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(54)名稱

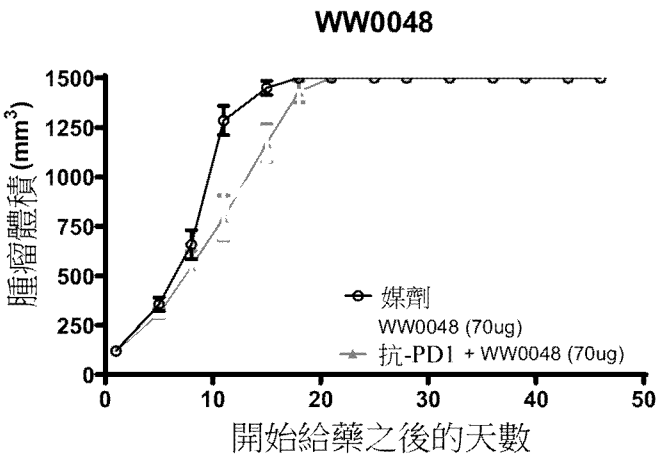
誘導型細胞激素前藥及 PD-1/PD-L1 組合療法

(57)摘要

本發明係關於使用誘導型細胞激素前藥治療包括淋巴瘤之癌症的方法及組合物，及包含與抗 PD-1 及抗 PD-L1 抗體組合之誘導型細胞激素前藥的組合療法。

This disclosure relates to methods and compositions for treating cancer including lymphoma using an inducible cytokine prodrug, and to a combination therapy comprising an inducible cytokine prodrug in combination with anti-PD-1 and anti-PD-L1 antibodies.

指定代表圖：



【圖1A】

【發明摘要】

【中文發明名稱】

誘導型細胞激素前藥及PD-1/PD-L1組合療法

【英文發明名稱】

INDUCIBLE CYTOKINE PRODRUG AND PD-1/PD-L1 COMBINATION THERAPY

【中文】

本發明係關於使用誘導型細胞激素前藥治療包括淋巴瘤之癌症的方法及組合物，及包含與抗PD-1及抗PD-L1抗體組合之誘導型細胞激素前藥的組合療法。

【英文】

This disclosure relates to methods and compositions for treating cancer including lymphoma using an inducible cytokine prodrug, and to a combination therapy comprising an inducible cytokine prodrug in combination with anti-PD-1 and anti-PD-L1 antibodies.

【指定代表圖】

圖1A

【代表圖之符號簡單說明】

無

【發明說明書】

【中文發明名稱】

誘導型細胞激素前藥及PD-1/PD-L1組合療法

【英文發明名稱】

INDUCIBLE CYTOKINE PRODRUG AND PD-1/PD-L1 COMBINATION THERAPY

【技術領域】

【先前技術】

【0001】 國際公開案第WO2019/222294號、第WO2019/222295號、第WO2019/222296號、第WO2021/097376號中描述了誘導型細胞激素前藥，其在腫瘤微環境中經由蛋白酶裂解有條件地活化，從而在腫瘤內釋放出完全活性的天然細胞激素，以刺激強效抗腫瘤免疫反應。此等前藥通常包括天然細胞激素多肽，其經由蛋白酶可裂解連接子連接至細胞激素阻斷域(blocking domain)及通常半衰期延長域(half-life extension domain)。例如，IL-2前藥可包括天然IL-2分子，其經由蛋白酶可裂解連接子連接至半衰期延長域(例如，抗人類血清白蛋白抗體結合片段，諸如VH域)及IL-2阻斷元件(blocking element) (例如，抗IL-2抗體結合片段，諸如Fab)，從而阻斷IL-2與周邊正常組織上之IL-2β/γ受體的結合。在腫瘤微環境中蛋白酶可裂解連接子裂解後，在腫瘤內釋放出完全活性的天然IL-2以刺激強效抗腫瘤免疫反應。

【0002】 免疫檢查點抑制劑為調節T細胞功能之蛋白。T細胞效應功能對於治療腫瘤之免疫治療方法至關重要。但隨著腫瘤生長及癌症惡化，經常看到免疫抑制及效應功能降低。此現象背後之一種機制為癌細胞活化

了免疫檢查點抑制劑，導致對抗腫瘤免疫反應的抑制。此通常發生在癌細胞表面上表現的蛋白可與腫瘤微環境中之T細胞表面上的免疫檢查點蛋白相互作用以抑制T細胞活性時。免疫檢查點蛋白包括例如PD-1，其結合配位體PD-L1 (B7-H1，CD274)及PD-L2 (B7-DC，CD273)；CTLA-4 (CD152)，其結合B7-1 (CD80)及B7-2 (CD86)；LAG 3 (CD223)，其結合Galectin3、LSECtin及FGL1；TIM3 (HAVCR2)，其結合配位體Ceacam1及Galectin9；TIGIT (VSTM3，WUCAM)，其結合CD112及CD155；BTLA (CD272)，其結合HVEM (TNFRSF14)；B7-H3 (CD276)、B7-H4 (VTCN1)、VISTA (B7-H5)、KIR、CD44 (2B4)、CD160 (BY55)，其結合HVEM；CD134 (TNRFSR4，OX40)，其結合CD252 (OX-40L)。

【0003】 已研發出作為抗腫瘤劑之結合免疫檢查點蛋白且抑制其免疫抑制活性的諸如抗體之治療劑。現可商購用於癌症療法之若干此類藥劑，包括抗PD1抗體，亦即帕博利珠單抗(pembrolizumab) (KEYTRUDA)、多斯利單抗(dostarlimab) (JEMPERLI)、測米匹單抗(cemiplimab)-rwlc (LIBATYO)、納武利尤單抗(nivolumab) (OPDIVO)、坎立珠單抗(camrelizumab)、緹勒珠單抗(tislelizumab)、特瑞普利單抗(toripalimab)及斯迪利單抗(sintilimab) (TYVYT)；抗PD-L1抗體，亦即阿維魯單抗(avelumab) (BAVENCIO)、德瓦魯單抗(durvalumab) (IMFINZI)及阿特珠單抗(atezolizumab) (TECENTRIQ)；抗-CTLA-4抗體，亦即伊匹單抗(ipilimumab) (YERVOY)。儘管使用此類免疫檢查點抑制劑之療法為癌症療法提供了優勢，但整體成功率仍較低，會出現復發且產生對檢查點抑制之抗性。

【0004】 淋巴瘤為一組異質的血液惡性腫瘤，起源於淋巴樣細胞。

在淋巴瘤中，免疫系統之活化與抑制之間的正常平衡經常被腫瘤細胞轉向深入的免疫抑制，此可保護腫瘤細胞免於T細胞介導之殺滅。(Ansell, SM Hematology Am Soc, Hematol Educ Program (2017), 2017(1):618-621。)使用促效劑抗體(例如，抗CD27、抗CD40、抗CD137)之免疫調控已嘗試用於治療淋巴瘤，但在臨床研究中僅可見適度的治療益處，突顯克服淋巴瘤中之免疫抑制腫瘤微環境之挑戰(同上)。

【0005】 對治療癌症的改良方法存在未滿足的醫療需求。

【發明內容】

【0006】 本發明係關於治療個體中之淋巴瘤的方法，該方法包含投與有效量的誘導型細胞激素前藥，其視情況與額外治療劑，諸如化學治療劑及/或免疫檢查點抑制劑(例如，抗PD-1抗體或抗PD-L1抗體)組合。本發明亦關於一種可用於治療淋巴瘤之組合，其包含誘導型細胞激素前藥及額外治療劑，諸如化學治療劑及/或免疫檢查點抑制劑(例如，抗PD-1抗體或抗PD-L1抗體)。

【0007】 本發明係關於治療個體中之癌症的方法，其包含投與有效量的誘導型細胞激素前藥及抗PD-1抗體或抗PD-L1抗體。本發明亦關於一種可用於治療癌症之組合，其包含誘導型細胞激素前藥及抗PD-1抗體或抗PD-L1抗體。在一些情況下，抗PD-1抗體將與誘導型細胞激素前藥組合。在一些情況下，抗PD-L1抗體將與誘導型細胞激素前藥組合。

【0008】 誘導型細胞激素前藥包含細胞激素多肽[A]、阻斷元件[D]、視情況存在之半衰期延長元件[H]及蛋白酶可裂解的多肽連接子。細胞激素多肽及細胞激素阻斷元件以及視情況存在之半衰期延長元件(若存在)藉由蛋白酶可裂解的多肽連接子以可操作方式連接且誘導型細胞激素

前藥具有減弱的細胞激素受體活化活性。誘導型細胞激素前藥的細胞激素-受體活化活性比含有藉由裂解蛋白酶可裂解連接子產生之細胞激素多肽之多肽的細胞激素受體活化活性低至少約10倍。

【0009】 細胞激素多肽可為IL-2、IL-12、干擾素α、干擾素β、干擾素γ或突變蛋白(mutein)，或前述任一者之活性片段。細胞激素多肽可為IL-2或突變蛋白、變異體、活性片段，或前述任一者之次單元。細胞激素多肽可為IL-12或突變蛋白、變異體、活性片段，或前述任一者之次單元。細胞激素多肽可為干擾素α、干擾素β、干擾素γ或突變蛋白，或前述任一者之活性片段。

【0010】 誘導型細胞激素前藥可具有下式：

[A]-[L1]-[H]-[L2]-[D]

[D]-[L2]-[H]-[L1]-[A]

[A]-[L1]-[D]-[L2]-[H]

[H]-[L2]-[D]-[L1]-[A]

[H]-[L1]-[A]-[L2']-[D]

[D]-[L1]-[A]-[L2']-[H]

【0011】 A為細胞激素多肽，D為阻斷部分，H為半衰期延長部分，L1為蛋白酶可裂解的多肽連接子，L2為視情況蛋白酶可裂解的多肽連接子，且L2'為蛋白酶可裂解的多肽連接子。

【0012】 誘導型細胞激素前藥可為單一多肽鏈。誘導型細胞激素前藥可包含至少兩條多肽鏈。誘導型細胞激素前藥可包含至少三條多肽鏈。

【0013】 細胞激素前藥可包含化合物1、化合物2、化合物3、化合物4或前述之胺基酸序列變異體。化合物1可包含SEQ ID NO:1之第一多肽

鏈及SEQ ID NO:5之第二多肽鏈，且化合物1之胺基酸序列變異體可包含與SEQ ID NO:1具有至少約80%一致性之第一多肽鏈及與SEQ ID NO:5具有至少約80%一致性之第二多肽鏈。化合物2可包含SEQ ID NO:2之第一多肽鏈及SEQ ID NO:5之第二多肽鏈，且化合物2之胺基酸序列變異體可包含與SEQ ID NO:2具有至少約80%一致性之第一多肽鏈及與SEQ ID NO:5具有至少約80%一致性之第二多肽鏈。化合物3可包含SEQ ID NO:3之第一多肽鏈及SEQ ID NO:5之第二多肽鏈，且化合物3之胺基酸序列變異體可包含與SEQ ID NO:3具有至少約80%一致性之第一多肽鏈及與SEQ ID NO:5具有至少約80%一致性之第二多肽鏈。化合物4可包含SEQ ID NO:4之第一多肽鏈及SEQ ID NO:5之第二多肽鏈，且化合物4之胺基酸序列變異體可包含與SEQ ID NO:4具有至少約80%一致性之第一多肽鏈及與SEQ ID NO:5具有至少約80%一致性之第二多肽鏈。

【0014】 誘導型細胞激素前藥可為化合物5、化合物6、化合物7、化合物8、化合物9或化合物10，或前述之胺基酸序列變異體。化合物5可包含SEQ ID NO: 6之第一多肽鏈及SEQ ID NO:12之第二多肽鏈，且化合物5之胺基酸序列變異體可包含與SEQ ID NO: 6具有至少約80%一致性之第一多肽鏈及與SEQ ID NO: 12具有至少約80%一致性之第二多肽鏈。化合物6可包含SEQ ID NO: 7之第一多肽鏈及SEQ ID NO: 12之第二多肽鏈，且化合物6之胺基酸序列變異體可包含與SEQ ID NO:7具有至少約80%一致性之第一多肽鏈及與SEQ ID NO: 12具有至少約80%一致性之第二多肽鏈。化合物7可包含SEQ ID NO: 8之第一多肽鏈及SEQ ID NO: 13之第二多肽鏈，且化合物7之胺基酸序列變異體可包含與SEQ ID NO: 8具有至少約80%一致性之第一多肽鏈及與SEQ ID NO: 13具有至少約80%一

致性之第二多肽鏈。化合物8可包含SEQ ID NO: 9之第一多肽鏈及SEQ ID NO: 13之第二多肽鏈，且化合物8之胺基酸序列變異體可包含與SEQ ID NO: 9具有至少約80%一致性之第一多肽鏈及與SEQ ID NO: 13具有至少約80%一致性之第二多肽鏈。化合物9可包含SEQ ID NO: 10之第一多肽鏈及SEQ ID NO: 13之第二多肽鏈，且化合物9之胺基酸序列變異體包含與SEQ ID NO: 10具有至少約80%一致性之第一多肽鏈及與SEQ ID NO: 13具有至少約80%一致性之第二多肽鏈。化合物10可包含SEQ ID NO: 11之第一多肽鏈及SEQ ID NO: 13之第二多肽鏈，且化合物10之胺基酸序列變異體可包含與SEQ ID NO: 11具有至少約80%一致性之第一多肽鏈及與SEQ ID NO: 13具有至少約80%一致性之第二多肽鏈。

【0015】 誘導型細胞激素前藥可包含選自SEQ ID NO 14-20之胺基酸或與SEQ ID NO 14-20具有至少約80%一致性之胺基酸序列。

【0016】 半衰期延長元件可為人類血清白蛋白、結合人類血清白蛋白之抗原結合多肽、或免疫球蛋白Fc或其片段。

【0017】 蛋白酶可裂解連接子可包含能夠藉由選自以下之蛋白酶裂解的序列：激肽釋放素(kallikrein)、凝血酶、凝乳酶、羧肽酶A、組織蛋白酶、彈性蛋白酶、PR-3、顆粒酶M、鈣蛋白酶、基質金屬蛋白酶(matrix metalloproteinase，MMP)、ADAM、FAP、纖維蛋白溶酶原活化因子(plasminogen activator)、凋亡蛋白酶、類胰蛋白酶(tryptase)或腫瘤蛋白酶。

【0018】 特別地，蛋白酶可選自組織蛋白酶B、組織蛋白酶C、組織蛋白酶D、組織蛋白酶E、組織蛋白酶K、組織蛋白酶L或組織蛋白酶G。特別地，蛋白酶可選自基質金屬蛋白酶(MMP)，其為MMP1、MMP2、

MMP3、MMP8、MMP9、MMP10、MMP11、MMP12、MMP13或MMP14。

【0019】阻斷元件可結合細胞激素多肽。阻斷元件可包含細胞激素多肽之同族受體的配位體結合域或片段、結合於細胞激素多肽之抗體或抗體之抗原結合片段。抗體或抗原結合片段可為結合細胞激素多肽之單域抗體、Fab或scFv。

【0020】誘導型細胞激素前藥可在額外治療劑，例如化學治療劑、免疫檢查點抑制劑(諸如抗PD-1抗體或抗PD-L1抗體)之前、與其同時或在其之後投與。

【0021】抗PD-1抗體可選自由以下組成之群：AMP-224 (AstraZeneca)、609A (3SBio)、704 (3SBio)、705 (3SBio)、ABBV-181 (AbbVie)、ADU-1503 / bion-004 (Chinook Therapeutics)、AGEN2034 / 巴提利單抗(balstilimab) (Agenus)、AK103 (Akeso)、AK104 (Akeso)、AK112 (Akeso)、AK123 (Akeso)、AMG 256 (Amgen)、AMG 404 (Amgen)、ANB030 (AnaptysBio)、ANKEBIO抗PD1產品(Anhui Anke Biotechnology)、抗PD-1 /抗CD47 (DiNonA)、ASKG915 (Ask Gene Pharmaceuticals)、AV-MEL-1 (Aivita Biomedical)、BCD-100 (Biocad CJSC)、BI 754091 (Boehringer Ingelheim)、BiCKI-IL-7 (OSE Immunotherapeutics)、Boehringer-PD-1-未知(unknown) (Boehringer Ingelheim)、BSK-050K01 (Biosion)、坎立珠單抗(Jiangsu Hengrui Medicine)、CB201 (Crescendo Biologics)、CB213 (Crescendo Biologics)、CC-90006 (AnaptsBio)、賽曲利單抗(cetrelimab) (J&J)、chPD1 (Kiromic Biopharma)、CMAB819 (Mabpharm)、CS1003 (CStone

Pharmaceuticals)、CS17938 (Shenzhen Chipscreen Biosciences)、CTX-8371 (Compass Therapeutics)、CX-072 (CytomX Therapeutics)、CX-188 (CytomX Therapeutics)、帕利珠單抗(palivizumab) (Harbin Gloria Pharmaceuticals)、DB004 (DotBio)、EMB02 (EpimAb Biotherapeutics)、蓋普坦單抗(Geptanblimab) / 傑諾珠單抗(genolimzumab) (Apollomics)、GS19 (Suzhou Zelgen Biopharmaceuticals)、HLX10 (Shanghai Henlius Biotech)、HX008 (Taizhou HanZhong Pharmaceuticals)、HY003 (Juventas Cell Therapy)、IBI315 / BH2950 (Innovent Biologics)、IBI318 (Innovent Biologics)、IBI319 (Innovent Biologics)、IMM1802 (ImmuneOnco Biopharma)、IMT200 (TrueBinding)、Jemperli /多斯利單抗(AnaptysBio)、JTX-4014 (Jounce Therapeutics)、Keytruda /帕博利珠單抗(Merck)、LBL-006 (Nanjing Leads Biolabs)、Libtayo /測米匹單抗-rwlc (Regeneron Pharmaceuticals)、LVGN3616 (Lyvgen Biopharma)、LXF821 (Novartis)、LY01015 (Luye Pharma Group)、LY3462817 (Eli Lilly)、MCLA-134 (Merus N.V.)、MEDI5752 (AstraZenica)、NIR178 (Novartis)、ONCR-177 (Oncorus)、ONO-4685 (Ono Pharmaceutical)、Opdivo /納武利尤單抗(Ono Pharmaceutical)、MGD019 (MacroGenius)、PD1-GDT CAR-T (Kiromic Biopharma)、派安普利單抗(penpulimab) (Akeso)、PSB205 (Qilu Puget Sound Biotherapeutics)、PT-001 (Merck)、PT627 (Merck)、RB-M1 (Refuge Biotechnologies)、瑞弗利單抗(Retifanlimab) (MacroGenics)、RG6139 (Roche)、RG6279 (Roche)、RTX-002 (RubrYc Therapeutics)、薩桑利單抗(sasanlimab) (Pfizer)、

Servier-PD1xLAG3-未知(Servier)、SL-279252 / TAK-252 (Shattuck Labs)、Sofusa抗-PD1 (Sorrento Therapeutics)、斯帕塔利單抗(spartalizumab) (Novartis)、SSI-361 (Lyvgen Biopharma)、Sym021 (Servier)、特泊利單抗(Tebotelimab) (MacroGenics)、緹勒珠單抗(BeiGene)、TSR-075 (AnaptsBio)、Tuhura-DO/PD-1-未知(Tuhura Biopharma)、特瑞普利單抗(Shanghai Junshi Biosciences)、斯迪利單抗(Innovent Biologics)、Unicar-CAR-T&PD-1-未知(Shanghai Unicar-Therapy Bio-Medicine Technology)、Xdivane (Xbrane Biopharma)、XmAb20717 (Xencor)、XmAb23104 (Xencor)、YBL-006 (Y-Biologics)、賽帕利單抗(zimberelimab) (Arcus Biosciences)。

【0022】帕博利珠單抗、多斯利單抗、測米匹單抗-rwlc、納武利尤單抗、坎立珠單抗、緹勒珠單抗、特瑞普利單抗、斯迪利單抗或前述任一者之生物類似物為較佳的抗PD-L1抗體。

【0023】抗PD-L1抗體可選自由以下組成之群：A167 (Sichuan Kelun)、ABL501 (ABL Bio)、ABL503 (ABL Bio)、ABSK041 (Abbisko Therapeutics)、ACE1708 (Acepodia)、ACE-NK-PDL1 (Acepodia)、ADG104 (Adagene)、AK106 (Akeso)、ALPN-202 (Alpine Immune Sciences)、AN4005 (Adlai Nortye Biopharma)、BMS-936559 / MDX-1105 (BMS)、APL-502 / TQB2450 (Apollomics)、Arbutus-PD-L1-未知(Arbutus Biopharma)、ASC22 (Ascletis Pharma)、ATG-101 (Antengene)、AVA-004 (Avacta Group)、AVA021 (Avacta Group)、AVA027 (Avacta Group)、AVA-040-100 (Avacta Group)、AVA04-Vbp (Avacta Group)、Bavencio /阿維魯單抗(Merck)、BCD-135 (Biocad

CJSC)、BGB-A333 (BeiGene)、Bintrafusp alfa/ GSK4045154 (Merck)、CA-170 / aupm-170 (Dr. Reddy's Laboratories) 、 CCX559 (ChemoCentryx) 、 CDR101 (CDR-Life) 、 柯希利單抗(cosibelimab) (Checkpoint Therapeutics) 、 CTX-8371 (Compass Therapeutics) 、 DiNonA-實體腫瘤-未知(DiNonA) 、 DR30207 (Zhejiang Doer Biologics)、DuoBody-PD-L1x4-1BB (Ligand Pharmaceuticals)、恩沃利單抗(envafolimab) (Alphamab Oncology) 、 EPIM-001 (Elpis Biopharmaceuticals) 、 ES101 (Elpiscience Biopharma) 、 INBRX-105 (Inhibrx) 、 FAZ053 (Novartis) 、 FS118 (F-star Therapeutics) 、 GB262 (Genor Biopharma) 、 GS-4224 (Gilead) 、 GT900008 (Kintor Pharmaceuticals) 、 GX-P2 (Genexine) 、 Hamni-PS-L1/CD47-未知(Hanmi Pharmaceutical) 、 HBM7015 (HBM Holdings) 、 HBM9167 (HBM Holdings) 、 HLX20 (Shanghai Henlius Biotech) 、 HTI-1088 (Jiangsu Hengrui Medicine) 、 IBI318 (Innovent Biologics) 、 IBI322 (Innovent Biologics) 、 IBI323 (Innovent Biologics) 、 IGM-7354 (IGM Biosciences) 、 IMC-001 (Sorrento Therapeutics) 、 Imfinzi /德瓦魯單抗 (AstraZenica) 、 IMM25 (ImmuneOnco Biopharma) 、 IMM2502 (ImmuneOnco Biopharma) 、 IMM2503 (ImmuneOnco Biopharma) 、 IMM2504 (ImmuneOnco Biopharma) 、 INCB86550 (Incyte) 、 IO103 (IO Biotech) 、 JS003 (Shanghai Junshi Biosciences) 、 Jubilant-PD-L1-未知 (Jubilant Therapeutics) 、 KD033 (Kadmon Holdings) 、 KN046 (Alphamab Oncology) 、 KY1003 (Sanofi) 、 KY1043 (Sanofi) 、 LY3300054 (Eli Lilly) 、 LY3415244 (Eli Lilly) 、 MRNA-6981 (Moderna) 、 MSB2311

(Transcenta Holding)、MT-6035 (Molecular Templates)、ND021 / NM21-1480 (Numab Therapeutics)、OX001R (Oxford BioTherapeutics)、基於PD-L1之BsAb (I-Mab)、PD-L1 Boltbody ISAC (Bolt Biotherapeutics)、PDL-GEX (Glycotope GmbH)、PMC-122 (PharmAbcine)、PMI06 (D&D Pharmatech)、Protheragen-RV-scFv-PDL1-未知(Protheragen)、PRS-344 (Pieris Pharmaceuticals)、Q-1802 (Merck)、RC98 (Yantai Rongchang Pharmaceutical)、RV-scFv-PDL1 (Protheragen)、SenI_TAAx22P (Hebei Senlang Biotechnology)、SHC020 (Nanjing Sanhome Pharmaceutical)、舒格利單抗(sugemalimab) (Ligand Pharmaceuticals)、阿特珠單抗(Roche)、TST005 (Transcenta Holding)、TT-01 (Topmunnity Therapeutics)、TTX-siPDL1 (TransCode Therapeutics)、UniCAR-T-PD-L1 (GEMoaB monoclonals)、Vaximm (VXM10)及YBL-013 (Y-Biologics)。

【0024】阿維魯單抗、德瓦魯單抗、阿特珠單抗或前述任一者之生物類似物為較佳的抗PD-1抗體。

【0025】化學治療劑例如可為環磷醯胺、甲基二(氯乙基)胺(mechlorethamine)、美法侖(melphalan)、氯芥苯丁酸、異環磷醯胺(ifosfamide)、硫酸布他卡因(busulfan)、N-亞硝基-N-甲基脲(MNU)、卡莫司汀(carmustine) (BCNU)、洛莫司汀(lomustine) (CCNU)、司莫司汀(semustine) (MeCCNU)、福莫司汀(fotemustine)、鏈佐黴素(streptozotocin)、達卡巴嗪(dacarbazine)、米托唑胺(mitozolomide)、替莫唑胺(temozolomide)、噻替派(thiotepa)、絲裂黴素、地吖醌(diaziquone) (AZQ)、順鉑(cisplatin)、卡鉑(carboplatin)、奧沙利鉑

(oxaliplatin)、丙卡巴肼(procarbazine)、六甲蜜胺(hexamethylmelamine)、甲胺喋呤、培美曲塞(pemetrexed)、氟尿嘧啶(例如，5-氟尿嘧啶)、卡培他濱(capecitabine)、阿糖胞苷(cytarabine)、吉西他濱(gemcitabine)、地西他濱(decitabine)、阿紮胞苷(azacitidine)、氟達拉濱(fludarabine)、奈拉濱(nelarabine)、克拉屈濱(cladribine)、氯法拉濱(clofarabine)、噴司他丁(pentostatin)、硫鳥嘌呤(thioguanine)、巯嘌呤(mercaptopurine)、長春新鹼(vincristine)、長春花鹼(vinblastine)、長春瑞賓(vinorelbine)、長春地辛(vindesine)、長春氟寧(vinflunine)、紫杉醇(paclitaxel)、多西他賽(docetaxel)、依託泊苷(etoposide)、替尼泊苷(teniposide)、小紅莓(doxorubicin)、道諾比星(daunorubicin)、表柔比星(epirubicin)、伊達比星(idarubicin)、吡柔比星(pirarubicin)、阿柔比星(aclarubicin)、米托蒽醌(mitoxantrone)、放射菌素(actinomycin)、博萊黴素(bleomycin)、比生群(bisantrene)、吉西他濱及/或阿糖胞苷以及其任何組合。

【0026】本文所揭示之方法可適合於任何癌症。例示性癌症包括但不限於腎上腺皮質癌、肛門癌、闌尾癌、星形細胞瘤、基底細胞癌、腦瘤、膽管癌、膀胱癌、骨癌、乳癌、支氣管腫瘤、原發性不明癌(carcinoma of unknown primary origin)、心臟腫瘤、子宮頸癌、脊索瘤、大腸癌、大腸直腸癌、顱咽管瘤、乳管癌(ductal carcinoma)、胚胎細胞瘤、子宮內膜瘤、室管膜瘤、食道癌、敏感性神經胚細胞瘤、纖維組織細胞瘤、尤文氏肉瘤(Ewing sarcoma)、眼癌、生殖細胞腫瘤、膽囊癌、胃癌、胃腸類癌腫瘤、胃腸基質腫瘤、妊娠期滋養細胞疾病(gestational trophoblastic disease)、神經膠質瘤、頭頸癌、肝細胞癌、組織細胞增生

症、下咽癌(hypopharyngeal cancer)、眼內黑色素瘤、胰島細胞腫瘤、卡波西氏肉瘤(Kaposi sarcoma)、腎癌、蘭格罕細胞組織球增多症(Langerhans cell histiocytosis)、喉癌(laryngeal cancer)、唇及口腔癌、肝癌、小葉原位癌、肺癌、巨球蛋白血症、惡性纖維組織細胞瘤、黑色素瘤、梅克爾細胞癌(Merkel cell carcinoma)、間皮瘤、具有隱性原發性之轉移性鱗狀頸癌、涉及NUT基因之中線癌(midline tract carcinoma)、口癌、多發性內分泌瘤症候群、蕈樣黴菌病(mycosis fungoide)、骨髓發育不良症候群、骨髓發育不良/骨髓增生性腫瘤、鼻腔及副鼻竇癌、鼻咽癌、神經母細胞瘤、非小細胞肺癌、口咽癌、骨肉瘤、卵巢癌、胰臟癌、乳頭狀瘤症、副神經節瘤、副甲狀腺癌、陰莖癌、咽癌、嗜鉻細胞瘤、垂體腫瘤、胸膜肺母細胞瘤、前列腺癌、直腸癌、腎細胞癌、腎盂及尿管癌、視網膜母細胞瘤、橫紋肌瘤、唾液腺癌、塞紮萊症候群(Sezary syndrome)、皮膚癌、小細胞肺癌、小腸癌、軟組織肉瘤、脊髓腫瘤、胃癌、T細胞淋巴瘤、類畸胎瘤、睪丸癌、咽喉癌(throat cancer)、胸腺瘤及胸腺癌、甲狀腺癌、尿道癌、子宮癌、陰道癌、外陰癌及威爾姆氏瘤(Wilms tumor)。方法較佳適用於大腸癌、肺癌、黑色素瘤、腎細胞癌或乳癌。癌症可為黑色素瘤、非小細胞肺癌(NSCLC)、小細胞肺癌(SCLC)、頭頸部鱗狀細胞癌(HNSCC)、典型何傑金氏淋巴瘤(classical Hodgkin lymphoma，cHL)、原發性縱隔大B細胞淋巴瘤(primary mediastinal large B cell lymphoma，PMBCL)、高度微衛星不穩定性或錯配修復缺陷型癌症(microsatellite instability high or mismatch repair deficient cancer)、高度微衛星不穩定性或錯配修復缺陷型大腸直腸癌、胃癌、食道癌、子宮頸癌、肝細胞癌(HCC)、梅克爾細胞癌(MCC)、腎細

胞癌(RCC)、子宮內膜癌、高度腫瘤突變負荷癌症(tumor mutational burden high cancer)、皮膚鱗狀細胞癌(cutaneous squamous cell carcinoma，cSCC)、三陰性乳癌(triple negative breast cancer，TNBC)、尿道上皮癌、大腸直腸癌或食道癌瘤。癌症可為轉移性腎透明細胞癌或轉移性皮膚惡性黑色素瘤。

【0027】在某些實施例中，癌症為淋巴瘤，諸如B細胞淋巴瘤、T細胞淋巴瘤、非何傑金氏淋巴瘤、何傑金氏淋巴瘤、彌漫性大B細胞淋巴瘤、原發性縱隔B細胞淋巴瘤、濾泡性淋巴瘤、小淋巴球性淋巴瘤、慢性淋巴球性白血病、邊緣區淋巴瘤、被套細胞淋巴瘤、瓦爾登斯特倫氏巨球蛋白血症(Waldenstrom's macroglobulinemia)、伯基特淋巴瘤(Burkitt lymphoma)、周邊T細胞淋巴瘤、退行性大細胞淋巴瘤、血管免疫母細胞淋巴瘤、皮膚T細胞淋巴瘤、中樞神經系統淋巴瘤、灰區淋巴瘤(grey zone lymphoma)、雙重打擊淋巴瘤(double hit lymphoma)、三重打擊淋巴瘤(triple hit lymphoma)、未列名(not otherwise specified)之高級別B細胞淋巴瘤、淋巴母細胞淋巴瘤、淋巴漿細胞淋巴瘤、MALT淋巴瘤、單核球樣B細胞淋巴瘤、自然殺手(natural killer，NK)細胞淋巴瘤、蕈樣黴菌病、塞紮萊症候群、腸病型T細胞淋巴瘤、肝脾γ/δ T細胞淋巴瘤及其類似淋巴瘤。

【0028】在特定實施例中，癌症係選自由以下組成之群：黑色素瘤、非小細胞肺癌、頭頸部鱗狀細胞癌、典型何傑金氏淋巴瘤、原發性縱隔大B細胞淋巴瘤、尿道上皮癌、高度微衛星不穩定性或錯配修復缺陷型癌症、胃癌、食道癌、子宮頸癌、肝細胞癌、梅克爾細胞癌、腎細胞癌、子宮內膜癌、以具有高突變負荷之腫瘤為特徵的癌症、皮膚鱗狀細胞癌及

三陰性乳癌。

【0029】 本發明亦關於包含誘導型細胞激素前藥、額外治療劑(諸如化學治療劑及/或免疫檢查點抑制劑(例如，抗PD-1抗體或抗PD-L1抗體))及適合載劑的醫藥組合物。本發明亦關於包含誘導型細胞激素前藥、抗PD-1或抗PD-L1抗體及適合載劑的醫藥組合物。醫藥組合物可為用於靜脈內投與之液體組合物。醫藥組合物可為凍乾組合物。醫藥組合物可為用於使用水復原以獲得適合靜脈內投與之調配物的凍乾組合物。

【圖式簡單說明】

【0030】 **圖1A至圖1F**展示用誘導型IL-2前藥、抗PD1抗體或誘導型IL-2前藥及抗PD1抗體處理之小鼠的資料(腫瘤體積及/或體重)。

【0031】 **圖2A至圖2B**展示用誘導型IL-2前藥、抗PD1抗體或誘導型IL-2前藥及抗PD1抗體處理之小鼠的資料(腫瘤體積及/或體重)。

【0032】 **圖3A**為展示B16F10腫瘤模型中之腫瘤體積進展的圖，其中用100 μg化合物1、200 μg化合物1或僅媒劑處理小鼠。將1×10^5個腫瘤細胞植入動物的側腹中且監測腫瘤生長。一旦腫瘤達到30至60 mm^3之平均體積，將動物隨機分組且給藥。每週記錄三次腫瘤體積及體重。

【0033】 **圖3B**為展示B16F10腫瘤模型中之腫瘤體積進展的圖，其中用100 μg化合物1、200 μg單獨的抗PD-1抗體(RMP1-14)、100 μg化合物1及200 μg抗PD-1抗體(RMP1-14)或僅媒劑處理小鼠。將1×10^5個腫瘤細胞植入動物的側腹中且監測腫瘤生長。一旦腫瘤達到30至60 mm^3之平均體積，將動物隨機分組且給藥。每週記錄三次腫瘤體積及體重。

【0034】 **圖4**為展示B16F10腫瘤模型之體重進展的圖，其中用化合物1、化合物1及RMP1-14或僅媒劑處理小鼠。將1×10^5個腫瘤細胞植入動

物的側腹中且監測腫瘤生長。一旦腫瘤達到30至60 mm^3之平均體積，將動物隨機分組且給藥。每週記錄三次體重。

【0035】 **圖5A**為展示在同基因型A20小鼠腫瘤模型中分析誘導型IL-12前藥(WW0757/636)之結果的圖。該圖展示用30 μg WW0757/636 (菱形)、100 μg WW0757/636 (方塊)及300 μg WW0757/636 (圓圈)處理之小鼠隨時間推移的平均腫瘤體積。單獨媒劑由黑色圓圈指示(具有最大腫瘤體積之上方線條(top line))。資料顯示，用WW0757/636以更高濃度處理之小鼠中的腫瘤體積增加隨時間推移以劑量依賴性方式抑制。

【0036】 **圖5B**為展示在同基因型A20小鼠腫瘤模型中分析誘導型IFNα前藥WW0610之結果的圖。其展示用45 μg WW0610 (菱形)及133 μg WW0610 (方塊)處理之小鼠隨時間推移的平均腫瘤體積。單獨媒劑由黑色圓圈指示(具有最大腫瘤體積之上方線條)。資料顯示，用WW0610以更高濃度處理之小鼠中的腫瘤體積增加隨時間推移以劑量依賴性方式抑制。

【0037】 **圖6A**為展示在同基因型EG7.OVA小鼠腫瘤模型中分析誘導型IL-12前藥(WW0757/636)之結果的圖。其展示用30 μg WW0757/636 (菱形)、100 μg WW0757/636 (方塊)及300 μg WW0757/636 (圓圈)處理之小鼠隨時間推移的平均腫瘤體積。單獨媒劑由黑色圓圈指示(至第18天具有最大腫瘤體積資料之上方線條)。資料顯示，用WW0757/636以更高濃度處理之小鼠中的腫瘤體積增加隨時間推移以劑量依賴性方式抑制。

【0038】 **圖6B**為展示在同基因型EG7.OVA小鼠腫瘤模型中分析誘導型IFNα前藥(WW0610)之結果的圖。其展示用45 μg WW0610 (菱形)及133 μg WW0610 (方塊)處理之小鼠隨時間推移的平均腫瘤體積。單獨媒劑由黑色圓圈指示(至第18天具有最大腫瘤體積資料之上方線條)。資料顯

示，用WW0610以更高濃度處理之小鼠中的腫瘤體積增加隨時間推移以劑量依賴性方式抑制。

【0039】 **圖7A**為展示用媒劑(PBS，圓圈)、誘導型IL-2前藥(WW0621/WW0523，方塊)、抗PD-1 (三角)、或WW0621/WW0523及抗PD-1 (菱形)處理之小鼠之平均腫瘤體積的圖。亦展示給藥時程(箭頭)。

【0040】 **圖7B至圖7E**為用媒劑(圖7B)、WW0621/WW0523 (圖7C)、抗PD-1 (圖7D)、或WW0621/WW0523及抗PD-1 (圖7E)處理之個別小鼠之腫瘤體積的圖。

【0041】 **圖7F**為展示用媒劑(PBS圓圈)、誘導型IL-2前藥(WW0621/WW0523，方塊)、抗PD-1 (三角)、以及WW0621/WW0523及抗PD-1 (菱形)處理之小鼠之平均體重的圖。

【實施方式】

相關申請案

【0042】 本申請案主張於2021年8月17日申請之美國臨時申請案第63/234,001號及於2021年11月4日申請之美國臨時申請案第63/275,714號之權利，其各自以全文引用之方式併入。

A. 誘導型細胞激素

【0043】 本發明係關於含有至少一條多肽鏈且必要時可含有兩個或更多個多肽之誘導型細胞激素前藥。誘導型細胞激素前藥包含細胞激素(例如，IL-2、IL-12或IFN)、阻斷元件、蛋白酶可裂解連接子及半衰期延長元件。任何相關細胞激素可適合於本發明之誘導型細胞激素多肽前藥。例示性細胞激素包括但不限於介白素，諸如IL-2、IL-7、IL-12、IL-15、IL-18、IL-21、IL-23；IFN-α (例如，人類IFN-α1、人類IFN-α2、人類

IFN-α4、人類IFN-α5、人類IFN-α6、人類IFN-α7、人類IFN-α8、人類IFN-α10、人類IFN-α13、人類IFN-α14、人類IFN-α16、人類IFN-α17、人類IFN-α2)、IFN-β、IFN-κ或IFN-ε；淋巴毒素；TGF-β1；TGFβ2；TGFβ3；GM-CSF；CXCL10；CCL19；CCL20；CCL21及前述任一者之功能片段或突變蛋白。用於本文所揭示之誘導型細胞激素前藥的較佳細胞激素為IL-2、IL-12、IFN、突變蛋白、功能變異體及功能片段或前述任一者之次單元。

【0044】 本發明之誘導型細胞激素(例如，IL-2、IL-12或IFN)前藥具有減弱的細胞激素受體促效劑活性且循環半衰期延長。誘導型細胞激素受體促效劑活性經由阻斷元件減弱。半衰期延長元件亦可例如經由空間效應促進減弱。阻斷元件能夠藉由非共價結合於細胞激素(例如，結合於IL-2、IL-12或IFN)及/或空間阻斷受體結合來阻斷細胞激素之全部或一些受體促效劑活性。在蛋白酶可裂解連接子裂解時，釋放具有活性(例如，比細胞激素多肽前藥更具活性)的細胞激素形式。通常，所釋放之細胞激素具有比細胞激素多肽前藥高至少10倍的活性。較佳地，所釋放之細胞激素具有比細胞激素多肽複合物高至少20倍、至少30倍、至少50倍、至少100倍、至少200倍、至少300倍、至少500倍、至少1000倍、至少約10,000倍或更高的活性。

【0045】 在誘導型細胞激素前藥裂解時釋放之細胞激素形式通常具有短半衰期，其常常在實質上類似於天然存在之細胞激素的半衰期。儘管誘導型細胞激素前藥之半衰期延長，但毒性減少或消除，因為循環誘導型細胞激素前藥之促效劑活性減弱且活性細胞激素靶向所要活性位點(例如，腫瘤微環境)。

【0046】 熟習此項技術者應瞭解，多肽鏈的數目及元件、半衰期延長元件、蛋白酶可裂解連接子及阻斷元件(及此類元件之組分，諸如VH域或VL域)在多肽鏈上的位置可變化且常常視設計偏好而定。本發明涵蓋所有此類變化。

【0047】 誘導型細胞激素前藥可包含單一多肽鏈。通常，單一多肽複合物包含細胞激素多肽[A]、阻斷元件[D]、半衰期延長元件[H]及蛋白酶可裂解連接子[L]。細胞激素[A]多肽可藉由蛋白酶可裂解連接子以可操作方式連接至阻斷元件、半衰期延長元件或阻斷元件及半衰期延長元件兩者。

【0048】 例如，多肽可具有式(I)至(VI)中之任一者。

[A]-[L1]-[H]-[L2]-[D] (I)；

[D]-[L2]-[H]-[L1]-[A] (II)；

[A]-[L1]-[D]-[L2]-[H] (III)；

[H]-[L2]-[D]-[L1]-[A] (IV)；

[H]-[L1]-[A]-[L2']-[D] (V)；

[D]-[L1]-[A]-[L2']-[H] (VI)；

【0049】 在式(I)至(VI)中，[A]為細胞激素多肽，[D]為阻斷元件，[H]為半衰期延長元件，[L1]為蛋白酶可裂解的多肽連接子，[L2]為視情況蛋白酶可裂解的多肽連接子，且[L2']為蛋白酶可裂解的多肽連接子。[L1]及[L2]或[L1]及[L2']可視需要具有相同或不同的胺基酸序列及/或蛋白酶-裂解位點(當L2為蛋白酶可裂解時)。

【0050】 SEQ ID NO: 21-30為由式(I)至(VI)涵蓋且根據本發明使用之誘導型IL-2前藥的特定實例。SEQ ID NO 21-30及關於其活性之額外細

節揭示於國際公開案第WO2021/097376號中。

【0051】 SEQ ID NO: 31-40為由式(I)至(VI)涵蓋且根據本發明使用之誘導型IL-12前藥的特定實例。SEQ ID NO: 31-40及關於其活性之額外細節揭示於國際申請案第PCT/US2021/33014號及國際公開案第WO2019/222295號中。

【0052】 在一些情況下，單一多肽複合物包含細胞激素多肽[A]、阻斷元件(亦即空間阻斷多肽) [D]、蛋白酶可裂解連接子[L]及視情況存在之半衰期延長元件。阻斷元件[D]可為例如HSA或結合HSA之抗體或抗體片段(例如，scFv)。

【0053】 作為實例，多肽可具有式(VII)：[D]-[L1]-[A]-[L2]-[D]。SEQ ID NO: 14-20為根據本發明使用之誘導型IFN前藥的特定實例。SEQ ID NO: 14-20及關於其活性之額外細節揭示於國際申請案第PCT/US2020/060624號中。

【0054】 在一些情況下，誘導型IFN前藥可包含IFN多肽[A]、阻斷元件[D]、半衰期延長元件[H]及蛋白酶可裂解連接子[L]。IFN [A]多肽可藉由蛋白酶可裂解連接子以可操作方式連接至阻斷元件、半衰期延長元件或阻斷元件、半衰期延長元件兩者。

【0055】 IFN多肽及阻斷元件及半衰期延長元件藉由蛋白酶可裂解的多肽以可操作方式連接。例如，多肽可具有式(I)至(IX)中之任一者。

[A]-[L1]-[H]-[L2]-[D] (I)；

[D]-[L2]-[H]-[L1]-[A] (II)；

[A]-[L1]-[D]-[L2]-[H] (III)；

[H]-[L2]-[D]-[L1]-[A] (IV)；

[H]-[L1]-[A]-[L2']-[D] (V)；

[D]-[L1]-[A]-[L2']-[H] (VI)；

[H]-[L]-[D]-[L2]-[A]-[L3]-[D'] (VII)；

[D]-[L]-[A]-[L2]-[D']-[L3]-[H] (VIII)；

[D]-[L]-[H]-[L2]-[D']-[L3]-[A] (IX)；

【0056】 在式(I)至(IX)中，[A]為IFN多肽，[D]為IFN阻斷元件(例如，IFNα受體1 (IFNAR1)或IFNα受體2 (IFNAR2)之胞外部分)，[D']為IFNα受體1 (IFNAR1)或IFNα受體2 (IFNAR2)，其不存在於[D]中，[H]為半衰期延長元件，[L1]為蛋白酶可裂解的多肽連接子，[L2]為視情況蛋白酶可裂解之多肽連接子，且[L2']為蛋白酶可裂解的多肽連接子。[L1]及[L2]或[L1]及[L2']可視需要具有相同或不同的胺基酸序列及/或蛋白酶-裂解位點(當L2為蛋白酶可裂解時)。

【0057】 雖然本文所揭示之誘導型細胞激素前藥較佳含有一個半衰期延長元件及一個阻斷元件，但此類元件可含有存在於同一多肽鏈上或不同多肽鏈上的兩個或更多個組分。對此進行說明且如本文所揭示及例示，阻斷元件之組分可存在於獨立的多肽鏈上。例如，第一多肽鏈可包括抗體輕鏈(VL+CL)或輕鏈可變域(VL)，且第二多肽可包括與第一多肽上之VL+ CL或VL互補之抗體重鏈Fab片段(VH + CH1)或重鏈可變域(VH)。在此類情況下，此等組分可在肽複合物中締合以形成抗原結合位點，諸如結合於細胞激素(例如，IL-2、IL-12或IFN)且減弱細胞激素活性之Fab。

【0058】 例如，誘導型細胞激素前藥可具有式(X-XI)之第一多肽。式X：[D]-[L]-[A]-[L2]-[H]或式XI：[H]-[L]-[A]-[L2]-[D]。在式(X)至(XI)中，[A]為細胞激素多肽，[D]為抗體重鏈Fab片段(VH + CH1)或重鏈

可變域(VH)，[H]為半衰期延長元件，[L1]為蛋白酶可裂解的多肽連接子，[L2]為視情況蛋白酶可裂解的多肽連接子，且[L2']為蛋白酶可裂解的多肽連接子。[L1]及[L2]或[L1]及[L2']可視需要具有相同或不同的胺基酸序列及/或蛋白酶-裂解位點(當L2為蛋白酶可裂解時)。第二多肽抗體輕鏈(VL+CL)或輕鏈可變域(VL)與VH + CH1或VH互補。

【0059】 例如，誘導型細胞激素前藥可包含兩條多肽鏈。第一多肽鏈可包含細胞激素多肽、蛋白酶可裂解連接子、半衰期延長元件(例如，結合單一抗體可變域之抗人類血清白蛋白(HSA))及結合細胞激素(例如，IL-2、IL-12次單元(亦即p35、p40或p35p40雜二聚複合物)或IFN)之抗體的VH及CH1。第二多肽鏈可包含抗體之VL及CL，該抗體結合細胞激素(例如，IL-2、IL-12次單元(亦即p35、p40或p35p40雜二聚體複合物)或IFN)且與第一多肽鏈之VH及CH1一起形成結合細胞激素(例如，IL-2、IL-12次單元(亦即p35、p40或p35p40雜二聚體複合物)或IFN)多肽的Fab。

【0060】 化合物1、2、3及4為根據本發明使用之包含兩條多肽鏈之誘導型IL-2前藥的特定實例。化合物1、2、3及4及關於其活性之額外細節揭示於WO2021/097376中。

表1.誘導型IL-2前藥

IL-2前藥	第一多肽	第二多肽
化合物1	SEQ ID NO:1	SEQ ID NO:5
化合物2	SEQ ID NO:2	SEQ ID NO:5
化合物3	SEQ ID NO:3	SEQ ID NO:5
化合物4	SEQ ID NO:4	SEQ ID NO:5

【0061】 包含兩個次單元(諸如IL-12)之細胞激素亦可包含兩個或更多個不同的多肽。例如，第一多肽可包含IL-12次單元及視情況存在之阻

斷元件。若存在，阻斷元件可經由第一蛋白酶可裂解連接子以可操作方式連接至IL-12次單元。第二多肽鏈可包含經由第二蛋白酶可裂解連接子及視情況存在之IL-12阻斷元件以可操作方式連接至半衰期延長元件的IL-12次單元。若存在，IL-12阻斷元件可經由蛋白酶可裂解連接子以可操作方式連接至IL-12次單元，或可經由視情況蛋白酶可裂解之連接子以可操作方式連接至半衰期延長元件。第一及第二多肽中僅一者含有IL-12阻斷元件。當第一多肽中之IL-12次單元為p35時，第二多肽中之IL-12次單元為p40，且當第一多肽中之IL-12次單元為p40時，第二多肽中之IL-12次單元為p35。阻斷元件可為結合IL-12之單鏈抗體或其抗原結合片段。此複合物中之可裂解連接子可相同或不同。

【0062】 誘導型細胞激素多肽前藥可包含三個不同的多肽。例如，一條多肽鏈包含p35或p40 IL-12次單元但並非兩者，且第二多肽包含另一IL-12次單元且第三多肽包含阻斷元件之至少一部分(組分)。第一多肽可包含IL-12次單元，且視情況包含半衰期延長元件。若存在，半衰期延長元件可經由蛋白酶可裂解連接子以可操作方式連接至IL-12次單元。

【0063】 第二多肽可包含IL-12次單元、抗體輕鏈之至少抗原結合部分或抗體重鏈之抗原結合部分及視情況存在之半衰期延長元件。當存在半衰期延長元件時，其可經由蛋白酶可裂解連接子以可操作方式連接至IL-12次單元，且抗體重鏈或輕鏈a)經由第二蛋白酶可裂解連接子以可操作方式連接至IL-12次單元，或b)經由視情況存在之可裂解連接子以可操作方式連接至半衰期延長元件。

【0064】 第三多肽可包含與第二多肽中之輕鏈互補之抗體重鏈的抗原結合部分，或與第二多肽中之重鏈互補且與該輕鏈一起形成IL-12結合

位點的抗體輕鏈。當第一多肽中之IL-12次單元為p35時，第二多肽中之IL-12次單元為p40，且當第一多肽中之IL-12次單元為p40時，第二多肽中之IL-12次單元為p35。在此複合物中，IL-12阻斷元件較佳為抗體之抗原結合片段。抗原結合片段包含作為單獨組分之抗體輕鏈的至少抗原結合部分及互補抗體重鏈的至少抗原結合部分。此誘導型IL-12多肽複合物中之蛋白酶可裂解連接子可相同或不同。

【0065】 誘導型多肽複合物可包含兩個不同的多肽，其中p35及p40位於同一多肽鏈上。第一多肽鏈可包含p35、p40、半衰期延長元件及抗體輕鏈之至少抗原結合部分。p35及p40可以以可操作方式連接，且半衰期延長元件可經由第一蛋白酶可裂解連接子以可操作方式連接至p40且抗體輕鏈之抗原結合部分可經由蛋白酶可裂解連接子以可操作方式連接至p35。

【0066】 替代地，半衰期延長元件可經由蛋白酶可裂解連接子以可操作方式連接至p35且抗體輕鏈之抗原結合部分經由蛋白酶可裂解連接子以可操作方式連接至p40。第二多肽包含與第二多肽中之輕鏈互補且連同該輕鏈形成IL-12結合位點之抗體重鏈的至少抗原結合部分。此複合物中之蛋白酶可裂解連接子可相同或不同。

【0067】 在替代形式中，第一多肽鏈可包含p35、p40、半衰期延長元件及抗體重鏈之至少抗原結合部分。p35及p40可以以可操作方式連接，且半衰期延長元件可經由蛋白酶可裂解連接子以可操作方式連接至p40，且抗體重鏈之抗原結合部分可經由蛋白酶可裂解連接子以可操作方式連接至p35。替代地，半衰期延長元件可經由蛋白酶可裂解連接子以可操作方式連接至p35且抗體重鏈之抗原結合部分可經由第二蛋白酶可裂解

連接子以可操作方式連接至p40。第二多肽包含與第二多肽中之重鏈互補且連同該輕鏈形成IL-12結合位點之抗體輕鏈的至少抗原結合部分。此複合物中之蛋白酶可裂解連接子可相同或不同。

【0068】 在實例中，IL-12多肽複合物包含：不包含阻斷元件之第一多肽及具有下式之第二多肽：[A]-[L1]-[B]-[L3]-[D]或[D]-[L3]-[B]-[L1]-[A]或[B]-[L1]-[A]-[L2]-[D]或[D]-[L1]-[A]-[L2]-[B]，其中A為IL-12次單元；L1為第一蛋白酶可裂解的連接子；L2為第二蛋白酶可裂解連接子；L3為視情況存在之可裂解連接子；B為半衰期延長元件；且D為阻斷元件。

【0069】 在另一實例中，第一多肽包含下式：[A]-[L1]-[D]或[D]-[L1]-[A]；且第二多肽具有下式：[A']-[L2]-[B]或[B]-[L2]-[A']，其中A為p35或p40，其中當A為p35時，A'為p40，且當A為p40時，A'為p35；A'為p35或p40；L1為第一蛋白酶可裂解連接子；L2為第二蛋白酶可裂解連接子；B為半衰期延長元件；且D為阻斷元件。

【0070】 化合物5、6、7、8、9及10為根據本發明使用之包含兩條多肽鏈之誘導型IL-12前藥的特定實例。化合物5、6、7、8、9及10及關於其活性之額外細節揭示於國際申請案第PCT/US2021/33014號中。

表2.誘導型IL-12前藥

IL-12前藥	第一多肽	第二多肽
化合物5	SEQ ID NO: 6	SEQ ID NO: 12
化合物6	SEQ ID NO: 7	SEQ ID NO: 12
化合物7	SEQ ID NO: 8	SEQ ID NO:13
化合物8	SEQ ID NO: 9	SEQ ID NO:13
化合物9	SEQ ID NO: 10	SEQ ID NO:13
化合物10	SEQ ID NO: 11	SEQ ID NO:13

【0071】 如上文所描述，若需要，細胞激素可為突變蛋白。細胞激素突變蛋白保留活性，例如固有IL-12/IL-2/IFN受體促效劑活性。

B. 半衰期延長元件

【0072】 半衰期延長元件增加活體內半衰期且提供誘導型細胞激素前藥之經改變之藥效學及藥物動力學。不受理論束縛，半衰期延長元件改變藥效學特性，包括改變誘導型細胞激素前藥之組織分佈、滲透及擴散。在一些實施例中，相較於不具有半衰期延長元件之蛋白，半衰期延長元件可改良組織靶向、組織滲透、組織內之擴散及增強之功效。不受理論束縛，改良多肽之藥物動力學的例示性方式係藉由在多肽鏈中表現結合於受體之元件，該等受體(諸如內皮細胞上之FcRn受體及運鐵蛋白受體)再循環至細胞之質膜而非在溶酶體中降解。三種類型之蛋白(例如，人類IgG、HSA (或片段)及運鐵蛋白)在人類血清中之存留時間比僅由其大小預測之時間長得多，該大小隨其與再循環而非在溶酶體中降解之受體結合的能力而變。此等蛋白或片段保留FcRn結合且通常連接至其他多肽以延長其血清半衰期。HSA亦可直接結合於醫藥組合物或經由短連接子結合。亦可使用HSA之片段。HSA及其片段可充當阻斷元件及半衰期延長元件兩者。人類IgG及Fc片段亦可發揮類似功能。

【0073】 血清半衰期延長元件亦可為結合於具有長血清半衰期之蛋白的抗原結合多肽，該蛋白諸如血清白蛋白、運鐵蛋白及其類似物。此類多肽之實例包括抗體及其片段，包括多株抗體、重組抗體、人類抗體、人類化抗體、單鏈可變片段(scFv)、單域抗體(諸如重鏈可變域(VH)、輕鏈可變域(VL)及駱駝型(camelid-type)奈米抗體之可變域(VHH))、dAb及其類似物。其他適合之抗原結合域包括模擬抗體結合及/或結構之非免疫球

蛋白型蛋白，諸如抗運載蛋白(anticalin)、阿非林(affilin)、親和體分子(affibody molecule)、阿非莫(affimer)、阿非汀(affitin)、α體(alphabody)、高親和性多聚體(avimer)、預設計之錨蛋白重複蛋白(DARPin)、非諾莫(fynomer)、孔尼茲域肽(kunitz domain peptide)、單功能抗體及基於其他經工程改造之骨架(諸如SpA、GroEL、纖維結合蛋白、脂質運載蛋白(lipocallin)及CTLA4骨架)的結合域。抗原結合多肽之其他實例包括所要受體之配位體、受體之配位體結合部分、凝集素(lectin)及結合於一或多種靶向抗原或與一或多種靶向抗原締合之肽。

【0074】 如本文所提供之半衰期延長元件較佳為人類血清白蛋白(HSA)結合域，以及結合人類血清白蛋白或免疫球蛋白Fc或其片段之抗原結合多肽。

【0075】 誘導型細胞激素前藥之半衰期延長元件延長誘導型細胞激素前藥之半衰期至少約兩天、約三天、約四天、約五天、約六天、約七天、約八天、約九天、約10天或更多天。

C. 阻斷元件

【0076】 阻斷元件可為結合於細胞激素且抑制細胞激素多肽結合及活化其受體之能力的任何元件。阻斷元件可抑制細胞激素(例如，IL-2、IL-12或IFN)結合及/或活化其受體的能力，例如藉由空間阻斷及/或藉由非共價結合於細胞激素多肽。本文所揭示之阻斷元件可結合於IL-2、IL-12 (例如，p35、p40或雜二聚體)或IFN (例如，IFN-α (例如，人類IFN-α1、人類IFN-α2、人類IFN-α4、人類IFN-α5、人類IFN-α6、人類IFN-α7、人類IFN-α8、人類IFN-α10、人類IFN-α13、人類IFN-α14、人類IFN-α16、人類IFN-α17、人類IFN-α2)、IFN-β、IFN-γ)。

【0077】 適合阻斷元件之實例包括細胞激素(例如，IL-2、IL-12或IFN)之同族受體的全長或細胞激素-結合片段或突變蛋白。IL-2之同族受體可為IL-2 α鏈、IL-2 β鏈、IL-2 γ鏈或其組合。IL-12之同族受體可為IL-12Rβ1及/或IL-12Rβ2。IFN之同族受體可為IFNGR受體或其部分。例如，當干擾素多肽為IFNα，諸如INFα2a時，阻斷元件可為INFα受體1(IFNAR1)或其干擾素結合部分或突變蛋白之胞外部分，或IFNα受體2(IFNAR2)或其干擾素結合部分或突變蛋白之胞外部分。當干擾素多肽為IFNγ時，阻斷元件可為IFNγ受體1 (IFNGR1)或其干擾素結合部分或突變蛋白之胞外部分，或IFNγ受體2 (IFNGR2)或其干擾素結合部分或突變蛋白之胞外部分。

【0078】 亦可使用抗體及其抗原結合片段，包括多株抗體、重組抗體、人類抗體、人類化抗體、單鏈可變片段(scFv)、單域抗體(諸如重鏈可變域(VH))、輕鏈可變域(VL)及駱駝型奈米抗體之可變域(VHH))、dAb及其類似物，其結合於細胞激素(例如，IL-2、IL-12或IFN)。亦可使用結合於細胞激素多肽之其他適合的抗原結合域，包括模擬抗體結合及/或結構之非免疫球蛋白型蛋白，諸如抗運載蛋白、阿非林、親和體分子、阿非莫、阿非汀、α體、高親和性多聚體、預設計之錨蛋白重複蛋白、非諾莫、孔尼茲域肽、單功能抗體及基於其他經工程改造之骨架(諸如SpA、GroEL、纖維結合蛋白、脂質運載蛋白及CTLA4骨架)的結合域。適合之阻斷多肽的其他實例包括空間抑制或阻斷其同族受體之結合的多肽。有利地，此類部分亦可充當半衰期延長元件。例如，藉由結合至水溶性聚合物(諸如PEG)而經修飾之肽可在空間上抑制或阻止細胞激素與其受體之結合。亦可使用具有長血清半衰期之多肽或其片段，諸如血清白蛋白(人類

血清白蛋白)、免疫球蛋白Fc、運鐵蛋白及其類似物，以及此類多肽之片段及突變蛋白。

【0079】 特別適合之阻斷元件為單鏈可變片段(scFv)或Fab片段。

【0080】 本文亦揭示一種誘導型細胞激素前藥e，其含有對細胞激素具有特異性之阻斷元件且進一步含有半衰期延長元件。

【0081】 阻斷元件可含有兩種或更多種存在於同一多肽鏈上或單獨多肽鏈上之組分。第一多肽鏈可包括抗體輕鏈(VL+CL)或輕鏈可變域(VL)且第二多肽可包括與第一多肽上之VL + CL或VL互補之抗體重鏈Fab片段(VH + CH1)或重鏈可變域(VH)。在此類情況下，此等組分可在肽複合物中締合以形成抗原結合位點，諸如結合細胞激素(例如，IL-2、IL-12、IFN)且減弱細胞激素活性之Fab。

D. 蛋白酶可裂解連接子

【0082】 如本文所揭示，誘導型細胞激素前藥包含一或多個連接子序列。連接子序列用以在多肽之間提供可撓性，使得例如阻斷元件能夠抑制細胞激素之活性。連接子可位於細胞激素次單元、半衰期延長元件及/或阻斷元件之間。如本文所描述，誘導型細胞激素前藥包含蛋白酶可裂解連接子。蛋白酶可裂解連接子可包含用於一或多種所要蛋白酶之一或多個裂解位點。較佳地，所要蛋白酶富集或選擇性地表現於細胞激素活性之所要靶向位點(例如，腫瘤微環境)。因此，誘導型細胞激素前藥優先或選擇性地在所要細胞激素活性之靶向位點處裂解。

【0083】 適合之連接子通常小於約100個胺基酸。此類連接子可具有不同長度，諸如1個胺基酸(例如，Gly)至30個胺基酸、1個胺基酸至40個胺基酸、1個胺基酸至50個胺基酸、1個胺基酸至60個胺基酸、1至70個

胺基酸、1至80個胺基酸、1至90個胺基酸及1至100個胺基酸。在一些實施例中，連接子之長度為至少約1、約2、約3、約4、約5、約10、約15、約20、約25、約30、約35、約40、約45、約50、約55、約60、約65、約70、約75、約80、約85、約90、約95或約100個胺基酸。較佳連接子通常為約5個胺基酸至約30個胺基酸。

【0084】 連接子之長度較佳在2至30個胺基酸之間變化，針對各條件最佳化從而使連接子不對所連接之域的構形或相互作用施加任何限制。在較佳實施例中，連接子可藉由例如酶之裂解劑裂解。較佳地，連接子包含蛋白酶裂解位點。在一些情況下，連接子包含一或多個裂解位點。連接子可包含單一蛋白酶裂解位點。連接子亦可包含2個或更多個蛋白酶裂解位點。例如，2個裂解位點、3個裂解位點、4個裂解位點、5個裂解位點或更多。在連接子包含2個或更多個蛋白酶裂解位點之情況下，裂解位點可由相同蛋白酶或不同蛋白酶裂解。包含兩個或更多個裂解位點之連接子稱為「串聯連接子」。兩個或更多個裂解位點可以任何所要取向配置，包括但不限於一個裂解位點與另一裂解位點相鄰、一個裂解位點與另一裂解位點重疊，或一個裂解位點後接另一裂解位點且在兩個裂解位點之間介入胺基酸。

【0085】 本發明尤其關注疾病特異性蛋白酶可裂解的連接子。亦較佳的為相對於周邊循環優先在諸如腫瘤微環境之體內所要位置處裂解的蛋白酶可裂解的連接子。例如，與周邊循環(例如，在血漿中)相比，在例如腫瘤微環境之體內所要位置中，蛋白酶可裂解的連接子在腫瘤微環境中之裂解的速率可至少快約10倍、至少約100倍、至少約1000倍或至少約10,000倍。

【0086】已知與病變細胞或組織相關之蛋白酶包括但不限於絲胺酸蛋白酶、半胱胺酸蛋白酶、天冬胺酸蛋白酶、蘇胺酸蛋白酶、麩胺酸蛋白酶、金屬蛋白酶、天冬醯胺肽裂解酶、血清蛋白酶、組織蛋白酶、組織蛋白酶B、組織蛋白酶C、組織蛋白酶D、組織蛋白酶E、組織蛋白酶G、組織蛋白酶K、組織蛋白酶L、激肽釋放素、hKl、hK10、hK15、纖維蛋白溶酶、膠原蛋白酶、IV型膠原蛋白酶、基質溶素、因子Xa、胰凝乳蛋白酶樣蛋白酶、胰蛋白酶樣蛋白酶、彈性蛋白酶樣蛋白酶、枯草桿菌蛋白酶樣蛋白酶、奇異果蛋白酶(actinidain)、鳳梨酵素、鈣蛋白酶、凋亡蛋白酶、凋亡蛋白酶-3、Mirl-CP、木瓜酶、HIV-1蛋白酶、HSV蛋白酶、CMV蛋白酶、凝乳酶、腎素、胃蛋白酶、間質蛋白酶、豆莢蛋白、半胱胺酸蛋白酶、豬籠草蛋白酶、金屬外肽酶(metalloexopeptidase)、金屬內肽酶(metalloendopeptidase)、基質金屬蛋白酶(MMP)、MMP1、MMP2、MMP3、MMP8、MMP9、MMP13、MMP11、MMP14、尿激酶纖維蛋白溶酶原活化因子(urokinase plasminogen activator，uPA)、腸激酶、前列腺特異性抗原(PSA，hK3)、介白素-1β轉化酶、凝血酶、FAP(FAPα)、二肽基肽酶、安眠蛋白酶(meprin)、顆粒酶及二肽基肽酶IV(DPPIV/CD26)。能夠裂解連接子胺基酸序列(其可由本文所提供之嵌合核酸序列編碼)之蛋白酶可例如選自由以下組成之群：前列腺特異性抗原(PSA)、基質金屬蛋白酶(MMP)、解聚素及金屬蛋白酶(A Disintigrin and a Metalloproteinase，ADAM)、纖維蛋白溶酶原活化因子、組織蛋白酶、凋亡蛋白酶、腫瘤細胞表面蛋白酶及彈性蛋白酶。MMP可例如為基質金屬蛋白酶2 (MMP2)、基質金屬蛋白酶9 (MMP9)、基質金屬蛋白酶14(MMP14)。另外或替代地，連接子可藉由組織蛋白酶，諸如組織蛋白酶

B、組織蛋白酶C、組織蛋白酶D、組織蛋白酶E、組織蛋白酶G、組織蛋白酶K及/或組織蛋白酶L裂解。較佳地，連接子可藉由MMP14或組織蛋白酶L裂解。

【0087】 適用於連接子之裂解及用於本文所揭示之誘導型細胞激素前藥的蛋白酶呈現於表3中，且例示性蛋白酶及其裂解位點呈現於表4中。

表3.與發炎及癌症有關之蛋白酶

蛋白酶	特異性	其他態樣
由殺手T細胞分泌：		
顆粒酶B (grB)	在Asp殘基之後裂解(asp-ase)	絲胺酸蛋白酶之類型；很大程度上與誘導穿孔蛋白依賴性靶向細胞凋亡有關
顆粒酶A (grA)	胰蛋白酶樣，在鹼性殘基之後裂解	絲胺酸蛋白酶之類型；
顆粒酶H (grH)	未知受質特異性	絲胺酸蛋白酶之類型； *其他顆粒酶亦由殺手T細胞分泌，但並非全部存在於人類中*
凋亡蛋白酶-8	在Asp殘基之後裂解	半胱胺酸蛋白酶之類型；在TCR誘導之細胞擴增中起重要作用-尚未知曉確切的分子作用
黏膜相關淋巴組織(MALT1)	在精胺酸殘基之後裂解	半胱胺酸蛋白酶之類型；可能在CBM依賴性信號傳導路徑中充當骨架及蛋白分解活性酶兩者
類胰蛋白酶	目標：血管收縮素I、血纖維蛋白原、前尿激酶(prourokinase)、 TGFβ；優先在離胺酸或精胺酸殘基之後裂解蛋白	肥大細胞特異性絲胺酸蛋白酶之類型；胰蛋白酶樣；由於其四聚體結構而對哺乳動物中表現之大分子蛋白酶抑制劑之抑制具有抗性，其中所有位點面對狹窄中心孔；*亦與發炎相關*
與發炎相關：		
凝血酶	目標：FGF-2、 HB-EGF、骨橋蛋白(Osteo-pontin)、PDGF、VEGF	絲胺酸蛋白酶之類型；調控血管生長因子、趨化激素及胞外蛋白之活性；強化VEGF誘導之增殖；誘導細胞遷移；血管生成因子；調節止血
凝乳酶	展現胰凝乳蛋白酶樣特異性，在芳族胺基酸殘基之後裂解蛋白	肥大細胞特異性絲胺酸蛋白酶之類型
羧肽酶A (MC-CPA)	自肽及蛋白之C端裂解胺基酸殘基	鋅依賴性金屬蛋白酶之類型
激肽釋放素	目標：高分子量 激肽原、前尿激酶(pro-urokinase)	絲胺酸蛋白酶之類型；調控鬆弛反應；促進發炎反應；纖維蛋白降解

蛋白酶	特異性	其他態樣
彈性蛋白酶	目標：E-鈣黏蛋白(E-cadherin)、GM-CSF、IL-1、IL-2、IL-6、IL8、$p38^{MAPK}$、TNFα、VE-鈣黏蛋白	嗜中性球絲胺酸蛋白酶之類型；降解ECM組分；調節發炎反應；活化促凋亡信號傳導
組織蛋白酶G	目標：EGF、ENA-78、IL-8、MCP-1、MMP-2、MT1-MMP、PAI-1、RANTES、TGFβ、TNFα	絲胺酸蛋白酶之類型；降解ECM組分；白血球之化學引誘劑；調節發炎反應；促進細胞凋亡
PR-3	目標：ENA-78、IL-8、IL-18、JNK、$p38^{MAPK}$、TNFα	絲胺酸蛋白酶之類型；促進發炎反應；活化促凋亡信號傳導
顆粒酶M (grM)	在Met及其他非分支長鏈疏水性殘基之後裂解	絲胺酸蛋白酶之類型；僅在NK細胞中表現
鈣蛋白酶	在Arg與Gly之間裂解	半胱胺酸蛋白酶家族；鈣依賴性；活化涉及多種發炎相關疾病之過程

表4.例示性蛋白酶及蛋白酶識別序列

蛋白酶	裂解域序列	SEQ ID NO:
MMP7	KRALGLPG	375
MMP7	$(DE)_8$RPLALWRS$(DR)_8$	376
MMP9	PR(S/T)(L/I)(S/T)	
MMP9	LEATA	378
MMP11	GGAANLVRGG	379
MMP14	SGRIGFLRTA	380
MMP	PLGLAG	381
MMP	PLGLAX	382
MMP	PLGC(me)AG	383
MMP	ESPAYYTA	384
MMP	RLQLKL	385
MMP	RLQLKAC	386
MMP2、MMP9、MMP14	EP(Cit)G(Hof)YL	387
尿激酶纖維蛋白溶酶原活化因子(uPA)	SGRSA	388
尿激酶纖維蛋白溶酶原活化因子(uPA)	DAFK	389
尿激酶纖維蛋白溶酶原活化因子(uPA)	GGGRR	390
溶酶體酶	GFLG	391
溶酶體酶	ALAL	392
溶酶體酶	FK	
組織蛋白酶B	NLL	
組織蛋白酶D	PIC(Et)FF	395
組織蛋白酶K	GGPRGLPG	396
前列腺特異性抗原	HSSKLQ	397
前列腺特異性抗原	HSSKLQL	398

蛋白酶	裂解域序列	SEQ ID NO:
前列腺特異性抗原	HSSKLQEDA	399
單純疱疹病毒蛋白酶	LVLASSSFGY	400
HIV蛋白酶	GVSQNYPIVG	401
CMV蛋白酶	GVVQASCRLA	402
凝血酶	F(Pip)RS	
凝血酶	DPRSFL	404
凝血酶	PPRSFL	405
凋亡蛋白酶-3	DEVD	406
凋亡蛋白酶-3	DEVDP	407
凋亡蛋白酶-3	KGSGDVEG	408
介白素1β轉化酶	GWEHDG	409
腸激酶	EDDDDKA	410
FAP	KQEQNPGST	411
激肽釋放素2	GKAFRR	412
纖維蛋白溶酶	DAFK	413
纖維蛋白溶酶	DVLK	414
纖維蛋白溶酶	DAFK	415
TOP	ALLLALL	416
	GPLGVRG	417
	IPVSLRSG	418
	VPLSLYSG	419
	SGESPAYYTA	420

【0088】 例示性蛋白酶可裂解連接子包括但不限於激肽釋放素可裂解連接子、凝血酶可裂解連接子、凝乳酶可裂解連接子、羧肽酶A可裂解連接子、組織蛋白酶可裂解連接子、彈性蛋白酶可裂解連接子、FAP可裂解連接子、ADAM可裂解連接子、PR-3可裂解連接子、顆粒酶M可裂解連接子、鈣蛋白酶可裂解連接子、基質金屬蛋白酶(MMP)可裂解連接子、纖維蛋白溶酶原活化因子可裂解連接子、凋亡蛋白酶可裂解連接子、類胰蛋白酶可裂解連接子或腫瘤細胞表面蛋白酶。特定言之，MMP9可裂解連接子、ADAM可裂解連接子、CTSL1可裂解連接子、FAPα可裂解連接子及組織蛋白酶可裂解連接子。一些較佳蛋白酶可裂解的連接子係由MMP及/或組織蛋白酶裂解。

【0089】 本文所揭示之分離部分通常小於100個胺基酸。此類分離

部分可具有不同長度，諸如1個胺基酸(例如，Gly)至30個胺基酸、1個胺基酸至40個胺基酸、1個胺基酸至50個胺基酸、1個胺基酸至60個胺基酸、1至70個胺基酸、1至80個胺基酸、1至90個胺基酸及1至100個胺基酸。在一些實施例中，連接子之長度為至少約1、約2、約3、約4、約5、約10、約15、約20、約25、約30、約35、約40、約45、約50、約55、約60、約65、約70、約75、約80、約85、約90、約95或約100個胺基酸。較佳連接子通常為約5個胺基酸至約30個胺基酸。

【0090】 連接子之長度較佳在2至30個胺基酸之間變化，針對各條件最佳化從而使連接子不對所連接之域之構形或相互作用施加任何限制。

【0091】 在一些實施例中，連接子包含以下序列：GPAGLYAQ (SEQ ID NO: 195)；GPAGMKGL (SEQ ID NO: 196)；PGGPAGIG (SEQ ID NO: 197)；ALFKSSFP (SEQ ID NO: 198)；ALFFSSPP (SEQ ID NO: 199)；LAQRLRSS (SEQ ID NO: 200)；LAQKLKSS (SEQ ID NO: 201)；GALFKSSFPSGGGPAGLYAQGGSGKGGSGK (SEQ ID NO: 202)；RGSGGGPAGLYAQGSGGGPAGLYAQGGSGK (SEQ ID NO: 203)；KGGGPAGLYAQGPAGLYAQGPAGLYAQGSR (SEQ ID NO: 204)；RGGPAGLYAQGGPAGLYAQGGGPAGLYAQK (SEQ ID NO: 205)；KGGALFKSSFPGGPAGIGPLAQKLKSSGGS (SEQ ID NO: 206)；SGGPGGPAGIGALFKSSFPLAQKLKSSGGG (SEQ ID NO: 207)；RGPLAQKLKSSALFKSSFPGGPAGIGGGGK (SEQ ID NO: 208)；GGGALFKSSFPLAQKLKSSPGGPAGIGGGR (SEQ ID NO: 209)；RGPGGPAGIGPLAQKLKSSALFKSSFPGGG (SEQ ID NO: 210)；RGGPLAQKLKSSPGGPAGIGALFKSSFPGK (SEQ ID NO: 211)；

RSGGPAGLYAQALFKSSFPLAQKLKSSGGG (SEQ ID NO: 212)；GGPLAQKLKSSALFKSSFPGPAGLYAQGGR (SEQ ID NO: 213)；GGALFKSSFPGPAGLYAQPLAQKLKSSGGK (SEQ ID NO: 214)；RGGALFKSSFPLAQKLKSSGPAGLYAQGGK (SEQ ID NO: 215)；RGGGPAGLYAQPLAQKLKSSALFKSSFPGG (SEQ ID NO: 216)；SGPLAQKLKSSGPAGLYAQALFKSSFPGSK (SEQ ID NO: 217)；KGGPGGPAGIGPLAQRLRSSALFKSSFPGR (SEQ ID NO: 218)；KSGPGGPAGIGALFFSSPPLAQKLKSSGGR (SEQ ID NO: 219)；或SGGFPRSGGSFNPRTFGSKRKRRGSRGGGG (SEQ ID NO: 220)。

【0092】某些較佳分離部分包含序列GPAGLYAQ (SEQ ID NO: 195)或ALFKSSFP (SEQ ID NO: 198)。本文所揭示之分離部分可包含一或多種相同或不同的裂解模體或功能變異體。分離部分可包含1、2、3、4、5或更多個裂解模體或功能變異體。包含30個胺基酸之分離部分可含有2個裂解模體或功能變異體、3個裂解模體或功能變異體或者更多。連接子之「功能變異體」保留在靶向位點(例如，表現高含量蛋白酶之腫瘤微環境)處以高效率裂解且在周邊(例如，血清)中不裂解或以低效率裂解的能力。例如，功能變異體保留包含SEQ ID NO: 195-220或SEQ ID NO: 447-448中之任一者之連接子的至少約50%、約55%、約60%、約70%、約80%、約85%、約95%或更高的裂解功效。

【0093】包含多於一個裂解模體之分離部分可選自SEQ ID NO: 195-201或SEQ ID NO: 447-448及其組合。包含多於一個裂解模體之較佳分離部分包含選自SEQ ID NO: 202-220之胺基酸。

【0094】連接子可包含ALFKSSFP (SEQ ID NO: 198)及

GPAGLYAQ (SEQ ID NO: 195)兩者。連接子可包含各自具有序列GPAGLYAQ (SEQ ID NO: 195)之兩個裂解模體。替代地或另外，連接子可包含各自具有序列ALFKSSFP (SEQ ID NO: 198)之兩個裂解模體。連接子可包含相同或不同的第三裂解模體。

【0095】在一些實施例中，連接子包含在SEQ ID NO: 195-220或SEQ ID NO: 447-448之全長上與SEQ ID NO: 195至SEQ ID NO: 220或SEQ ID NO: 447-448至少約90%、至少約95%、至少約96%、至少約97%、至少約98%或至少99%一致之胺基酸序列。

【0096】本發明亦關於包含SEQ ID NO: 195-220或SEQ ID NO: 447-448之分離部分的功能變異體。包含SEQ ID NO: 195-220或SEQ ID NO: 447-448之分離部分的功能變異體一般與SEQ ID NO: 195-220或SEQ ID NO: 447-448相差一個或幾個胺基酸(包括取代、缺失、插入或其任何組合)，且實質上保持其藉由蛋白酶裂解之能力。

【0097】相對於包含SEQ ID NO: 195-220或SEQ ID NO: 447-448之分離部分，功能變異體可含有至少一或多個胺基酸取代、缺失或插入。相較於包含SEQ ID NO: 195-220或SEQ ID NO: 447-448之分離部分，功能變異體可包含1、2、3、4、5、6、7、8、9或10個胺基酸變化。在一些較佳實施例中，功能變異體與包含SEQ ID NO: 195-220之連接子相差小於10、小於8、小於5、小於4、小於3、小於2或一個胺基酸變化，例如胺基酸取代或缺失。在其他實施例中，相較於SEQ ID NO: 195-220或SEQ ID NO: 447-448，功能變異體可包含1、2、3、4、5、6、7、8、9或10個胺基酸取代。胺基酸取代可為保守性取代或非保守性取代，但較佳為保守性取代。

【0098】 在其他實施例中，相較於包含SEQ ID NO: 195-220或SEQ ID NO: 447-448之分離部分，分離部分之功能變異體可包含1、2、3、4或5個或更多個非保守性胺基酸取代。非保守性胺基酸取代可由熟習此項技術者識別。連接子之功能變異體較佳含有不大於1、2、3、4或5個胺基酸缺失。

【0099】 分離部分中所揭示之胺基酸序列可藉由關於易碎(scissile)鍵之連接子中的相對線性位置描述。如熟習此項技術者將充分理解，包含8個胺基酸蛋白酶受質(例如，SEQ ID No: 195-201或SEQ ID No: 447-448)之分離部分在位置P4、P3、P2、P1、P1'、P2'、P3'、P4'處含有胺基酸，其中易碎鍵在P1與P1'之間。例如，包含序列GPAGLYAQ (SEQ ID NO: 195)之連接子的胺基酸位置可描述如下：

G	P	A	G	L	Y	A	Q
P4	P3	P2	P1	P1'	P2'	P3'	P4'

揭示為SEQ ID NO: 195之「GPAGLYAQ」。

【0100】 包含序列ALFKSSFP (SEQ ID NO: 198)之連接子的胺基酸位置可描述如下：

A	L	F	K	S	S	F	P
P4	P3	P2	P1	P1'	P2'	P3'	P4'

揭示為SEQ ID NO: 198之「ALFKSSFP」。

【0101】 較佳地，圍繞裂解位點(例如，SEQ ID NO: 195-201或SEQ ID NO: 447-448之位置P1及P1')的胺基酸未經取代。

【0102】 在實施例中，連接子包含序列GPAGLYAQ (SEQ ID NO: 195)或ALFKSSFP (SEQ ID NO: 198)或SEQ ID NO: 195之功能變異體或SEQ ID NO: 198之功能變異體。如本文所描述，PAGLYAQ (SEQ ID NO: 447)或ALFKSSFP (SEQ ID NO: 198)之功能變異體可包含一或多個胺基

酸取代，且實質上保留其由蛋白酶裂解之能力。特定言之，GPAGLYAQ (SEQ ID NO: 195)之功能變異體係由MMP14裂解，且ALFKSSFP (SEQ ID NO: 198)之功能變異體係由組織蛋白酶L (CTSL1)裂解。功能變異體亦保留其在靶向位點(例如，表現高含量蛋白酶之腫瘤微環境)處以高效率裂解之能力。例如，GPAGLYAQ (SEQ ID NO: 195)或ALFKSSFP (SEQ ID NO: 198)之功能變異體分別保留包含胺基酸序列GPAGLYAQ (SEQ ID NO: 195)或ALFKSSFP (SEQ ID NO: 198)之連接子的至少約50%、約55%、約60%、約70%、約80%、約85%、約95%或更高的裂解功效。

【0103】較佳地，相較於GPAGLYAQ (SEQ ID NO: 195)或ALFKSSFP (SEQ ID NO: 198)，GPAGLYAQ (SEQ ID NO: 195)或ALFKSSFP (SEQ ID NO: 198)之功能變異體包含不大於1、2、3、4或5個保守性胺基酸取代。較佳地，位置P1及P1'處之胺基酸未經取代。SEQ ID NO: 195中之位置P1及P1'處的胺基酸為G及L，且SEQ ID NO: 198中之位置P1及P1'處的胺基酸為K及S。

【0104】GPAGLYAQ (SEQ ID NO: 195)之功能變異體可較佳包含以下中之一或多者：a)位置P4處之精胺酸胺基酸取代；b)位置P3處之白胺酸、纈胺酸、天冬醯胺或脯胺酸胺基酸取代；c)位置P2處之天冬醯胺胺基酸取代；d)位置P1處之組胺酸、天冬醯胺或甘胺酸胺基酸取代；e)位置P1'處之天冬醯胺、異白胺酸或白胺酸胺基酸取代；f)位置P2'處之酪胺酸或精胺酸胺基酸取代；g)位置P3'處之甘胺酸、精胺酸或丙胺酸胺基酸取代；h)或位置P4'處之絲胺酸、麩醯胺酸或離胺酸胺基酸取代。以下胺基酸取代在GPAGLYAQ (SEQ ID NO: 195)之功能變異體中為不利的：a)位置P3處之精胺酸或異白胺酸；b)位置P2處之丙胺酸；c)位置P1處之纈胺

酸；d)位置P1'處之精胺酸、甘胺酸、天冬醯胺或蘇胺酸；e)位置P2'處之天冬胺酸或麩胺酸；f)位置P3'處之異白胺酸；g)位置P4'處之纈胺酸。在一些實施例中，GPAGLYAQ (SEQ ID NO: 195)之功能變異體不包含位置P1及/或P1'處之胺基酸取代。

【0105】 GPAGLYAQ (SEQ ID NO: 195)之功能變異體的胺基酸取代較佳包含位置P4及/或P4'處之胺基酸取代。例如，GPAGLYAQ (SEQ ID NO: 195)之功能變異體可包含位置P4處之白胺酸，或位置P4處之絲胺酸、麩醯胺酸、離胺酸或苯丙胺酸。替代地或另外，GPAGLYAQ (SEQ ID NO: 195)之功能變異體可包含位置P4'處之甘胺酸、苯丙胺酸或脯胺酸。

【0106】 在一些實施例中，GPAGLYAQ (SEQ ID NO: 195)之位置P2或P2'處的胺基酸取代並非較佳的。

【0107】 在一些實施例中，GPAGLYAQ (SEQ ID NO: 195)之功能變異體包含選自SEQ ID NO: 221-295之胺基酸序列。GPAGLYAQ (SEQ ID NO: 195)之特定功能變異體包括GPLGLYAQ (SEQ ID NO: 259)及GPAGLKGA (SEQ ID NO: 249)。

【0108】 LFKSSFP (SEQ ID NO: 448)之功能變異體較佳包含疏水性胺基酸取代。LFKSSFP (SEQ ID NO: 448)之功能變異體可較佳包含以下中之一或多者：(a)位置P4處之離胺酸、組胺酸、絲胺酸、麩醯胺酸、白胺酸、脯胺酸或苯丙胺酸；(b)位置P3處之離胺酸、組胺酸、甘胺酸、脯胺酸、天冬醯胺、苯丙胺酸；(c)位置P2處之精胺酸、白胺酸、丙胺酸、麩醯胺酸或組胺酸；(d)位置P1處之苯丙胺酸、組胺酸、蘇胺酸、丙胺酸或麩醯胺酸；(e)位置P1'處之組胺酸、白胺酸、離胺酸、丙胺酸、異

白胺酸、精胺酸、苯丙胺酸、天冬醯胺、麩胺酸或甘胺酸；(f)位置P2'處之苯丙胺酸、白胺酸、異白胺酸、離胺酸、丙胺酸、麩醯胺酸或脯胺酸；(g)位置P3'處之苯丙胺酸、白胺酸、甘胺酸、絲胺酸、纈胺酸、組胺酸、丙胺酸或天冬醯胺；及苯丙胺酸、組胺酸、甘胺酸、丙胺酸、絲胺酸、纈胺酸、麩醯胺酸、離胺酸或白胺酸。

【0109】 在SEQ ID NO: 448之功能變異體中包括天冬胺酸及/或麩胺酸一般為不利的且係避免的。以下胺基酸取代在LFKSSFP (SEQ ID NO: 448)之功能變異體中亦為不利的：(a)位置P3處之丙胺酸、絲胺酸或麩胺酸；(b)位置P2處之脯胺酸、蘇胺酸、甘胺酸或天冬胺酸；(c)位置P1處之脯胺酸；(d)位置P1'處之脯胺酸；(e)位置P2'處之甘胺酸；(f)位置P3'處之離胺酸或麩胺酸；(g)位置P4'處之天冬胺酸。

【0110】 LFKSSFP (SEQ ID NO: 448)之功能變異體的胺基酸取代較佳包含位置P4及/或P1處之胺基酸取代。在一些實施例中，位置P4'處之LFKSSFP (SEQ ID NO: 448)之功能變異體的胺基酸取代並非較佳的。

【0111】 在一些實施例中，LFKSSFP (SEQ ID NO: 448)之功能變異體包含選自SEQ ID NO: 296-374之胺基酸序列。LFKSSFP (SEQ ID NO: 448)之特定功能變異體包括ALFFSSPP (SEQ ID NO: 199)、ALFKSFPP (SEQ ID NO: 346)、ALFKSLPP (SEQ ID NO: 347)；ALFKHSPP (SEQ ID NO: 335)；ALFKSIPP (SEQ ID NO: 348)；ALFKSSLP (SEQ ID NO: 356)；或SPFRSSRQ (SEQ ID NO: 297)。

【0112】 本文所揭示之分離部分可在生理條件下與其連接之胺基酸序列(例如，域)形成穩定前藥，同時能夠由蛋白酶裂解。例如，連接子在循環中為穩定的(例如，不裂解或以低效率裂解)且在靶向位點(亦即腫瘤

微環境)以較高效率裂解。因此，與呈獨立分子實體形式之融合多肽的組分相比，包括本文所揭示之連接子的融合多肽必要時在循環中可具有延長的循環半衰期及/或較低的生物活性。然而，當在所要位置(例如，腫瘤微環境)中時，連接子可有效地裂解以釋放由連接子接合在一起之組分且恢復或幾乎恢復呈獨立分子實體形式之組分的半衰期及生物活性。

【0113】 連接子宜在循環中保持穩定至少2小時、至少5小時、至少10小時、至少15小時、至少20小時、至少24小時、至少30小時、至少35小時、至少40小時、至少45小時、至少50小時、至少60小時、至少65小時、至少70小時、至少80小時、至少90小時或更久。

【0114】 在一些實施例中，連接子在循環中之裂解比在靶向位置少90%、80%、70%、60%、50%、40%、30%、20%、20%、5%或1%。在不存在能夠裂解連接子之酶的情況下，連接子亦為穩定的。然而，當暴露於適合之酶(亦即蛋白酶)時，連接子裂解以引起所連接之域分離。

額外抗癌劑

【0115】 本發明係關於本文所揭示之誘導型細胞激素前藥(例如，包含IL-2多肽及IL-12多肽或IFN多肽之誘導型細胞激素)中之任一者與一或多種額外試劑組合以治療癌症(諸如淋巴瘤)的治療組合，諸如化學治療劑(例如，環磷醯胺、甲基二(氯乙基)胺、美法侖、氯芥苯丁酸、異環磷醯胺、硫酸布他卡因、N-亞硝基-N-甲基脲(MNU)、卡莫司汀(BCNU)、洛莫司汀(CCNU)、司莫司汀(MeCCNU)、福莫司汀、鏈佐黴素、達卡巴嗪、米托唑胺、替莫唑胺、噻替派、絲裂黴素、地吖醌(AZQ)、順鉑、卡鉑、奧沙利鉑、丙卡巴肼、六甲蜜胺、甲胺喋呤、培美曲塞、氟尿嘧啶(例如，5-氟尿嘧啶)、卡培他濱、阿糖胞苷、吉西他濱、地西他濱、阿紮

胞苷、氟達拉濱、奈拉濱、克拉屈濱、氯法拉濱、噴司他丁、硫鳥嘌呤、巯嘌呤、長春新鹼、長春花鹼、長春瑞賓、長春地辛、長春氟甯、紫杉醇、多西他賽、依託泊苷、替尼泊苷、小紅莓、道諾比星、表柔比星、伊達比星、吡柔比星、阿柔比星、米托蒽醌、放射菌素、博萊黴素、比生群、吉西他濱、阿糖胞苷及其類似物)；免疫腫瘤學試劑及免疫檢查點抑制劑(例如，抗PD-L1、抗CTLA4、抗PD-1、抗CD47、抗GD2)；溶瘤病毒及其類似物。

【0116】本文所揭示之誘導型細胞激素(例如，IL-2、IL-12及IFN)前藥可與任何所要額外抗癌劑組合。本文所揭示之誘導型細胞激素(例如，IL-2、IL-12及IFN)前藥可與任何所要抗PD-1抗體或任何所要抗PD-L1抗體組合。

【0117】可與誘導型細胞激素前藥組合之例示性抗PD-1抗體包括但不限於AMP-224 (AstraZenica)、609A (3SBio)、704 (3SBio)、705 (3SBio)、ABBV-181 (AbbVie)、ADU-1503 / bion-004 (Chinook Therapeutics)、AGEN2034 /巴提利單抗(Agenus)、AK103 (Akeso)、AK104 (Akeso)、AK112 (Akeso)、AK123 (Akeso)、AMG 256 (Amgen)、AMG 404 (Amgen)、ANB030 (AnaptysBio)、ANKEBIO抗PD1產品(Anhui Anke Biotechnology)、抗PD-1 /抗CD47 (DiNonA)、ASKG915 (Ask Gene Pharmaceuticals)、AV-MEL-1 (Aivita Biomedical)、BCD-100 (Biocad CJSC)、BI 754091 (Boehringer Ingelheim)、BiCKI-IL-7 (OSE Immunotherapeutics)、Boehringer-PD-1-未知(Boehringer Ingelheim)、BSK-050K01 (Biosion)、坎立珠單抗(Jiangsu Hengrui Medicine)、CB201 (Crescendo Biologics)、CB213

(Crescendo Biologics)、CC-90006 (AnaptsBio)、賽曲利單抗(J&J)、chPD1 (Kiromic Biopharma)、CMAB819 (Mabpharm)、CS1003 (CStone Pharmaceuticals)、CS17938 (Shenzhen Chipscreen Biosciences)、CTX-8371 (Compass Therapeutics)、CX-072 (CytomX Therapeutics)、CX-188 (CytomX Therapeutics)、帕利珠單抗(Harbin Gloria Pharmaceuticals)、DB004 (DotBio)、EMB02 (EpimAb Biotherapeutics)、蓋普坦單抗/傑諾珠單抗(Apollomics)、GS19 (Suzhou Zelgen Biopharmaceuticals)、HLX10 (Shanghai Henlius Biotech)、HX008 (Taizhou HanZhong Pharmaceuticals)、HY003 (Juventas Cell Therapy)、IBI315 / BH2950 (Innovent Biologics)、IBI318 (Innovent Biologics)、IBI319 (Innovent Biologics)、IMM1802 (ImmuneOnco Biopharma)、IMT200 (TrueBinding)、Jemperli /多斯利單抗(AnaptysBio)、JTX-4014 (Jounce Therapeutics)、Keytruda /帕博利珠單抗(Merck)、LBL-006 (Nanjing Leads Biolabs)、Libtayo / 測米匹單抗-rwlc (Regeneron Pharmaceuticals)、LVGN3616 (Lyvgen Biopharma)、LXF821 (Novartis)、LY01015 (Luye Pharma Group)、LY3462817 (Eli Lilly)、MCLA-134 (Merus N.V.)、MEDI5752 (AstraZenica)、NIR178 (Novartis)、ONCR-177 (Oncorus)、ONO-4685 (Ono Pharmaceutical)、Opdivo /納武利尤單抗(Ono Pharmaceutical)、MGD019 (MacroGenius)、PD1-GDT CAR-T (Kiromic Biopharma)、派安普利單抗(Akeso)、PSB205 (Qilu Puget Sound Biotherapeutics)、PT-001 (Merck)、PT627 (Merck)、RB-M1 (Refuge Biotechnologies)、瑞弗利單抗 (MacroGenics)、RG6139 (Roche)、RG6279 (Roche)、RTX-002 (RubrYc

Therapeutics)、薩桑利單抗(Pfizer)、Servier-PD1xLAG3-未知(Servier)、SL-279252 / TAK-252 (Shattuck Labs)、Sofusa抗-PD1 (Sorrento Therapeutics)、斯帕塔利單抗(Novartis)、SSI-361 (Lyvgen Biopharma)、Sym021 (Servier)、特泊利單抗(MacroGenics)、緹勒珠單抗(BeiGene)、TSR-075 (AnaptsBio)、Tuhura-DO/PD-1-未知(Tuhura Biopharma)、特瑞普利單抗(Shanghai Junshi Biosciences)、斯迪利單抗(Innovent Biologics)、Unicar-CAR-T&PD-1-未知(Shanghai Unicar-Therapy Bio-Medicine Technology)、Xdivane (Xbrane Biopharma)、XmAb20717 (Xencor)、XmAb23104 (Xencor)、YBL-006 (Y-Biologics)及賽帕利單抗(Arcus Biosciences)。

【0118】可與誘導型細胞激素前藥組合的抗PD-1抗體通常為核准抗PD-1抗體。核准抗PD-1抗體包括但不限於帕博利珠單抗(KEYTRUDA)、多斯利單抗(JEMPERLI)、測米匹單抗-rwlc (LIBATYO)、納武利尤單抗(OPDIVO)、坎立珠單抗、緹勒珠單抗、特瑞普利單抗及斯迪利單抗(TYVYT)。

【0119】可與誘導型細胞激素前藥組合的例示性抗PD-L1抗體包括但不限於A167 (Sichuan Kelun)、ABL501 (ABL Bio)、ABL503 (ABL Bio)、ABSK041 (Abbisko Therapeutics)、ACE1708 (Acepodia)、ACE-NK-PDL1 (Acepodia)、ADG104 (Adagene)、AK106 (Akeso)、ALPN-202 (Alpine Immune Sciences)、AN4005 (Adlai Nortye Biopharma)、BMS-936559 / MDX-1105 (BMS)、APL-502 / TQB2450 (Apollomics)、Arbutus-PD-L1-未知(Arbutus Biopharma)、ASC22 (Ascletis Pharma)、ATG-101 (Antengene)、AVA-004 (Avacta Group)、AVA021 (Avacta

Group)、AVA027 (Avacta Group)、AVA-040-100 (Avacta Group)、AVA04-Vbp (Avacta Group)、Bavencio /阿維魯單抗(Merck)、BCD-135 (Biocad CJSC)、BGB-A333 (BeiGene)、Bintrafusp alfa / GSK4045154 (Merck)、CA-170 / aupm-170 (Dr. Reddy's Laboratories)、CCX559 (ChemoCentryx)、CDR101 (CDR-Life)、柯希利單抗(Checkpoint Therapeutics)、CTX-8371 (Compass Therapeutics)、DiNonA-實體腫瘤-未知(DiNonA)、DR30207 (Zhejiang Doer Biologics)、DuoBody-PD-L1x4-1BB (Ligand Pharmaceuticals)、恩沃利單抗(Alphamab Oncology)、EPIM-001 (Elpis Biopharmaceuticals)、ES101 (Elpiscience Biopharma)、INBRX-105 (Inhibrx)、FAZ053 (Novartis)、FS118 (F-star Therapeutics)、GB262 (Genor Biopharma)、GS-4224 (Gilead)、GT900008 (Kintor Pharmaceuticals)、GX-P2 (Genexine)、Hamni-PS-L1/CD47-未知(Hanmi Pharmaceutical)、HBM7015 (HBM Holdings)、HBM9167 (HBM Holdings)、HLX20 (Shanghai Henlius Biotech)、HTI-1088 (Jiangsu Hengrui Medicine)、IBI318 (Innovent Biologics)、IBI322 (Innovent Biologics)、IBI323 (Innovent Biologics)、IGM-7354 (IGM Biosciences)、IMC-001 (Sorrento Therapeutics)、Imfinzi /德瓦魯單抗(AstraZenica)、IMM25 (ImmuneOnco Biopharma)、IMM2502 (ImmuneOnco Biopharma)、IMM2503 (ImmuneOnco Biopharma)、IMM2504 (ImmuneOnco Biopharma)、INCB86550 (Incyte)、IO103 (IO Biotech)、JS003 (Shanghai Junshi Biosciences)、Jubilant-PD-L1-未知(Jubilant Therapeutics)、KD033 (Kadmon Holdings)、KN046 (Alphamab Oncology)、KY1003 (Sanofi)、KY1043 (Sanofi)、LY3300054 (Eli

Lilly)、LY3415244 (Eli Lilly)、MRNA-6981 (Moderna)、MSB2311 (Transcenta Holding)、MT-6035 (Molecular Templates)、ND021 / NM21-1480 (Numab Therapeutics)、OX001R (Oxford BioTherapeutics)、基於PD-L1之BsAb (I-Mab)、PD-L1 Boltbody ISAC (Bolt Biotherapeutics)、PDL-GEX (Glycotope GmbH)、PMC-122 (PharmAbcine)、PMI06 (D&D Pharmatech)、Protheragen-RV-scFv-PDL1-未知(Protheragen)、PRS-344 (Pieris Pharmaceuticals)、Q-1802 (Merck)、RC98 (Yantai Rongchang Pharmaceutical)、RV-scFv-PDL1 (Protheragen)、SenI_TAAx22P (Hebei Senlang Biotechnology)、SHC020 (Nanjing Sanhome Pharmaceutical)、舒格利單抗(Ligand Pharmaceuticals)、阿特珠單抗(Roche)、TST005 (Transcenta Holding)、TT-01 (Topmunnity Therapeutics)、TTX-siPDL1 (TransCode Therapeutics)、UniCAR-T-PD-L1 (GEMoaB monoclonals)、Vaximm (VXM10)及YBL-013 (Y-Biologics)。

【0120】可與誘導型細胞激素前藥組合的抗PD-L1抗體通常為核准抗PD-L1抗體。核准抗PD-1抗體包括但不限於阿維魯單抗(BAVENCIO)、德瓦魯單抗(IMFINZI)及阿特珠單抗(TECENTRIQ)。

E. 療法及醫藥組合物

【0121】本發明係關於使用誘導型細胞激素前藥(例如，IL-2、IL-12或IFN)治療癌症(淋巴瘤)的方法，且係關於適用於此類方法之醫藥組合物，包括含有誘導型細胞激素前藥(例如，IL-2、IL-12或IFN)以及如本文所描述之賦形劑的醫藥組合物。

【0122】本發明進一步係關於一種治療癌症(淋巴瘤)的方法，其係

使用包含誘導型細胞激素前藥(例如，IL-2、IL-12或IFN)與一或多種如本文所揭示治療癌症(諸如淋巴瘤)之額外試劑組合的組合療法，且係關於用於此類方法之醫藥組合物，包括含有誘導型細胞激素前藥(例如，IL-2、IL-12或IFN)與一或多種如本文所說明治療癌症(諸如淋巴瘤)之額外試劑組合的醫藥組合物。

【0123】 本發明進一步關於使用包含與如本文所揭示之抗PD-1抗體或抗PD-L1抗體組合之誘導型細胞激素前藥(例如，IL-2、IL-12或IFN)的組合療法治療癌症的方法，且關於用於此類方法之醫藥組合物，包括含有與抗PD-1抗體或抗PD-L1抗體組合之誘導型細胞激素前藥(例如，IL-2、IL-12或IFN)的醫藥組合物。

【0124】 本發明係關於治療癌症之方法，其包含向有需要之個體投與有效量的組合療法，該組合療法包括誘導型細胞激素前藥及抗PD-1抗體或抗PD-L1抗體。向個體投與誘導型細胞激素前藥及抗PD-1抗體或抗PD-L1抗體，使得兩種治療劑之藥理學活性重疊。因此，誘導型細胞激素前藥可在抗PD-1抗體或抗PD-L1抗體之前、之後、與其同時或在其周邊(periprocedurally)投與。在方法之一些實踐中，抗PD-1抗體或抗PD-L1抗體係在誘導型細胞激素前藥之前投與。在方法之一些實踐中，投與抗PD-1抗體或抗PD-L1抗體，隨後在投與完成之後，投與誘導型細胞激素前藥。

【0125】 誘導型細胞激素前藥及抗PD-1/抗PD-L1抗體通常例如藉由靜脈內注射或較佳靜脈內輸注全身性投與。可使用其他類型之投與，諸如經口、非經腸、靜脈內、經靜脈內、關節內、腹膜內、肌肉內、皮下、腔內、經皮、肝內、顱內、噴霧/吸入、藉由經由支氣管鏡(bronchoscopy)

安裝或瘤內。

【0126】本文所揭示之方法及組合物可用於治療任何適合之癌症，尤其實體腫瘤，諸如肉瘤及癌瘤。例如，本文所揭示之方法及組合物可用於治療急性淋巴母細胞白血病(ALL)、急性骨髓白血病(AML)、腎上腺皮質癌、肛門癌、闌尾癌、星形細胞瘤、基底細胞癌、腦瘤、膽管癌、膀胱癌、骨癌、乳癌、支氣管腫瘤、原發性不明癌、心臟腫瘤、子宮頸癌、脊索瘤、大腸癌、大腸直腸癌、顱咽管瘤、乳管癌、胚胎細胞瘤、子宮內膜瘤、室管膜瘤、食道癌、敏感性神經胚細胞瘤、纖維組織細胞瘤、尤文氏肉瘤、眼癌、生殖細胞腫瘤、膽囊癌、胃癌、胃腸類癌腫瘤、胃腸基質腫瘤、妊娠期滋養細胞疾病、神經膠質瘤、頭頸癌、肝細胞癌、組織細胞增生症、何傑金氏淋巴瘤、下咽癌、眼內黑色素瘤、胰島細胞腫瘤、卡波西氏肉瘤、腎癌、蘭格罕細胞組織球增多症、喉癌、唇及口腔癌、肝癌、小葉原位癌、肺癌、巨球蛋白血症、惡性纖維組織細胞瘤、黑色素瘤、梅克爾細胞癌、間皮瘤、具有隱性原發性之轉移性鱗狀頸癌、涉及NUT基因之中線癌、口癌、多發性內分泌瘤症候群、多發性骨髓瘤、蕈樣黴菌病、骨髓發育不良症候群、骨髓發育不良/骨髓增生性腫瘤、鼻腔及副鼻竇癌、鼻咽癌、神經母細胞瘤、非小細胞肺癌、口咽癌、骨肉瘤、卵巢癌、胰臟癌、乳頭狀瘤症、副神經節瘤、副甲狀腺癌、陰莖癌、咽癌、嗜鉻細胞瘤、垂體腫瘤、胸膜肺母細胞瘤、原發性中樞神經系統淋巴瘤、前列腺癌、直腸癌、腎細胞癌、腎盂及尿管癌、視網膜母細胞瘤、橫紋肌瘤、唾液腺癌、塞紮萊症候群、皮膚癌、小細胞肺癌、小腸癌、軟組織肉瘤、脊髓腫瘤、胃癌、T細胞淋巴瘤、類畸胎瘤、睪丸癌、咽喉癌、胸腺瘤及胸腺癌、甲狀腺癌、尿道癌、子宮癌、陰道癌、外陰癌及威爾姆氏瘤。

【0127】在某些實施例中，本文所揭示之方法及組合物可用於治療腎上腺皮質癌、肛門癌、闌尾癌、星形細胞瘤、基底細胞癌、腦瘤、膽管癌、膀胱癌、骨癌、乳癌、支氣管腫瘤、原發性不明癌、心臟腫瘤、子宮頸癌、脊索瘤、大腸癌、大腸直腸癌、顱咽管瘤、乳管癌、胚胎細胞瘤、子宮內膜瘤、室管膜瘤、食道癌、敏感性神經胚細胞瘤、纖維組織細胞瘤、尤文氏肉瘤、眼癌、生殖細胞腫瘤、膽囊癌、胃癌、胃腸類癌腫瘤、胃腸基質腫瘤、妊娠期滋養細胞疾病、神經膠質瘤、頭頸癌、肝細胞癌、組織細胞增生症、何傑金氏淋巴瘤、下咽癌、眼內黑色素瘤、胰島細胞腫瘤、卡波西氏肉瘤、腎癌、蘭格罕細胞組織球增多症、喉癌、唇及口腔癌、肝癌、小葉原位癌、肺癌、巨球蛋白血症、惡性纖維組織細胞瘤、黑色素瘤、梅克爾細胞癌、間皮瘤、具有隱性原發性之轉移性鱗狀頸癌、涉及NUT基因之中線癌、口癌、多發性內分泌瘤症候群、蕈樣黴菌病、鼻腔及副鼻竇癌、鼻咽癌、神經母細胞瘤、非小細胞肺癌、口咽癌、骨肉瘤、卵巢癌、胰臟癌、乳頭狀瘤症、副神經節瘤、副甲狀腺癌、陰莖癌、咽癌、嗜鉻細胞瘤、垂體腫瘤、胸膜肺母細胞瘤、原發性中樞神經系統淋巴瘤、前列腺癌、直腸癌、腎細胞癌、腎盂及尿管癌、視網膜母細胞瘤、橫紋肌瘤、唾液腺癌、塞紮萊症候群、皮膚癌、小細胞肺癌、小腸癌、軟組織肉瘤、脊髓腫瘤、胃癌、T細胞淋巴瘤、類畸胎瘤、睪丸癌、咽喉癌、胸腺瘤及胸腺癌、甲狀腺癌、尿道癌、子宮癌、陰道癌、外陰癌、非何傑金氏淋巴瘤、頭頸部鱗狀癌瘤、惡性胸膜間皮瘤及威爾姆氏瘤。

【0128】在某些較佳實施例中，本文所揭示之方法及組合物用於治療黑色素瘤、非小細胞肺癌(NSCLC)、小細胞肺癌(SCLC)、頭頸部鱗狀細胞癌(HNSCC)、典型何傑金氏淋巴瘤(cHL)、原發性縱隔大B細胞淋巴

瘤(PMBCL)、尿道上皮癌、高度微衛星不穩定性或錯配修復缺陷型癌症、高度微衛星不穩定性或錯配修復缺陷型大腸直腸癌、胃癌、食道癌、子宮頸癌、肝細胞癌(HCC)、梅克爾細胞癌(MCC)、腎細胞癌(RCC)、子宮內膜癌、高度腫瘤突變負荷癌症、皮膚鱗狀細胞癌(cSCC)、三陰性乳癌(TNBC)、尿道上皮癌、大腸直腸癌或食道癌瘤。

【0129】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療梅克爾細胞癌(MCC)、尿道上皮癌(UC)、腎細胞癌(RCC)、非小細胞肺癌(NSCLC)、小細胞肺癌(SCLC)、三陰性乳癌(TNBC)、子宮內膜癌、皮膚鱗狀細胞癌(CSCC)、基底細胞癌(BCC)、黑色素瘤、惡性胸膜間皮瘤、典型何傑金氏淋巴瘤(cHL)、頭頸部鱗狀細胞癌(SCCHN)、肝細胞癌(HCC)、食道鱗狀細胞癌(ESCC)、非鱗狀非小細胞肺癌或鼻咽癌(NPC)。

【0130】 較佳地，本文所揭示之方法及組合物用於治療大腸癌、肺癌、黑色素瘤、腎細胞癌或乳癌。

【0131】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療黑色素瘤。作為實例，本文所揭示之方法及組合物可用於治療患有不可切除性或轉移性黑色素瘤之個體中的黑色素瘤。作為另一實例，本文所揭示之方法及組合物可用於患有在完全切除之後具有淋巴結受累(involvement of lymph node)之黑色素瘤之個體的輔助治療。

【0132】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療非小細胞肺癌(NSCLC)。作為實例，本文所揭示之方法及組合物可用於治療患有表現PD-L1之NSCLC (例如，腫瘤比例評分(Tumor Proportion Score，TPS) ≥1%)之個體中的NSCLC，以由FDA批准之測試測定，其中無EGFR或ALK基因體腫瘤畸變，且為：III期，其中個體不為手術切除或

確定性化學放射之候選者，或轉移性。作為另一實例，本文所揭示之方法及組合物可用於治療患有轉移性NSCLC之患者中的NSCLC，以由FDA批准之測試測定，患者之腫瘤表現PD-L1 (TPS ≥1%)，其中疾病在進行含鉑化學療法時或在其之後進展。作為另一實例，本文所揭示之方法及組合物可與培美曲塞及鉑化學療法組合用作患有轉移性非鱗狀NSCLC、無EGFR或ALK基因體腫瘤畸變之患者的一線(first-line)治療。作為另一實例，本文所揭示之方法及組合物可與卡鉑及紫杉醇或蛋白-結合紫杉醇(paclitaxel protein-bound)組合用作為患有轉移性鱗狀NSCLC之患者的第一線治療。

【0133】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療SCLC。作為實例，本文所揭示之方法及組合物可用於治療患有轉移性SCLC之個體中的SCLC，其中疾病在進行基於鉑之化學療法時或在其之後進展且具有至少一種其他先前治療線。

【0134】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療HNSCC。作為實例，本文所揭示之方法及組合物可用於治療患有轉移性或患有不可切除性、復發性HNSCC之個體中的HNSCC，其腫瘤表現PD-L1 (例如，綜合陽性評分(Combined Positive Score，CPS) ≥1)，以由FDA批准之測試測定。作為另一實例，本文所揭示之方法及組合物可用於治療患有復發性或轉移性HNSCC之個體中的HNSCC，其中疾病在進行含鉑化學療法時或在其之後進展。作為另一實例，本文所揭示之方法及組合物可與鉑及氟尿嘧啶組合用於患有轉移性或患有不可切除性、復發性HNSCC之患者的第一線治療。

【0135】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療cHL。作為實例，本文所揭示之方法及組合物可用於治療患有復發性或

難治性cHL之個體中的cHL。作為另一實例，本文所揭示之方法及組合物可用於治療患有難治性cHL或在2種或更多種治療線之後復發之cHL的兒童個體中的cHL。

【0136】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療PMBCL。作為實例，本文所揭示之方法及組合物可用於治療患有難治性PMBCL的個體或在2種或更多種先前治療線之後復發的個體中的PMBCL。

【0137】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療尿道上皮癌。作為實例，本文所揭示之方法及組合物可用於治療個體中之尿道上皮癌，其中該等個體患有局部晚期或轉移性尿道上皮癌，不符合含順鉑化學療法之條件且其腫瘤表現以由FDA批准之測試測定的PD-L1(例如，綜合陽性評分(CPS) ≥10)，或不管PD-L1狀態如何，該等個體不符合任何含鉑化學療法之條件。作為另一實例，本文所揭示之方法及組合物可用於治療患有局部晚期或轉移性尿道上皮癌之個體中的尿道上皮癌，該等個體在含鉑化學療法期間或之後或在用含鉑化學療法進行新輔助(neoadjuvant)或輔助治療之12個月內具有疾病進展。作為另一實例，本文所揭示之方法及組合物可用於治療個體中之尿道上皮癌，該等個體患有卡介苗(Bacillus Calmette-Guerin，BCG)-無反應、高風險、非肌肉侵襲性膀胱癌(non-muscle invasive bladder cancer，NMIBC)伴以具有或不具有乳頭狀腫瘤之原位癌(CIS)而不符合進行膀胱切除術之資格或選擇不進行膀胱切除術。

【0138】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療微衛星不穩定性-較高(MSI-H)或錯配修復缺陷型(dMMR)癌症。作為實

例，本文所揭示之方法及組合物可用於治療患有不可切除性或轉移性MSI-H或dMMR癌症之個體中的MSI-H或dMMR癌症，其中實體腫瘤在先前治療之後進展且個體不具有令人滿意的替代治療選項，或其中大腸直腸癌在用氟嘧啶、奧沙利鉑及伊立替康(irinotecan)治療之後進展。

【0139】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療微衛星穩定性-較高(MSI-H)或錯配修復缺陷型(dMMR)大腸直腸癌。作為實例，本文所揭示之方法及組合物可用於治療患有不可切除性或轉移性MSI-H或dMMR大腸直腸癌之個體中的MSI-H或dMMR大腸直腸癌。

【0140】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療胃癌。作為實例，本文所揭示之方法及組合物可用於治療個體中之胃癌，該等個體患有復發性局部晚期或轉移性胃或胃食道接合處腺癌(junction adenocarcinoma)，其腫瘤表現以由FDA批准之測試測定的PD-L1 (例如，綜合陽性評分(CPS) ≥1)，其中疾病在進行2種或更多種先前治療線時或在其後進展，該等治療線包括含氟嘧啶及含鉑化學療法且若適當包括HER2/neu-靶向療法。

【0141】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療食道癌。作為實例，本文所揭示之方法及組合物可用於治療患有局部晚期或轉移性食道或胃食道接合處(gastroesophageal junction，GEJ) (例如，腫瘤具有高於GEJ 1至5公分之中心(epicenter))癌之個體中的食道癌，其不適合於手術切除或確定性化學放射以及基於鉑及基於氟嘧啶之化學療法。作為另一實例，在一或多種用於患有表現以由FDA批准之測試測定之PD-L1 (CPS ≥10)之鱗狀細胞組織學腫瘤的患者的先前全身性治療線之後，本文所揭示之方法及組合物可用於治療患有局部晚期或轉移性食道

或胃食道接合處(GEJ) (例如，腫瘤具有高於GEJ 1至5公分之中心)癌之個體中的食道癌，其不適合於手術切除或確定性化學放射。

【0142】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療子宮頸癌。作為實例，本文所揭示之方法及組合物可用於治療患有復發性或轉移性子宮頸癌之個體中的子宮頸癌，其中疾病在進行化學療法時或在其之後進展，個體之腫瘤表現以由FDA批准之測試測定的PD-L1 (例如，綜合陽性評分(CPS) ≥1)。

【0143】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療HCC。作為實例，本文所揭示之方法及組合物可用於治療已預先用索拉非尼(sorafenib)治療之個體中的HCC。

【0144】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療MCC。作為實例，本文所揭示之方法及組合物可用於治療患有復發性局部晚期或轉移性MCC之個體中的MCC。

【0145】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療RCC。作為實例，本文所揭示之方法及組合物可與阿昔替尼(axitinib)組合用於患有晚期RCC之患者的第一線治療。

【0146】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療子宮內膜癌。作為實例，本文所揭示之方法及組合物可與樂伐替尼(lenvatinib)組合用於治療患有晚期子宮內膜癌，即非MSI-H或dMMR之個體，該等個體在先前全身性療法後具有疾病進展且不為進行治癒性手術或放射之候選者。

【0147】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療腫瘤突變負荷-較高(TMB-H)癌症。作為實例，本文所揭示之方法及組

合物可用於治療患有不可切除性或轉移性腫瘤突變負荷-較高(例如，≥10個突變/兆鹼基(megabase) (mut/Mb))實體腫瘤之個體中的TMB-H癌症，以由FDA批准之測試所測定，該等個體在先前治療之後已有進展且不具有令人滿意的替代治療選項。

【0148】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療皮膚鱗狀細胞癌(cSCC)。作為實例，本文所揭示之方法及組合物可用於治療患有不可由手術或放射治癒之復發性或轉移性皮膚鱗狀細胞癌之個體中的cSCC。

【0149】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療三陰性乳癌(TNBC)。作為實例，本文所揭示之方法及組合物可與化學療法組合用於治療患有局部復發性不可切除性或轉移性TNBC之個體，該等個體之腫瘤表現以由FDA批准之測試測定的PD-L1 (例如，綜合陽性評分(CPS) ≥10)。

【0150】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療梅克爾細胞癌(MCC)。作為實例，包含阿維魯單抗之組合可用於治療患有轉移性MCC之個體中的MCC。

【0151】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療尿道上皮癌(UC)。作為實例，包含阿維魯單抗之組合可用於治療患有局部晚期或轉移性UC之個體中的UC，該等個體在進行含鉑化學療法期間或在其之後具有疾病進展。作為另一實例，包含阿維魯單抗之組合可用於治療患有局部晚期或轉移性UC之個體中的UC，該等個體在用含鉑化學療法進行新輔助或輔助治療之12個月內具有疾病進展。

【0152】 在某些較佳實施例中，本文所揭示之方法及組合物可用於

治療腎細胞癌(RCC)。作為實例，包含阿維魯單抗及阿昔替尼之組合可用於患有晚期RCC之個體中。

【0153】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療尿道上皮癌(UC)。作為實例，包含德瓦魯單抗之組合可用於治療患有局部晚期或轉移性尿道上皮癌之個體中的UC，該等個體在進行含鉑化學療法期間或在其之後具有疾病進展。作為另一實例，包含德瓦魯單抗之組合可用於治療患有局部晚期或轉移性尿道上皮癌之個體中的UC，該等個體在用含鉑化學療法進行新輔助或輔助治療之12個月內具有疾病進展。

【0154】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療非小細胞肺癌(NSCLC)。作為實例，包含德瓦魯單抗之組合可用於治療患有不可切除性、III期非小細胞肺癌(NSCLC)之個體中的NSCLC，該等個體之疾病在同時發生的基於鉑之化學療法及放射療法之後尚未有進展。

【0155】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療小細胞肺癌(SCLC)。作為實例，包含德瓦魯單抗之組合可與依託泊苷及卡鉑或順鉑組合使用，作為患有廣泛期小細胞肺癌(extensive-stage small cell lung cancer，ES-SCLC)之成年個體的第一線治療。

【0156】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療尿道上皮癌(UC)。作為實例，包含阿特珠單抗之組合可用於治療患有局部晚期或轉移性尿道上皮癌之成年個體中的UC，該等個體不符合含順鉑化學療法之條件且其腫瘤表現以由FDA批准之測試測定的PD-L1（例如，PD-L1染色腫瘤-浸潤性免疫細胞[IC]覆蓋≥ 5%腫瘤區域)，或不管PD-L1狀態如何，該等個體不符合任何含鉑化學療法之條件，或在任何含

鉑化學療法期間或在其之後或在進行新輔助或輔助化學療法之12個月內具有疾病進展。

【0157】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療NSCLC。作為實例，包含阿特珠單抗之組合可用於治療患有轉移性NSCLC之成年個體中的NSCLC，以由FDA批准之測試測定，該等個體之腫瘤具有高PD-L1表現(例如，PD-L1染色≥ 50%腫瘤細胞[TC ≥ 50%]或PD-L1染色腫瘤-浸潤性免疫細胞[IC]覆蓋≥ 10%腫瘤區域[IC ≥ 10%])，無EGFR或ALK基因體腫瘤畸變。作為另一實例，包含阿特珠單抗之組合可與貝伐珠單抗(bevacizumab)、紫杉醇及卡鉑組合用於無EGFR或ALK基因體腫瘤畸變之患有轉移性非鱗狀NSCLC之成年個體的第一線治療。作為另一實例，包含阿特珠單抗之組合可與蛋白-結合紫杉醇及卡鉑組合用於無EGFR或ALK基因體腫瘤畸變之患有轉移性非鱗狀NSCLC之成年個體的第一線治療。作為另一實例，包含阿特珠單抗之組合可用於治療患有轉移性NSCLC之成年個體中的NSCLC，該等個體在進行含鉑化學療法期間或在其之後具有疾病進展。

【0158】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療三陰性乳癌(TNBC)。作為實例，以由FDA批准之測試測定，包含阿特珠單抗之組合可與蛋白-結合紫杉醇組合用於治療患有不可切除性局部晚期或轉移性TNBC之成年個體，該等個體之腫瘤表現PD-L1 (例如，任何強度之PD-L1染色腫瘤-浸潤性免疫細胞[IC]覆蓋≥ 1%腫瘤區域)。

【0159】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療小細胞肺癌(SCLC)。作為實例，包含阿特珠單抗之組合可與卡鉑及依託泊苷組合用於患有廣泛期小細胞肺癌(ES-SCLC)之成年個體的第一線

治療。

【0160】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療子宮內膜癌。作為實例，以由FDA批准之測試測定，包含多斯利單抗之組合可用於治療具有錯配修復缺陷型(dMMR)復發性或晚期子宮內膜癌之成年個體中的子宮內膜癌，其已在用含鉑方案進行先前治療時或在其之後進展。

【0161】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療皮膚鱗狀細胞癌(CSCC)。作為實例，包含測米匹單抗-rwlc之組合可用於治療患有轉移性皮膚鱗狀細胞癌(mCSCC)或局部晚期CSCC (laCSCC)之個體中的CSCC，該等個體並非為進行治癒性手術或治癒性放射之候選者。

【0162】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療基底細胞癌(BCC)。作為實例，包含測米匹單抗-rwlc之組合可用於治療患有先前用刺蝟路徑抑制劑(hedgehog pathway inhibitor)治療之局部晚期BCC (laBCC)或不適合於刺蝟路徑抑制劑之個體中的BCC。

【0163】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療NSCLC。作為實例，包含測米匹單抗-rwlc之組合可用於治療個體中之NSCLC，以由FDA批准之測試測定，該等個體之腫瘤具有高PD-L1表現(例如，腫瘤比例評分(TPS) ≥ 50%)，無EGFR、ALK或ROS1畸變，且為局部晚期，其中個體不為手術切除或確定性化學放射之候選者，或為轉移性。

【0164】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療黑色素瘤。作為實例，包含納武利尤單抗之組合可作為單一試劑或與

伊匹單抗組合用於治療患有不可切除性或轉移性黑色素瘤之個體中的黑色素瘤。作為另一實例，包含納武利尤單抗之組合可用於在輔助環境中治療已經歷完全切除之患有具有淋巴結受累(lymph node involvement)或轉移性疾病之黑色素瘤的個體中的黑色素瘤。

【0165】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療NSCLC。作為實例，以由FDA批准之測試測定，包含納武利尤單抗之組合可用於治療患有表現PD-L1 (≥1%)之轉移性非小細胞肺癌之成年個體中的NSCLC，其中無EGFR或ALK基因體腫瘤畸變，作為與伊匹單抗組合之第一線治療。作為另一實例，包含NSCLC之組合可用於治療患有轉移性或復發性非小細胞肺癌且無EGFR或ALK基因體腫瘤畸變之成年個體中的黑色素瘤，作為與伊匹單抗及2個週期之鉑-二重峰(doublet)化學療法組合的第一線治療。作為另一實例，包含NSCLC之組合可用於治療患有轉移性非小細胞肺癌之個體中的黑色素瘤且在進行基於鉑之化學療法時或在其之後的進展。

【0166】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療惡性胸膜間皮瘤。作為實例，包含納武利尤單抗之組合可作為與伊匹單抗組合之第一線治療用於治療患有不可切除性惡性胸膜間皮瘤之成年個體中的惡性胸膜間皮瘤。

【0167】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療RCC。作為實例，包含納武利尤單抗之組合可作為與伊匹單抗組合之第一線治療用於治療患有中度或不良風險晚期腎細胞癌之個體中的RCC。作為另一實例，包含納武利尤單抗之組合可作為與卡博替尼(cabozantinib)組合之第一線治療用於治療患有晚期腎細胞癌之個體中的

RCC。作為另一實例，包含納武利尤單抗之組合可用於治療已接受先前抗血管生成療法之患有晚期腎細胞癌之個體中的RCC。

【0168】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療典型何傑金氏淋巴瘤(cHL)。作為實例，包含納武利尤單抗之組合可用於治療患有cHL之成年個體中的cHL，該cHL在自體造血幹細胞移植(HSCT)及本妥昔單抗維多汀(brentuximab vedotin)或在3種或更多種包括自體HSCT之全身性治療線之後復發或進展。

【0169】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療頭頸部鱗狀細胞癌(SCCHN)。作為實例，包含納武利尤單抗之組合可用於治療患有復發性或轉移性頭頸部鱗狀細胞癌、在進行基於鉑之療法時或在其之後具有疾病進展之個體中的SCCHN。

【0170】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療尿道上皮癌(UC)。作為實例，包含納武利尤單抗之組合可用於治療患有局部晚期或轉移性尿道上皮癌之個體中的UC，該等個體在進行含鉑化學療法期間或在其之後具有疾病進展或在用含鉑化學療法進行新輔助或輔助治療之12個月內具有疾病進展。

【0171】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療大腸直腸癌。作為實例，包含納武利尤單抗之組合可用於治療患有微衛星不穩定性-較高(MSI-H)或錯配修復缺陷型(dMMR)轉移性大腸直腸癌之個體中的大腸直腸癌，其在用氟嘧啶、奧沙利鉑及伊立替康作為單一試劑或與伊匹單抗組合治療後已具有進展。

【0172】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療肝細胞癌(HCC)。作為實例，包含納武利尤單抗之組合可用於治療患

有HCC之已預先用索拉非尼作為單一試劑或與伊匹單抗組合治療之個體中的HCC。

【0173】 在某些較佳實施例中，本文所揭示之方法及組合物可用於治療食道鱗狀細胞癌(ESCC)。作為實例，包含納武利尤單抗之組合可用於治療在先前基於氟嘧啶及基於鉑之化學療法之後患有不可切除性晚期、復發性或轉移性食道鱗狀細胞癌之個體中的ESCC。

【0174】 在某些較佳實施例中，包含坎立珠單抗之組合可用於治療cHL。

【0175】 在某些較佳實施例中，包含緹勒珠單抗之組合可用於治療非鱗狀非小細胞肺癌。在某些較佳實施例中，包含緹勒珠單抗之組合可用於治療肝細胞癌(HCC)。

【0176】 在某些較佳實施例中，包含特瑞普利單抗之組合可用於治療尿道上皮癌。在某些較佳實施例中，包含特瑞普利單抗之組合可用於治療黑色素瘤。在某些較佳實施例中，包含特瑞普利單抗之組合可用於治療鼻咽癌(NPC)。

【0177】 在某些較佳實施例中，包含斯迪利單抗之組合可用於治療非鱗狀非小細胞肺癌。在某些較佳實施例中，包含斯迪利單抗之組合可用於治療cHL。

【0178】 欲使用本發明之方法及組合物治療的癌症可為轉移性癌症。本文所揭示之方法及組合物可用於治療轉移性腎透明細胞癌或轉移性皮膚惡性黑色素瘤。

【0179】 在某些實施例中，癌症為淋巴瘤，諸如非何傑金氏淋巴瘤、何傑金氏淋巴瘤、彌漫性大B細胞淋巴瘤、原發性縱隔B細胞淋巴

瘤、濾泡性淋巴瘤、小淋巴球性淋巴瘤、慢性淋巴球性白血病、邊緣區淋巴瘤、被套細胞淋巴瘤、瓦爾登斯特倫氏巨球蛋白血症、伯基特淋巴瘤、周邊T細胞淋巴瘤、退行性大細胞淋巴瘤、血管免疫母細胞淋巴瘤、皮膚T細胞淋巴瘤、中樞神經系統淋巴瘤、灰區淋巴瘤、雙重打擊淋巴瘤、三重打擊淋巴瘤、未列名之高級別B細胞淋巴瘤、淋巴母細胞淋巴瘤、淋巴漿細胞淋巴瘤、MALT淋巴瘤、單核球樣B細胞淋巴瘤、自然殺手(NK)細胞淋巴瘤、蕈樣黴菌病、塞紮萊症候群、腸病型T細胞淋巴瘤、肝脾γ/δ T細胞淋巴瘤及其類似淋巴瘤。

【0180】 必要時，可向個體投與如本文所描述之額外治療劑。通常，此類額外治療劑為抗癌劑，諸如化學治療劑(例如，阿德力黴素(adriamycin)、柔紅黴素(cerubidine)、博萊黴素、阿爾克蘭(alkeran)、長春鹼(velban)、安可平(oncovin)、氟尿嘧啶、噻替派、甲胺喋呤、比生群、能滅瘤(noantrone)、硫鳥嘌呤(thiguanine)、阿糖胞苷(cytaribine)、丙卡巴肼(procarabizine))；其他免疫檢查點抑制劑(例如，抗CTLA4 (伊匹單抗(YERVOY))；其他細胞激素(諸如IL-12、誘導型IL-12前藥、誘導型IFN、誘導型IFN前藥、IL-2或IL-2前藥)；血管生成抑制劑；抗體藥物結合物(例如，曲妥珠單抗恩他新(trastuzumab emtansine) (KADCYLA)、曲妥珠單抗德魯特坎(deruxtecan) (ENHERTU)、恩諾單抗(enfortumab)維多汀(PADCEV)、戈沙妥珠單抗戈維特坎(sacituzumab govitecan) (TRODELVY)；細胞治療劑(例如，CAR-T、TCT-T、T-細胞療法，諸如腫瘤浸潤淋巴球(TIL)療法)；溶瘤病毒；放射療法及/或小分子。

【0181】 額外治療劑可為例如培美曲塞、鉑化學治療劑、卡鉑、紫杉醇、蛋白-結合紫杉醇、氟尿嘧啶、基於氟嘧啶之化學治療劑或阿昔替

尼。

【0182】 本發明亦關於含有誘導型細胞激素前藥及抗PD-1或抗PD-L1抗體之醫藥組合物，且關於此類醫藥組合物用於治療癌症之用途。

【0183】 醫藥組合物可呈多種形式，例如液體、凍乾形式，且通常含有適合的醫藥學上可接受之載劑。醫藥學上可接受之載劑(或賦形劑)為醫藥組合物之非活性成分組分且不為生物學上或其他方面不合需要的，亦即向個體投與材料不會引起不合需要之生物效應或以有害方式與其所含有之醫藥調配物或組合物的其他組分相互作用。頻繁選擇載劑以使活性成分之降解降至最低且使個體中之不良副作用降至最低。

【0184】 適合之載劑及其調配物描述於Remington: The Science and Practice of Pharmacy,第21版, David B. Troy編, Lippicott Williams & Wilkins (2005)中。醫藥學上可接受之載劑的實例包括但不限於無菌水、生理鹽水、諸如林格氏溶液(Ringer's solution)之緩衝溶液及右旋糖溶液。其他載劑包括持續釋放製劑，諸如含有免疫原性多肽之固態疏水性聚合物的半滲透基質。基質呈成形物品形式，例如膜、脂質體或微粒。某些載劑可為更佳的，此視例如投與途徑及所投與之組合物的濃度而定。載劑為適用於向人類或其他個體投與嵌合多肽或編碼嵌合多肽之核酸序列的載劑。

【0185】 用於非經腸投與之製劑包括無菌水性或非水性溶液、懸浮液及乳液。非水性溶劑之實例為丙二醇、聚乙二醇、植物油(諸如橄欖油)及可注射有機酯(諸如油酸乙酯)。水性載劑包括水、醇溶液/水溶液、乳液或懸浮液，包括生理鹽水及緩衝介質。非經腸媒劑包括氯化鈉溶液、林格氏右旋糖、右旋糖及氯化鈉、乳酸林格氏液或不揮發性油。靜脈內媒劑包括流體及營養補充劑、電解質補充劑(諸如基於林格氏右旋糖之彼等電解

質補充劑)及其類似物。視情況存在防腐劑及其他添加劑，諸如抗菌劑、抗氧化劑、螯合劑及惰性氣體及其類似物。通常，在調配物中使用適量的醫藥學上可接受之鹽以使調配物為等張的，但必要時調配物可為高張或低張的。溶液之pH一般為約5至約8或約7至7.5。

【0186】 用於局部投與之調配物包括軟膏、乳劑、乳膏、凝膠、滴劑、栓劑、噴霧劑、液體及散劑。習知的醫藥載劑、水溶液、散劑或油性基劑、增稠劑及其類似物視情況為必需或合乎需要的。

【0187】 用於經口投與之組合物包括水或非水性介質、膠囊、藥囊或錠劑中之散劑或顆粒劑、懸浮液或溶液。增稠劑、調味劑、稀釋劑、乳化劑、分散助劑或黏合劑視情況為合乎需要的。

【0188】 本發明亦關於一種套組，其包括醫藥組合物，該醫藥組合物含有：a)在適合容器(例如，小瓶、袋子或其類似物)中例如呈液體組合物或凍乾組合物形式的誘導型細胞激素前藥組合物；及b)在適合容器(例如，小瓶、袋子或其類似物)中例如呈液體組合物或凍乾組合物形式的帕博利珠單抗組合物。套組可進一步包括其他組分，諸如用於復原凍乾組合物之無菌水或生理鹽水。

F. 定義

【0189】 除非另外定義，否則本文所使用之所有技術、符號及其他科學術語意欲具有熟習本發明所屬技術者通常所瞭解之含義。在一些情況下，為了清楚起見及/或為便於參考，本文所定義之具有通常所理解之含義的術語，及本文包括之此類定義不應必然解釋為表示與此項技術中一般理解之差異。熟習此項技術者一般良好理解本文中所描述或提及之技術及程序且通常使用習知方法採用，諸如Sambrook等人, Molecular Cloning:

A Laboratory Manual第4版(2012) Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY中所描述之廣泛利用之分子選殖方法。視需要，除非另外指出，否則涉及使用市售套組及試劑之程序通常係根據製造商所定義之方案及條件進行。

【0190】「細胞激素」為一種熟知的此項技術術語，其係指由免疫系統之細胞特別分泌且作為免疫系統之調控劑的一類免疫調節蛋白(諸如介白素或干擾素)中之任一者。可用於本文所揭示之融合蛋白中的細胞激素多肽包括但不限於轉型生長因子，諸如TGF-α及TGF-β (例如，TGFβ1、TGFβ2、TGFβ3)；干擾素，諸如干擾素-α、干擾素-β、干擾素-γ、干擾素-κ及干擾素-ω；介白素，諸如IL-1、IL-1α、IL-2、IL-3、IL-4、IL-5、IL-6、IL-7、IL-8、IL-9、IL-10、IL-11、IL-12、IL-13、IL-14、IL-15、IL-16、IL-17、IL-18、IL-21及IL-25；腫瘤壞死因子，諸如腫瘤壞死因子α及淋巴毒素；趨化激素(例如，C-X-C模體趨化激素10 (CXCL10)、CCL19、CCL20、CCL21)及顆粒球-群落刺激因子(GM-CS)，以及活化細胞激素之同族受體之此類多肽的片段(亦即前述之功能性片段)。「趨化激素」為此項技術中之一術語，其係指具有在鄰近反應性細胞中誘導定向趨化性之能力的一系列小細胞激素中之任一者。

【0191】如本文所用，術語「誘導型」係指作為前藥之一部分的蛋白(亦即IL-2、IL-12或IFN)結合其受體且在腫瘤微環境中裂解前藥時實現活性的能力。本文所揭示之誘導型細胞激素前藥具有減弱的或無細胞激素促效劑活性，但在腫瘤微環境中裂解時釋放活性細胞激素。

【0192】「減弱的」活性意謂與天然細胞激素(亦即，IL-2、IL-12或IFN)之活性相比，生物活性及通常細胞激素(亦即，IL-2、IL-12或IFN)

促效劑活性降低。相較於天然細胞激素(亦即，IL-2、IL-12或IFN)，本文所揭示之誘導型細胞激素前藥具有至少約10倍、至少約50倍、至少約100倍、至少約250倍、至少約500倍、至少約1000倍或更低促效劑活性之減弱的細胞激素受體促效劑活性。在腫瘤微環境中裂解時，釋放具有活性之細胞激素。通常，所釋放之細胞激素具有比前藥之IL-2受體活化活性高至少約10倍、至少約50倍、至少約100倍、至少約250倍、至少約500倍或至少約1000倍之細胞激素受體促效劑活性。

【0193】 如本文所用，術語「肽」、「多肽」或「蛋白」廣泛地用於意謂由肽鍵連接之兩個或更多個胺基酸。蛋白、肽及多肽在本文中亦可互換地用於指代胺基酸序列。應認識到，術語多肽在本文中不用於表示包含分子之胺基酸的特定大小或數目且本發明之肽可含有至多若干個胺基酸殘基或更多。

【0194】 如全篇中所用，「個體」可為脊椎動物，更特定地哺乳動物(例如，人類、馬、貓、犬、牛、豬、綿羊、山羊、小鼠、兔、大鼠及天竺鼠(guinea pig))、鳥類、爬行動物、兩棲動物、魚及任何其他動物。該術語不指示具體年齡或性別。因此，意欲涵蓋雄性或雌性的成年及新生兒個體。如本文所用，「患者」或「個體」可互換使用且可指患有疾病或病症(例如，癌症)之個體。術語患者或個體包括人類及獸醫學個體。

【0195】 如本文所用，術語「治療(treatment/ treat/ treating)」係指減少疾病或病狀之影響或疾病或病狀之症狀的方法。因此，在所揭示之方法中，治療可指至少約10%、至少約20%、至少約30%、至少約40%、至少約50%、至少約60%、至少約70%、至少約80%、至少約90%或實質上完全減少所形成之疾病或病狀的嚴重程度或疾病或病狀的症狀，諸如腫瘤

體積減少、腫瘤負荷減少、死亡人數減少。例如，若個體中之疾病的一或多種症狀相較於對照組減少10%，則用於治療疾病的方法即視為治療。因此，相較於天然或對照組程度，減少可為10%、20%、30%、40%、50%、60%、70%、80%、90%、100%或10%與100%之間的任何減少百分比。應理解，治療未必係指疾病、病狀或者疾病或病狀之症狀的治癒或完全去除。

【0196】如本文所用，術語疾病或病症之「預防(prevent/ preventing/ prevention)」係指例如投與嵌合多肽或編碼嵌合多肽之核酸序列的行為，該行為發生於個體開始展示疾病或病症之一或多種症狀之前或大約相同的時間，其抑制或延緩疾病或病症之一或多種症狀的發作或惡化。

【0197】如本文所用，相較於適合的對照組程度，提及「降低(decreasing)」、「減少(reducing)」或「抑制」包括至少約10%、至少約20%、至少約30%、至少約40%、至少約50%、至少約60%、至少約70%、至少約80%、至少約90%或更大的變化。此類術語可包括(但未必包括)功能或特性(諸如促效劑活性)之完全消除。

【0198】術語「序列變異體」係指與參考多肽具有實質上類似之生物活性但胺基酸序列不同的多肽之胺基酸序列，或係指與參考序列具有實質上類似之生物活性(例如，編碼具有實質上類似活性之蛋白質)但核苷酸序列不同的核酸之核苷酸序列。通常，「序列變異體」之胺基酸或核苷酸序列與參考序列之彼胺基酸或核苷酸序列高度類似(例如，至少約80%類似)。熟習此項技術者容易地理解如何確定兩種多肽或兩種核酸之一致性。例如，可在比對兩個序列之後計算一致性，因此一致性係在限定數目

之核苷酸或胺基酸上處於其最高程度。用於比較之序列的最佳比對可藉由以下進行：Smith及Waterman Adv. Appl. Math. 2:482 (1981)之局部一致性算法(local identity algorithm)；Needleman及Wunsch, J. Mol. Biol. 48:443 (1970)之一致性比對算法；Pearson及Lipman, Proc. Natl. Acad. Sci. USA 85:2444 (1988)之相似性檢索方法；此等算法之電腦化實施方式(computerized implementation) (Wisconsin Genetics Software Package, Genetics Computer Group, 575 Science Dr., Madison, Wis.中之GAP、BESTFIT、FASTA及TFASTA)；或檢驗。

【0199】 術語「保守性胺基酸取代」為此項技術中之術語，其係指多肽中之胺基酸經與參考胺基酸具有類似之生物化學特性(諸如尺寸、負荷及疏水性)的另一胺基酸置換。熟知多肽之胺基酸序列中的保守性胺基酸置換常常不顯著改變多肽之整體結構或功能。胺基酸之保守性取代已為熟習此項技術者所知。胺基酸之保守性取代可包括但不限於在以下群組內之胺基酸中進行的取代：(a) M、I、L、V；(b) F、Y、W；(c) K、R、H；(d) A、G；(e) S、T；(f) Q、N；及(g) E、D。例如，一般熟習此項技術者合理地預期異白胺酸或纈胺酸對白胺酸、麩胺酸對天冬胺酸、絲胺酸對蘇胺酸的獨立置換，或結構上相關之胺基酸對胺基酸的類似置換將不會對所得分子之生物活性產生顯著影響。

【0200】 如本文所用，術語「有效量」係指在投與條件下投與以達成所要作用之試劑(誘導型細胞激素前藥及抗PD-1或抗PD-L1抗體)的量，此類量減少腫瘤大小、減少腫瘤負荷、延長無進展存活期或延長總存活期。所選的實際有效量將取決於所治療之特定癌症及其階段及其他因素，諸如個體之年齡、性別、體重、種族、先前治療及對彼等治療之反應以及

其他因素。待投與之誘導型細胞激素前藥及帕博利珠單抗的適合量及特定患者之給藥時程可由一般技術臨床醫師基於此等及其他考慮因素來確定。

【0201】 較佳地，本文所揭示之方法及組合物係用於治療大腸癌、肺癌、黑色素瘤、腎細胞癌、乳癌、頭頸部鱗狀癌瘤。

【0202】 在某些較佳實施例中，本文所揭示之方法及組合物用於治療黑色素瘤、非小細胞肺癌(NSCLC)、小細胞肺癌(SCLC)、頭頸部鱗狀細胞癌(HNSCC)、典型何傑金氏淋巴瘤(cHL)、原發性縱隔大B細胞淋巴瘤(PMBCL)、尿道上皮癌、高度微衛星不穩定性或錯配修復缺陷型癌症、高度微衛星不穩定性或錯配修復缺陷型大腸直腸癌、胃癌、食道癌、子宮頸癌、肝細胞癌(HCC)、梅克爾細胞癌(MCC)、腎細胞癌(RCC)、子宮內膜癌、高度腫瘤突變負荷癌症、皮膚鱗狀細胞癌(cSCC)、三陰性乳癌(TNBC)、尿道上皮癌、大腸直腸癌或食道癌瘤。

6. 等效物

【0203】 熟習此項技術者將顯而易見，本文所描述之本發明方法的其他適合修改及調適為顯而易見的，且可在不脫離本發明或實施例之範疇的情況下使用適合等效物進行。現已詳細描述某些化合物及方法，參考以下實例將更清楚地理解該等化合物及方法，該等實例係僅出於說明而引入且不意欲為限制性的。

7. 實例

【0204】 以下為本發明之方法及組合物的實例。應理解，考慮到本文提供之一般說明，可實施各種其他實施例。

實例1. CT26實驗-單獨用ACP16或與抗PD1抗體組合處理

【0205】 使用CT26細胞株，其為活體外表現MMP9之快速生長的大

腸腺癌細胞株。使用此腫瘤模型，檢驗融合蛋白影響腫瘤生長之能力。

表5.

群組	N	試劑	調配物劑量	途徑	時程
1#	12	媒劑1 // 媒劑2	na // na	ip //ip	第1、4、8、11天// 第3、6、10、13天
2	10	媒劑1 // ACP16	na // 70 μg/動物	ip //ip	第1、4、8、11天// 第3、6、10、13天
3	10	媒劑1 // ACP16	na // 232 μg/動物	ip //ip	第1、4、8、11天// 第3、6、10、13天
4	10	媒劑1 // ACP16	na // 500 μg/動物	ip //ip	第1、4、8、11天// 第3、6、10、13天
5	10	抗PD-1 RMP1-14 // 媒劑2	200 μg/動物// na	ip //ip	第1、4、8、11天/ 第3、6、10、13天
6	10	抗PD-1 RMP1-14 // ACP16	200 μg/動物// 70 μg/動物	ip //ip	第1、4、8、11天// 第3、6、10、13天
7	10	抗PD-1 RMP1-14 // ACP16	200 μg/動物// 232 μg/動物	ip //ip	第1、4、8、11天// 第3、6、10、13天
8	10	抗PD-1 RMP1-14 // ACP16	200 μg/動物// 500 μg/動物	ip //ip	第1、4、8、11天// 第3、6、10、13天
9	10	媒劑1 // IL-2	na // 12 μg/動物	ip //ip	第1、4、8、11天// bid×5第一天每週1劑量×2
10	10	抗PD-1 RMP1-14 // IL-2	200 μg/動物// 12 μg/動物	ip //ip	第1、4、8、11天// bid×5第一天每週1劑量×2

【0206】 用異氟醚麻醉小鼠以植入細胞，從而減少潰瘍。CR雌性BALB/c小鼠在側腹中sc植入含3×10^5個CT26腫瘤細胞之0%基質膠。細胞注射體積為0.1 mL/小鼠。小鼠在起始日期之年齡為8至12週。當腫瘤達至100至150 mm^3之平均大小時，進行配對，且開始處理。ACP16以70、230或500 μg/動物給藥，使用或不使用200 μg/動物之抗PD-1抗體(RMP1-14)(參見表5)。在開始時記錄體重且隨後每兩週一次直至結束。每兩週一次進行卡尺量測直至結束。立即報導任何不良反應。將任何單次觀測到體重減輕>30%或三次連續量測到體重減輕>25%之個別動物安樂死。對平均體重減輕>20%或死亡率>10%之任何組停止給藥；不將該組安樂死且允許進

行恢復。在體重減輕>20%之組中，將達到個體體重減輕終點之個體安樂死。若群組處理相關體重損失恢復至原始體重之10%內，則以較低劑量或頻率較低之給藥時程恢復給藥。基於個案情況，允許非處理性體重恢復%之例外情況。終點為腫瘤生長延緩(tumor growth delay，TGD)。個別地監測動物。實驗終點為1500 mm^3之腫瘤體積或45天，以先出現者為準。追蹤反應者更長時間。當達成終點時，將動物安樂死。結果示於圖1A至圖1F及圖2A至圖2B中。

實例2. IL-2與抗PD1抗體之組合

【0207】 在添加或不添加抗PD1抗體(RMP1-14)之B16F10同基因型腫瘤模型中測試誘導型IL-2前藥。將1×10^5個腫瘤細胞植入動物的側腹中且監測腫瘤生長。一旦腫瘤達到30至60 mm^3之平均體積，將動物隨機分組且給藥，如表6中所描述。

表6.

群組	N	試劑1	劑量	試劑2	劑量	時程
1	10	媒劑	N/A	N/A	100 μL	Biwk x 2
2	10	誘導型IL-2前藥	100 μg/小鼠	N/A	N/A	Biwk x 2
3	10	誘導型IL-2前藥	200 μg/小鼠	N/A	N/A	Biwk x 2
4	10	N/A	N/A	抗PD-1	200 μg/小鼠	Biwk x 2
5	10	誘導型IL-2前藥	100 μg/小鼠	抗PD-1	200 μg/小鼠	Biwk x 2
6	10	誘導型IL-2前藥	200 μg/小鼠	抗PD-1	200 μg/小鼠	Biwk x 2

【0208】 每週記錄三次腫瘤體積及體重，其中兩次量測之間的間隔為2至3天。用誘導型IL-2前藥處理展示作為單藥療法之劑量依賴性功效。在此模型中使用抗PD1之單藥療法在經抗PD1處理之小鼠中無功效且腫瘤體積類似於僅用媒劑處理之小鼠中的彼等腫瘤體積。但使用誘導型IL-2前藥及抗PD1之組合療法協同改善腫瘤控制，且比誘導型IL-2前藥或抗PD-1更有效。結果示於圖3A、圖3B及圖4中。

實例3. CT26實驗-單獨用誘導型IFN前藥或與抗PD1抗體組合處理

【0209】將使用CT26細胞株，其為活體外表現MMP9之快速生長的大腸腺癌細胞株。使用此腫瘤模型，將檢驗融合蛋白影響腫瘤生長之能力。

表7.

群組	N	試劑	調配物劑量	途徑	時程
1#	12	媒劑1 // 媒劑2	na // na	ip //ip	第1、4、8、11天// 第3、6、10、13天
2	10	媒劑1 // 誘導型IFN前藥	na // 70 μg/動物	ip //ip	第1、4、8、11天// 第3、6、10、13天
3	10	媒劑1 // 誘導型IFN前藥	na // 232 μg/動物	ip //ip	第1、4、8、11天// 第3、6、10、13天
4	10	媒劑1 // 誘導型IFN前藥	na // 500 μg/動物	ip //ip	第1、4、8、11天// 第3、6、10、13天
5	10	抗PD-1 RMP1-14 // 媒劑2	200 μg/動物// na	ip //ip	第1、4、8、11天// 第3、6、10、13天
6	10	抗PD-1 RMP1-14 // 誘導型IFN前藥	200 μg/動物// 70 μg/動物	ip //ip	第1、4、8、11天// 第3、6、10、13天
7	10	抗PD-1 RMP1-14 // 誘導型IFN前藥	200 μg/動物// 232 μg/動物	ip //ip	第1、4、8、11天// 第3、6、10、13天
8	10	抗PD-1 RMP1-14 // ACP16	200 μg/動物// 500 μg/動物	ip //ip	第1、4、8、11天// 第3、6、10、13天
9	10	媒劑1 // IL-2	na // 12 μg/動物	ip //ip	第1、4、8、11天// bid×5第一天每週1劑量×2
10	10	抗PD-1 RMP1-14 // IL-2	200 μg/動物// 12 μg/動物	ip //ip	第1、4、8、11天// bid×5第一天每週1劑量×2

【0210】將用異氟醚麻醉小鼠以植入細胞，從而減少潰瘍。CR雌性BALB/c小鼠將在側腹中sc安裝有3×10^5個CT26腫瘤細胞/ 0%基質膠。細胞注射體積為0.1 mL/小鼠。小鼠在起始日期之年齡將為8至12週。當腫瘤達至100至150 mm^3之平均大小且如表7中所示開始處理時，將進行配對。ACP16將以70、230或500 μg/動物給藥，具有或不具有以200 μg/動物之抗PD-1抗體(RMP1-14)。將在開始時記錄體重且隨後每兩週一次直至結

束。將每兩週一次進行卡尺量測直至結束。將立即報導任何不良反應。任何單次觀測到體重減輕>30%或三次連續量測到體重減輕>25%之個別動物將會被安樂死。對平均體重減輕>20%或死亡率>10%之任何組停止給藥；該組將不會被安樂死且允許進行恢復。在體重減輕>20%之組中，達到個體體重減輕終點之個體將會被安樂死。若群組處理相關體重損失恢復至原始體重之10%內，則將以較低劑量或頻率較低之給藥時程恢復給藥。視情況而定，將允許存在非處理性體重%恢復之例外情況。終點將為腫瘤生長延緩(TGD)。將個別地監測動物。實驗終點將為1500 mm^3之腫瘤體積或45天，以先出現者為準。追蹤反應者更長時間。當達成終點時，動物將會被安樂死。

實例4. IFN與抗PD1抗體之組合

【0211】 將在添加或不添加抗PD1抗體(RMP1-14)之B16F10同基因型腫瘤模型中測試誘導型IFN前藥。將把1×10^5個腫瘤細胞植入動物的側腹中且將監測腫瘤生長。一旦腫瘤達到30至60 mm^3之平均體積，動物將被隨機分組且給藥，如表8中所描述。

表8.

群組	N	試劑1	劑量	試劑2	劑量	時程
1	10	媒劑	N/A	N/A	100 µL	Biwk x 2
2	10	誘導型IFN前藥	100 µg/小鼠	N/A	N/A	Biwk x 2
3	10	誘導型IFN前藥	200 µg/小鼠	N/A	N/A	Biwk x 2
4	10	N/A	N/A	抗PD-1	200 µg/小鼠	Biwk x 2
5	10	誘導型IFN前藥	100 µg/小鼠	抗PD-1	200 µg/小鼠	Biwk x 2
6	10	誘導型IFN前藥	200 µg/小鼠	抗PD-1	200 µg/小鼠	Biwk x 2

【0212】 將每週記錄三次腫瘤體積及體重，其中兩次量測之間的間隔為2至3天。用誘導型IFN前藥處理將展示作為單藥療法之劑量依賴性功效。在此模型中使用抗PD1之單藥療法在經抗PD1處理之小鼠中將無功效

且腫瘤體積將類似於僅用媒劑處理之小鼠中的彼等腫瘤體積。但預期使用誘導型IFN前藥及抗PD1之組合療法將協同改善腫瘤控制，且將比誘導型IFN前藥或抗PD-1更有效。

實例5. A20淋巴瘤模型

【0213】 使用A20細胞株，其為快速生長的B細胞淋巴瘤細胞株。使用此腫瘤模型，檢驗誘導型細胞激素前藥影響腫瘤生長之能力。因為人類IL-12及IFNα2b在小鼠中不具有交叉反應性，所以產生替代性誘導型細胞激素前藥分子，其由小鼠/人類嵌合IL-12 (WW0757/636)或小鼠IFNα1 (WW0610)組成以探究同基因型血液癌模型中之抗腫瘤反應。

表9.

群組	N	試劑	劑量	途徑	時程
1	10	媒劑	-	ip	biwk x 2
2	10	WW0757/636	30 ug/動物	ip	biwk x 2
3	10	WW0757/636	100 ug/動物	ip	biwk x 2
4	10	WW0757/636	300 ug/動物	ip	biwk x 2
5	10	WW0610	45 ug/動物	ip	biwk x 2
6	10	WW0610	133 ug/動物	ip	biwk x 2

【0214】 60隻雌性BALB/c小鼠在側腹中sc安裝有5×10^5個A20腫瘤細胞/ 0%基質膠。細胞注射體積為0.1 mL/小鼠。小鼠在起始日期之年齡為8至12週。當腫瘤達到90至130 mm^3之平均大小時進行配對且根據表9開始處理。此為研究開始之第11天。每兩週一次進行卡尺量測直至結束。立即報導任何不良反應。將任何單次觀測到體重減輕>25%或三次連續量測到體重減輕>20%之個別動物安樂死。若任何組具有>20%之平均體重減輕或>10%之死亡率，則停止給藥；不將該組安樂死且允許進行恢復。在體重減輕>20%之組中，將達到個體體重減輕終點之個體安樂死。若群組處理相關體重損失恢復至原始體重之10%內，則以較低劑量或頻率較低之給

藥時程恢復給藥。視情況而定，允許存在非處理性體重%恢復之例外情況。終點為腫瘤生長延緩(TGD)。個別地監測動物。實驗終點為2000 mm^3之腫瘤體積或40天，以先出現者為準。當達成終點時，將動物安樂死。結果示於圖5A及圖5B中。

實例6. EG7.OVA淋巴瘤模型

【0215】 使用EG7.OVA細胞株，其為快速生長的T淋巴母細胞細胞株。使用此腫瘤模型，檢驗融合蛋白影響腫瘤生長之能力。因為人類IL-12及IFNα2b在小鼠中不具有交叉反應性，所以產生替代性誘導型細胞激素前藥分子，其由小鼠/人類嵌合IL-12 (WW0757/636)或小鼠IFNα1 (WW0610)組成以探究同基因型血液癌模型中之抗腫瘤反應。

表10.

群組	N	試劑	劑量	途徑	時程
1	10	媒劑	-	ip	biwk x 2
2	10	WW0757/636	30 ug/動物	ip	biwk x 2
3	10	WW0757/636	100 ug/動物	ip	biwk x 2
4	10	WW0757/636	300 ug/動物	ip	biwk x 2
5	10	WW0610	45 ug/動物	ip	biwk x 2
6	10	WW0610	133 ug/動物	ip	biwk x 2

【0216】 60隻雌性C57Bl/6小鼠在側腹中sc安裝有10×10^5個EG7.OVA腫瘤細胞/ 0%基質膠。細胞注射體積為0.1 mL/小鼠。小鼠在起始日期之年齡為8至12週。當腫瘤達到63至135 mm^3之平均大小且根據表10開始處理時，進行配對。此為研究開始之第5天。每兩週一次進行卡尺量測直至結束。立即報導任何不良反應。將任何單次觀測到體重減輕>25%或三次連續量測到體重減輕>20%之個別動物安樂死。若任何組具有>20%之平均體重減輕或>10%之死亡率，則停止給藥；不將該組安樂死且允許進行恢復。在體重減輕>20%之組中，將達到個體體重減輕終點之個體安樂

死。若群組處理相關體重損失恢復至原始體重之10%內，則以較低劑量或頻率較低之給藥時程恢復給藥。視情況而定，允許存在非處理性體重%恢復之例外情況。終點為腫瘤生長延緩(TGD)。個別地監測動物。實驗終點為2000 mm^3之腫瘤體積或40天，以先出現者為準。當達成終點時，將動物安樂死。結果示於圖6A及圖6B中。

實例7. CT26實驗-單獨用誘導型IL-2前藥或與抗PD1組合處理

【0217】使用CT26細胞株，其為活體外表現MMP9之快速生長的大腸腺癌細胞株。使用此腫瘤模型，檢驗融合蛋白影響腫瘤生長之能力。

表11.

群組	N	處理	誘導型IL-2前藥劑量	抗PD1劑量	誘導型IL-2前藥時程	抗PD1時程
1#	8	媒劑	na	na	na	na
2	8	誘導型IL-2前藥	100 μg/動物	na	第1天及第8天	na
3	8	抗PD-1	na	200 μg/動物	na	第1、4、8及11天
4	8	誘導型IL-2前藥+抗PD-1	100 μg/動物	200 μg/動物	第1天及第8天	第1、4、8及11天

【0218】用異氟醚麻醉小鼠以植入細胞，從而減少潰瘍。雌性BALB/c小鼠在側腹中sc安裝有1.5×10^5個CT26腫瘤細胞。細胞注射體積為0.1 mL/小鼠。小鼠在起始日期之年齡為8至12週。當腫瘤達到100至150 mm^3之平均大小時進行配對且根據表11開始處理。誘導型IL-2前藥為含有WW0621及WW0523之雙鏈多肽，且抗PD-1抗體為RMP1-14。在開始時記錄體重且隨後每兩週一次直至研究結束。每兩週一次進行腫瘤大小之卡尺量測直至研究結束。立即報導任何不良反應。將任何單次觀測到體重減輕>30%或三次連續量測到體重減輕>25%之個別動物安樂死。對平均體重減輕>20%或死亡率>10%之任何組停止給藥；不將該組安樂死且允許

進行恢復。個別地監測動物。研究終點為1500 mm^3之腫瘤體積或45天，以先出現者為準。追蹤反應者更長時間。當達成終點時，將動物安樂死。結果示於圖7A至圖7F中。

8. 構築體

【0219】 表8中所提供之多肽構築體的元件含有如下縮寫：「X」係指連接子。「X」係指可裂解連接子。連接子3係指包含CTSL-1受質模體序列之連接子。

表11.例示性誘導型細胞激素前藥構築體

構築體編號	構築體描述
WW0706	抗HSA-X-人類_p40-L-小鼠_p35-XL-Fab_Lambda_阻斷子(Blocker)_(阻斷子=Lambda_Fab_R27E_T32D_IGLC2-01_X=連接子2)
WW0707	抗HSA-X-人類_p40-L-人類_p35-XL-Fab_Lambda_阻斷子_(阻斷子=Lambda_Fab_R27E_T32D_IGLC2-01_X=連接子2)
WW0708	抗HSA-X-人類_p40-L-小鼠_p35-XL-Fab_Lambda_阻斷子_(阻斷子=Lambda_Fab_S30E_IGLC2-01_X=連接子2)
WW0709	抗HSA-X-人類_p40-L-人類_p35-XL-Fab_Lambda_阻斷子_(阻斷子=Lambda_Fab_S30E_IGLC2-01_X=連接子2)
WW0710	抗HSA-X-人類_p40-L-小鼠_p35-XL-Fab_Lambda_阻斷子_(阻斷子=Lambda_Fab_S30E_N31E_IGLC2-01_X=連接子2)
WW0711	抗HSA-X-人類_p40-L-人類_p35-XL-Fab_Lambda_阻斷子_(阻斷子=Lambda_Fab_S30E_N31E_IGLC2-01_X=連接子2)
WW0700	抗HSA-X-人類_p40-L-小鼠_p35-XL-Fab_Lambda_阻斷子_(阻斷子=Lambda_Fab_N31E_IGLC2-01_X=連接子2)
WW0701	抗HSA-X-人類_p40-L-人類_p35-XL-Fab_Lambda_阻斷子_(阻斷子=Lambda_Fab_N31E_IGLC2-01_X=連接子2)
WW0712	抗HSA-X-人類_p40-L-小鼠_p35-XL-Fab_Lambda_阻斷子_(阻斷子=Lambda_Fab_IGLC2-01_X=連接子3)
WW0713	抗HSA-X-人類_p40-L-人類_p35-XL-Fab_Lambda_阻斷子_(阻斷子=Lambda_Fab_IGLC2-01_X=連接子3)
WW0714	抗HSA-X-人類_p40-L-小鼠_p35-XL-Fab_Lambda_阻斷子_(阻斷子=Lambda_Fab_N31E_IGLC2-01_X=連接子3)
WW0715	抗HSA-X-人類_p40-L-人類_p35-XL-Fab_Lambda_阻斷子_(阻斷子=Lambda_Fab_N31E_IGLC2-01_X=連接子3)
WW0805	人類_p35-X-抗HSA-L-阻斷子_(阻斷子=Opt1_Hv_D53E_D61E_Vl-Vh_X=連接子3)
WW0754	抗HSA-X-人類_p35-XL-Fab_Lambda_阻斷子_(阻斷子=Lambda_Fab_IGLC2-01_X=連接子2)

WW0756	抗HSA-X-人類_p35-XL-Fab_Lambda_阻斷子_(阻斷子=Lambda_Fab_S30D_N31E_IGLC2-01_X=連接子2)
WW0762	抗HSA-X-人類_p35-XL-Fab_Lambda_阻斷子_(阻斷子=Lambda_Fab_IGLC2-01_X=連接子3)
WW0770	人類_p40-L-人類_p35-X-抗HSA-L-Fab_Lambda_阻斷子_(阻斷子=Lambda_Fab_IGLC2-01_X=連接子2)
WW0636	人類_IL12B_(p40)
WW0727	Fab_重_阻斷子_(阻斷子=IL-12_重_Fab_D53E_D61E_IgG1_Fab)
WW0045	阻斷子2-連接子-(可裂解連接(cleav. link.))-IL2- (可裂解連接)-(抗HSA)-6xHis
WW0046	(抗HSA)-(可裂解連接)-阻斷子2-連接子-(可裂解連接)-IL2-6xHis
WW0203	IL2-(可裂解連接)-(抗HSA)-連接子(可裂解連接)-阻斷子2
WW0204	IL2-X-抗HSA-LX-阻斷子_(X=連接子4_阻斷子=Vh-Vl)
WW0205	IL2-X-抗HSA-LX-阻斷子_(X=連接子5_阻斷子=Vh-Vl)
WW0234	IL2-X-HSA-LX-阻斷子_(X=連接子1；阻斷子=3TOW69)
WW0235	IL2-X-HSA-LX-阻斷子_(X=連接子1；阻斷子=3TOW85)
WW0236	IL2-X-HSA-LX-阻斷子_(X=連接子1；阻斷子=2TOW91)
WW0308	IL2-X-HSA-LX-阻斷子(QAPRL_FR2)_(X=連接子1；阻斷子=Vh/Vl)
WW0415	IL2-X-抗HSA-LX-阻斷子_(阻斷子=VHVL.F2.高. A02_Vh/Vl_A46S；X=連接子2)
WW0621	IL2-X-抗HSA-LX-重_阻斷子_Fab_(阻斷子= VH-CH1；X=連接子3)
WW0520	IL2-X-抗HSA-LX-重_阻斷子_Fab_(阻斷子=VH-CH1；X=連接子2)
WW0735	IL2-X-抗HSA-LL-重_阻斷子_Fab_(阻斷子=VH-CH1_X=連接子2)
WW0736	IL2-X-抗HSA-LL-重_阻斷子_Fab_(阻斷子=VH-CH1_X=連接子3)
WW0523	Kappa_阻斷子_Fab_(阻斷子=VHVL.F2.高. A02_A46S_Kappa)

9.序列表揭示內容

SEQ ID NO:	描述	序列
1	WW0621 (雜二聚誘導型IL-2前藥)	APTSSSTKKTQLQLEHLLLDLQMILNGINNYKNPK LTRMLTFKFYMPKKATELKHLQCLEEELKPLEEV LNLAQSKNFHLRPRDLISNINVIVLELKGSETTFM CEYADETATIVEFLNRWITFCQSIISTLTSGGPALF KSSFPPGSEVQLVESGGGLVQPGNSLRLSCAASGF TFSKFGMSWVRQAPGKGLEWVSSISGSGRDTLYA ESVKGRFTISRDNAKTTLYLQMNSLRPEDTAVYY CTIGGSLSVSSQGTLVTVSSGGGGSGGGGSGGGG SGGGGSGGGGSGGGGSSGGPALFKSSFPPGSEVQ LVESGGGLVQPGGSLRLSCAASGFTFSSYTLAWV RQAPGKGLEWVAAIDSSSYTYSPDTVRGRFTISRD NAKNSLYLQMNSLRAEDTAVYYCARDSNWDAL DYWGQGTTVTVSSASTKGPSVFPLAPSSKSTSGG TAALGCLVKDYFPEPVTVSWNSGALTSGVHTFPA VLQSSGLYSLSSVVTVPSSSLGTQTYICNVNHKPS NTKVDKRVEPKSC**

2	WW0520 (雜二聚誘導型IL-2前藥)	APTSSSTKKTQLQLEHLLLDLQMILNGINNYKNPK LTRMLTFKFYMPKKATELKHLQCLEEELKPLEEV LNLAQSKNFHLRPRDLISNINVIVLELKGSETTFM CEYADETATIVEFLNRWITFCQSIISTLTSGGPGPA GLYAQPGSEVQLVESGGGLVQPGNSLRLSCAASG FTFSKFGMSWVRQAPGKGLEWVSSISGSGRDTLY AESVKGRFTISRDNAKTTLYLQMNSLRPEDTAVY YCTIGGSLSVSSQGTLVTVSSGGGGSGGGGSGGG GSGGGGSGGGGSGGGGSSGGPGPAGLYAQPGSE VQLVESGGGLVQPGGSLRLSCAASGFTFSSYTLA WVRQAPGKGLEWVAAIDSSSYTYSPDTVRGRFTI SRDNAKNSLYLQMNSLRAEDTAVYYCARDSNW DALDYWGQGTTVTVSSASTKGPSVFPLAPSSKST SGGTAALGCLVKDYFPEPVTVSWNSGALTSGVH TFPAVLQSSGLYSLSSVVTVPSSSLGTQTYICNVN HKPSNTKVDKRVEPKSC**
3	WW0735 (雜二聚誘導型IL-2前藥)	APTSSSTKKTQLQLEHLLLDLQMILNGINNYKNPK LTRMLTFKFYMPKKATELKHLQCLEEELKPLEEV LNLAQSKNFHLRPRDLISNINVIVLELKGSETTFM CEYADETATIVEFLNRWITFCQSIISTLTSGGPGPA GLYAQPGSEVQLVESGGGLVQPGNSLRLSCAASG FTFSKFGMSWVRQAPGKGLEWVSSISGSGRDTLY AESVKGRFTISRDNAKTTLYLQMNSLRPEDTAVY YCTIGGSLSVSSQGTLVTVSSGGGGSGGGGSGGG GSGGGGSGGGGSGGGGSGGGGSGGGGSGGGGSE VQLVESGGGLVQPGGSLRLSCAASGFTFSSYTLA WVRQAPGKGLEWVAAIDSSSYTYSPDTVRGRFTI SRDNAKNSLYLQMNSLRAEDTAVYYCARDSNW DALDYWGQGTTVTVSSASTKGPSVFPLAPSSKST SGGTAALGCLVKDYFPEPVTVSWNSGALTSGVH TFPAVLQSSGLYSLSSVVTVPSSSLGTQTYICNVN HKPSNTKVDKRVEPKSC
4	WW0736 (雜二聚誘導型IL-2前藥)	APTSSSTKKTQLQLEHLLLDLQMILNGINNYKNPK LTRMLTFKFYMPKKATELKHLQCLEEELKPLEEV LNLAQSKNFHLRPRDLISNINVIVLELKGSETTFM CEYADETATIVEFLNRWITFCQSIISTLTSGGPALF KSSFPPGSEVQLVESGGGLVQPGNSLRLSCAASGF TFSKFGMSWVRQAPGKGLEWVSSISGSGRDTLYA ESVKGRFTISRDNAKTTLYLQMNSLRPEDTAVYY CTIGGSLSVSSQGTLVTVSSGGGGSGGGGSGGGG SGGGGSGGGGSGGGGSGGGGSGGGGSGGGGSEV QLVESGGGLVQPGGSLRLSCAASGFTFSSYTLAW VRQAPGKGLEWVAAIDSSSYTYSPDTVRGRFTISR DNAKNSLYLQMNSLRAEDTAVYYCARDSNWDA LDYWGQGTTVTVSSASTKGPSVFPLAPSSKSTSG GTAALGCLVKDYFPEPVTVSWNSGALTSGVHTFP AVLQSSGLYSLSSVVTVPSSSLGTQTYICNVNHKP SNTKVDKRVEPKSC

5	WW0523 Kappa_阻斷子_Fab_(阻斷子=VHVL.F2.高.A02_A46S_Kappa)	DIQMTQSPSSLSASVGDRVTITCKAREKLWSAVA WYQQKPGKAPKSLIYSASFRYSGVPSRFSGSGSGT DFTLTISSLQPEDFATYYCQQYYTYPYTFGGGTK VEIKRTVAAPSVFIFPPSDEQLKSGTASVVCLLNN FYPREAKVQWKVDNALQSGNSQESVTEQDSKDS TYSLSSTLTLSKADYEKHKVYACEVTHQGLSSPV TKSFNRGEC
6	WW0758 雜二聚IL-12多肽，抗HSA sdAb，scFv阻斷子，2個裂解位點	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSsggpALFKSSFPpgsrnlpvatpdpgmfp clhhsqnllravsnmlqkarqtlefypctseeidheditkdktstveaclplelt knesclnsretsfitngsclasrktsfmmalclssiyedlkmyqvefktmna kllmdpkrqifldqnmlavidelmqalnfnsetvpqkssleepdfyktkikl cillhafriravtidrvmsylnassggpALFKSSFPpgsggggsggggs ggggsggggsggggsggggsQSVLTQPPSVSGAPGQRVTI SCSGSRSNIGSNTVKWYQQLPGTAPKLLIYYNDQ RPSGVPDRFSGSKSGTSASLAITGLQAEDEADYYC QSYDRYTHPALLFGTGTKVTVLggggsggggsggggsQ VQLVESGGGVVQPGRSLRLSCAASGFTFSSYGMH WVRQAPGKGLEWVAFIRYeGSNKYYAeSVKGRF TISRDNSKNTLYLQMNSLRAEDTAVYYCKTHGSH DNWGQGTMVTVSS**
7	WW0805 雜二聚IL-12多肽，抗HSA sdAb，scFv阻斷子，1個裂解位點	rnlpvatpdpgmfpclhhsqnllravsnmlqkarqtlefypctseeidhedi tkdktstveaclpleltknesclnsretsfitngsclasrktsfmmalclssiye dlkmyqvefktmnakllmdpkrqifldqnmlavidelmqalnfnsetvp qkssleepdfyktkiklcillhafriravtidrvmsylnassggpALFKSS FPpgsEVQLVESGGGLVQPGNSLRLSCAASGFTFS KFGMSWVRQAPGKGLEWVSSISGSGRDTLYAES VKGRFTISRDNAKTTLYLQMNSLRPEDTAVYYCT IGGSLSVSSQGTLVTVSSggggsggggsggggsggggsggg gsggggsQSVLTQPPSVSGAPGQRVTISCSGSRSNIGS NTVKWYQQLPGTAPKLLIYYNDQRPSGVPDRFSG SKSGTSASLAITGLQAEDEADYYCQSYDRYTHPA LLFGTGTKVTVLggggsggggsggggsQVQLVESGGGV VQPGRSLRLSCAASGFTFSSYGMHWVRQAPGKG LEWVAFIRYeGSNKYYAeSVKGRFTISRDNSKNTL YLQMNSLRAEDTAVYYCKTHGSHDNWGQGTMV TVSS**
8	WW0754 雜二聚IL-12多肽，抗HSA sdAb，Fab阻斷子，2個裂解位點	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSsggpGPAGLYAQpgsrnlpvatpdpgmf pclhhsqnllravsnmlqkarqtlefypctseeidheditkdktstveaclple ltknesclnsretsfitngsclasrktsfmmalclssiyedlkmyqvefktmn akllmdpkrqifldqnmlavidelmqalnfnsetvpqkssleepdfyktki klcillhafriravtidrvmsylnassggpGPAGLYAQpgsgggsgg

		ggsggggsggggsggggsggggsQSVLTQPPSVSGAPGQR VTISCSGSRSNIGSNTVKWYQQLPGTAPKLLIYYN DQRPSGVPDRFSGSKSGTSASLAITGLQAEDEADY YCQSYDRYTHPALLFGTGTKVTVLgqpkaapsvtlfpps seelqankatlvclisdfypgavtvawkadsspvkagvetttpskqsnnky aassylsltpeqwkshrsyscqvthegstvektvaptecs**
9	WW0756 雜二聚IL-12多肽，抗HSA sdAb，Fab阻斷子，2個裂解位點	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSsggpGPAGLYAQpgsrnlpvatpdpgmf pclhhsqnllravsnmlqkarqtlefypctseeidheditkdktstveaclple ltknesclnsretsfitngsclasrktsfmmalclssiyedlkmyqvefktmn akllmdpkrqifldqnmlavidelmqalnfnsetvpqkssleepdfyktki klcillhafriravtidrvmsylnassggpGPAGLYAQpgsggggsgg ggsggggsggggsggggsggggsQSVLTQPPSVSGAPGQR VTISCSGSRSNIGdeTVKWYQQLPGTAPKLLIYYN DQRPSGVPDRFSGSKSGTSASLAITGLQAEDEADY YCQSYDRYTHPALLFGTGTKVTVLgqpkaapsvtlfpps seelqankatlvclisdfypgavtvawkadsspvkagvetttpskqsnnky aassylsltpeqwkshrsyscqvthegstvektvaptecs**
10	WW0762 雜二聚IL-12多肽，抗HSA sdAb，Fab阻斷子，2個裂解位點	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSsggpALFKSSFPpgsrnlpvatpdpgmfp clhhsqnllravsnmlqkarqtlefypctseeidheditkdktstveaclplelt knesclnsretsfitngsclasrktsfmmalclssiyedlkmyqvefktmna kllmdpkrqifldqnmlavidelmqalnfnsetvpqkssleepdfyktkikl cillhafriravtidrvmsylnassggpALFKSSFPpgsggggsggggs ggggsggggsggggsggggsQSVLTQPPSVSGAPGQRVTI SCSGSRSNIGSNTVKWYQQLPGTAPKLLIYYNDQ RPSGVPDRFSGSKSGTSASLAITGLQAEDEADYYC QSYDRYTHPALLFGTGTKVTVLgqpkaapsvtlfppssee lqankatlvclisdfypgavtvawkadsspvkagvetttpskqsnnkyaas sylsltpeqwkshrsyscqvthegstvektvaptecs**
11	WW0770 單體IL-12多肽，抗HSA sdAb，Fab阻斷子，1個裂解位點	iwelkkdvyvveldwypdapgemvvltcdtpeedgitwtldqssevlgs gktltiqvkefgdagqytchkggevlshsllllhkkedgiwstdilkdqkep knktflrceaknysgrftcwwlttistdltfsvkssrgssdpqgvtcgaatlsa ervrgdnkeyeysvecqedsacpaaeeslpievmvdavhklkyenytssf firdiikpdppknlqlkplknsrqvevsweypdtwstphsyfsltfcvqvq gkskrekkdrvftdktsatvicrknasisvraqdryyssswsewasvpcsg gggsggggsggggsrnlpvatpdpgmfpclhhsqnllravsnmlqkarqt lefypctseeidheditkdktstveaclpleltknesclnsretsfitngsclasr ktsfmmalclssiyedlkmyqvefktmnakllmdpkrqifldqnmlavi delmqalnfnsetvpqkssleepdfyktkiklcillhafriravtidrvmsyln assggpGPAGLYAQpgsEVQLVESGGGLVQPGNSLR LSCAASGFTFSKFGMSWVRQAPGKGLEWVSSISG SGRDTLYAESVKGRFTISRDNAKTTLYLQMNSLR

		PEDTAVYYCTIGGSLSVSSQGTLVTVSSggggsggggsggggsggggsggggsggggsQSVLTQPPSVSGAPGQRVTISCSGSRSNIGSNTVKWYQQLPGTAPKLLIYYNDQRPSGVPDRFSGSKSGTSASLAITGLQAEDEADYYCQSYDRYTHPALLFGTGTKVTVLgqpkaapsvtlfppsseelqankatlvclisdfypgavtvawkadsspvkagvetttpskqsnnkyaassylsltpeqwkshrsyscqvthegstvektvaptecs**
12	WW0636	iwelkkdvyvveldwypdapgemvvltcdtpeedgitwtldqssevlgsgktltiqvkefgdagqytchkggevlshsllllhkkedgiwstdilkdqkepknktflrceaknysgrftcwwlttistdltfsvkssrgssdpqgvtcgaatlsaervrgdnkeyeysvecqedsacpaaeeslpievmvdavhklkyenytssffirdiikpdppknlqlkplknsrqvevsweypdtwstphsyfsltfcvqvqgkskrekkdrvftdktsatvicrknasisvraqdryysssswsewasvpcs**
13	WW0727 單體IL-12多肽，抗HSA sdAb，Fab阻斷子，2個裂解位點	QVQLVESGGGVVQPGRSLRLSCAASGFTFSSYGMHWVRQAPGKGLEWVAFIRYeGSNKYYAeSVKGRFTISRDNSKNTLYLQMNSLRAEDTAVYYCKTHGSHDNWGQGTMVTVSSastkgpsvfplapsskstsggtaalgclvkdyfpepvtvswnsgaltsgvhtfpavlqssglyslssvvtvpssslgtqtyicnvnhkpsntkvdkrvepksc**
14	WW0613	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGMSWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRFTISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLSVSSQGTLVTVSSSGGPALFKSSFPPGSCDLPQTHSLGSRRTLMLLAQMRRISLFSCLKDRHDFGFPQEEFGNQFQKAETIPVLHEMIQQIFNLFSTKDSSAAWDETLLDKFYTELYQQLNDLEACVIQGVGVTETPLMKEDSILAVRKYFQRITLYLKEKKYSPCAWEVVRAEIMRSFSLSTNLQESLRSKESGGPALFKSSFPPGSEVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGMSWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRFTISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLSVSSQGTLVTVSS
15	WW0614	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGMSWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRFTISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLSVSSQGTLVTVSSSGGPPLAQKLKSSPGSCDLPQTHSLGSRRTLMLLAQMRRISLFSCLKDRHDFGFPQEEFGNQFQKAETIPVLHEMIQQIFNLFSTKDSSAAWDETLLDKFYTELYQQLNDLEACVIQGVGVTETPLMKEDSILAVRKYFQRITLYLKEKKYSPCAWEVVRAEIMRSFSLSTNLQESLRSKESGGPPLAQKLKSSPGSEVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGMSWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRFTISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLSVSSQGTLVTVSS

16	WW0819	EAHKSEIAHRYNDLGEQHFKGLVLIAFSQYLQKC SYDEHAKLVQEVTDFAKTCVADESAANCDKSLH TLFGDKLCAIPNLRENYGELADCCTKQEPERNEC FLQHKDDNPSLPPFERPEAEAMCTSFKENPTTFM GHYLHEVARRHPYFYAPELLYYAEQYNEILTQCC AEADKESCLTPKLDGVKEKALVSSVRQRMKCSS MQKFGERAFKAWAVARLSQTFPNADFAEITKLA TDLTKVNKECCHGDLLECADDRAELAKYMCENQ ATISSKLQTCCDKPLLKKAHCLSEVEHDTMPADL PAIAADFVEDQEVCKNYAEAKDVFLGTFLYEYSR RHPDYSVSLLLRLAKKYEATLEKCCAEANPPACY GTVLAEFQPLVEEPKNLVKTNCDLYEKLGEYGFQ NAILVRYTQKAPQVSTPTLVEAARNLGRVGTKCC TLPEDQRLPCVEDYLSAILNRVCLLHEKTPVSEHV TKCCSGSLVERRPCFSALTVDETYVPKEFKAETFT FHSDICTLPEKEKQIKKQTALAELVKHKPKATAE QLKTVMDDFAQFLDTCCKAADKDTCFSTEGPNL VTRCKDALASGGPALFKSSFPPGSCDLPQTHNLR NKRALTLLVQMRRLSPLSCLKDRKDFGFPQEKVD AQQIKKAQAIPVLSELTQQILNIFTSKDSSAAWNT TLLDSFCNDLHQQLNDLQGCLMQQVGVQEFPLT QEDALLAVRKYFHRITVYLREKKHSPCAWEVVR AEVWRALSSSANVLGRLREEKSGGPALFKSSFPP GSEVQLVESGGGLVQPGNSLRLSCAASGFTFSKF GMSWVRQAPGKGLEWVSSISGSGRDTLYAESVK GRFTISRDNAKTTLYLQMNSLRPEDTAVYYCTIG GSLSVSSQGTLVTVSSHHHHHH
17	WW0821	DAHKSEVAHRFKDLGEENFKALVLIAFAQYLQQC PFEDHVKLVNEVTEFAKTCVADESAENCDKSLHT LFGDKLCTVATLRETYGEMADCCAKQEPERNEC FLQHKDDNPNLPRLVRPEVDVMCTAFHDNEETFL KKYLYEIARRHPYFYAPELLFFAKRYKAAFTECC QAADKAACLLPKLDELRDEGKASSAKQRLKCAS LQKFGERAFKAWAVARLSQRFPKAEFAEVSKLV TDLTKVHTECCHGDLLECADDRADLAKYICENQ DSISSKLKECCEKPLLEKSHCIAEVENDEMPADLP SLAADFVESKDVCKNYAEAKDVFLGMFLYEYAR RHPDYSVVLLLRLAKTYETTLEKCCAAADPHECY AKVFDEFKPLVEEPQNLIKQNCELFEQLGEYKFQ NALLVRYTKKVPQVSTPTLVEVSRNLGKVGSKCC KHPEAKRMPCAEDYLSVVLNQLCVLHEKTPVSD RVTKCCTESLVNRRPCFSALEVDETYVPKEFNAE TFTFHADICTLSEKERQIKKQTALVELVKHKPKAT KEQLKAVMDDFAAFVEKCCKADDKETCFAEEGK KLVAASQAALGLSGGPALFKSSFPPGSCDLPQTHS LGSRRTLMLLAQMRRISLFSCLKDRHDFGFPQEEF GNQFQKAETIPVLHEMIQQIFNLFSTKDSSAAWDE

		TLLDKFYTELYQQLNDLEACVIQGVGVTETPLMK EDSILAVRKYFQRITLYLKEKKYSPCAWEVVRAEI MRSFSLSTNLQESLRSKESGGPALFKSSFPPGSDA HKSEVAHRFKDLGEENFKALVLIAFAQYLQQCPF EDHVKLVNEVTEFAKTCVADESAENCDKSLHTLF GDKLCTVATLRETYGEMADCCAKQEPERNECFL QHKDDNPNLPRLVRPEVDVMCTAFHDNEETFLK KYLYEIARRHPYFYAPELLFFAKRYKAAFTECCQ AADKAACLLPKLDELRDEGKASSAKQRLKCASL QKFGERAFKAWAVARLSQRFPKAEFAEVSKLVT DLTKVHTECCHGDLLECADDRADLAKYICENQD SISSKLKECCEKPLLEKSHCIAEVENDEMPADLPS LAADFVESKDVCKNYAEAKDVFLGMFLYEYARR HPDYSVVLLLRLAKTYETTLEKCCAAADPHECYA KVFDEFKPLVEEPQNLIKQNCELFEQLGEYKFQN ALLVRYTKKVPQVSTPTLVEVSRNLGKVGSKCCK HPEAKRMPCAEDYLSVVLNQLCVLHEKTPVSDR VTKCCTESLVNRRPCFSALEVDETYVPKEFNAETF TFHADICTLSEKERQIKKQTALVELVKHKPKATK EQLKAVMDDFAAFVEKCCKADDKETCFAEEGKK LVAASQAALGL
18	WW0834	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSSGGPALFKSSFPPGSCDLPQTHS LGNRRALILLAQMGRISHFSCLKDRYDFGFPQEVF DGNQFQKAQAISAFHEMIQQTFNLFSTKDSSAAW DETLLDKFYIELFQQLNDLEACVTQEVGVEEIAL MNEDSILAVRKYFQRITLYLMGKKYSPCAWEVV RAEIMRSFSFSTNLQKGLRRKDSGGPALFKSSFPP GSEVQLVESGGGLVQPGNSLRLSCAASGFTFSKF GMSWVRQAPGKGLEWVSSISGSGRDTLYAESVK GRFTISRDNAKTTLYLQMNSLRPEDTAVYYCTIG GSLSVSSQGTLVTVSS
19	WW0742	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSSGGPALFKSSFPPGSMSYNLLGF LQRSSNFQCQKLLWQLNGRLEYCLKDRMNFDIPE EIKQLQQFQKEDAALTIYEMLQNIFAIFRQDSSST GWNETIVENLLANVYHQINHLKTVLEEKLEKEDF TRGKLMSSLHLKRYYGRILHYLKAKEYSHCAWTI VRVEILRNFYFINRLTGYLRNSGGPALFKSSFPPGS EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSS

20	WW0612	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSSGGPGPAGLYAQPGSCDLPQTH SLGSRRTLMLLAQMRRISLFSCLKDRHDFGFPQEE FGNQFQKAETIPVLHEMIQQIFNLFSTKDSSAAWD ETLLDKFYTELYQQLNDLEACVIQGVGVTETPLM KEDSILAVRKYFQRITLYLKEKKYSPCAWEVVRA EIMRSFSLSTNLQESLRSKESGGPGPAGLYAQPGS EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSS
21	WW0045 (單體IL-2誘導型前藥)	EVQLVESGGGLVQPGGSLRLSCAASGFTFSSYTL AWVRQAPGKGLEWVAAIDSSSYTYSPDTVRGRF TISRDNAKNSLYLQMNSLRAEDTAVYYCARDSN WDALDYWGQGTTVTVSSGGGGSGGGGSGGGGS DIQMTQSPSSLSASVGDRVTITCKASQNVGTNVG WYQQKPGKAPKALIYSASFRYSGVPSRFSGSGSG TDFTLTISSLQPEDFATYYCQQYYTYPYTFGGGTK VEIKGGGGSGGGGSGGGGSGGGGSGGGGSGGGG SSGGPGPAGMKGLPGSAPTSSSTKKTQLQLEHLL LDLQMILNGINNYKNPKLTRMLTFKFYMPKKATE LKHLQCLEEELKPLEEVLNLAQSKNFHLRPRDLIS NINVIVLELKGSETTFMCEYADETATIVEFLNRWI TFCQSIISTLTSGGPGPAGMKGLPGSEVQLVESGG GLVQPGNSLRLSCAASGFTFSKFGMSWVRQAPG KGLEWVSSISGSGRDTLYAESVKGRFTISRDNAKT TLYLQMNSLRPEDTAVYYCTIGGSLSVSSQGTLV TVSSHHHHHH
22	WW0046 (單體IL-2誘導型前藥)	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSSGGPGPAGMKGLPGSEVQLVES GGGLVQPGGSLRLSCAASGFTFSSYTLAWVRQAP GKGLEWVAAIDSSSYTYSPDTVRGRFTISRDNAK NSLYLQMNSLRAEDTAVYYCARDSNWDALDYW GQGTTVTVSSGGGGSGGGGSGGGGSDIQMTQSPS SLSASVGDRVTITCKASQNVGTNVGWYQQKPGK APKALIYSASFRYSGVPSRFSGSGSGTDFTLTISSL QPEDFATYYCQQYYTYPYTFGGGTKVEIKGGGGS GGGGSGGGGSGGGGSGGGGSGGGGSSGGPGPAG MKGLPGSAPTSSSTKKTQLQLEHLLLDLQMILNGI NNYKNPKLTRMLTFKFYMPKKATELKHLQCLEE ELKPLEEVLNLAQSKNFHLRPRDLISNINVIVLELK GSETTFMCEYADETATIVEFLNRWITFCQSIISTLT HHHHHH

23	WW0203 (單體IL-2誘導型前藥)	APTSSSTKKTQLQLEHLLLDLQMILNGINNYKNPK LTRMLTFKFYMPKKATELKHLQCLEEELKPLEEV LNLAQSKNFHLRPRDLISNINVIVLELKGSETTFM CEYADETATIVEFLNRWITFCQSIISTLTSGGPALF KSSFPPGSEVQLVESGGGLVQPGNSLRLSCAASGF TFSKFGMSWVRQAPGKGLEWVSSISGSGRDTLYA ESVKGRFTISRDNAKTTLYLQMNSLRPEDTAVYY CTIGGSLSVSSQGTLVTVSSGGGGSGGGGSGGGG SGGGGSGGGGSGGGGSSGGPALFKSSFPPGSEVQ LVESGGGLVQPGGSLRLSCAASGFTFSSYTLAWV RQAPGKGLEWVAAIDSSSYTYSPDTVRGRFTISRD NAKNSLYLQMNSLRAEDTAVYYCARDSNWDAL DYWGQGTTVTVSSGGGGSGGGGSGGGGSDIQMT QSPSSLSASVGDRVTITCKASQNVGTNVGWYQQ KPGKAPKALIYSASFRYSGVPSRFSGSGSGTDFTL TISSLQPEDFATYYCQQYYTYPYTFGGGTKVEIKH HHHHHEPEA
24	WW0204 (單體IL-2誘導型前藥)	APTSSSTKKTQLQLEHLLLDLQMILNGINNYKNPK LTRMLTFKFYMPKKATELKHLQCLEEELKPLEEV LNLAQSKNFHLRPRDLISNINVIVLELKGSETTFM CEYADETATIVEFLNRWITFCQSIISTLTSGGPPLA QKLKSSPGSEVQLVESGGGLVQPGNSLRLSCAAS GFTFSKFGMSWVRQAPGKGLEWVSSISGSGRDTL YAESVKGRFTISRDNAKTTLYLQMNSLRPEDTAV YYCTIGGSLSVSSQGTLVTVSSGGGGSGGGGSGG GGSGGGGSGGGGSGGGGSSGGPPLAQKLKSSPGS EVQLVESGGGLVQPGGSLRLSCAASGFTFSSYTL AWVRQAPGKGLEWVAAIDSSSYTYSPDTVRGRF TISRDNAKNSLYLQMNSLRAEDTAVYYCARDSN WDALDYWGQGTTVTVSSGGGGSGGGGSGGGGS DIQMTQSPSSLSASVGDRVTITCKASQNVGTNVG WYQQKPGKAPKALIYSASFRYSGVPSRFSGSGSG TDFTLTISSLQPEDFATYYCQQYYTYPYTFGGGTK VEIKHHHHHHHEPEA
25	WW0205 (單體IL-2誘導型前藥)	APTSSSTKKTQLQLEHLLLDLQMILNGINNYKNPK LTRMLTFKFYMPKKATELKHLQCLEEELKPLEEV LNLAQSKNFHLRPRDLISNINVIVLELKGSETTFM CEYADETATIVEFLNRWITFCQSIISTLTSGGPPGG PAGIGALFKSSFPPLAQKLKSSPGSEVQLVESGGG LVQPGNSLRLSCAASGFTFSKFGMSWVRQAPGK GLEWVSSISGSGRDTLYAESVKGRFTISRDNAKTT LYLQMNSLRPEDTAVYYCTIGGSLSVSSQGTLVT VSSGGGGSGGGGSGGGGSGGGGSGGGGSGGGGS SGGPPGGPAGIGALFKSSFPPLAQKLKSSPGSEVQ LVESGGGLVQPGGSLRLSCAASGFTFSSYTLAWV RQAPGKGLEWVAAIDSSSYTYSPDTVRGRFTISRD NAKNSLYLQMNSLRAEDTAVYYCARDSNWDAL

		DYWGQGTTVTVSSGGGGSGGGGSGGGGSDIQMT QSPSSLSASVGDRVTITCKASQNVGTNVGWYQQ KPGKAPKALIYSASFRYSGVPSRFSGSGSGTDFTL TISSLQPEDFATYYCQQYYTYPYTFGGGTKVEIKH HHHHHEPEA
26	WW0234 (單體IL-2誘導型前藥)	APTSSSTKKTQLQLEHLLLDLQMILNGINNYKNPK LTRMLTFKFYMPKKATELKHLQCLEEELKPLEEV LNLAQSKNFHLRPRDLISNINVIVLELKGSETTFM CEYADETATIVEFLNRWITFCQSIISTLTSGGPGPA GMKGLPGSEVQLVESGGGLVQPGNSLRLSCAAS GFTFSKFGMSWVRQAPGKGLEWVSSISGSGRDTL YAESVKGRFTISRDNAKTTLYLQMNSLRPEDTAV YYCTIGGSLSVSSQGTLVTVSSGGGGSGGGGSGG GGSGGGGSGGGGSGGGGSSGGPGPAGMKGLPGQ VQLQESGGGLVQTGGSLRLSCTTSGTIFSGYTMG WYRQAPGEQRELVAVISGGGDTNYADSVKGRFTI SRDNTKDTMYLQMNSLKPEDTAVYYCYSREVTP PWKLYWGQGTQVTVSSAAAYPYDVPDYGSHHH HHH
27	WW0235 (單體IL-2誘導型前藥)	APTSSSTKKTQLQLEHLLLDLQMILNGINNYKNPK LTRMLTFKFYMPKKATELKHLQCLEEELKPLEEV LNLAQSKNFHLRPRDLISNINVIVLELKGSETTFM CEYADETATIVEFLNRWITFCQSIISTLTSGGPGPA GMKGLPGSEVQLVESGGGLVQPGNSLRLSCAAS GFTFSKFGMSWVRQAPGKGLEWVSSISGSGRDTL YAESVKGRFTISRDNAKTTLYLQMNSLRPEDTAV YYCTIGGSLSVSSQGTLVTVSSGGGGSGGGGSGG GGSGGGGSGGGGSGGGGSSGGPGPAGMKGLPGQ VQLQESGGGLVQEGGSLRLSCAASERIFSTDVMG WYRQAAEKQRELVAVVSARGTTNYLDAVKGRF TISRDNARNTLTLQMNDLKPEDTASYYCYVRETT SPWRIYWGQGTQVTVSSAAAYPYDVPDYGSHHH HHH
28	WW0236 (單體IL-2誘導型前藥)	APTSSSTKKTQLQLEHLLLDLQMILNGINNYKNPK LTRMLTFKFYMPKKATELKHLQCLEEELKPLEEV LNLAQSKNFHLRPRDLISNINVIVLELKGSETTFM CEYADETATIVEFLNRWITFCQSIISTLTSGGPGPA GMKGLPGSEVQLVESGGGLVQPGNSLRLSCAAS GFTFSKFGMSWVRQAPGKGLEWVSSISGSGRDTL YAESVKGRFTISRDNAKTTLYLQMNSLRPEDTAV YYCTIGGSLSVSSQGTLVTVSSGGGGSGGGGSGG GGSGGGGSGGGGSGGGGSSGGPGPAGMKGLPGQ VQLQESGGGLVQAGGSLRLSCAASGSIFSANAMG WYRQAPGKQRELVAVISSGGSTNYADSVKGRFTI SRDNAKNTVYLQMNSLKPEDTAVYYCMYSGSY YYTPNDYWGQGTQVTVSSAAAYPYDVPDYGSH HHHHH

29	WW0308 (單體IL-2誘導型前藥)	APTSSSTKKTQLQLEHLLLDLQMILNGINNYKNPK LTRMLTFKFYMPKKATELKHLQCLEEELKPLEEV LNLAQSKNFHLRPRDLISNINVIVLELKGSETTFM CEYADETATIVEFLNRWITFCQSIISTLTSGGPGPA GMKGLPGSEVQLVESGGGLVQPGNSLRLSCAAS GFTFSKFGMSWVRQAPGKGLEWVSSISGSGRDTL YAESVKGRFTISRDNAKTTLYLQMNSLRPEDTAV YYCTIGGSLSVSSQGTLVTVSSGGGGSGGGGSGG GGSGGGGSGGGGSGGGGSSGGPGPAGMKGLPGS EVQLVESGGGLVQPGGSLRLSCAASGFTFSSYTL AWVRQAPGKGLEWVAAIDSSSYTYSPDTVRGRF TISRDNAKNSLYLQMNSLRAEDTAVYYCARDSN WDALDYWGQGTTVTVSSGGGGSGGGGSGGGGS DIQMTQSPSSLSASVGDRVTITCKASQNVGTNVG WYQQKPGQAPRLLIYSASFRYSGVPSRFSGSGSGT DFTLTISSLQPEDFATYYCQQYYTYPYTFGGGTK VEIKHHHHHH
30	WW0415 (單體IL-2誘導型前藥)	APTSSSTKKTQLQLEHLLLDLQMILNGINNYKNPK LTRMLTFKFYMPKKATELKHLQCLEEELKPLEEV LNLAQSKNFHLRPRDLISNINVIVLELKGSETTFM CEYADETATIVEFLNRWITFCQSIISTLTSGGPGPA GLYAQPGSEVQLVESGGGLVQPGNSLRLSCAASG FTFSKFGMSWVRQAPGKGLEWVSSISGSGRDTLY AESVKGRFTISRDNAKTTLYLQMNSLRPEDTAVY YCTIGGSLSVSSQGTLVTVSSGGGGSGGGGSGGG GSGGGGSGGGGSGGGGSSGGPGPAGLYAQPGSE VQLVESGGGLVQPGGSLRLSCAASGFTFSSYTLA WVRQAPGKGLEWVAAIDSSSYTYSPDTVRGRFTI SRDNAKNSLYLQMNSLRAEDTAVYYCARDSNW DALDYWGQGTTVTVSSGGGGSGGGGSGGGGSDI QMTQSPSSLSASVGDRVTITCKAREKLWSAVAW YQQKPGKAPKSLIYSASFRYSGVPSRFSGSGSGTD FTLTISSLQPEDFATYYCQQYYTYPYTFGGGTKVE IK
31	WW0706 單體IL-12 (嵌合)多肽，抗HSA sdAb，Fab阻斷子，2個裂解位點	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSsggpGPAGLYAQpgsiwelkkdvyvvel dwypdapgemvvltcdtpeedgitwtldqssevlgsgktltiqvkefgdag qytchkggevlshsllllhkkedgiwstdilkdqkepknktflrceaknysg rftcwwlttistdltfsvkssrgssdpqgvtcgaatlsaervrgdnkeyeysve cqedsacpaaeeslpievmvdavhklkyenytssffirdiikpdppknlql kplknsrqvevsweypdtwstphsyfsltfcvqvqgkskrekkdrvftdkt satvicrknasisvraqdryyssswsewasvpcsggggsggggsggggsr vipvsgparclsqsrnllkttddmvktareklkhysctaedidheditrdqtst lktclplelhknesclatretssttrgsclppqktslmmtlclgsiyedlkmyqt efqainaalqnhnhqqiildkgmlvaidelmqslnhngetlrqkppvgea

		dpyrvkmklcillhafstrvvtinrvmgylssasggpGPAGLYAQpg sggggsggggsggggsggggsggggsggggsQSVLTQPPSVSG APGQRVTISCSGSeSNIGSNdVKWYQQLPGTAPKL LIYYNDQRPSGVPDRFSGSKSGTSASLAITGLQAE DEADYYCQSYDRYTHPALLFGTGTKVTVLgqpkaa psvtlfppsseelqankatlvclisdfypgavtvawkadsspvkagvetttps kqsnnkyaassylsltpeqwkshrsyscqvthegstvektvaptecs**
32	WW0707 單體IL-12多肽，抗HSA sdAb，Fab阻斷子，2個裂解位點	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSsggpGPAGLYAQpgsiwelkkdvyvvel dwypdapgemvvltcdtpeedgitwtldqssevlgsgktltiqvkefgdag qytchkggevlshsllllhkkedgiwstdilkdqkepknktflrceaknysg rftcwwlttistdltfsvkssrgssdpqgvtcgaatlsaervrgdnkeyeysve cqedsacpaaeeslpievmvdavhklkyenytssffirdiikpdppknlql kplknsrqvevsweypdtwstphsyfsltfcvqvqgkskrekkdrvftdkt satvicrknasisvraqdryyssswsewasvpcsggggsggggsggggsr nlpvatpdpgmfpclhhsqnllravsnmlqkarqtlefypctseeidhedit kdktstveaclpleltknesclnsretsfitngsclasrktsfmmalclssiyed lkmyqvefktmnakllmdpkrqifldqnmlavidelmqalnfnsetvpq kssleepdfyktkiklcillhafriravtidrvmsylnassggpGPAGLY AQpgsggggsggggsggggsggggsggggsggggsQSVLTQPP SVSGAPGQRVTISCSGSeSNIGSNdVKWYQQLPGT APKLLIYYNDQRPSGVPDRFSGSKSGTSASLAITG LQAEDEADYYCQSYDRYTHPALLFGTGTKVTVLg qpkaapsvtlfppsseelqankatlvclisdfypgavtvawkadsspvkag vetttpskqsnnkyaassylsltpeqwkshrsyscqvthegstvektvapte cs**
33	WW0708 單體IL-12 (嵌合)多肽，抗HSA sdAb，Fab阻斷子，2個裂解位點	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSsggpGPAGLYAQpgsiwelkkdvyvvel dwypdapgemvvltcdtpeedgitwtldqssevlgsgktltiqvkefgdag qytchkggevlshsllllhkkedgiwstdilkdqkepknktflrceaknysg rftcwwlttistdltfsvkssrgssdpqgvtcgaatlsaervrgdnkeyeysve cqedsacpaaeeslpievmvdavhklkyenytssffirdiikpdppknlql kplknsrqvevsweypdtwstphsyfsltfcvqvqgkskrekkdrvftdkt satvicrknasisvraqdryyssswsewasvpcsggggsggggsggggsr vipvsgparclsqsrnllkttddmvktareklkhysctaedidheditrdqtst lktclplelhknesclatretssttrgsclppqktslmmtlclgsiyedlkmyqt efqainaalqnhnhqqiildkgmlvaidelmqslnhngetlrqkppvgea dpyrvkmklcillhafstrvvtinrvmgylssasggpGPAGLYAQpg sggggsggggsggggsggggsggggsggggsQSVLTQPPSVSG APGQRVTISCSGSRSNIGeNTVKWYQQLPGTAPKL LIYYNDQRPSGVPDRFSGSKSGTSASLAITGLQAE DEADYYCQSYDRYTHPALLFGTGTKVTVLgqpkaa psvtlfppsseelqankatlvclisdfypgavtvawkadsspvkagvetttps kqsnnkyaassylsltpeqwkshrsyscqvthegstvektvaptecs**

34	WW0709 單體IL-12多肽，抗HSA sdAb，Fab阻斷子，2個裂解位點	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSsggpGPAGLYAQpgsiwelkkdvyvvel dwypdapgemvvltcdtpeedgitwtldqssevlgsgktltiqvkefgdag qytchkggevlshsllllhkkedgiwstdilkdqkepknktflrceaknysg rftcwwlttistdltfsvkssrgssdpqgvtcgaatlsaervrgdnkeyeysve cqedsacpaaeeslpievmvdavhklkyenytssffirdiikpdppknlql kplknsrqvevsweypdtwstphsyfsltfcvqvqgkskrekkdrvftdkt satvicrknasisvraqdryyssswsewasvpcsggggsggggsggggsr nlpvatpdpgmfpclhhsqnllravsnmlqkarqtlefypctseeidhedit kdktstveaclpleltknesclnsretsfitngsclasrktsfmmalclssiyed lkmyqvefktmnakllmdpkrqifldqnmlavidelmqalnfnsetvpq kssleepdfyktkiklcillhafriravtidrvmsylnassggpGPAGLY AQpgsggggsggggsggggsggggsggggsggggsQSVLTQPP SVSGAPGQRVTISCSGSRSNIGeNTVKWYQQLPGT APKLLIYYNDQRPSGVPDRFSGSKSGTSASLAITG LQAEDEADYYCQSYDRYTHPALLFGTGTKVTVLg qpkaapsvtlfppsseelqankatlvclisdfypgavtvawkadsspvkag vetttpskqsnnkyaassylsltpeqwkshrsyscqvthegstvektvapte cs**
35	WW0710 單體IL-12 (嵌合)多肽，抗HSA sdAb，Fab阻斷子，2個裂解位點	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSsggpGPAGLYAQpgsiwelkkdvyvvel dwypdapgemvvltcdtpeedgitwtldqssevlgsgktltiqvkefgdag qytchkggevlshsllllhkkedgiwstdilkdqkepknktflrceaknysg rftcwwlttistdltfsvkssrgssdpqgvtcgaatlsaervrgdnkeyeysve cqedsacpaaeeslpievmvdavhklkyenytssffirdiikpdppknlql kplknsrqvevsweypdtwstphsyfsltfcvqvqgkskrekkdrvftdkt satvicrknasisvraqdryyssswsewasvpcsggggsggggsggggsr vipvsgparclsqsrnllkttddmvktareklkhysctaedidheditrdqtst lktclplelhknesclatretssttrgsclppqktslmmtlclgsiyedlkmyqt efqainaalqnhnhqqiildkgmlvaidelmqslnhngetlrqkppvgea dpyrvkmklcillhafstrvvtinrvmgylssasggpGPAGLYAQpg sggggsggggsggggsggggsggggsggggsQSVLTQPPSVSG APGQRVTISCSGSRSNIGeeTVKWYQQLPGTAPKL LIYYNDQRPSGVPDRFSGSKSGTSASLAITGLQAE DEADYYCQSYDRYTHPALLFGTGTKVTVLgqpkaa psvtlfppsseelqankatlvclisdfypgavtvawkadsspvkagvetttps kqsnnkyaassylsltpeqwkshrsyscqvthegstvektvaptecs**
36	WW0711 單體IL-12多肽，抗HSA sdAb，Fab阻斷子，2個裂解位點	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSsggpGPAGLYAQpgsiwelkkdvyvvel dwypdapgemvvltcdtpeedgitwtldqssevlgsgktltiqvkefgdag qytchkggevlshsllllhkkedgiwstdilkdqkepknktflrceaknysg

		rftcwwlttistdltfsvkssrgssdpqgvtcgaatlsaervrgdnkeyeysve cqedsacpaaeeslpievmvdavhklkyenytssffirdiikpdppknlql kplknsrqvevsweypdtwstphsyfsltfcvqvqgkskrekkdrvftdkt satvicrknasisvraqdryyssswsewasvpcsggggsggggsggggsr nlpvatpdpgmfpclhhsqnllravsnmlqkarqtlefypctseeidhedit kdktstveaclpleltknesclnsretsfitngsclasrktsfmmalclssiyed lkmyqvefktmnakllmdpkrqifldqnmlavidelmqalnfnsetvpq kssleepdfyktkiklcillhafriravtidrvmsylnassggpGPAGLY AQpgsggggsggggsggggsggggsggggsggggsQSVLTQPP SVSGAPGQRVTISCSGSRSNIGeeTVKWYQQLPGT APKLLIYYNDQRPSGVPDRFSGSKSGTSASLAITG LQAEDEADYYCQSYDRYTHPALLFGTGTKVTVLg qpkaapsvtlfppsseelqankatlvclisdfypgavtvawkadsspvkag vetttpskqsnnkyaassylsltpeqwkshrsyscqvthegstvektvapte cs**
37	WW0712 單體IL-12 (嵌合)多肽，抗HSA sdAb，Fab阻斷子，2個裂解位點	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSsggpALFKSSFPpgsiwelkkdvyvveld wypdapgemvvltcdtpeedgitwtldqssevlgsgktltiqvkefgdagq ytchkggevlshsllllhkkedgiwstdilkdqkepknktflrceaknysgrf tcwwlttistdltfsvkssrgssdpqgvtcgaatlsaervrgdnkeyeysvec qedsacpaaeeslpievmvdavhklkyenytssffirdiikpdppknlqlk plknsrqvevsweypdtwstphsyfsltfcvqvqgkskrekkdrvftdkts atvicrknasisvraqdryyssswsewasvpcsggggsggggsggggsrv ipvsgparclsqsrnllkttddmvktareklkhysctaedidheditrdqtstl ktclplelhknesclatretssttrgsclppqktslmmtlclgsiyedlkmyqt efqainaalqnhnhqqiildkgmlvaidelmqslnhngetlrqkppvgea dpyrvkmklcillhafstrvvtinrvmgylssasggpALFKSSFPpgs ggggsggggsggggsggggsggggsggggsQSVLTQPPSVSG APGQRVTISCSGSRSNIGSNTVKWYQQLPGTAPK LLIYYNDQRPSGVPDRFSGSKSGTSASLAITGLQA EDEADYYCQSYDRYTHPALLFGTGTKVTVLgqpka apsvtlfppsseelqankatlvclisdfypgavtvawkadsspvkagvettt pskqsnnkyaassylsltpeqwkshrsyscqvthegstvektvaptecs**
38	WW0713 單體IL-12多肽，抗HSA sdAb，Fab阻斷子，2個裂解位點	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSsggpALFKSSFPpgsiwelkkdvyvveld wypdapgemvvltcdtpeedgitwtldqssevlgsgktltiqvkefgdagq ytchkggevlshsllllhkkedgiwstdilkdqkepknktflrceaknysgrf tcwwlttistdltfsvkssrgssdpqgvtcgaatlsaervrgdnkeyeysvec qedsacpaaeeslpievmvdavhklkyenytssffirdiikpdppknlqlk plknsrqvevsweypdtwstphsyfsltfcvqvqgkskrekkdrvftdkts atvicrknasisvraqdryyssswsewasvpcsggggsggggsggggsrn lpvatpdpgmfpclhhsqnllravsnmlqkarqtlefypctseeidheditk dktstveaclpleltknesclnsretsfitngsclasrktsfmmalclssiyedl

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39	WW0714 單體IL-12 (嵌合)多肽，抗HSA sdAb，Fab阻斷子，2個裂解位點	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSsggpALFKSSFPpgsiwelkkdvyvveld wypdapgemvvltcdtpeedgitwtldqssevlgsgktltiqvkefgdagq ytchkggevlshsllllhkkedgiwstdilkdqkepknktflrceaknysgrf tcwwlttistdltfsvkssrgssdpqgvtcgaatlsaervrgdnkeyeysvec qedsacpaaeeslpievmvdavhklkyenytssffirdiikpdppknlqlk plknsrqvevsweypdtwstphsyfsltfcvqvqgkskrekkdrvftdkts atvicrknasisvraqdryyssswsewasvpcsggggsggggsggggsrv ipvsgparclsqsrnllkttddmvktareklkhysctaedidheditrdqtstl ktclplelhknesclatretssttrgsclppqktslmmtlclgsiyedlkmyqt efqainaalqnhnhqqiildkgmlvaidelmqslnhngetlrqkppvgea dpyrvkmklcillhafstrvvtinrvmgylssasggpALFKSSFPpgs ggggsggggsggggsggggsggggsggggsQSVLTQPPSVSG APGQRVTISCSGSRSNIGSeTVKWYQQLPGTAPKL LIYYNDQRPSGVPDRFSGSKSGTSASLAITGLQAE DEADYYCQSYDRYTHPALLFGTGTKVTVLgqpkaa psvtlfppsseelqankatlvclisdfypgavtvawkadsspvkagvetttps kqsnnkyaassylsltpeqwkshrsyscqvthegstvektvaptecs**
40	WW0715 單體IL-12多肽，抗HSA sdAb，Fab阻斷子，2個裂解位點	EVQLVESGGGLVQPGNSLRLSCAASGFTFSKFGM SWVRQAPGKGLEWVSSISGSGRDTLYAESVKGRF TISRDNAKTTLYLQMNSLRPEDTAVYYCTIGGSLS VSSQGTLVTVSSsggpALFKSSFPpgsiwelkkdvyvveld wypdapgemvvltcdtpeedgitwtldqssevlgsgktltiqvkefgdagq ytchkggevlshsllllhkkedgiwstdilkdqkepknktflrceaknysgrf tcwwlttistdltfsvkssrgssdpqgvtcgaatlsaervrgdnkeyeysvec qedsacpaaeeslpievmvdavhklkyenytssffirdiikpdppknlqlk plknsrqvevsweypdtwstphsyfsltfcvqvqgkskrekkdrvftdkts atvicrknasisvraqdryyssswsewasvpcsggggsggggsggggsrn lpvatpdpgmfpclhhsqnllravsnmlqkarqtlefypctseeidheditk dktstveaclpleltknesclnsretsfitngsclasrktsfmmalclssiyedl kmyqvefktmnakllmdpkrqifldqnmlavidelmqalnfnsetvpqk ssleepdfyktkiklcillhafriravtidrvmsylnassggpALFKSSFP pgsggggsggggsggggsggggsggggsggggsQSVLTQPPSVS GAPGQRVTISCSGSRSNIGSeTVKWYQQLPGTAPK LLIYYNDQRPSGVPDRFSGSKSGTSASLAITGLQA EDEADYYCQSYDRYTHPALLFGTGTKVTVLgqpka

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【發明申請專利範圍】

【請求項1】

一種組合，其包含治療有效量的：(i)誘導型細胞激素前藥，其包含細胞激素多肽[A]、阻斷元件[D]、視情況存在之半衰期延長元件[H]及蛋白酶可裂解的多肽連接子；及(ii)抗PD-1抗體或抗PD-L1抗體，其用於治療有需要個體之癌症；

其中該細胞激素多肽及該細胞激素阻斷元件及該視情況存在之半衰期延長元件在存在時，係藉由該蛋白酶可裂解的多肽連接子以可操作方式連接，且該誘導型細胞激素前藥具有減弱的細胞激素受體活化活性，其中該誘導型細胞激素前藥的該細胞激素-受體活化活性比含有藉由裂解該蛋白酶可裂解連接子產生之該細胞激素多肽之該多肽的該細胞激素受體活化活性低至少約10倍。

【請求項2】

一種治療個體之癌症的方法，其包含向有需要之該個體投與治療有效量的(i)包含細胞激素多肽[A]、阻斷元件[D]、視情況存在之半衰期延長元件[H]及蛋白酶可裂解的多肽連接子的誘導型細胞激素前藥；及(ii)抗PD-1抗體或抗PD-L1抗體；

其中該細胞激素多肽及該細胞激素阻斷元件及該視情況存在之半衰期延長元件在存在時，係藉由該蛋白酶可裂解的多肽連接子以可操作方式連接，且該誘導型細胞激素前藥具有減弱的細胞激素受體活化活性，其中該誘導型細胞激素前藥的該細胞激素-受體活化活性比含有藉由裂解該蛋白酶可裂解連接子產生之該細胞激素多肽之該多肽的該細胞激素受體活化活性低至少約10倍。

【請求項3】

如請求項1之用途或如請求項2之方法，其中該細胞激素多肽為IL-2、IL-12、干擾素α、干擾素β、干擾素γ或突變蛋白(mutein)，或前述任一者之活性片段。

【請求項4】

如請求項3之用途或方法，其中該細胞激素多肽為IL-2或突變蛋白、變異體、活性片段，或前述任一者之次單元。

【請求項5】

如請求項3之用途或方法，其中該細胞激素多肽為IL-12或突變蛋白、變異體、活性片段，或前述任一者之次單元。

【請求項6】

如請求項3之用途或方法，其中該細胞激素多肽為干擾素α、干擾素β、干擾素γ或突變蛋白，或前述任一者之活性片段。

【請求項7】

如前述請求項中任一項之用途或方法，其中該誘導型細胞激素前藥具有下式：

[A]-[L1]-[H]-[L2]-[D]

[D]-[L2]-[H]-[L1]-[A]

[A]-[L1]-[D]-[L2]-[H]

[H]-[L2]-[D]-[L1]-[A]

[H]-[L1]-[A]-[L2']-[D]

[D]-[L1]-[A]-[L2']-[H]

其中A為細胞激素多肽，D為阻斷部分，H為半衰期延長部分，L1為

蛋白酶可裂解的多肽連接子，L2為視情況蛋白酶可裂解的多肽連接子，且L2'為蛋白酶可裂解的多肽連接子。

【請求項8】

如前述請求項中任一項之用途或方法，其中該誘導型細胞激素前藥為單一多肽鏈。

【請求項9】

如請求項1至8中任一項之用途或方法，其中該誘導型細胞激素前藥包含至少兩條多肽鏈。

【請求項10】

如請求項1至8中任一項之用途或方法，其中該誘導型細胞激素前藥包含至少三條多肽鏈。

【請求項11】

如前述請求項中任一項之用途或方法，其中該細胞激素多肽包含化合物1、化合物2、化合物3、化合物4或前述之胺基酸序列變異體。

【請求項12】

如請求項11之用途或方法，其中a)化合物1包含SEQ ID NO:1之第一多肽鏈及SEQ ID NO:5之第二多肽鏈，且化合物1之該胺基酸序列變異體包含與SEQ ID NO:1具有至少約80%一致性之第一多肽鏈及與SEQ ID NO:5具有至少約80%一致性之第二多肽鏈；b)化合物2包含SEQ ID NO:2之第一多肽鏈及SEQ ID NO:5之第二多肽鏈，且化合物2之該胺基酸序列變異體包含與SEQ ID NO:2具有至少約80%一致性之第一多肽鏈及與SEQ ID NO:5具有至少約80%一致性之第二多肽鏈；C)化合物3包含SEQ ID NO:3之第一多肽鏈及SEQ ID NO:5之第二多肽鏈，且化合物3之該胺基酸

序列變異體包含與SEQ ID NO:3具有至少約80%一致性之第一多肽鏈及與SEQ ID NO:5具有至少約80%一致性之第二多肽鏈；及c)化合物4包含SEQ ID NO:1之第一多肽鏈及SEQ ID NO:4之第二多肽鏈，且化合物4之該胺基酸序列變異體包含與SEQ ID NO:4具有至少約80%一致性之第一多肽鏈及與SEQ ID NO:5具有至少約80%一致性之第二多肽鏈。

[請求項12]

如請求項1至9中任一項之用途或方法，其中該細胞激素多肽為化合物5、化合物6、化合物7、化合物8、化合物9或化合物10或前述之胺基酸序列變異體。

【請求項13】

如請求項12之用途或方法，其中a)化合物5包含SEQ ID NO: 6之第一多肽鏈及SEQ ID NO:12之第二多肽鏈，且化合物5之該胺基酸序列變異體包含與SEQ ID NO: 6具有至少約80%一致性之第一多肽鏈及與SEQ ID NO: 12具有至少約80%一致性之第二多肽鏈；b)化合物6包含SEQ ID NO: 7之第一多肽鏈及SEQ ID NO: 12之第二多肽鏈，且化合物6之該胺基酸序列變異體包含與SEQ ID NO:7具有至少約80%一致性之第一多肽鏈及與SEQ ID NO: 12具有至少約80%一致性之第二多肽鏈；C)化合物7包含SEQ ID NO: 8之第一多肽鏈及SEQ ID NO: 13之第二多肽鏈，且化合物7之該胺基酸序列變異體包含與SEQ ID NO: 8具有至少約80%一致性之第一多肽鏈及與SEQ ID NO: 13具有至少約80%一致性之第二多肽鏈；c)化合物8包含SEQ ID NO: 9之第一多肽鏈及SEQ ID NO: 13之第二多肽鏈，且化合物8之該胺基酸序列變異體包含與SEQ ID NO: 9具有至少約80%一致性之第一多肽鏈及與SEQ ID NO: 13具有至少約80%一致性之第二多肽鏈；d)化

合物9包含SEQ ID NO: 10之第一多肽鏈及SEQ ID NO: 13之第二多肽鏈，且化合物9之該胺基酸序列變異體包含與SEQ ID NO: 10具有至少約80%一致性之第一多肽鏈及與SEQ ID NO: 13具有至少約80%一致性之第二多肽鏈；及e)化合物10包含SEQ ID NO: 11之第一多肽鏈及SEQ ID NO: 13之第二多肽鏈，且化合物10之該胺基酸序列變異體包含與SEQ ID NO: 11具有至少約80%一致性之第一多肽鏈及與SEQ ID NO: 13具有至少約80%一致性之第二多肽鏈。

【請求項14】

如請求項1至9中任一項之用途或方法，其中該誘導型細胞激素前藥包含選自SEQ ID NO 14-20之胺基酸或與SEQ ID NO 14-20具有至少約80%一致性之胺基酸序列。

【請求項15】

如前述請求項中任一項之用途或方法，其中投與抗PD-1抗體。

【請求項16】

如請求項15之用途或方法，其中該抗PD-1抗體係選自由以下組成之群：AMP-224 (AstraZenica)、609A (3SBio)、704 (3SBio)、705 (3SBio)、ABBV-181 (AbbVie)、ADU-1503 / bion-004 (Chinook Therapeutics)、AGEN2034 /巴提利單抗(balstilimab) (Agenus)、AK103 (Akeso)、AK104 (Akeso)、AK112 (Akeso)、AK123 (Akeso)、AMG 256 (Amgen)、AMG 404 (Amgen)、ANB030 (AnaptysBio)、ANKEBIO抗PD1產品(Anhui Anke Biotechnology)、抗PD-1 /抗CD47 (DiNonA)、ASKG915 (Ask Gene Pharmaceuticals)、AV-MEL-1 (Aivita Biomedical)、BCD-100 (Biocad CJSC)、BI 754091 (Boehringer

Ingelheim)、BiCKI-IL-7 (OSE Immunotherapeutics)、Boehringer-PD-1-未知(unknown) (Boehringer Ingelheim)、BSK-050K01 (Biosion)、坎立珠單抗(Camrelizumab) (Jiangsu Hengrui Medicine)、CB201 (Crescendo Biologics)、CB213 (Crescendo Biologics)、CC-90006 (AnaptsBio)、賽曲利單抗(cetrelimab) (J&J)、chPD1 (Kiromic Biopharma)、CMAB819 (Mabpharm)、CS1003 (CStone Pharmaceuticals)、CS17938 (Shenzhen Chipscreen Biosciences)、CTX-8371 (Compass Therapeutics)、CX-072 (CytomX Therapeutics)、CX-188 (CytomX Therapeutics)、帕利珠單抗(palivizumab) (Harbin Gloria Pharmaceuticals)、DB004 (DotBio)、EMB02 (EpimAb Biotherapeutics)、蓋普坦單抗(Geptanblimab) /傑諾珠單抗(genolimzumab) (Apollomics)、GS19 (Suzhou Zelgen Biopharmaceuticals)、HLX10 (Shanghai Henlius Biotech)、HX008 (Taizhou HanZhong Pharmaceuticals)、HY003 (Juventas Cell Therapy)、IBI315 / BH2950 (Innovent Biologics)、IBI318 (Innovent Biologics)、IBI319 (Innovent Biologics)、IMM1802 (ImmuneOnco Biopharma)、IMT200 (TrueBinding)、Jemperli / 多斯利單抗(dostarlimab)(AnaptysBio)、JTX-4014 (Jounce Therapeutics)、Keytruda / 帕博利珠單抗(pembrolizumab) (Merck)、LBL-006 (Nanjing Leads Biolabs)、Libtayo / 測米匹單抗(cemiplimab)-rwlc (Regeneron Pharmaceuticals)、LVGN3616 (Lyvgen Biopharma)、LXF821 (Novartis)、LY01015 (Luye Pharma Group)、LY3462817 (Eli Lilly)、MCLA-134 (Merus N.V.)、MEDI5752 (AstraZenica)、NIR178 (Novartis)、ONCR-177 (Oncorus)、ONO-4685 (Ono Pharmaceutical)、

Opdivo /納武利尤單抗(nivolumab) (Ono Pharmaceutical)、MGD019 (MacroGenius)、PD1-GDT CAR-T (Kiromic Biopharma)、派安普利單抗(penpulimab) (Akeso)、PSB205 (Qilu Puget Sound Biotherapeutics)、PT-001 (Merck)、PT627 (Merck)、RB-M1 (Refuge Biotechnologies)、瑞弗利單抗(Retifanlimab) (MacroGenics)、RG6139 (Roche)、RG6279 (Roche)、RTX-002 (RubrYc Therapeutics)、薩桑利單抗(sasanlimab) (Pfizer)、Servier-PD1xLAG3-未知(Servier)、SL-279252 / TAK-252 (Shattuck Labs)、Sofusa抗-PD1 (Sorrento Therapeutics)、斯帕塔利單抗(spartalizumab) (Novartis)、SSI-361 (Lyvgen Biopharma)、Sym021 (Servier)、特泊利單抗(Tebotelimab) (MacroGenics)、緹勒珠單抗(tislelizumab) (BeiGene)、TSR-075 (AnaptsBio)、Tuhura-DO/PD-1-未知(Tuhura Biopharma)、特瑞普利單抗(Shanghai Junshi Biosciences)、斯迪利單抗(sintilimab) (Innovent Biologics)、Unicar-CAR-T&PD-1-未知(Shanghai Unicar-Therapy Bio-Medicine Technology)、Xdivane (Xbrane Biopharma)、XmAb20717 (Xencor)、XmAb23104 (Xencor)、YBL-006 (Y-Biologics)、賽帕利單抗(zimberelimab) (Arcus Biosciences)。

【請求項17】

如請求項16之用途或方法，其中該抗PD-1抗體為帕博利珠單抗、多斯利單抗、測米匹單抗-rwlc、納武利尤單抗、坎立珠單抗、緹勒珠單抗、特瑞普利單抗、斯迪利單抗或前述任一者之生物類似物。

【請求項18】

如請求項1至17中任一項之用途或方法，其中投與抗PD-L1抗體。

【請求項19】

如請求項18之用途或方法，其中該抗PD-L1抗體係選自由以下組成之群：A167 (Sichuan Kelun)、ABL501 (ABL Bio)、ABL503 (ABL Bio)、ABSK041 (Abbisko Therapeutics)、ACE1708 (Acepodia)、ACE-NK-PDL1 (Acepodia)、ADG104 (Adagene)、AK106 (Akeso)、ALPN-202 (Alpine Immune Sciences)、AN4005 (Adlai Nortye Biopharma)、BMS-936559 / MDX-1105 (BMS)、APL-502 / TQB2450 (Apollomics)、Arbutus-PD-L1-未知(Arbutus Biopharma)、ASC22 (Ascletis Pharma)、ATG-101 (Antengene)、AVA-004 (Avacta Group)、AVA021 (Avacta Group)、AVA027 (Avacta Group)、AVA-040-100 (Avacta Group)、AVA04-Vbp (Avacta Group)、Bavencio /阿維魯單抗(avelumab) (Merck)、BCD-135 (Biocad CJSC)、BGB-A333 (BeiGene)、Bintrafusp alfa / GSK4045154 (Merck)、CA-170 / aupm-170 (Dr. Reddy's Laboratories)、CCX559 (ChemoCentryx)、CDR101 (CDR-Life)、柯希利單抗(cosibelimab) (Checkpoint Therapeutics)、CTX-8371 (Compass Therapeutics)、DiNonA-實體腫瘤-未知(DiNonA)、DR30207 (Zhejiang Doer Biologics)、DuoBody-PD-L1x4-1BB (Ligand Pharmaceuticals)、恩沃利單抗(envafolimab) (Alphamab Oncology)、EPIM-001 (Elpis Biopharmaceuticals)、ES101 (Elpiscience Biopharma)、INBRX-105 (Inhibrx)、FAZ053 (Novartis)、FS118 (F-star Therapeutics)、GB262 (Genor Biopharma)、GS-4224 (Gilead)、GT900008 (Kintor Pharmaceuticals)、GX-P2 (Genexine)、Hamni-PS-L1/CD47-未知(Hanmi Pharmaceutical)、HBM7015 (HBM Holdings)、HBM9167 (HBM Holdings)、HLX20 (Shanghai Henlius Biotech)、HTI-1088 (Jiangsu

Hengrui Medicine)、IBI318 (Innovent Biologics)、IBI322 (Innovent Biologics)、IBI323 (Innovent Biologics)、IGM-7354 (IGM Biosciences)、IMC-001 (Sorrento Therapeutics)、Imfinzi /德瓦魯單抗(durvalumab) (AstraZenica)、IMM25 (ImmuneOnco Biopharma)、IMM2502 (ImmuneOnco Biopharma)、IMM2503 (ImmuneOnco Biopharma)、IMM2504 (ImmuneOnco Biopharma)、INCB86550 (Incyte)、IO103 (IO Biotech)、JS003 (Shanghai Junshi Biosciences)、Jubilant-PD-L1- 未知 (Jubilant Therapeutics)、KD033 (Kadmon Holdings)、KN046 (Alphamab Oncology)、KY1003 (Sanofi)、KY1043 (Sanofi)、LY3300054 (Eli Lilly)、LY3415244 (Eli Lilly)、MRNA-6981 (Moderna)、MSB2311 (Transcenta Holding)、MT-6035 (Molecular Templates)、ND021 / NM21-1480 (Numab Therapeutics)、OX001R (Oxford BioTherapeutics)、基於PD-L1之BsAb (I-Mab)、PD-L1 Boltbody ISAC (Bolt Biotherapeutics)、PDL-GEX (Glycotope GmbH)、PMC-122 (PharmAbcine)、PMI06 (D&D Pharmatech)、Protheragen-RV-scFv-PDL1-未知(Protheragen)、PRS-344 (Pieris Pharmaceuticals)、Q-1802 (Merck)、RC98 (Yantai Rongchang Pharmaceutical)、RV-scFv-PDL1 (Protheragen)、SenI_TAAx22P (Hebei Senlang Biotechnology)、SHC020 (Nanjing Sanhome Pharmaceutical)、舒格利單抗(sugemalimab) (Ligand Pharmaceuticals)、阿特珠單抗(atezolizumab) (Roche)、TST005 (Transcenta Holding)、TT-01 (Topmunnity Therapeutics)、TTX-siPDL1 (TransCode Therapeutics)、UniCAR-T-PD-L1 (GEMoaB monoclonals)、Vaximm (VXM10)及YBL-013 (Y-Biologics)。

【請求項20】

如請求項19之用途或方法，其中該抗PD-1抗體為阿維魯單抗、德瓦魯單抗、阿特珠單抗或前述任一者之生物類似物。

【請求項21】

如前述請求項中任一項之用途或方法，其中該半衰期延長元件為人類血清白蛋白、結合人類血清白蛋白之抗原結合多肽、或免疫球蛋白Fc、或其片段。

【請求項22】

如前述請求項中任一項之用途或方法，其中該蛋白酶可裂解連接子包含能夠藉由選自以下之蛋白酶裂解的序列：激肽釋放素(kallikrein)、凝血酶、凝乳酶、羧肽酶A、組織蛋白酶(cathepsin)、彈性蛋白酶、PR-3、顆粒酶M (granzyme M)、鈣蛋白酶(calpain)、基質金屬蛋白酶(matrix metalloproteinase) (MMP)、ADAM、FAP、纖維蛋白溶酶原活化因子、凋亡蛋白酶(caspase)、類胰蛋白酶(tryptase)或腫瘤蛋白酶。

【請求項23】

如前述請求項中任一項之用途或方法，其中該蛋白酶係選自組織蛋白酶B、組織蛋白酶C、組織蛋白酶D、組織蛋白酶E、組織蛋白酶K、組織蛋白酶L或組織蛋白酶G。

【請求項24】

如前述請求項中任一項之用途或方法，其中蛋白酶係選自基質金屬蛋白酶(MMP)，其為MMP1、MMP2、MMP3、MMP8、MMP9、MMP10、MMP11、MMP12、MMP13或MMP14。

【請求項25】

如前述請求項中任一項之用途或方法，其中該阻斷元件結合該細胞激素多肽。

【請求項26】

如前述請求項中任一項之用途或方法，其中該阻斷元件包含IFN之同族受體的配位體結合域或片段、結合於IFN多肽之抗體或抗體之抗原結合片段。

【請求項27】

如前述請求項中任一項之用途或方法，其中該抗體或抗原結合片段係結合該IFN多肽之單域抗體、Fab或scFv。

【請求項28】

如前述請求項中任一項之用途或方法，其中該誘導型細胞激素前藥在該抗PD-1抗體或該抗PD-L1抗體之前、與其同時或在其之後投與。

【請求項29】

如前述請求項中任一項之用途或方法，其中該癌症為腎上腺皮質癌、肛門癌、闌尾癌、星形細胞瘤、基底細胞癌、腦瘤、膽管癌、膀胱癌、骨癌、乳癌、支氣管腫瘤、原發性不明癌(carcinoma of unknown primary origin)、心臟腫瘤、子宮頸癌、脊索瘤、大腸癌、大腸直腸癌、顱咽管瘤、乳管癌(ductal carcinoma)、胚胎細胞瘤、子宮內膜癌、室管膜瘤、食道癌、敏感性神經胚細胞瘤、纖維組織細胞瘤、尤文氏肉瘤(Ewing sarcoma)、眼癌、生殖細胞腫瘤、膽囊癌、胃癌、胃腸類癌腫瘤、胃腸基質腫瘤、妊娠期滋養細胞疾病(gestational trophoblastic disease)、神經膠質瘤、頭頸癌、肝細胞癌、組織細胞增生症、下咽癌(hypopharyngeal cancer)、眼內黑色素瘤、胰島細胞腫瘤、卡波西氏肉瘤

(Kaposi sarcoma)、腎癌、蘭格罕細胞組織球增多症(Langerhans cell histiocytosis)、喉癌(laryngeal cancer)、唇及口腔癌、肝癌、小葉原位癌、肺癌、巨球蛋白血症、惡性纖維組織細胞瘤、黑色素瘤、梅克爾細胞癌(Merkel cell carcinoma)、間皮瘤、具有隱性原發性之轉移性鱗狀頸癌、涉及NUT基因之中線癌(midline tract carcinoma)、口癌、多發性內分泌瘤症候群、蕈樣黴菌病(mycosis fungoide)、骨髓發育不良症候群、骨髓發育不良/骨髓增生性腫瘤、鼻腔及副鼻竇癌、鼻咽癌、神經母細胞瘤、非小細胞肺癌、口咽癌、骨肉瘤、卵巢癌、胰臟癌、乳頭狀瘤症、副神經節瘤、副甲狀腺癌、陰莖癌、咽癌、嗜鉻細胞瘤、垂體腫瘤、胸膜肺母細胞瘤、前列腺癌、直腸癌、腎細胞癌、腎盂及尿管癌、視網膜母細胞瘤、橫紋肌瘤、唾液腺癌、塞紮萊症候群(Sezary syndrome)、皮膚癌、小細胞肺癌、小腸癌、軟組織肉瘤、脊髓腫瘤、胃癌、T細胞淋巴瘤、類畸胎瘤、睪丸癌、咽喉癌(throat cancer)、胸腺瘤及胸腺癌、甲狀腺癌、尿道癌、子宮癌、陰道癌、外陰癌及威爾姆氏瘤(Wilms tumor)。

【請求項30】

如請求項29之用途或方法，其中該癌症為大腸癌、肺癌、黑色素瘤、腎細胞癌或乳癌。

【請求項31】

如請求項29之用途或方法，其中該癌症可為黑色素瘤、非小細胞肺癌(NSCLC)、小細胞肺癌(SCLC)、頭頸部鱗狀細胞癌(HNSCC)、典型何傑金氏淋巴瘤(classical Hodgkin lymphoma，cHL)、原發性縱隔大B細胞淋巴瘤(PMBCL)、尿道上皮癌、高度微衛星不穩定性或錯配修復缺陷型癌症(microsatellite instability high or mismatch repair deficient cancer)、

高度微衛星不穩定性或錯配修復缺陷型大腸直腸癌、胃癌、食道癌、子宮頸癌、肝細胞癌(HCC)、梅克爾細胞癌(MCC)、腎細胞癌(RCC)、子宮內膜癌、高度腫瘤突變負荷癌症(tumor mutational burden high cancer)、皮膚鱗狀細胞癌(cSCC)、三陰性乳癌(TNBC)、大腸直腸癌或食道癌瘤。

【請求項32】

如請求項29之用途或方法，其中該癌症為轉移性腎透明細胞癌或轉移性皮膚惡性黑色素瘤。

【請求項33】

一種醫藥組合物，其包含該誘導型細胞激素前藥、抗PD-1抗體或抗PD-L1抗體及適合載劑。

【請求項34】

如請求項33之醫藥組合物，其中該組合物為用於靜脈內投與之液體組合物。

【請求項35】

如請求項33之醫藥組合物，其中該組合物為凍乾組合物。

【請求項36】

如請求項35之醫藥組合物，其中該凍乾組合物係用於使用水復原以獲得適合靜脈內投與之調配物。

【請求項37】

如請求項1至32中任一項之用途、方法或組合物，其中該癌症為淋巴瘤。

【請求項38】

如請求項37之用途、方法或組合物，其中該淋巴瘤為B細胞淋巴瘤或

T細胞淋巴瘤。

【請求項39】

如請求項37之用途、方法或組合物，其中該淋巴瘤為非何傑金氏淋巴瘤或何傑金氏淋巴瘤。

【請求項40】

如請求項37之用途、方法或組合物，其中該淋巴瘤為彌漫性大B細胞淋巴瘤、原發性縱隔B細胞淋巴瘤、濾泡性淋巴瘤、小淋巴球性淋巴瘤、慢性淋巴球性白血病、邊緣區淋巴瘤、被套細胞淋巴瘤、瓦爾登斯特倫氏巨球蛋白血症(Waldenstrom's macroglobulinemia)、伯基特淋巴瘤(Burkitt lymphoma)、周邊T細胞淋巴瘤、退行性大細胞淋巴瘤、血管免疫母細胞性淋巴瘤、皮膚T細胞淋巴瘤、中樞神經系統淋巴瘤、灰區淋巴瘤(grey zone lymphoma)、雙重打擊淋巴瘤(double hit lymphoma)、三重打擊淋巴瘤(triple hit lymphoma)、未列名(not otherwise specified)之高級別B細胞淋巴瘤、淋巴母細胞淋巴瘤、淋巴漿細胞淋巴瘤、MALT淋巴瘤、單核球樣B細胞淋巴瘤、自然殺手(NK)細胞淋巴瘤、蕈樣黴菌病、塞紮萊症候群、腸病型T細胞淋巴瘤或肝脾γ/δ T細胞淋巴瘤。

【請求項41】

一種用於治療淋巴瘤之方法，其包含向有需要之個體投與有效量的誘導型細胞激素前藥。

【請求項42】

一種用於治療淋巴瘤的誘導型細胞激素前藥。

【請求項43】

如請求項41或42之方法或用途，其中該誘導型細胞激素前藥為誘導

型IL-12前藥或誘導型IFNα前藥。

【請求項44】

如請求項41或42之方法或用途，其中該淋巴瘤為B細胞淋巴瘤或T細胞淋巴瘤。

【請求項45】

如請求項41或42之方法或用途，其中該淋巴瘤為非何傑金氏淋巴瘤或何傑金氏淋巴瘤。

【請求項46】

如請求項41或42之方法或用途，其中該淋巴瘤為彌漫性大B細胞淋巴瘤、原發性縱隔B細胞淋巴瘤、濾泡性淋巴瘤、小淋巴球性淋巴瘤、慢性淋巴球性白血病、邊緣區淋巴瘤、被套細胞淋巴瘤、瓦爾登斯特倫氏巨球蛋白血症、伯基特淋巴瘤、周邊T細胞淋巴瘤、退行性大細胞淋巴瘤、血管免疫母細胞性淋巴瘤、皮膚T細胞淋巴瘤、中樞神經系統淋巴瘤、灰區淋巴瘤、雙重打擊淋巴瘤、三重打擊淋巴瘤、未列名之高級別B細胞淋巴瘤、淋巴母細胞淋巴瘤、淋巴漿細胞淋巴瘤、MALT淋巴瘤、單核球樣B細胞淋巴瘤、自然殺手(NK)細胞淋巴瘤、蕈樣黴菌病、塞紮萊症候群、腸病型T細胞淋巴瘤或肝脾γ/δ T細胞淋巴瘤。

圖(發明圖式)

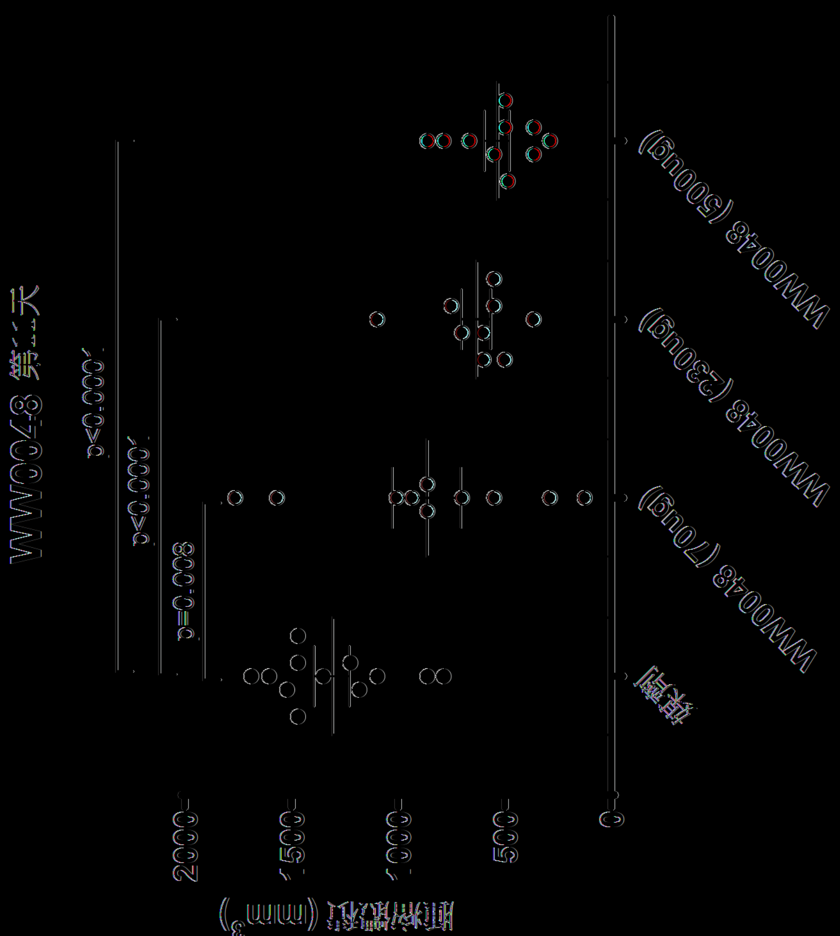
圖 7(A)

圖 7(B)

圖 7(C)

圖 7(D)

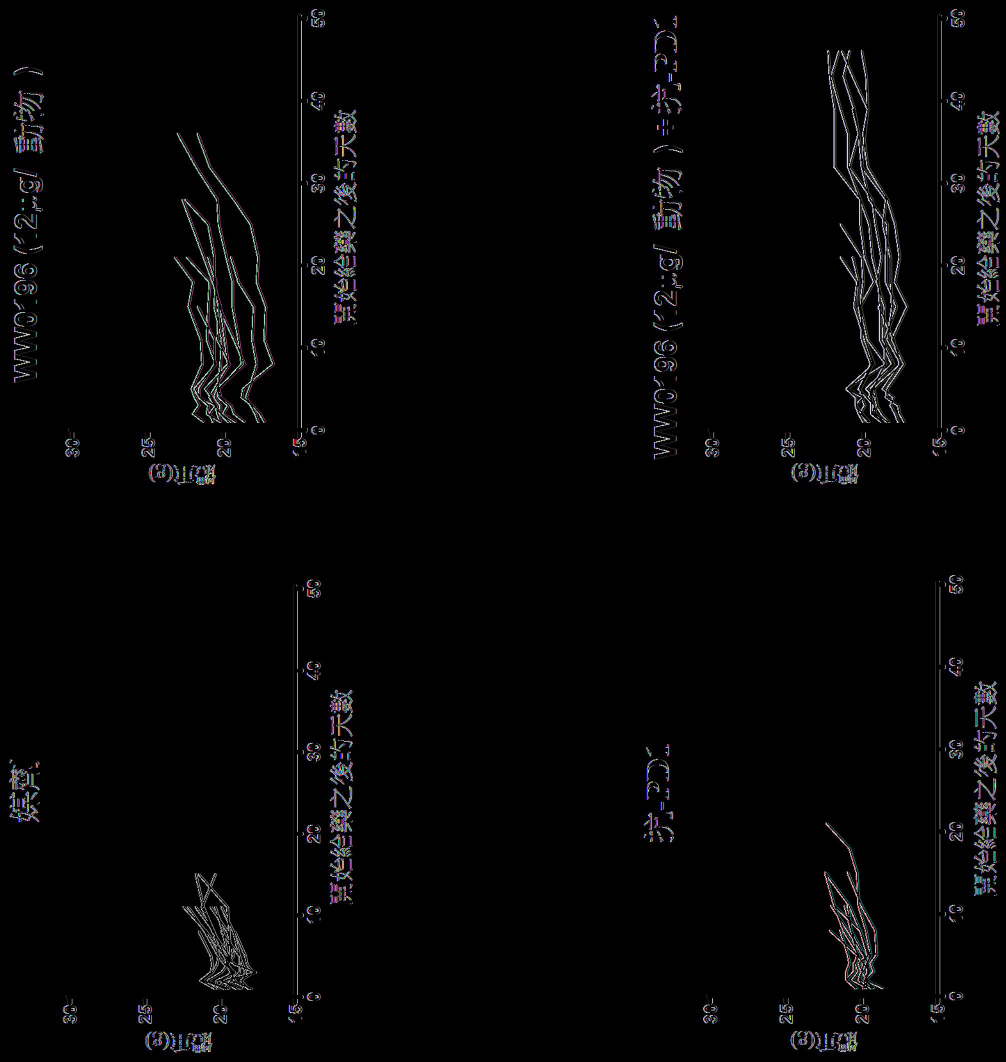
第2D圖
腫瘤體積(mm³)
試驗結束之後的天數
第2E圖
腫瘤體積(mm³)
試驗結束之後的天數
第2F圖
腫瘤體積(mm³)
試驗結束之後的天數
第2G圖
腫瘤體積(mm³)
試驗結束之後的天數
第2H圖
腫瘤體積(mm³)
試驗結束之後的天數
第2I圖
腫瘤體積(mm³)
試驗結束之後的天數


WW0048 第11天
p<0.0001
p<0.0001
p=0.008
腫瘤體積 (mm³)
2000
1500
1000
500
0
媒劑
WW0048 (70ug)
WW0048 (230ug)
WW0048 (500ug)

【圖13】

WW0048 (500mg/kg 對照)
WW0048 (230mg/kg 對照)
WW0048 (70mg/kg 對照)
WW0048 (500mg/kg 非洛昔考)
WW0048 (230mg/kg 非洛昔考)
WW0048 (70mg/kg 非洛昔考)
體重(g)
最近給藥之後的天數

（圖2A）

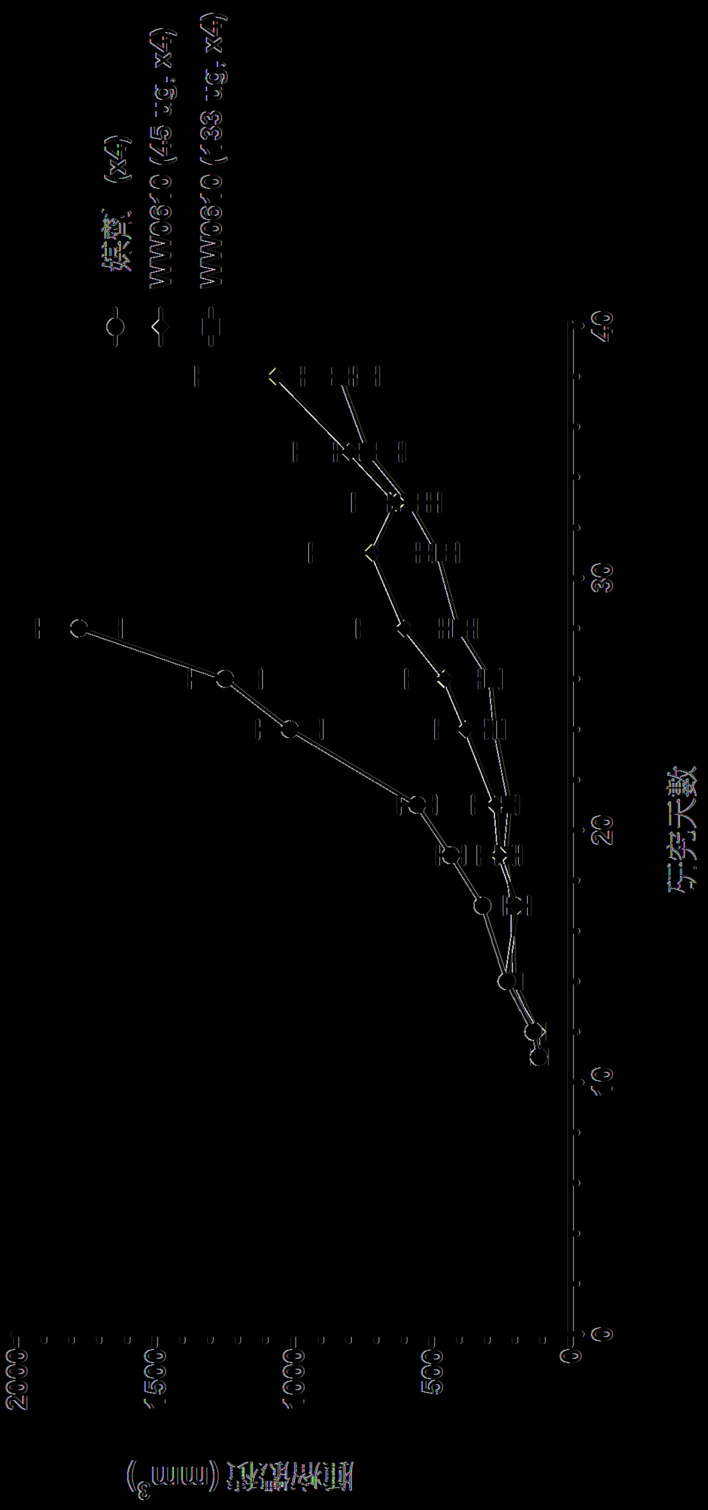


【圖23】

待測物
待測物
Roller
(mm)

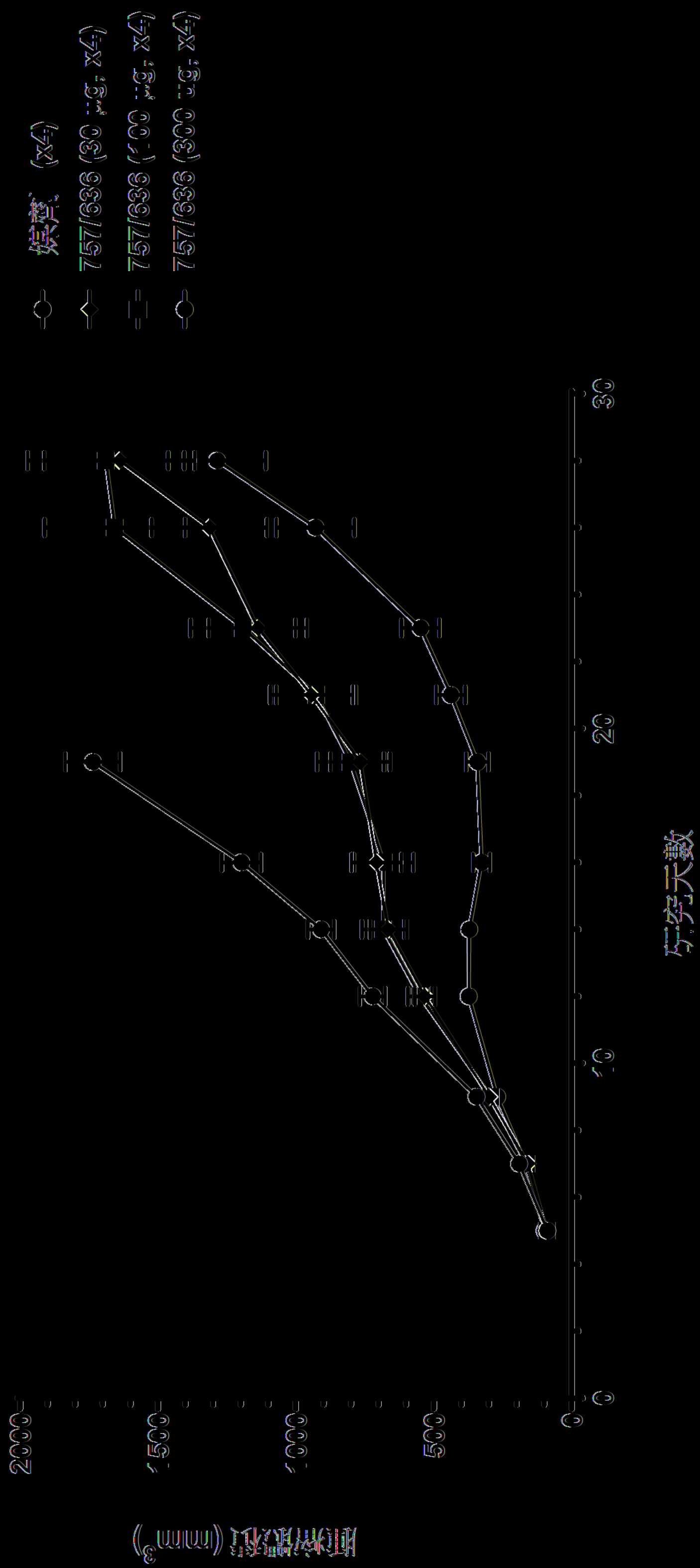

媒劑 (x4)
757/636 (30 μg; x4)
757/636 (100 μg; x4)
757/636 (300 μg; x4)
腫瘤體積 (mm³)
2000
1500
1000
500
0
0
10
20
30
40
研究天數

【圖5A】



腫瘤體積 (mm³)
2000
1500
1000
500
0
0
10
20
30
40
研究天數
媒劑 (x4)
WW0610 (4.5 μg, x4)
WW0610 (1.33 μg, x4)

【圖53】


媒劑 (x4)
757/836 (30 μg; x4)
757/836 (100 μg; x4)
757/836 (300 μg; x4)
腫瘤體積 (mm³)
2000
1500
1000
500
0
0
10
20
30
研究天數

【圖6A】

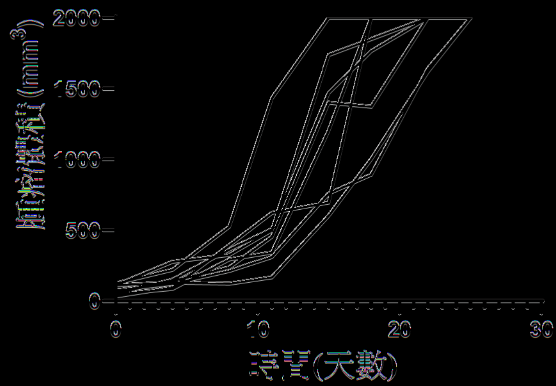

腫瘤體積 (mm³)
2000
1500
1000
500
0
0
10
20
30
40
研究天數
媒劑 (x4)
WW0610 (45 μg, x4)
WW0610 (133 μg, x4)

【圖63】


CT26
腫瘤體積(mm3)
2000
1500
1000
500
0
0
10
20
30
αPD-1
WW0621/WW0523
時間(天數)
媒劑
WW0621/WW0523
抗-PD-1
WW0621/WW0523 + 抗-PD-1

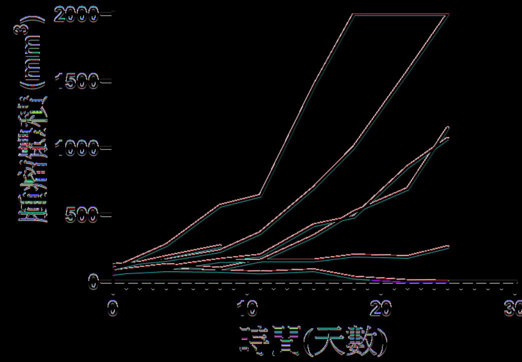
【圖7A】

媒劑



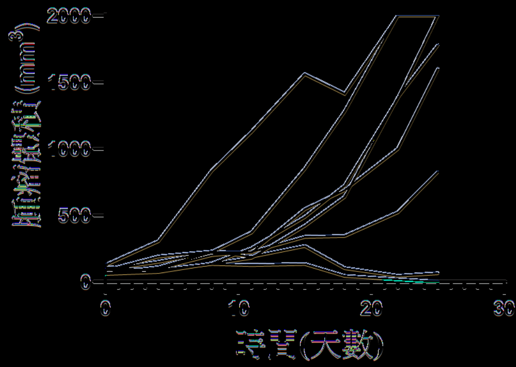
【圖7B】

WW0621/WW0523



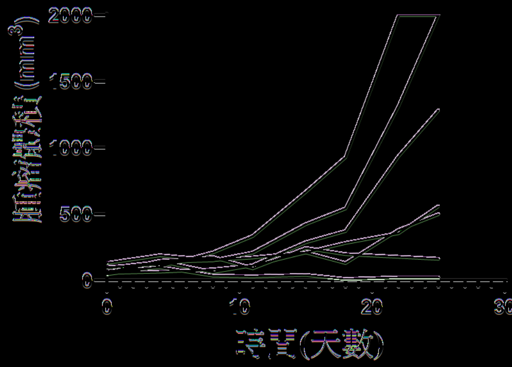
【圖7C】

抗-PD-1

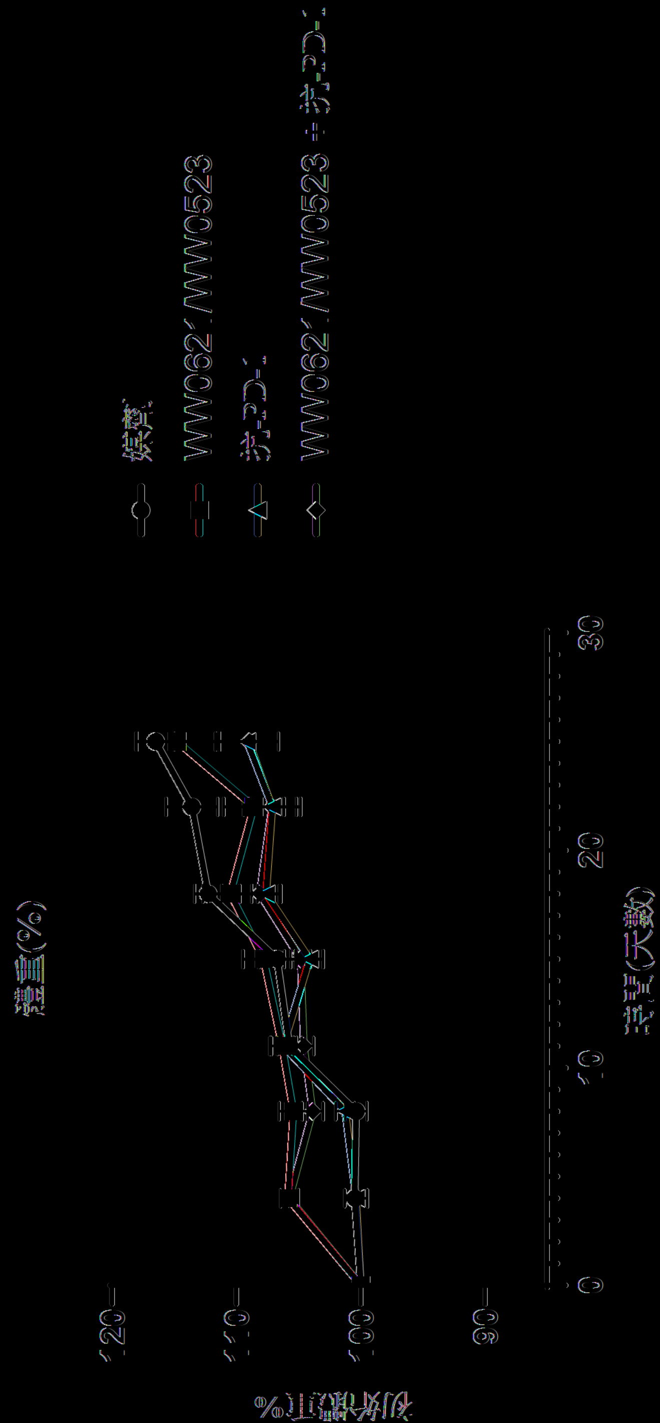


【圖7D】

WW0621/WW0523 + 抗-PD-1



【圖7E】


體重(%)
初始體重%
120
110
100
90
0
10
20
30
時間(天數)
媒劑
WW0621/WW0523
抗-PD-1
WW0621/WW0523 + 抗-PD-1

【圖7F】