%, at least about 30%, at least about 35%, at least about 40%, at least about 45%, at least about 50%, at least about 55%, at least about 60%, at least about 65%, at least about 70%, at least about 75%, at least about 80%, at least about 85%, at least about 90%, at least about 95%, at least about 100%, at least about 125%, at least about 150%, at least about 175%, at least about 200%, at least about 225%, at least about 250%, at least about 275%, or at least about 300% higher than the average *IFN* γ inflammatory signature score.

17. The use of any one of claims 1 to 5 and 9 to 15, IDO1 inhibitor for use of any one of claims 6 and 9 to 15, or combined biomarker for use of any one of claims 7 to 15, wherein the *IFN* γ high inflammatory signature score is characterized by an *IFN* γ inflammatory signature score that is at least about 50% higher than the average *IFN* γ inflammatory signature score.

18. The use of any one of claims 1 to 5 and 9 to 15, IDO1 inhibitor for use of any one of claims 6 and 9 to 15, or combined biomarker for use of any one of claims 7 to 15, wherein the high *IFN* γ inflammatory signature score is characterized by an *IFN* γ inflammatory signature score that is at least about 75% higher than the average *IFN* γ inflammatory signature score.

19. The use of any one of claims 1 to 5 and 9 to 18, IDO1 inhibitor for use of any one of claims 6 and 9 to 18, or combined biomarker for use of any one of claims 7 to 18, wherein the low *TDO2* gene expression score is characterized by a *TDO2* gene expression that is smaller than an average *TDO2* gene expression score, wherein the average *TDO2* gene expression score is determined by averaging the expression of the *TDO2* gene in cancer samples obtained from a population of subjects afflicted with the cancer.

20. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 19, wherein the average *TDO2* gene expression score is determined by averaging the expression of the *TDO2* genes in cancer samples obtained from the population of subjects.

21. The use of any one of claims 1 to 5 and 9 to 18, IDO1 inhibitor for use of any one of claims 6 and 9 to 18, or combined biomarker for use of any one of claims 7 to 18, wherein the

low *TDO2* gene expression score is characterized by a *TDO2* gene expression that is lower than the average *TDO2* gene expression score of a reference sample.

22. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 21, wherein the reference sample comprises a non-tumor tissue of the subject, a corresponding non-tumor tissue of the subject, or the corresponding tissue of subjects without a tumor.

23. The use, IDO1 inhibitor for use, or combined biomarker for use of any one of claims 19 to 22, wherein the low *TDO2* gene expression score is characterized by a *TDO2* gene expression score that is at least about 25%, at least about 30%, at least about 35%, at least about 40%, at least about 45%, at least about 50%, at least about 55%, at least about 60%, at least about 65%, at least about 70%, at least about 75%, at least about 80%, at least about 85%, at least about 90%, at least about 95%, at least about 100%, at least about 125%, at least about 150%, at least about 175%, at least about 200%, at least about 225%, at least about 250%, at least about 275%, or at least about 300% lower than the average *TDO2* gene expression score.

24. The use, IDO1 inhibitor for use, or combined biomarker for use of any one of claims 19 to 22, wherein the low *TDO2* gene expression score is characterized by a *TDO2* gene expression score that is at least about 50% lower than the average *TDO2* gene expression score.

25. The use, IDO1 inhibitor for use, or combined biomarker for use of any one of claims 19 to 22, wherein the low *TDO2* gene expression score is characterized by a *TDO2* gene expression score that is at least about 75% lower than the average *TDO2* gene expression score.

26. The use of any one of claims 1 to 5 and 9 to 25, IDO1 inhibitor for use of any one of claims 6 and 9 to 25, or combined biomarker for use of any one of claims 7 to 25, wherein the cancer is a tumor.

27. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 26, wherein the tumor is a carcinoma.

28. The use, IDO1 inhibitor for use, or combined biomarker for use of claims 26 or 27, wherein the tumor is selected from bladder cancer, cervical cancer, lung cancer, pancreatic cancer, kidney cancer, head and neck cancer, hepatocellular carcinoma, glioblastoma, melanoma, and endometrial cancer.

29. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 28, wherein the lung cancer is non-small cell lung cancer (NSCLC).

30. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 28, wherein kidney cancer is renal cell carcinoma (RCC).

31. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 28, wherein the head and neck cancer is squamous cell carcinoma of the head and neck (SCCHN).

32. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 28, wherein the tumor is not melanoma.

33. The use of any one of claims 1 to 5 and 9 to 32, IDO1 inhibitor for use of any one of claims 6 and 9 to 32, or combined biomarker for use of any one of claims 7 to 32, wherein the sample is a tumor tissue biopsy.

34. The use of any one of claims 1 to 5 and 9 to 33, IDO1 inhibitor for use of any one of claims 6 and 9 to 33, or combined biomarker for use of any one of claims 7 to 33, wherein the sample is obtained from the stroma of a tumor.

35. The use of any one of claims 1 to 5 and 9 to 34, IDO1 inhibitor for use of any one of claims 6 and 9 to 34, or combined biomarker for use of any one of claims 7 to 34, wherein the cancer is a hematological cancer.

36. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 35, wherein the hematological cancer is lymphoma.

37. The use or IDO1 inhibitor for use, or combined biomarker for use of claim 36, wherein the lymphoma is diffuse large B-cell lymphoma (DLBCL).

38. The use of any one of claims 1 to 5 and 9 to 37, IDO1 inhibitor for use of any one of claims 6 and 9 to 37, or combined biomarker for use of any one of claims 7 to 37, wherein the sample is a formalin-fixed paraffin-embedded tissue, a fresh-frozen tissue, or a blood sample.

39. The use of any one of claims 1 to 5 and 9 to 38, IDO1 inhibitor for use of any one of claims 6 and 9 to 38, or combined biomarker for use of any one of claims 7 to 38, wherein the expression of the genes in the IFN γ inflammatory gene panel and/or *TDO2* gene expression is

determined by detecting the presence gene mRNA, the presence of a protein encoded by the gene, or both.

40. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 39, wherein the presence of mRNA encoding the genes in the IFN γ inflammatory gene panel and/or the *TDO2* gene is determined using reverse transcriptase PCR.

41. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 39, wherein the presence of the protein encoded by the genes in the IFN γ inflammatory gene panel and/or the *TDO2* gene is determined using an IHC assay.

42. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 41, wherein the IHC assay is an automated IHC assay.

43. The use of any one of claims 1 to 5 and 9 to 42, IDO1 inhibitor for use of any one of claims 6 and 9 to 42, or combined biomarker for use of any one of claims 7 to 42, wherein the anti-PD-1 antagonist is an anti-PD-1 antibody.

44. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 43, wherein the anti-PD-1 antibody cross-competes with nivolumab for binding to human PD-1.

45. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 43, wherein the anti-PD-1 antibody binds to the same epitope as nivolumab.

46. The use, IDO1 inhibitor for use, or combined biomarker for use of any one of claims 43 to 45, wherein the anti-PD-1 antibody is a chimeric, humanized or human monoclonal antibody or a portion thereof.

47. The use, IDO1 inhibitor for use, or combined biomarker for use of any one of claims 43 to 46, wherein the anti-PD-1 antibody comprises a heavy chain constant region which is of a human IgG1 or IgG4 isotype.

48. The use, IDO1 inhibitor for use, or combined biomarker for use of any one of claims 43 to 47, wherein the anti-PD-1 antibody comprises nivolumab, pembrolizumab, or an antigen-binding portion thereof.

49. The use, IDO1 inhibitor for use, or combined biomarker for use of any one of claims 43 to 48, wherein the anti-PD-1 antibody is nivolumab, pembrolizumab, or cemiplimab.

50. The use of any one of claims 1 to 5 and 9 to 42, IDO1 inhibitor for use of any one of claim 6 and 9 to 42, or combined biomarker for use of any one of claims 7 to 42, wherein the anti-PD-1 antagonist is an anti-PD-L1 antibody.

51. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 50, wherein the anti-PD-L1 antibody comprises avelumab, atezolizumab, durvalumab, or an antigen-binding portion thereof.

52. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 50 or 51, wherein the anti-PD-L1 antibody is avelumab, atezolizumab, or durvalumab.

53. The use of any one of claims 1 to 5 and 9 to 52, IDO1 inhibitor for use of any one of claim 6 and 9 to 52, or combined biomarker for use of any one of claims 7 to 52, wherein the anti-PD-1 or anti-PD-L1 antibody is to be administered at a dose ranging from at least about 0.1 mg/kg to at least about 10.0 mg/kg body weight once about every 1, 2 or 3 weeks.

54. The use, IDO1 inhibitor for use, or combined biomarker for use of any one claims 43 to 53, wherein the anti-PD-1 or anti-PD-L1 antibody is to be administered at a dose of at least about 3 mg/kg body weight once about every 2 weeks.

55. The use, IDO1 inhibitor for use, or combined biomarker for use of any one claims 43 to 54, wherein the anti-PD-1 or anti-PD-L1 antibody or an antigen-binding portion thereof is to be administered at a flat dose.

56. The use, IDO1 inhibitor for use, or combined biomarker for use of any one claims 43 to 55, wherein the anti-PD-1 or anti-PD-L1 antibody or antigen-binding portion thereof is to be administered at a flat dose of at least about 200, at least about 220, at least about 240, at least about 260, at least about 280, at least about 300, at least about 320, at least about 340, at least about 360, at least about 380, at least about 400, at least about 420, at least about 440, at least about 460, at least about 480, at least about 500 or at least about 550 mg.

57. The use, IDO1 inhibitor for use, or combined biomarker for use of any one claims 43 to 56, wherein the anti-PD-1 or anti-PD-L1 antibody or antigen-binding portion thereof is to be administered at a flat dose of about 240 mg.

58. The use, IDO1 inhibitor for use, or combined biomarker for use of any one claims 43 to 57, wherein the anti-PD-1 or anti-PD-L1 antibody or antigen-binding portion thereof is to be administered at a flat dose of about 480 mg.

59. The use, IDO1 inhibitor for use, or combined biomarker for use of any one claims 43 to 58, wherein the anti-PD-1 or anti-PD-L1 antibody or antigen-binding portion thereof is to be administered at a flat dose about once every 1, 2, 3 or 4 weeks.

60. The use, IDO1 inhibitor for use, or combined biomarker for use of any one claims 43 to 59, wherein the anti-PD-1 or anti-PD-L1 antibody or antigen-binding portion thereof is to be administered at a flat dose of about 240 mg once about every two weeks.

61. The use, IDO1 inhibitor for use, or combined biomarker for use of any one claims 43 to 60, wherein the anti-PD-1 or anti-PD-L1 antibody or antigen-binding portion thereof is to be administered at a flat dose of about 480 mg once about every four weeks.

62. The use, IDO1 inhibitor for use, or combined biomarker for use of any one claims 43 to 61, wherein the anti-PD-1 or anti-PD-L1 antibody is to be administered for as long as clinical benefit is observed or until unmanageable toxicity or disease progression occurs.

63. The use, IDO1 inhibitor for use, or combined biomarker for use of any one claims 43 to 62, wherein the anti-PD-1 or anti-PD-L1 antibody is formulated to be administered intravenously.

64. The use, IDO1 inhibitor for use, or combined biomarker for use of any one claims 43 to 63, wherein the anti-PD-1 or anti-PD-L1 antibody is to be administered at a subtherapeutic dose.

65. The use of any one of claims 1 to 5 and 9 to 64, IDO1 inhibitor for use of any one of claim 6 and 9 to 64, or combined biomarker for use of any one of claims 7 to 64, wherein the IDO1 inhibitor selectively inhibits IDO1.

66. The use of any one of claims 1 to 5 and 9 to 65, IDO1 inhibitor for use of any one of claim 6 and 9 to 65, or combined biomarker for use of any one of claims 7 to 65, wherein the IDO1 inhibitor does not inhibit TDO2 enzymatic activity.

67. The use of any one of claims 1 to 5 and 9 to 66, IDO1 inhibitor for use of any one of claim 6 and 9 to 66, or combined biomarker for use of any one of claims 7 to 66, wherein the IDO1 inhibitor is linrodostat mesylate ((2R)-N-(4-chlorophenyl)-2-(cis-4-(6-fluoroquinolin-4-yl)cyclohexyl)propanamide).

68. The use of any one of claims 1 to 5 and 9 to 67, IDO1 inhibitor for use of any one of claim 6 and 9 to 67, or combined biomarker for use of any one of claims 7 to 67, wherein the IDO1 inhibitor is selected from the group consisting of linrodostat, indoximod, p-(3-benzofuranyl)-DL-alanine, p-[3-benzo(b)thienyl]-DL-alanine; 6-nitro-L-tryptophan, and any combination thereof.

69. The use of any one of claims 1 to 5 and 9 to 68, IDO1 inhibitor for use of any one of claim 6 and 9 to 68, or combined biomarker for use of any one of claims 7 to 68, wherein the IDO1 inhibitor is formulated to be administered orally.

70. The use of any one of claims 1 to 5 and 9 to 69, IDO1 inhibitor for use of any one of claim 6 and 9 to 69, or combined biomarker for use of any one of claims 7 to 69, wherein the IDO1 inhibitor is to be administered at a flat dose of about 100 mg.

71. The use of any one of claims 1 to 5 and 9 to 70, IDO1 inhibitor of any one of claim 6 and 9 to 70, or combined biomarker for use of any one of claims 7 to 70, wherein the IDO1 inhibitor is to be administered at a flat dose of about 200 mg.

72. The use of any one of claims 1 to 5 and 9 to 71, IDO1 inhibitor for use of any one of claim 6 and 9 to 71, or combined biomarker for use of any one of claims 7 to 71, wherein the IDO1 inhibitor is to be administered at a flat dose of about 100 mg every day.

73. The use of any one of claims 1 to 5 and 9 to 72, IDO1 inhibitor of any one of claim 6 and 9 to 72, or combined biomarker for use of any one of claims 7 to 72, wherein the IDO1 inhibitor is to be administered at a flat dose of about 200 mg every day.

74. The use of any one of claims 1 to 5 and 9 to 73, IDO1 inhibitor for use of any one of claim 6 and 9 to 73, or combined biomarker for use of any one of claims 7 to 73, wherein the anti-PD-1 antagonist is an anti-PD-1 antibody to be administered intravenously at a 240 mg every two weeks or 480 mg dose every four weeks, and the IDO1 inhibitor is to be administered orally at a 100 mg or 200 mg dose every day.

75. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 74, wherein the anti-PD-1 antibody is nivolumab and the IDO1 inhibitor is linrodostat mesylate.

76. The use of any one of claims 1 to 5 and 9 to 75, IDO1 inhibitor for use of any one of claim 6 and 9 to 75, or combined biomarker for use of any one of claims 7 to 75, wherein the cancer is relapsed.

77. The use of any one of claims 1 to 5 and 9 to 76, IDO1 inhibitor for use of any one of claim 6 and 9 to 76, or combined biomarker for use of any one of claims 7 to 76, wherein the cancer is refractory.

78. The use of any one of claims 1 to 5 and 9 to 77, IDO1 inhibitor for use of any one of claims 6 and 9 to 77, or combined biomarker for use of any one of claims 7 to 77, wherein the PD-1 antagonist is to be administered before or after the IDO1 inhibitor.

79. The use of any one of claims 1 to 5 and 9 to 77, IDO1 inhibitor for use of any one of claims 6 and 9 to 77, or combined biomarker for use of any one of claims 7 to 77, wherein the PD-1 antagonist is to be administered concurrently with the IDO1 inhibitor.

80. The use of any one of claims 1 to 5 and 9 to 79, IDO1 inhibitor for use of any one of claim 6 and 9 to 79, or combined biomarker for use of any one of claims 7 to 79, wherein the cancer is refractory following at least one prior therapy comprising of at least one anticancer agent.

81. The use, IDO1 inhibitor for use, or combined biomarker for use of claim 80, wherein the at least one anticancer agent comprises a standard of care therapy.

82. The use or IDO1 inhibitor for use, or combined biomarker for use of claims 80 or 81, wherein the at least one anticancer agent comprises an immunotherapy.

83. The use of any one of claims 1 to 5 and 9 to 82, IDO1 inhibitor for use of any one of claim 6 and 9 to 82, or combined biomarker for use of any one of claims 7 to 82, wherein the cancer is locally advanced.

84. The use of any one of claims 1 to 5 and 9 to 83, IDO1 inhibitor for use of any one of claim 6 and 9 to 83, or combined biomarker for use of any one of claims 7 to 83, wherein the cancer is metastatic.

85. The use of any one of claims 1 to 5 and 9 to 84, IDO1 inhibitor for use of any one of claim 6 and 9 to 84, or combined biomarker for use of any one of claims 7 to 84, wherein the medicament, IDO1 inhibitor for use or combined biomarker for use is to be administered to treat the cancer.

86. The use of any one of claims 1 to 5 and 9 to 85, IDO1 inhibitor for use of any one of claim 6 and 9 to 85, or combined biomarker for use of any one of claims 7 to 85, wherein the medicament, IDO1 inhibitor for use or combined biomarker for use is to be administered to reduce the cancer burden.

87. The use or IDO1 inhibitor for use, or combined biomarker for use of claim 86, wherein cancer burden is reduced by at least about 10%, about 20%, about 30%, about 40%, or about 50% compared to the cancer burden prior to the medicament, IDO1 inhibitor for use or combined biomarker for use is to be administered.

88. The use of any one of claims 1 to 5 and 9 to 87, IDO1 inhibitor for use of any one of claim 6 and 9 to 87, or combined biomarker for use of any one of claims 7 to 87, wherein the subject exhibits progression-free survival of at least about one month, at least about 2 months, at least about 3 months, at least about 4 months, at least about 5 months, at least about 6 months, at least about 7 months, at least about 8 months, at least about 9 months, at least about 10 months, at least about 11 months, at least about one year, at least about eighteen months, at least about two years, at least about three years, at least about four years, or at least about five years after the medicament, IDO1 inhibitor for use or combined biomarker for use is to be initially administered.

89. The use of any one of claims 1 to 5 and 9 to 88, IDO1 inhibitor for use of any one of claim 6 and 9 to 88, or combined biomarker for use of any one of claims 7 to 88, wherein the

subject exhibits stable disease after the medicament, IDO1 inhibitor for use or combined biomarker for use is to be administered.

90. The use of any one of claims 1 to 5 and 9 to 88, IDO1 inhibitor for use of any one of claim 6 and 9 to 88, or combined biomarker for use of any one of claims 7 to 88, wherein the subject exhibits a partial response after the medicament, IDO1 inhibitor for use or combined biomarker for use is to be administered.

91. The use of any one of claims 1 to 5 and 9 to 88, IDO1 inhibitor for use of any one of claim 6 and 9 to 88, or combined biomarker for use of any one of claims 7 to 88, wherein the subject exhibits a complete response after the medicament, IDO1 inhibitor for use or combined biomarker for use is to be administered.

92. The use of any one of claims 1 to 5 and 9 to 91, IDO1 inhibitor for use of any one of claim 6 and 9 to 91, or combined biomarker for use of any one of claims 7 to 91, wherein the medicament, IDO1 inhibitor for use or combined biomarker for use is to be administered to improve progression-free survival probability by at least about 10%, at least about 20%, at least about 30%, at least about 40%, at least about 50%, at least about 60%, at least about 70%, at least about 80%, at least about 90%, at least about 100%, at least about 110%, at least about 120%, at least about 130%, at least about 140%, or at least about 150%, compared to the progression-free survival probability of a subject not exhibiting a combined biomarker comprising (a) a high *IFN* γ inflammatory signature score and (b) a low *TDO2* gene expression score.

93. The use of any one of claims 1 to 5 and 9 to 92, IDO1 inhibitor of any one of claim 6 and 9 to 92, or combined biomarker for use of any one of claims 7 to 92, wherein the medicament, IDO1 inhibitor for use or combined biomarker for use is to be administered to improve overall survival probability by at least about 25%, at least about 50%, at least about 75%, at least about 100%, at least about 125%, at least about 150%, at least about 175%, at least about 200%, at least about 225%, at least about 250%, at least about 275%, at least about 300%, at least about 325%, at least about 350%, or at least about 375%, compared to the overall survival probability of a subject not exhibiting a combined biomarker comprising (a) a high *IFN* γ inflammatory signature score and (b) a low *TDO2* gene expression score.

94. A kit for treating a subject afflicted with a cancer, the kit comprising:

- (a) a dosage of an anti-PD-1 antagonist;
- (b) a dosage of an IDO1 inhibitor; and
- (c) instructions for using the anti-PD-1 or anti-PD-L1 antibody and IDO1 inhibitor in the use of any of claims 1 to 5 and 9 to 93.

95. A gene panel comprising at least the *IFN γ* and *TDO2* genes, for use in

- (i) identifying a subject suitable for therapy with a combination comprising an anti-PD-1 antagonist and an IDO1 inhibitor;
- (ii) determining the prognosis of a subject undergoing therapy with a combination comprising an anti-PD-1 antagonist and an IDO1 inhibitor;
- (iii) initiating, suspending, or modifying the combination comprising an anti-PD-1 antagonist and an IDO1 inhibitor is to be administered; or,
- (iv) a combination therefor.

96. The kit of claim 94 or gene panel of claim 95, wherein the gene panel comprises *IFN γ* , *CXCL10*, *HLA-DRA*, *CXCR6*, *TIGIT*, *CD274 (PD-L1)*, *PDCD1LG2 (PD-L2)*, *LAG3*, *NKG7*, *PSMB10*, *CMKLR1*, *CD8A*, *IDO1*, *CCL5*, *CXCL9*, *HLA.DQA1*, *CD276*, *HLA.DRB1*, *STAT1*, *HLA.E*, *CCR5*, *CXCL11*, *GZMA*, *PRF1*, *IR2RG*, *CD3D*, *CD2*, *ITGAL*, *TAGAP*, *CIITA*, *PTPRC*, *CD3E*, *GZMK*, *GZMB*, *PDCD1*, *SLAMF6*, *CXCL13*, and *TDO2*, or any combination thereof

97. The kit of claims 94 or 96 or the gene panel of claims 95 or 96, wherein the gene panel consists or consists essentially of

- (i) *IFN γ* , *CXCL10*, *CXCL9*, *HLA-DRA*, *IDO1*, *STAT1*, and *TDO2*;
- (ii) *IFN γ* , *CXCL10*, *CXCL9*, *HLA-DRA*, *IDO1*, *STAT1*, *CCR5*, *CXCL11*, *GZMA*, *PRF1* and *TDO2*;
- (iii) *CXCR6*, *TIGIT*, *CD274 (PD-L1)*, *PDCD1LG2 (PD-L2)*, *LAG3*, *NKG7*, *PSMB10*, *CMKLR1*, *CD8A*, *IDO1*, *CCL5*, *CXCL9*, *HLA.DQA1*, *CD276*, *HLA.DRB1*, *STAT1*, *HLA.E*, and *TDO2*;
- (iv) *IFN γ* , *IR2RG*, *CXCR6*, *CD3D*, *CD2*, *ITGAL*, *TAGAP*, *CIITA*, *HLA-DRA*, *PTPRC*, *CXCL9*, *CCL5*, *NKG7*, *GZMA*, *PRF1*, *CCR5*, *CD3E*, *GZMK*, *HLA-E*, *GZMB*, *PDCD1*, *SLAMF6*, *CXCL13*, *CXCL10*, *IDO1*, *LAG3*, *STAT1*, *CXCL11*, and *TDO2*; or,
- (iii) any combination thereof.