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(54)名稱

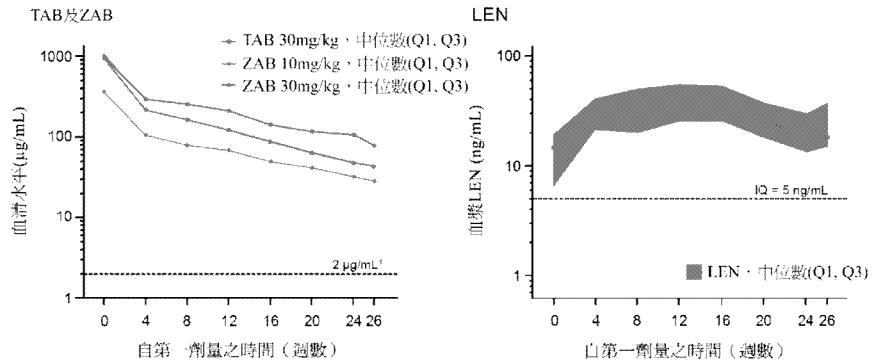
用於廣泛中和抗體之給藥及排程方案

(57)摘要

提供用於每年兩次，例如 Q6M、Q24W、Q25W、或 Q26W 投予長效抗 HIV 廣泛中和抗體之方法。

Provided are methods for administering long-acting anti-HIV broadly neutralizing antibodies twice annually, e.g., Q6M, Q24W, Q25W or Q26W.

指定代表圖：



【圖2】

202408576

【發明摘要】

【中文發明名稱】　用於廣泛中和抗體之給藥及排程方案

【英文發明名稱】　DOSING AND SCHEDULING REGIMEN FOR BROADLY NEUTRALIZING ANTIBODIES

【中文】

提供用於每年兩次，例如Q6M、Q24W、Q25W、或Q26W投予長效抗HIV廣泛中和抗體之方法。

【英文】

Provided are methods for administering long-acting anti-HIV broadly neutralizing antibodies twice annually, *e.g.*, Q6M, Q24W, Q25W or Q26W.

【指定代表圖】圖2

【代表圖之符號簡單說明】無

【特徵化學式】無

【發明說明書】

【中文發明名稱】　用於廣泛中和抗體之給藥及排程方案

【英文發明名稱】　DOSING AND SCHEDULING REGIMEN FOR BROADLY NEUTRALIZING ANTIBODIES

【技術領域】

無

【先前技術】

【0001】　人類免疫缺乏病毒第1型(Human immunodeficiency virus type 1, HIV-1)感染會導致嚴重的危及生命之疾病，且仍然是全球發病率及死亡率的主因之一。在美國(United States, US)，存在大約1百萬人患有HIV (people with HIV, PWH)感染，且全球有超過3800萬名(UNAIDS.Fact Sheet - Global HIV Statistics 2021)。HIV之抗反轉錄病毒(ARV)療法(antiretroviral therapy, ART)之進展藉由抑制病毒複製、保存免疫功能、及避免疾病進展為AIDS，顯著改善了發病率及死亡率。然而，目前治療策略已無法消除病毒並且治癒HIV-1感染。

【0002】　雖然用於治療HIV-1感染之當前組合ART係有效且良好耐受的，但此等藥劑需要每天服用，且需要接近完美的依從性以最小化耐藥變體之出現。因此，在接受慢性或終生治療之患者中，可發生「治療疲勞(treatment fatigue)」，定義為「在依從治療方案時維持警惕之慾望及動力下降(decreased desire and motivation to maintain vigilance in adhering to a treatment regimen)」(Claborn, *et al.*, *Psychol Health Med* (2015) 20(3):255-65)，其可導致不依從及治療失敗。因此，仍然存在顯著的對於可以較低頻率投予之ARV（亦即長效藥物產品）之醫療需求，從而為HIV-1感染個體提供替代治療選項。

【0003】 利那卡帕韋(lenacapavir)係靶向治療HIV-1感染之HIV-1殼體功能之新穎、一流、多階段的選擇性抑制劑。利那卡帕韋具有與任何批准產品均無重疊抗性之強效抗病毒活性。其人體清除率低且經開發為用於治療及預防HIV-1之長效ARV。利那卡帕韋有潛力滿足PWH未滿足的醫療需求，他們可以從長效治療或新穎的作用機制中受益。

【0004】 已鑑別出具有針對增加效力及廣度之HIV-1套膜醣蛋白之中和活性之單株抗體(monoclonal antibody, mAb) (Burton and Mascola, *Nat Immunol* (2015) 16(6):571-6)，且廣泛中和mAb之腸胃外投予顯著降低了未經治療的PWH之血漿病毒血症，並且在經歷分析治療中斷之前已接受廣泛中和抗體(broadly neutralizing antibody, bNAb)之病毒學抑制的PWH中維持了病毒學抑制(Caskey, *et al.*, *Nature* (2015) 522 (7557):487-91；Caskey, *et al.*, *Nat Med* (2017) 23 (2):185-91；Mendoza, *et al.*, *Nature* (2018) 561:479-84)。抗體可為長效的且有可能減輕挑戰或終生遵守每日療法。抗體亦參與免疫系統，其可促成有益的HIV特異性免疫反應(Niessl, *et al.*, *Nat Med* (2020) 26 (2):222-7)，包括潛伏感染細胞之潛在清除(Gaebler, *et al.*, *Nature* (2022) 606(7913):368-374)，其未藉由ARV藥物達成。作為生物製劑，bNAb可使患者免受與慢性ARV療法相關之不良影響。然而，HIV-1係多樣化的病毒，其變體對任何bNAb均有不同水平之敏感性。因此，迄今為止鑑定之bNAb當測量其中和HIV-1單離株之多樣性之能力時具有不完整的廣度(Nishimura, *et al.*, Nature (2017) 543(7646):559-63)。3BNC117及10-1074係已鑑定及臨床測試之最強效bNAb中之二者(Mouquet, *et al.*, *Proc Natl Acad Sci U S A* (2012) 109 (47):E3268-77；Scheid, *et al.*, *Science*

(2011) 333(6049):1633-7)。然而，病毒對bNAb之抗性可在抗體效價下降之後發生(Bar-On, *et al.*, *Nat Med* (2018) 24:1701-7)。

【發明內容】

【0005】 在一個態樣中，提供了治療或預防有需要之人類對象的HIV之方法。在一些實施例中，該等方法包含：(a)在第一時間點共投予(i)有效量的第一抗體，其與結合至第三可變環(V3)及/或包含N332寡甘露糖聚醣之高甘露糖區塊內之gp120之表位的VH及VL區競爭或包含該等VH及VL區，及(ii)有效量的第二抗體，其與結合至包含CD4結合位點(CD4bs)之gp120之表位的VH及VL區競爭或包含該等VH及VL區，其中第一抗體及第二抗體均包含Fc胺基酸取代以延長血清半衰期；及(b)在第一時間點後至少約24週，例如至少約25週，例如至少約26週的第二時間點共投予有效量的第一抗體及有效量的第二抗體。在一些實施例中，第一抗體及第二抗體包含Fc區，該Fc區在所示位置（EU索引編號）包含下列胺基酸：(i)位置252之酪胺酸、位置254之蘇胺酸、及位置256之麩胺酸(YTE)；(ii)位置428之白胺酸及位置434之絲胺酸(LS)；(iii)位置433之離胺酸及位置434之苯丙胺酸；(iv)位置250之麩醯胺酸及位置428之白胺酸(QL)；(v)位置307之麩醯胺酸、位置311之纈胺酸、及位置378之纈胺酸(DF215)；(vi)在位置256處之天冬胺酸、在位置286處之天冬胺酸、在位置307之精胺酸、在位置311處之纈胺酸、及在位置378處之纈氨酸(DF228)；(vii)在位置309處之天冬胺酸、在位置311處之組胺酸、及在位置434處之絲胺酸(DHS)。在一些實施例中，第一抗體與選自下列的抗體之VH及VL區競爭或包含選自下列的抗體之VH及VL區：GS-2872（又名津利維單抗(zinlirvimab)）、10-1074、10-1074-J、GS-9722、GS-

9721、PGT-121、PGT-121.66、PGT-121.414、PGT-122、PGT-123、PGT-124、PGT-125、PGT-126、PGT-128、PGT-130、PGT-133、PGT-134、PGT-135、PGT-136、PGT-137、PGT-138、PGT-139、VRC24、2G12、BG18、354BG8、354BG18、354BG42、354BG33、354BG129、354BG188、354BG411、354BG426、DH270.1、DH270.6、PGDM12、VRC41.01、PGDM21、PCDN-33A、BF520.1、及VRC29.03；且該第二抗體與選自下列的抗體之VH及VL區競爭或包含選自下列的抗體之VH及VL區：GS-5423、3BNC117、GS-9723、3BNC60、b12、F105、VRC01、VRC07、VRC07-523、VRC03、VRC06、VRC06b01 VRC08、VRC0801、NIH45-46、PGV04 (VRC-PG04)；CH103、44-VRC13.01、1NC9、12A12、N6、1-18、N49-P7、NC-Cow1、IOMA、CH235及CH235.12、N49P6、N49P7、N49P11、N49P9、及N60P25。在一些實施例中，第一抗體與10-1074之VH及VL區競爭或包含10-1074之VH及VL區，且第二抗體與3BNC117之VH及VL區競爭或包含3BNC117之VH及VL區。在一些實施例中，第一抗體包含10-1074-LS（又名津利維單抗；GS-2872）及第二抗體包含3BNC117-LS（又名特羅帕單抗；GS-5423）。在一些實施例中，第一抗體及第二抗體係每6個月(every 6 months, Q6M)共投予。在一些實施例中，第一抗體及第二抗體係每24週(every 24 weeks, Q24W)共投予。在一些實施例中，第一抗體及第二抗體係每25週(every 24 weeks, Q25W)共投予。在一些實施例中，第一抗體及第二抗體係每26週(every 24 weeks, Q26W)共投予。在一些實施例中，第一抗體及第二抗體獨立地以在約500 mg至約3000 mg，例如約550 mg至約2900 mg、例如約600 mg至約2800 mg、例如約650 mg至約2700 mg、例如約700 mg至約2600 mg、例如約850 mg至約2550 mg範圍內的劑量靜脈內投予。在一些實施

例中，第一抗體係以2550 mg之劑量靜脈內投予，且第二抗體係以2550 mg之劑量靜脈內投予。在一些實施例中，第一抗體係以850 mg之劑量靜脈內投予，且第二抗體係以1275 mg之劑量靜脈內投予。在一些實施例中，第一抗體係以850 mg之劑量靜脈內投予，且第二抗體係以1700 mg之劑量靜脈內投予。在一些實施例中，第一抗體係以850 mg之劑量靜脈內投予，且第二抗體係以2550 mg之劑量靜脈內投予。在一些實施例中，該等方法進一步包含共投予一或多種長效HIV藥物。在一些實施例中，一或多種長效HIV藥物係選自長效殼體抑制劑、長效整合酶股轉移抑制劑(INSTI)、長效非核苷反轉錄酶抑制劑(NNRTI)、長效核苷反轉錄酶抑制劑(NRTI)、及長效蛋白酶抑制劑(PI)。在一些實施例中，一或多種長效HIV藥物包含長效殼體抑制劑。在一些實施例中，長效殼體抑制劑係選自利那卡帕韋、VH4004280、及VH4011499。在一些實施例中，長效殼體抑制劑包含利那卡帕韋。在一些實施例中，利那卡帕韋係以在300 mg至1000 mg範圍內的劑量投予。在一些實施例中，利那卡帕韋係口服或皮下投予。在一些實施例中，長效INSTI係選自比替拉韋(bictegravir)、雷特格韋(raltegravir)、埃替格韋(elvitegravir)、多替拉韋(dolutegravir)、卡博特韋(cabotegravir)、GS-1720、GS-6212、GS-1219、GS-3242、及VH4524184。在一些實施例中，長效NNRTI係選自利匹韋林(rilpivirine)、艾法韋林(elsulfavirine)、多拉韋林(doravirine)、及GS-5894。在一些實施例中，長效NRTI係選自伊司他韋(islatravir)及其前藥、替諾福韋艾拉酚胺(tenofovir alafenamide, TAF)及替諾福韋之前藥、羅法福韋艾他拉酚胺(rovafovir etalafenamide)、及GS-1614。在一些實施例中，長效蛋白酶抑制劑係選自阿扎那韋(atazanavir)、利托那韋(ritonavir)、地瑞那韋(darunavir)、GS-1156及GS-1156之前藥、及其組合。在一些實施例中，該等方法進一步包含判定對象之

HIV對第一抗體及第二抗體中之一或二者之敏感性。在一些實施例中，對象係病毒血症（即，HIV-1 RNA > 50個拷貝/mL）。在一些實施例中，對象係經病毒學抑制（即，HIV-1 RNA < 50個拷貝/mL）。在一些實施例中，對象正接受抗反轉錄病毒療法(ART)。在一些實施例中，抗反轉錄病毒療法(ART)係在投予第一抗體及第二抗體之前，例如在第一時間點之前中止。在一些實施例中，對象急性感染HIV。在一些實施例中，對象具有Fiebig第IV期或更早期HIV感染。在一些實施例中，對象未經血清轉化。在一些實施例中，對象最近受HIV感染。在一些實施例中，向具有Fiebig第V期或Fiebig第VI期HIV感染的對象投予抗體。在一些實施例中，對象慢性感染HIV。在一些實施例中，對象受HIV分支B病毒感染。

【0006】　在另一態樣中，提供了治療或預防有需要之人類對象的HIV之方法。在一些實施例中，該等方法包含：(a)在第一時間點共投予(i)有效量的10-1074-LS（津利維單抗；GS-2872）及(ii)有效量的3BNC117-LS（特羅帕單抗；GS-5423)；b)在第一時間點後至少約24週，例如至少約25週，例如至少約26週的第二時間點共投予有效量的10-1074-LS及有效量的3BNC117-LS。在一些實施例中，10-1074-LS及3BNC117-LS係每6個月(Q6M)共投予。在一些實施例中，10-1074-LS及3BNC117-LS係每24週(Q24W)共投予。在一些實施例中，10-1074-LS及3BNC117-LS係每25週(Q25W)共投予。在一些實施例中，10-1074-LS及3BNC117-LS係每26週(Q26W)共投予。在一些實施例中，10-1074-LS及3BNC117-LS係在1年內共投予2次。在一些實施例中，10-1074-LS及3BNC117-LS係在2年內共投予4次。在一些實施例中，10-1074-LS及3BNC117-LS係在3年內共投予6次。在一些實施例中，10-1074-LS及3BNC117-LS係在4年內共投予8次。在一些實施例中，10-1074-LS係以30 mg/kg之劑量靜脈內投予，且3BNC117-LS係

以30 mg/kg之劑量靜脈內投予。在一些實施例中，10-1074-LS係以10 mg/kg之劑量靜脈內投予，且3BNC117-LS係以30 mg/kg之劑量靜脈內投予。在一些實施例中，10-1074-LS及3BNC117獨立地以在約500 mg至約3000 mg，例如約550 mg至約2900 mg、例如約600 mg至約2800 mg、例如約650 mg至約2700 mg、例如約700 mg至約2600 mg、例如約850 mg至約2550 mg範圍內的劑量靜脈內投予。在一些實施例中，10-1074-LS係以850 mg之劑量靜脈內投予，且3BNC117-LS係以2550 mg之劑量靜脈內投予。在一些實施例中，10-1074-LS係以850 mg之劑量靜脈內投予，且3BNC117-LS係以1275 mg之劑量靜脈內投予。在一些實施例中，10-1074-LS係以850 mg之劑量靜脈內投予，且3BNC117-LS係以1700 mg之劑量靜脈內投予。在一些實施例中，10-1074-LS係以2550 mg之劑量靜脈內投予，且3BNC117-LS係以2550 mg之劑量靜脈內投予。在一些實施例中，在第一時間點之後26週，10-1074-LS及3BNC117-LS之血清濃度係至少10 μg/mL。在一些實施例中，在第一時間點之後26週，HIV RNA之血漿或血清濃度係低於50個拷貝/mL。在一些實施例中，該等方法進一步包含共投予一或多種長效HIV藥物。在一些實施例中，一或多種長效HIV藥物係選自長效殼體抑制劑、長效整合酶股轉移抑制劑(INSTI)、長效非核苷反轉錄酶抑制劑(NNRTI)、長效核苷反轉錄酶抑制劑(NRTI)、及長效蛋白酶抑制劑(PI)。在一些實施例中，長效殼體抑制劑係選自利那卡帕韋、VH4004280、及VH4011499。在一些實施例中，長效殼體抑制劑包含利那卡帕韋。在一些實施例中，利那卡帕韋係以在300 mg至1000 mg範圍內的劑量投予。在一些實施例中，利那卡帕韋係口服或皮下投予。在一些實施例中，長效INSTI係選自比替拉韋、雷特格韋、埃替格韋、多替拉韋、卡博特韋、GS-1720、GS-6212、GS-1219、GS-3242、及VH4524184。在一些實施例中，長

效NNRTI係選自利匹韋林、艾法韋林、多拉韋林、及GS-5894。在一些實施例中，長效NRTI係選自伊司他韋及其前藥、替諾福韋艾拉酚胺(tenofovir alafenamide, TAF)及替諾福韋之前藥、羅法福韋艾他拉酚胺、及GS-1614。在一些實施例中，長效蛋白酶抑制劑係選自阿扎那韋、利托那韋、地瑞那韋、GS-1156及GS-1156之前藥、及其組合。在一些實施例中，該等方法進一步包含判定對象之HIV對10-1074-LS及3BNC117-LS中之一或二者之敏感性。在一些實施例中，對象係病毒血症。在一些實施例中，對象係經病毒學抑制。在一些實施例中，對象正接受抗反轉錄病毒療法(ART)。在一些實施例中，抗反轉錄病毒療法(ART)已在投予10-1074-LS及3BNC117-LS之前中止。在一些實施例中，對象急性感染HIV。在一些實施例中，對象具有Fiebig第IV期或更早期HIV感染。在一些實施例中，對象未經血清轉化。在一些實施例中，對象最近受HIV感染。在一些實施例中，向具有Fiebig第V期或Fiebig第VI期HIV感染的對象投予抗體。在一些實施例中，對象慢性感染HIV。在一些實施例中，對象受HIV分支B病毒感染。

【0007】　在又一態樣中，提供了套組。在一些實施例中，套組包含一或多個單一劑量的結合HIV gp120 V3聚醣之第一抗體及結合HIV gp120 CD4bs之第二抗體，其中該第一抗體及該第二抗體具有延長血清半衰期的胺基酸取代，且其中該第一抗體及該第二抗體經調配用於每年兩次（例如，每6個月(Q6M)、每26週(Q26W)、每25週(Q25W)、或每24週(Q24W)）投予。在一些實施例中，第一抗體及第二抗體之一或多個單一劑量係獨立地在約500 mg至約3000 mg，例如約550 mg至約2900 mg、例如約600 mg至約2800 mg、例如約650 mg至約2700 mg、例如約700 mg至約2600 mg、例如約850 mg至約2550 mg範圍內。如

適當，該等單一劑量可相同或不同。在一些實施例中，套組進一步包含一或多個單一劑量的3BNC117-LS（特羅帕單抗；GS-5423）及10-1074-LS（津利維單抗；GS-2872），其中該3BNC117-LS（特羅帕單抗）及該10-1074-LS（津利維單抗）經調配用於每年兩次（例如，每6個月(Q6M)、每26週(Q26W)、每25週(Q25W)、或每24週(Q24W)）投予。在一些實施例中，10-1074-LS及3BNC117-LS之單一劑量係獨立地在約500 mg至約3000 mg，例如約550 mg至約2900 mg、例如約600 mg至約2800 mg、例如約650 mg至約2700 mg、例如約700 mg至約2600 mg、例如約850 mg至約2550 mg範圍內。在一些實施例中，10-1074-LS之一或多個單一劑量係2550 mg，且3BNC117-LS之一或多個單一劑量係2550 mg。在一些實施例中，10-1074-LS之一或多個單一劑量係850 mg，且3BNC117-LS之一或多個單一劑量係1275 mg。在一些實施例中，10-1074-LS之一或多個單一劑量係850 mg，且3BNC117-LS之一或多個單一劑量係1700 mg。在一些實施例中，10-1074-LS之一或多個單一劑量係850 mg，且3BNC117-LS之一或多個單一劑量係2550 mg。在一些實施例中，10-1074-LS及3BNC117-LS經調配用於靜脈內投予。在一些實施例中，一或多個單一劑量包含於一或多個容器中。在一些實施例中，一或多個容器係選自小瓶、安瓿、及預載注射器。在一些實施例中，套組進一步包含一或多個單一劑量的一或多種長效HIV藥物。在一些實施例中，一或多個單一劑量的一或多種長效HIV藥物係選自長效殼體抑制劑、長效整合酶股轉移抑制劑(INSTI)、長效非核苷反轉錄酶抑制劑(NNRTI)、長效核苷反轉錄酶抑制劑(NRTI)、及長效蛋白酶抑制劑(PI)。在一些實施例中，長效殼體抑制劑係選自利那卡帕韋、VH4004280、及VH4011499。在一些實施例中，長效殼體抑制劑包含利那卡帕韋。在一些實施例中，利那卡

帕韋之單一劑量係在300 mg至1000 mg範圍內。在一些實施例中，利那卡帕韋經調配用於口服或皮下投予。在一些實施例中，長效INSTI係選自比替拉韋、雷特格韋、埃替格韋、多替拉韋、卡博特韋、GS-1720、GS-6212、GS-1219、GS-3242、及VH4524184。在一些實施例中，長效NNRTI係選自利匹韋林、艾法韋林、多拉韋林、及GS-5894。在一些實施例中，長效NRTI係選自伊司他韋及其前藥、替諾福韋艾拉酚胺(tenofovir alafenamide, TAF)及替諾福韋之前藥、羅法福韋艾他拉酚胺、及GS-1614。在一些實施例中，長效蛋白酶抑制劑係選自阿扎那韋、利托那韋、地瑞那韋、GS-1156及GS-1156之前藥、及其組合。

【圖式簡單說明】

【0008】

〔圖 1A 至圖 1C〕圖 1A 繪示第 1b 期研究 GS-US-536-5816（ClinicalTrials.gov 上之 NCT04811040）之研究示意圖。圖 1B 繪示參與者處置。所有隨機分組之參與者均包括於安全分析中(N = 21)；接受完整研究方案（口服 LEN、SC LEN、及 bNAb）之彼等者包括於功效分析中(N = 20)。圖 1C 繪示藉由 FDA 快照演算法之第 26 週時之病毒學功效結果。20 名參與者中有 18 名在研究方案中維持病毒抑制直至第 26 週。一名參與者在第 12 週退出，且 HIV-1 RNA < 50 個拷貝/mL。一名參與者在第 16 週時具有確認之病毒學反彈，且在基線口服 ART 上重新抑制。

〔圖 2〕繪示在第 1b 期研究中特羅帕單抗(TAB)、津利維單抗(ZAB)、及利那卡帕韋(LEN)之藥物動力學。

〔圖 3A 至圖 3D〕繪示在每 6 個月 IV 投予 30 mg/kg 或 2550 mg GS-5423（圖 A 及圖 C）以及 10 mg/kg、30 mg/kg、850 mg 或 2550 mg GS-2872（圖 B 及圖 D）後，第 26 週的模擬 C_{max}（圖 A 及圖 B）及 C_{min}（圖 C 及圖 D）。盒：四分位數，水平線：中位數，鬚線：1.5 倍四分位數，不超過最小值及最大值，點：離群值。

〔圖 4A 至圖 4B〕繪示每 6 個月給予不同劑量的 GS-5423（特羅帕單抗）（圖 3A）及 GS-2872（津利維單抗）（圖 3B）的模擬中位數（線）及第 5 至第 95 個百分位數（陰影區域）之濃度-時間曲線。

〔圖 5〕繪示用於評估下列之濃度及清除持續時間之預測的 PK-PD 病毒動力學模型的示意圖：GS-5423（3BNC117-LS；特羅帕單抗；TAB）及 GS-2872（10-1074-LS；津利維單抗；ZAB）。C_1 及 C_2，分別為 3BNC117/TAB 及 10-1074/ZAB 之血清濃度；$EC_{50，藥物1}$ 及 $EC_{50，藥物2}$，其分別引起 3BNC117/TAB 及 10-1074/ZAB 之 50%最大效應的濃度；f_i，第 i 個病毒隔室的初始分數；k_g，最大病毒複製速率常數；$k_{del，藥物1}$ 及 $k_{del，藥物2}$，分別為 3BNC117/TAB 及 10-1074/ZAB 之病毒消除速率常數；$r_{d,i}$，第 i 個病毒隔室的病毒消除速率；$r_{g,i}$，第 i 個病毒隔室的病毒複製速率；TAB，特羅帕單抗；VL_1，對 3BNC117/TAB 及 10-1074/ZAB 兩者敏感的病毒拷貝；VL_2，對 3BNC117/TAB 敏感及對 10-1074/ZAB 具有抗性的病毒拷貝；VL_3，對 10-1074/ZAB 敏感及對 3BNC117/TAB 具有抗性的病毒拷貝；VL_4，對 3BNC117/TAB 及 10-1074/ZAB 兩者具有抗性的病毒拷貝（假設為 0）；$VL_{總計}$，總病毒負荷；VL_{ss}，穩態病毒負荷；ZAB，津利維單抗。

〔圖 6〕繪示觀察到的 bNAb 血清濃度與 PK 模型預測的 bNAb 血清濃度的比較（bNAb，廣泛中和抗體）；PK，藥物動力學；TAB，特羅帕單抗；ZAB，津

利維單抗。圓圈表示個別資料。實線表示 LOESS（局部評估的散佈圖平滑化）擬合。虛線表示身份線。

〔圖 7〕繪示單一劑量 30 mg/kg IV 輸注之後的模型預測 PK 概況。IV，靜脈內；PWH，患有 HIV 之人。使用 3BNC117、10-1074、TAB 及 ZAB 的群體 PK 模型模擬 1000 名虛擬對象。實線表示分別為單一治療及組合治療的模型預測中位數，而陰影區域表示群體之 90%預測區間。

〔圖 8〕繪示在患有 HIV 病毒血症之人接受 bNAb 治療後模型預測的病毒動力學與觀察到的病毒動力學的比較。Q5，第 5 百分位數；Q50，第 50 百分位數；Q95，第 95 百分位數。使用與用於模型化擬合之原始資料集相同數目之對象進行 100 次試驗模擬。預測分位數是根據所有試驗重複的分位數中位數計算的。箭頭表示 bNAb 給藥。

〔圖 9〕繪示在 bNAb 治療後 ATI 期間病毒反彈的模型預測時間與觀察到的時間。ATI，分析治療中斷；bNAb，廣泛中和抗體；CI，信賴區間。ATI 研究中之劑量：NCT02446847，每 3 週 2 劑 30 mg/kg 3BNC117 或每 2 週至多 4 劑 30 mg/kg 3BNC117；NCT02825797，每 3 週至多 3 劑 30 mg/kg 3BNC117 及 30 mg/kg 10-1074；NCT03526848，每 2 週 30 mg/kg 3BNC117 及 30 mg/kg 10-1074 達 3 劑，接著每 4 週達至多 4 劑（第 1 組，ATI 在第 2 天開始；第 2 組，ATI 在第 26 週開始[1 名參與者在第 21 週開始]）。使用與用於模型化擬合之原始資料集相同數目之對象進行 100 次試驗模擬。藍色實線（陰影區域）表示所有試驗重複的中位數（第 2.5 個百分位數至第 97.5 個百分位數）。箭頭表示 bNAb 給藥。紅色虛線指示 ATI 開始。

〔圖 10〕繪示在不同 ATI 開始時間的單一劑量 TAB/ZAB 組合治療後模型預測的病毒反彈動力學。PD，藥效動力學。水平虛線表示病毒反彈的臨限(200 cp/mL)。使用群體 PK-PD 模型模擬 1000 名虛擬對象。實線表示模型預測中位數，而陰影區域表示群體之 90%預測區間。箭頭表示 bNAb 給藥。紅色虛線指示 ATI 開始。

〔圖 11〕繪示單一劑量 TAB 30 mg/kg 及 ZAB 10 mg/kg IV 給藥後，模擬 bNAb 血清濃度及其與體內 EC_{50} 的比率隨時間的變化。EC_{50}，達到最大藥效 50%的濃度。使用群體 PK 模型模擬 1000 名虛擬對象。實線表示模型預測中位數，而陰影區域表示群體之 90%預測區間。根據 PK-PD 模型評估的 EC_{50} 值計算比率（TAB 為 25.4 μg/mL，ZAB 為 32.2 μg/mL）。黑色虛線指示建議的 ATI 最早開始時間。

〔圖 12〕繪示第 2 期研究 GS-US-539-5939 之研究示意圖。

【實施方式】

相關申請案之交互參照

【0009】 本申請案依據35 U.S.C. § 119(e)主張2022年8月26日申請之美國臨時專利申請案第63/373,597號及2023年7月20日申請之美國臨時專利申請案第63/514,711號之權益，其等全文出於所有目的特此以引用方式併入本文中。

序列表

【0010】 本申請案含有以XML格式電子提交之序列表，且其全文特此以引用方式併入本文中。該XML複本（建立於2023年07月20日）係命名為1445-WO-PCT_sequencelisting.XML，且檔案大小為512,134位元組。

1. 介紹

【0011】 因此，本發明方法部分基於下列發現：共投予第一抗HIV廣泛中和抗體(bNAb)及第二bNAb，可每年兩次（例如，Q6M、Q24W、Q25W、Q26W）投予，且達成治療功效，該第一抗HIV bNAb結合至第三可變環(V3)及/或包含N332寡甘露糖聚醣之高甘露糖區塊內之gp120之表位，該第二bNAb結合至包含CD4結合位點(CD4bs)之gp120之表位，其中該第一抗體及第二抗體具有延長血清半衰期的Fc胺基酸取代。迄今為止，即使具有延長血清半衰期的Fc胺基酸取代，亦每3個月或更頻繁地投予bNAb。

【0012】 一般而言，該等方法需要在第一時間點共投予(i)有效量的第一抗體，其與結合至第三可變環(V3)及/或包含N332寡甘露糖聚醣之高甘露糖區塊內之gp120之表位的VH及VL區競爭或包含該等VH及VL區，及(ii)有效量的第二抗體，其與結合至包含CD4結合位點(CD4bs)之gp120之表位的VH及VL區競爭或包含該等VH及VL區，其中第一抗體及第二抗體均包含Fc胺基酸取代以延長血清半衰期；然後在第一時間點之後至少約24週，例如至少約25週，例如至少約26週的第二時間點共投予有效量之第一抗體及有效量之第二抗體。

【0013】 3BNC117及10-1074已經歷修改以增加半衰期，產生GS 5423（特羅帕單抗；3BNC117-LS）及GS-2872（津利維單抗；10-1074-LS），且允許維持高bNAb濃度在長持續時間。由具有ARV藥物之長效bNAb組成的組合療法可

克服單獨的bNAb之局限性，且為PWH提供安全的長效治療選項。經修飾之LS版本在Fc中含有兩個胺基酸取代：Fc位置428的甲硫胺酸取代成白胺酸(M428L)及Fc位置434的天冬醯胺酸取代成絲胺酸(N434S)（EU編號）。此等取代增強抗體與新生兒Fc受體(FcRn)之結合親和力，延長bNAb之體內半衰期。與其他Fc受體之親和力結合保持不變。此等修飾不改變bNAb之片段抗原結合(fragment antigen-binding, Fab)域，且因此不改變其與抗原或安全概況之相互作用。

2. 共投予廣泛中和抗體

a. 一般廣泛中和抗體

【0014】 HIV-1係HIV之主要家族，且佔全球所有感染的95%。HIV-2主要在幾個西非國家中看到。

【0015】 將HIV病毒劃分為特定組：M、N、O、及P，其中M係「主要(major)」組且是全球大部分HIV/AIDS的罪魁禍首。基於其基因序列，組M進一步細分為在不同地理位置流行之亞型（亦稱為分枝）。

【0016】 組M「亞型(subtype)」或「分枝(clade)」係由基因序列資料定義之HIV-1組M之亞型。組M亞型之實例包括亞型A-K。已知一些亞型毒性較大或對不同藥物具有耐藥性。亦存在自不同亞型之病毒之間的重組衍生之「循環重組形式(circulating recombinant form)」或CRF，該等不同亞型各自指定編號。例如，CRF12_BF係亞型B與F之間的重組。在西非常見亞型A。亞型B係歐洲、美洲、日本、泰國、及澳大利亞之主要形式。亞型C係南非、東非、印度、尼泊爾、及中國部分地區之主要形式。亞型D一般僅見於東非及中非。亞型E從未以非重組形式鑑別，其僅與亞型A重組為CRF01_AE。已在中非、南

美、及東歐發現亞型F。已在非洲及中歐發現亞型G（及CRF02_AG）。亞型H限於中非。亞型I最初用於描述現在稱為CRF04_cpx之病毒株，其中cpx表示數種亞型之「複合(complex)」重組。亞型J主要在北非、中非及西非發現，且加勒比海亞型K限於剛果民主共和國及喀麥隆。此等亞型有時進一步分成次亞型，諸如A1及A2或F1及F2。在2015年，在古巴發現具有亞型D蛋白酶之病毒株CRF19（亞型A、亞型D、及亞型G之重組）與快速進展為AIDS高度相關。

【0017】 本揭露尤其提供需要投予人類抗HIV中和抗體（例如，廣泛中和Ab），該等人類抗HIV中和抗體靶向感染HIV的細胞之表面上之gp120多肽。針對病毒套膜蛋白之中和抗體藉由阻斷易感細胞之感染提供針對HIV-1暴露之適應性免疫防禦。廣譜中和作用表明這些抗體可中和來自不同分枝之HIV-1單離株。因此，本文所述之抗HIV gp120結合抗體具有交叉分枝結合活性。

【0018】 在某些實施例中，所投予抗體係或衍生自靶向HIV-1之人類中和抗體（例如，單株）。「中和抗體(neutralizing antibody)」係可體外中和HIV在宿主中及/或在目標細胞中引發及/或維持感染之能力的抗體。本揭露提供中和單株人類抗體，其中該抗體識別來自HIV之抗原，例如gp120多肽。在某些實施例中，「中和抗體」可抑制HIV-1病毒（例如SF162及/或JR-CSF）之進入，其中中和指數>1.5或>2.0 (Kostrikis LG et al., *J. Virol.*,70(1): 445-458 (1996))。

【0019】 在一些實施例中，所投予抗體係或衍生自靶向HIV-1之人類廣泛中和抗體（例如，單株）。「廣泛中和抗體(broadly neutralizing antibody)」意謂在中和檢定中中和多於一種HIV-1病毒物種（來自不同分枝及分枝內之不同病毒株）之抗體。廣泛中和抗體可中和HIV-1之至少2、3、4、5、6、7、8、9、或更多種不同病毒株，該等病毒株屬於相同或不同分枝。在特定實施例

中，廣譜中和抗體可中和屬於至少2、3、4、5、或6個不同分枝之多個HIV-1物種。在某些實施例中，在中和檢定中，抗HIV gp120 V3聚醣結合抗體或抗原結合片段中和約50%輸入病毒之抑制濃度可低於約0.0001 μg/ml、低於約0.001 μg/ml、低於約0.01 μg/ml、低於約0.1 μg/ml、低於約0.5 μg/ml、低於約1.0 μg/ml、低於約5 μg/ml、低於約10 μg/ml、低於約25 μg/ml、低於約50 μg/ml、或低於約100 μg/ml。

gp120

【0020】 套膜醣蛋白gp120（或gp120）係120 kDa醣蛋白，其係HIV外層之一部分。其自身呈現為由連接在一起且藉由gp41蛋白錨定至膜上之三個gp120分子組成的病毒膜刺突。Gp120對病毒感染至關重要，因為它通過與細胞表面受體的相互作用促進HIV進入宿主細胞。此等受體包括DC-SIGN、硫酸乙醯肝素蛋白聚醣、及CD4受體。與輔助T細胞上之CD4之結合引起gp120及gp41之構形變化的級聯起始，從而導致病毒與宿主細胞膜融合。

【0021】 Gp120由HIV *env*基因編碼。*env*基因編碼約850個胺基酸之基因產物。初級*env*產物係蛋白質gp160，其在內質網中經細胞蛋白酶弗林蛋白酶(furin)裂解為gp120（約480個胺基酸）及gp41（約345個胺基酸）。

【0022】 廣泛中和抗體綜述於例如Walsh and Seaman, *Front Immunol.*(2021) 12:712122；Julg and Barouch, *Semin Immunol.*(2021) 51:101475；Hsu, *et al.*, *Front Immunol.*(2021) 12:710044；Karuna and Corey, *Annu Rev Med.* (2020) 71:329-346；Haynes, *et al.*, *Sci Transl Med.* (2019) 11(516):eaaz2686；Dashti, *et al.*, *Trends Mol Med.* (2019) 25(3):228-240；McCoy, *Retrovirology* (2018)

15:70；Sok and Burton, *Nat Immunol*.2018 19(11):1179-1188；Possas, *et al., Expert Opin Ther Pat*. 2018 Jul; 28(7):551-560；及Stephenson及Barouch, *Curr HIV/AIDS Rep* (2016) 13:31–37，其全文出於所有目的特此以引用方式併入本文中。

b. 導向至HIV gp120之V3聚醣區之抗體

【0023】 gp120上之V3聚醣位點係部分藉由CCR5共受體位點之區段且部分藉由周圍偽裝聚醣（所謂的「高甘露糖區塊(high mannose patch)」）形成(Sok, *et al*., *Immunity* (2016) 45, 31–45)。針對V3聚醣位點之廣泛中和抗體(bnAb)是HIV感染中發現之所有Ab中最常見的*(Walker, et al*., *PLoS Pathog*.(2010) 6:e1001028 (2010)；Landais, *et al*., *PLoS Pathog*.(2016) 12:e1005369；Georgiev, *et al. Science* (2013) 340:751–756)。下文提供了gp120之V3區之共同序列(Milich et al., *J Virol*., 67(9):5623-5634 (1993)：CTRPNNNTRKSIHIGPGRAFYTTGEIIGDIRQAHC (SEQ ID NO: 1)。

【0024】 下文提供了HIV殖株WITO之例示性gp160多肽之胺基酸序列（V3高變環以粗體顯示，且N332潛在的N連接之醣化位點以粗體顯示且加底線）：

MKVMGTKKNYQHLWRWGIMLLGMLMMSSAAEQLWVTVYYGVPVWREA
NTTLFCASDAKAYDTEVHNVWATHACVPTDPNPQEVVMGNVTEDFNMW
KNNMVEQMHEDIISLWDQSLKPCVKLTPLCVTLHCTNVTISSTNGSTANVT
MREEMKNCSFNTTTVIRDKIQKEYALFYKLDIVPIEGKNTNTSYRLINCNTS
VITQACPKVSFEPIPIHYCAPAGFAILKCNNKTFNGKGPCRNVSTVQCTHGIK
PVVSTQLLLNGSLAEEDIIIRSENFTNNGKNIIVQLKEPVKIN**CTRPGNNTRR**

SINIGPGRAFYATGAIIGDIRKAHC<u>N</u>ISTEQWNNTLTQIVDKLREQFGNKTI

IFNQSSGGDPEVVMHTFNCGGEFFYCNSTQLFNSTWFNNGTSTWNSTADNI

TLPCRIKQVINMWQEVGKAMYAPPIRGQIDCSSNITGLILTRDGGSNSSQNE

TFRPGGGNMKDNWRSELYKYKVVKIEPLGIAPTRAKRRVVQREKRAVTLG

AVFLGFLGAAGSTMGAASLTLTVQARLLLSGIVQQQSNLLRAIEAQQHMLQ

LTVWGIKQLQARVLAIERYLKDQQLLGIWGCSGKLICTTTVPWNTSWSNKS

YDYIWNNMTWMQWEREIDNYTGFIYTLIEESQNQQEKNELELLELDKWAS

LWNWFNITNWLWYIKLFIMIIGGLVGLRIVCAVLSIVNRVRQGYSPLSFQTR

LPNPRGPDRPEETEGEGGERDRDRSARLVNGFLAIIWDDLRSLCLFSYHRLR

DLLLIVARVVEILGRRGWEILKYWWNLLKYWSQELKNSAVSLLNVTAIAV

AEGTDRVIEIVQRAVRAILHIPTRIRQGFERALL (SEQ ID NO: 2)

【0025】　下文提供了NCBI Ref Seq No. NP_057856.1中鑑別之HIV殖株之例示性gp160多肽之胺基酸序列（V3高變環以粗體顯示，且N332潛在的N連接之醣化位點以粗體顯示且加底線）：

MRVKEKYQHLWRWGWRWGTMLLGMLMICSATEKLWVTVYYGVPVWKE

ATTTLFCASDAKAYDTEVHNVWATHACVPTDPNPQEVVLVNVTENFNMW

KNDMVEQMHEDIISLWDQSLKPCVKLTPLCVSLKCTDLKNDTNTNSSSGRMI

MEKGEIKNCSFNISTSIRGKVQKEYAFFYKLDIIPIDNDTTSYKLTSCNTSVITQ

ACPKVSFEPIPIHYCAPAGFAILKCNNKTFNGTGPCTNVSTVQCTHGIRPVVST

QLLLNGSLAEEEVVIRSVNFTDNAKTIIVQLNTSVEIN**CTRPNNNTRKRIRIQ**

RGPGRAFVTIGKIGNMRQAHC<u>N</u>ISRAKWNNTLKQIASKLREQFGNNKTIIF

KQSSGGDPEIVTHSFNCGGEFFYCNSTQLFNSTWFNSTWSTEGSNNTEGSDTI

TLPCRIKQIINMWQKVGKAMYAPPISGQIRCSSNITGLLLTRDGGNSNNESEIF

RPGGGDMRDNWRSELYKYKVVKIEPLGVAPTKAKRRVVQREKRAVGIGAL
FLGFLGAAGSTMGAASMTLTVQARQLLSGIVQQQNNLLRAIEAQQHLLQLT
VWGIKQLQARILAVERYLKDQQLLGIWGCSGKLICTTAVPWNASWSNKSLE
QIWNHTTWMEWDREINNYTSLIHSLIEESQNQQEKNEQELLELDKWASLWN
WFNITNWLWYIKLFIMIVGGLVGLRIVFAVLSIVNRVRQGYSPLSFQTHLPTP
RGPDRPEGIEEEGGERDRDRSIRLVNGSLALIWDDLRSLCLFSYHRLRDLLLI
VTRIVELLGRRGWEALKYWWNLLQYWSQELKNSAVSLLNATAIAVAEGTD
RVIEVVQGACRAIRHIPRRIRQGLERILL (SEQ ID NO: 3)

【0026】 下文提供了HXB2亞型B HIV-1單離株（Genbank登錄號K0345；對應於NCBI Ref Seq No. NP_057856.1之殘基1-511）之例示性gp120多肽之胺基酸序列（V3高變環以粗體顯示，且N332潛在的N連接之醣化位點以粗體顯示且加底線；信號肽加底線）：

MRVKEKYQHLWRWGWRWGTMLLGMLMICSATEKLWVTVYYGVPVWKE
ATTTLFCASDAKAYDTEVHNVWATHACVPTDPNPQEVVLVNVTENFNMW
KNDMVEQMHEDIISLWDQSLKPCVKLTPLCVSLKCTDLKNDTNTNSSSGRMI
MEKGEIKNCSFNISTSIRGKVQKEYAFFYKLDIIPIDNDTTSYKLTSCNTSVITQ
ACPKVSFEPIPIHYCAPAGFAILKCNNKTFNGTGPCTNVSTVQCTHGIRPVVST
QLLLNGSLAEEEVVIRSVNFTDNAKTIIVQLNTSVEIN**CTRPNNNTRKRIRIQ**
RGPGRAFVTIGKIGNMRQAHCNISRAKWNNTLKQIASKLREQFGNNKTIIF
KQSSGGDPEIVTHSFNCGGEFFYCNSTQLFNSTWFNSTWSTEGSNNTEGSDTI
TLPCRIKQIINMWQKVGKAMYAPPISGQIRCSSNITGLLLTRDGGNSNNESEIF
RPGGGDMRDNWRSELYKYKVVKIEPLGVAPTKAKRRVVQREKR (SEQ ID NO: 4)

【0027】 下文提供了例示性gp120多肽之胺基酸序列：

AEQLWVTVYYGVPVWREANTTLFCASDAKAYDTEVHNVWATHACVPTDP
NPQEVVMGNVTEDFNMWKNNMVEQMHEDIISLWDQSLKPCVKLTPLCVT
LHCTNVTISSTNGSTANVTMREEMKNCSFNTTTVIRDKIQKEYALFYKLDIV
PIEGKNTNTSYRLINCNTSVITQACPKVSFEPIPIHYCAPAGFAILKCNNKTFN
GKGPCRNVSTVQCTHGIKPVVSTQLLLNGSLAEEDIIIRSENFTNNGKNIIVQ
LKEPVKIN**CTRPGNNTRRSINIGPGRAFYATGAIIGDIRKAHC<u>N</u>**ISTEQWN
NTLTQIVDKLREQFGNKTIIFNQSSGGDPEVVMHTFNCGGEFFYCNSTQLFN
STWFNNGTSTWNSTADNITLPCRIKQVINMWQEVGKAMYAPPIRGQIDCSS
NITGLILTRDGGSNSSQNETFRPGGGNMKDNWRSELYKYKVVKIEPLGIAPT
RAKRRVVQREKR (SEQ ID NO: 5)。

【0028】 下文提供了另一例示性gp120多肽之胺基酸序列（參見bioafrica.net/proteomics/ENV-GP120prot.html）：

TEKLWVTVYY GVPVWKEATT TLFCASDAKA YDTEVHNVWA
THACVPTDPN PQEVVLVNVT ENFNMWKNDM VEQMHEDIIS
LWDQSLKPCV KLTPLCVSLK CTDLKNDTNT NSSSGRMIME KGEIKNCSFN
ISTSIRGKVQ KEYAFFYKLD IIPIDNDTTS YKLTSCNTSV ITQACPKVSF
EPIPIHYCAP AGFAILKCNN KTFNGTGPCT NVSTVQCTHG IRPVVSTQLL
LNGSLAEEEV VIRSVNFTDN AKTIIVQLNT SVEINCTRPN NNTRKRIRIQ
RGPGRAFVTI GKIGNMRQAH CNISRAKWNN TLKQIASKLR EQFGNNKTII
FKQSSGGDPE IVTHSFNCGG EFFYCNSTQL FNSTWFNSTW STEGSNNTEG
SDTITLPCRI KQIINMWQKV GKAMYAPPIS GQIRCSSNIT GLLLTRDGGN

SNNESEIFRP GGGDMRDNWR SELYKYKVVK IEPLGVAPTK

AKRRVVQREK R (SEQ ID NO: 6)

【0029】 獨立人類免疫缺乏病毒第1型(HIV-1)單離株中、在較小程度上來自相同患者的連續單離株中、以及甚至單一患者單離株內的基因體多樣性係HIV-1的熟知特徵。儘管此序列異質性分布在整個基因體中，但大部分異質性位於*env*基因中。比較來自若干不同單離株之所預測胺基酸序列，顯示序列異質性簇聚在表面醣蛋白gp120之五個可變區（指定為V1至V5）中。V3區儘管僅有35個胺基酸長，但展現相當大的序列可變性。有趣的是，不管此可變性如何，V3區均包括介導與$CD4^+$細胞之相互作用的決定因素。gp120可變性增加使得病毒複製量更高，表明受不同HIV-1變體感染之個體之病毒適應性增加。潛在的N連接之醣化位點(potential N-linked glycosylation site, PNGS)之可變性亦使得病毒適應度增加。PNGS使得長鏈碳水化合物與gp120之高可變區結合。因此，*env*中之PNGS數目可藉由向中和抗體提供或多或少的敏感性而影響病毒之適應性。

【0030】 結合至第三可變環(V3)及/或包含N332寡甘露糖聚醣之高甘露糖區塊中之gp120且可用於本文所述之方法中之說明性廣泛中和抗體包括但不限於GS-9722（依帕韋單抗(elipovimab)）、GS-9721、PGT-121、PGT-121.66、PGT-121.414、PGT-122、PGT-123、PGT-124、PGT-125、PGT-126、PGT-128、PGT-130、PGT-133、PGT-134、PGT-135、PGT-136、PGT-137、PGT-138、PGT-139、10-1074、10-1074-LS（津利維單抗；GS-2872）、10-1074-J、VRC24、2G12、BG18、354BG8、354BG18、354BG42、354BG33、354BG129、354BG188、354BG411、354BG426、DH270.1、DH270.6、PGDM12、VRC41.01、PGDM21、PCDN-33A、BF520.1、及

VRC29.03。結合至第三可變環(V3)及/或包含N332寡甘露糖聚醣之高甘露糖區塊中之gp120且可用於本文所述之方法中之額外廣泛中和抗體係描述於例如WO 2012/030904；WO 2014/063059；WO 2016/149698；WO 2017/106346；WO 2018/075564、WO 2018/125813；WO 2018/237148、WO 2019/226829、WO 2020/023827、WO2020/056145、及Kerwin, *et al.*, *J Pharm Sci*. 2020 Jan; 109(1):233-246，其全文出於所有目的特此以引用方式併入本文中。

【0031】 表A1至表A4提供了靶向HIV gp120 V3聚醣區之抗體之互補決定區(complementarity determining region, CDR)之說明性序列。表B提供了靶向HIV gp120 V3聚醣區之抗體之VH及VL之說明性序列。

表A1-抗HIV gp120 V3聚醣結合抗體之CDR (Kabat)

Ab名稱	VH - CDR1	VH - CDR2	VH - CDR3	VL - CDR1	VL - CDR2	VL - CDR3
1	DSYWS SEQ ID NO:7	YVHKSGDTNYSPSLKS SEQ ID NO:8	TLHGRRIYGIVAFNEW FTYFYMDV SEQ ID NO:9	GEKSLGSRAVQ SEQ ID NO:10	NNQDRPS SEQ ID NO:11	HIWDSRVPTKWV SEQ ID NO:12
2	DSYWS SEQ ID NO:7	YVHKSGDTNYNPSLKS SEQ ID NO:13	TLHGRRIYGIVAFNEW FTYFYMDV SEQ ID NO:9	GEKSLGSRAVQ SEQ ID NO:10	NNQDRPS SEQ ID NO:11	HIWDSRVPTKWV SEQ ID NO:12
3	NYYWT SEQ ID NO:14	YISDRESATYNPSLNS SEQ ID NO:15	ARRGQRIYGVVSFGEF FYYYSMDV SEQ ID NO:16	GRQALGSRAVQ SEQ ID NO:17	NNQDRPS SEQ ID NO:11	HMWDSRSGFSWS SEQ ID NO:18
4	NYYWT SEQ ID NO:14	YISDRETTTYNPSLNS SEQ ID NO:19	ARRGQRIYGVVSFGEF FYYYYMDV SEQ ID NO:20	GRQALGSRAVQ SEQ ID NO:17	NNQDRPS SEQ ID NO:11	HMWDSRSGFSWS SEQ ID NO:18
5	GRFWS SEQ ID NO:21	YFSDTDRSEYNPSLRS SEQ ID NO:22	AQQGKRIYGIVSFGEF FYYYYMDA SEQ ID NO:23	GERSRGSRAVQ SEQ ID NO:24	NNQDRPA SEQ ID NO:25	HYWDSRSPISWI SEQ ID NO:26
6	GRFWS SEQ ID NO:21	YFSDTDRSEYNPSLRS SEQ ID NO:22	AQQGKRIYGIVSFGEL FYYYYMDA SEQ ID NO:27	GERSRGSRAVQ SEQ ID NO:24	NNQDRPA SEQ ID NO:25	HYWDSRSPISWI SEQ ID NO:26
7	DNYWS SEQ ID NO:28	YVHDSGDTNYNPSLKS SEQ ID NO:29	TKHGRRIYGVVAFKEW FTYFYMDV SEQ ID NO:30	GEESLGSRSVI SEQ ID NO:31	NNNDRPS SEQ ID NO:32	HIWDSRRPTNWV SEQ ID NO:33
8	DAYWS SEQ ID NO:34	YVHHSGDTNYNPSLKR SEQ ID NO:35	ALHGKRIYGIVALGEL FTYFYMDV SEQ ID NO:36	GKESIGSRAVQ SEQ ID NO:37	NNQDRPA SEQ ID NO:25	HIYDARGGTNWV SEQ ID NO:38
9	ACTYFWG SEQ ID NO:39	SLSHCQSFWGSGWTFH NPSLKS SEQ ID NO:40	FDGEVLVYNHWPKPAW VDL SEQ ID NO:41	NGTATNFVS SEQ ID NO:42	GVDKRPP SEQ ID NO:43	GSLVGNWDVI SEQ ID NO:44
10	ACDYFWG	GLSHCAGYYNTGWTYH NPSLKS	FDGEVLVYHDWPKPAW VDL	TGTSNRFVS	GVNKRPS	SSLVGNWDVI SEQ ID NO:50

表A1-抗HIV gp120 V3聚醣結合抗體之CDR (Kabat)

Ab名稱	VH – CDR1	VH – CDR2	VH – CDR3	VL – CDR1	VL – CDR2	VL – CDR3
	SEQ ID NO:45	SEQ ID NO:46	SEQ ID NO:47	SEQ ID NO:48	SEQ ID NO:49	
11	ACDYFWG SEQ ID NO:45	SLSHCAGYYNSGWTYH NPSLKS SEQ ID NO:51	FGGDVLVYHDWPKPAW VDL SEQ ID NO:52	TGNINNFVS SEQ ID NO:53	GVNKRPS SEQ ID NO:49	GSLAGNWDVV SEQ ID NO:54
12	ACNSFWG SEQ ID NO:55	SLSHCASYWNRGWTYH NPSLKS SEQ ID NO:56	FGGEVLRYTDWPKPAW VDL SEQ ID NO:57	TGTSNNFVS SEQ ID NO:58	DVNKRPS SEQ ID NO:59	GSLVGNWDVI SEQ ID NO:44
13	GCDYFWG SEQ ID NO:60	GLSHCAGYYNTGWTYH NPSLKS SEQ ID NO:46	FDGEVLVYNDWPKPAW VDL SEQ ID NO:61	TGTSNNFVS SEQ ID NO:58	GVNKRPS SEQ ID NO:49	GSLVGNWDVI SEQ ID NO:44
14	TGHYYWG SEQ ID NO:62	HIHYTTAVLHNPSLKS SEQ ID NO:63	SGGDILYYYEWQKPHW FSP SEQ ID NO:64	NGTSSDIGGWN FVS SEQ ID NO:65	EVNKRPS SEQ ID NO:66	SSLFGRWDVV SEQ ID NO:67
15	GTDWGENDFHY G SEQ ID NO:68	SIHWRGRTTHYKTSFR S SEQ ID NO:69	HKYHDIFRVVPVAGWF DP SEQ ID NO:70	RASQNVKNNLA SEQ ID NO:71	DASSRAG SEQ ID NO:72	QQYEEWPRT SEQ ID NO:73
16	GGEWGDSDYHW G SEQ ID NO:74	SIHWRGTTHYNAPFRG SEQ ID NO:75	HKYHDIVMVVPIAGWF DP SEQ ID NO:76	RASQSVKNNLA SEQ ID NO:77	DTSSRAS SEQ ID NO:78	QQYEEWPRT SEQ ID NO:73
17	GGEWGDKDYHW G SEQ ID NO:79	SIHWRGTTHYKESLRR SEQ ID NO:80	HRHHDVFMLVPIAGWF DV SEQ ID NO:81	RASQNINKNLA SEQ ID NO:82	ETYSKIA SEQ ID NO:83	QQYEEWPRT SEQ ID NO:73
18	SDHSWT	DIHYNGATTYNPSLRS SEQ ID NO:85	NAIRIYGVVALGEWFH YGMDV	SGAPLTSRFTY	RSSQRSS	QSSDTSDSYKM SEQ ID NO:89

表A1-抗HIV gp120 V3聚醣結合抗體之CDR (Kabat)

Ab名稱	VH - CDR1	VH - CDR2	VH - CDR3	VL - CDR1	VL - CDR2	VL - CDR3
	SEQ ID NO:84		SEQ ID NO:86	SEQ ID NO:87	SEQ ID NO:88	
19	SDHSWT SEQ ID NO:84	DVHYNGDNTYNPSLRG SEQ ID NO:90	NVIRVFGVISLGEWFH YGMDV SEQ ID NO:91	SGPPLASRYTY SEQ ID NO:92	RDRQFPS SEQ ID NO:93	QSSDTSDSYKM SEQ ID NO:89
20	SDHSWT SEQ ID NO:84	DVHYNGDTTYNPSLRG SEQ ID NO:94	NVIRVFGVISLGEWFH YGMDV SEQ ID NO:91	SGPPLASRYTY SEQ ID NO: 92	RDRQFPS SEQ ID NO:93	QSSDTSDSYKM SEQ ID NO:89
21	SDHSWT SEQ ID NO:84	DIHYNGATTYNPSLRS SEQ ID NO:85	NAIRIYGVVALGEWFH YGMDV SEQ ID NO: 86	SGAALTSRFTY SEQ ID NO:95	RTSQRSS SEQ ID NO:96	QSSDTSDSYKM SEQ ID NO:89
22	SDHSWT SEQ ID NO:84	DIHYGGDITYNPSLRS SEQ ID NO:97	NVIRVFGVIALGEWFH YGMDV SEQ ID NO:98	SGPPLASRYCY SEQ ID NO:99	RDRQFSS SEQ ID NO:100	QSSDINDSYKM SEQ ID NO:101
23	SDHSWT SEQ ID NO:84	DIHYGGDITYNPSLRS SEQ ID NO:97	NVIRVFGVIALGEWFH YGMDV SEQ ID NO:98	SGPPLASRYCY SEQ ID NO:99	RDRQFSS SEQ ID NO:100	QSSDTSDSFKM SEQ ID NO:102
24	SDHSWT SEQ ID NO:84	DIHYGGDITYNPSLRS SEQ ID NO:97	NVIRVFGVIALGEWFH YGMDV SEQ ID NO:98	SGPPLATRYCY SEQ ID NO:103	RDRQFSS SEQ ID NO:100	QSSDTSDSYKM SEQ ID NO:89
25	SDHSWT SEQ ID NO:84	DIHYNGDKTYNPSLRG SEQ ID NO:104	NVIRVFGVISLGEWFH YGMDV SEQ ID NO:91	SGPPLASRYTY SEQ ID NO:92	RDRQFPS SEQ ID NO:93	QSSDTSDSYKM SEQ ID NO:89
26	SDHSWT SEQ ID NO:84	DIHYGGDITYNPSLRS SEQ ID NO:97	NVIRVFGVIALGEWFH YGMDV SEQ ID NO:98	SGPPLASRYCY SEQ ID NO:99	RDRQFSS SEQ ID NO:100	QSSDNSDSFKM SEQ ID NO:105
27	DYAMA SEQ ID NO:106	FMRGWAYGGSAQFAAF AVG SEQ ID NO:107	EQRNKDYRYGQEGFGY SYGMDV SEQ ID NO:108	RASHFIANYVN SEQ ID NO:109	ESSTLQR SEQ ID NO:110	QQSHSPPVT SEQ ID NO:111

表A1-抗HIV gp120 V3聚醣結合抗體之CDR (Kabat)

Ab名稱	VH – CDR1	VH – CDR2	VH – CDR3	VL – CDR1	VL – CDR2	VL – CDR3
28	DYAMA SEQ ID NO:106	FIRGWAYGQAAQYGKS ASG SEQ ID NO:112	EQRGGDGRYSGDGFGY PYGMDV SEQ ID NO:113	RASHFIANYVN SEQ ID NO:109	QSWTLNR SEQ ID NO:114	QQSHSPPLS SEQ ID NO:115
29	DYAMA SEQ ID NO:106	FIRGWAYGQSAQYGKS ASG SEQ ID NO:116	EQRGANGRYGGDGFGY SYGMDV SEQ ID NO:117	RASHFIANYVN SEQ ID NO:109	ESSTLNR SEQ ID NO:118	QQSHSPPVS SEQ ID NO:119

表A2-抗HIV gp120 V3聚醣結合抗體之CDR (Chothia)

Ab名稱	VH – CDR1	VH – CDR2	VH – CDR3	VL – CDR1	VL – CDR2	VL – CDR3
30	GASISD SEQ ID NO:120	YVHKSGDTN SEQ ID NO:121	TLHGRRIYGIVAFNEWFTYFYM DV SEQ ID NO:9	GEKSLGSRAVQ SEQ ID NO:10	NNQDRPS SEQ ID NO:11	HIWDSRVPTKWV SEQ ID NO:12
31	GDSMNN SEQ ID NO:122	YISDRESAT SEQ ID NO:123	ARRGQRIYGVVSFGEFFYYYSM DV SEQ ID NO:16	GRQALGSRAVQ SEQ ID NO:17	NNQDRPS SEQ ID NO:11	HMWDSRSGFSWS SEQ ID NO:18
32	GGSISN SEQ ID NO:124	YISDRETTT SEQ ID NO:125	ARRGQRIYGVVSFGEFFYYYYM DV SEQ ID NO:20	GRQALGSRAVQ SEQ ID NO:17	NNQDRPS SEQ ID NO:11	HMWDSRSGFSWS SEQ ID NO:18
33	NGSVSG SEQ ID NO:126	YFSDTDRSE SEQ ID NO:127	AQQGKRIYGIVSFGEFFYYYYM DA SEQ ID NO:23	GERSRGSRAVQ SEQ ID NO:24	NNQDRPA SEQ ID NO:25	HYWDSRSPISWI SEQ ID NO:26
34	NGSVSG SEQ ID NO:126	YFSDTDRSE SEQ ID NO:127	AQQGKRIYGIVSFGELFYYYYM DA SEQ ID NO:27	GERSRGSRAVQ SEQ ID NO:24	NNQDRPA SEQ ID NO:25	HYWDSRSPISWI SEQ ID NO:26
35	GTLVRD SEQ ID NO:128	YVHDSGDTN SEQ ID NO:129	TKHGRRIYGVVAFKEWFTYFYM DV SEQ ID NO:30	GEESLGSRSVI SEQ ID NO:31	NNNDRPS SEQ ID NO:32	HIWDSRRPTNWV SEQ ID NO:33

表A2-抗HIV gp120 V3聚醣結合抗體之CDR (Chothia)

Ab名稱	VH – CDR1	VH – CDR2	VH – CDR3	VL – CDR1	VL – CDR2	VL – CDR3
36	GASIND SEQ ID NO:130	YVHHSGDTN SEQ ID NO:131	ALHGKRIYGIVALGELFTYFYM DV SEQ ID NO:36	GKESIGSRAVQ SEQ ID NO:37	NNQDRPA SEQ ID NO:25	HIYDARGGTNWV SEQ ID NO:38
37	GESTGACT SEQ ID NO:132	SLSHCQSFWGSGWTF SEQ ID NO:133	FDGEVLVYNHWPKPAWVDL SEQ ID NO:41	NGTATNFVS SEQ ID NO:42	GVDKRPP SEQ ID NO:43	GSLVGNWDVI SEQ ID NO:44
38	GDSTAACD SEQ ID NO:134	GLSHCAGYYNTGWTY SEQ ID NO:135	FDGEVLVYHDWPKPAWVDL SEQ ID NO:47	TGTSNRFVS SEQ ID NO:48	GVNKRPS SEQ ID NO:49	SSLVGNWDVI SEQ ID NO:50
39	GDSTAACD SEQ ID NO:134	SLSHCAGYYNSGWTY SEQ ID NO:136	FGGDVLVYHDWPKPAWVDL SEQ ID NO:52	TGNINNFVS SEQ ID NO:53	GVNKRPS SEQ ID NO:49	GSLAGNWDVV SEQ ID NO:54
40	GDSTAACN SEQ ID NO:137	SLSHCASYWNRGWTY HNPSLKS SEQ ID NO:56	FGGEVLRYTDWPKPAWVDL SEQ ID NO:57	TGTSNNFVS SEQ ID NO:58	DVNKRPS SEQ ID NO:59	GSLVGNWDVI SEQ ID NO:44
41	GDSTAGCD SEQ ID NO:138	GLSHCAGYYNTGWTY SEQ ID NO:135	FDGEVLVYNDWPKPAWVDL SEQ ID NO:61	TGTSNNFVS SEQ ID NO:58	GVNKRPS SEQ ID NO:49	GSLVGNWDVI SEQ ID NO:44
42	GESINTGH SEQ ID NO:139	HIHYTTAVL SEQ ID NO:140	SGGDILYYYEWQKPHWFSP SEQ ID NO:64	NGTSSDIGGWNF VS SEQ ID NO:65	EVNKRPS SEQ ID NO:66	SSLFGRWDVV SEQ ID NO:67
43	GGSMRGTDWGEND SEQ ID NO:141	SIHWRGRTTH SEQ ID NO:142	HKYHDIFRVVPVAGWFDP SEQ ID NO:70	RASQNVKNNLA SEQ ID NO:71	DASSRAG SEQ ID NO:72	QQYEEWPRT SEQ ID NO:73
44	GGSIRGGEWGDSD SEQ ID NO:143	SIHWRGTTH SEQ ID NO:144	HKYHDIVMVVPIAGWFDP SEQ ID NO:76	RASQSVKNNLA SEQ ID NO:77	DTSSRAS SEQ ID NO:78	QQYEEWPRT SEQ ID NO:73
45	GDSIRGGEWGDKD SEQ ID NO:145	SIHWRGTTH SEQ ID NO:144	HRHHDVFMLVPIAGWFDV SEQ ID NO:81	RASQNINKNLA SEQ ID NO:82	ETYSKIA	QQYEEWPRT SEQ ID NO:73

表A2-抗HIV gp120 V3聚醣結合抗體之CDR (Chothia)

Ab名稱	VH – CDR1	VH – CDR2	VH – CDR3	VL – CDR1	VL – CDR2	VL – CDR3
					SEQ ID NO:83	
46	QDSRPSDH SEQ ID NO:146	HYNGA SEQ ID NO:147	NAIRIYGVVALGEWFHYGMDV SEQ ID NO:86	SGAPLTSRFTY SEQ ID NO:87	RSSQRSS SEQ ID NO:88	QSSDTSDSYKM SEQ ID NO:89
47	NDSRPSDH SEQ ID NO:148	HYNGA SEQ ID NO:147	NAIRIYGVVALGEWFHYGMDV SEQ ID NO:86	SGAPLTSRFTY SEQ ID NO:87	RSSQRSS SEQ ID NO:88	QSSDTSDSYKM SEQ ID NO:89
48	GDSRPSDH SEQ ID NO:149	HYNGD SEQ ID NO:150	NVIRVFGVISLGEWFHYGMDV SEQ ID NO:91	SGPPLASRYTY SEQ ID NO:92	RDRQFPS SEQ ID NO:93	QSSDTSDSYKM SEQ ID NO:89
49	NDSRPSDH SEQ ID NO:148	HYNGA SEQ ID NO:147	NAIRIYGVVALGEWFHYGMDV SEQ ID NO:86	SGAALTSRFTY SEQ ID NO:95	RTSQRSS SEQ ID NO:96	QSSDTSDSYKM SEQ ID NO:89
50	GDSRPSDH SEQ ID NO:149	HYGGD SEQ ID NO:151	NVIRVFGVIALGEWFHYGMDV SEQ ID NO:98	SGPPLASRYCY SEQ ID NO:99	RDRQFSS SEQ ID NO:100	QSSDINDSYKM SEQ ID NO:101
51	GDSRPSDH SEQ ID NO:149	HYGGD SEQ ID NO:151	NVIRVFGVIALGEWFHYGMDV SEQ ID NO:98	SGPPLASRYCY SEQ ID NO:99	RDRQFSS SEQ ID NO:100	QSSDTSDSFKM SEQ ID NO:102
52	GDSRPSDH SEQ ID NO:149	HYGGD SEQ ID NO:151	NVIRVFGVIALGEWFHYGMDV SEQ ID NO:98	SGPPLATRYCY SEQ ID NO:103	RDRQFSS SEQ ID NO:100	QSSDTSDSYKM SEQ ID NO:89
53	GDSRPSDH SEQ ID NO:149	HYGGD SEQ ID NO:151	NVIRVFGVIALGEWFHYGMDV SEQ ID NO:98	SGPPLASRYCY SEQ ID NO:99	RDRQFSS SEQ ID NO:100	QSSDNSDSFKM SEQ ID NO:105
54	GFYFPDY SEQ ID NO:152	RGWAYGGS SEQ ID NO:153	EQRNKDYRYGQEGFGYSYGMDV SEQ ID NO:108	RASHFIANYVN SEQ ID NO:109	ESSTLQR SEQ ID NO:110	QQSHSPPVT SEQ ID NO:111

表A3-抗HIV gp120 V3聚醣結合抗體之CDR (IMGT)

Ab名稱	VH – CDR1	VH – CDR2	VH – CDR3	VL – CDR1	VL – CDR2	VL – CDR3
63	GTLVRDNY SEQ ID NO:175	VHDSGDT SEQ ID NO:176	ATTKHGRRIYGVVAFKEWFTYFYMDV SEQ ID NO:177	SIGSRA SEQ ID NO:178	NNQ SEQ ID NO:161	HIYDARGGTNWV SEQ ID NO:38
64	GASINDAY SEQ ID NO:179	VHHSGDT SEQ ID NO:180	ARALHGKRIYGIVALGELFTYFYMDV SEQ ID NO:181	SLGSRS SEQ ID NO:182	NNN SEQ ID NO:183	HIWDSRRPTNWV SEQ ID NO:33
65	GESTGACTYF SEQ ID NO:184	LSHCQSFWGSGWT SEQ ID NO:185	ARFDGEVLVYNHWPKPAWVDL SEQ ID NO:186	ATNF SEQ ID NO:187	GVD SEQ ID NO:188	GSLVGNWDVI SEQ ID NO:44
66	GDSTAACDYF SEQ ID NO:189	LSHCAGYYNTGWT SEQ ID NO:190	ARFDGEVLVYHDWPKPAWVDL SEQ ID NO:191	SNRF SEQ ID NO:192	GVN SEQ ID NO:193	SSLVGNWDVI SEQ ID NO:50
67	GDSTAACDYF SEQ ID NO:189	LSHCAGYYNSGWT SEQ ID NO:194	ARFGGDVLVYHDWPKPAWVDL SEQ ID NO:195	INNF SEQ ID NO:196	GVN SEQ ID NO:193	GSLAGNWDVV SEQ ID NO:54
68	GDSTAACNSF SEQ ID NO:197	LSHCASYWNRGWT SEQ ID NO:198	ARFGGEVLRYTDWPKPAWVDL SEQ ID NO:199	SNNF SEQ ID NO:200	DVN SEQ ID NO:201	GSLVGNWDVI SEQ ID NO:44
69	GDSTAGCDYF SEQ ID NO:202	LSHCAGYYNTGWT SEQ ID NO:203	ARFDGEVLVYNDWPKPAWVDL SEQ ID NO:204	SNNF SEQ ID NO:200	GVN SEQ ID NO:193	GSLVGNWDVI SEQ ID NO:44
70	GESINTGHYY SEQ ID NO:205	IHYTTAV SEQ ID NO:206	VRSGGDILYYYEWQKPHWFSP SEQ ID NO:207	SSDIGGWNF SEQ ID NO:208	EVN SEQ ID NO:209	SSLFGRWDVV SEQ ID NO:67
71	GGSMRGTDWG ENDFH SEQ ID NO:210	IHWRGRTT SEQ ID NO:211	ARHKYHDIFRVVPVAGWFDP SEQ ID NO:212	QNVKNN SEQ ID NO:213	DAS SEQ ID NO:214	QQYEEWPRT SEQ ID NO:73

表A3-抗HIV gp120 V3聚醣結合抗體之CDR (IMGT)

Ab名稱	VH – CDR1	VH – CDR2	VH – CDR3	VL – CDR1	VL – CDR2	VL – CDR3
72	GGSIRGGEWG DSDYH SEQ ID NO:215	IHWRGTT SEQ ID NO:216	VKHKYHDIVMVVPIAGWFDP SEQ ID NO:217	QSVKNN SEQ ID NO:218	DTS SEQ ID NO:219	QQYEEWPRT SEQ ID NO:73
73	GDSIRGGEWG DKDYH SEQ ID NO:220	IHWRGTT SEQ ID NO:216	ARHRHHDVFMLVPIAGWFDV SEQ ID NO:221	QNINKN SEQ ID NO:222	ETY SEQ ID NO:223	QQYEEWPRT SEQ ID NO:73
74	QDSRPSDHS SEQ ID NO:224	IHYNGAT SEQ ID NO:225	NAIRIYGVVALGEWFHYGMDV SEQ ID NO:86	PLTSRF SEQ ID NO:226	RSS SEQ ID NO:227	QSSDTSDSYKM SEQ ID NO:89
75	NDSRPSDHS SEQ ID NO:228	IHYNGAT SEQ ID NO:225	NAIRIYGVVALGEWFHYGMDV SEQ ID NO:86	PLTSRF SEQ ID NO:226	RSS SEQ ID NO:227	QSSDTSDSYKM SEQ ID NO:89
76	GDSRPSDHS SEQ ID NO:229	VHYNGDN SEQ ID NO:230	NVIRVFGVISLGEWFHYGMDV SEQ ID NO:91	PLASRY SEQ ID NO:231	RDR SEQ ID NO:232	QSSDTSDSYKM SEQ ID NO:89
77	GDSRPSDHS SEQ ID NO:229	VHYNGDT SEQ ID NO:233	NVIRVFGVISLGEWFHYGMDV SEQ ID NO:91	PLASRY SEQ ID NO:231	RDR SEQ ID NO:232	QSSDTSDSYKM SEQ ID NO:89
78	NDSRPSDHS SEQ ID NO:228	IHYNGAT SEQ ID NO:225	NAIRIYGVVALGEWFHYGMDV SEQ ID NO:86	ALTSRF SEQ ID NO:234	RTS SEQ ID NO:235	QSSDTSDSYKM SEQ ID NO:89
79	GDSRPSDHS SEQ ID NO:229	IHYGGDI SEQ ID NO:236	NVIRVFGVIALGEWFHYGMDV SEQ ID NO:98	PLASRY SEQ ID NO:231	RDR SEQ ID NO:232	QSSDINDSYKM SEQ ID NO:101
80	GDSRPSDHS SEQ ID NO:229	IHYGGDI SEQ ID NO:236	NVIRVFGVIALGEWFHYGMDV SEQ ID NO:98	PLASRY SEQ ID NO:231	RDR SEQ ID NO:232	QSSDTSDSFKM SEQ ID NO:102

表A3-抗HIV gp120 V3聚醣結合抗體之CDR (IMGT)						
Ab名稱	**VH – CDR1**	**VH – CDR2**	**VH – CDR3**	**VL – CDR1**	**VL – CDR2**	**VL – CDR3**
81	GDSRPSDHS SEQ ID NO:229	IHYGGDI SEQ ID NO:236	NVIRVFGVIALGEWFHYGMDV SEQ ID NO:98	PLATRY SEQ ID NO:237	RDR SEQ ID NO:232	QSSDTSDSYKM SEQ ID NO:89
82	GDSRPSDHS SEQ ID NO:229	IHYNGDK SEQ ID NO:238	NVIRVFGVISLGEWFHYGMDV SEQ ID NO:91	PLASRY SEQ ID NO:231	RDR SEQ ID NO:232	QSSDTSDSYKM SEQ ID NO:89
83	GDSRPSDHS SEQ ID NO:229	IHYGGDI SEQ ID NO:236	NVIRVFGVIALGEWFHYGMDV SEQ ID NO:98	PLASRY SEQ ID NO:231	RDR SEQ ID NO:232	QSSDNSDSFKM SEQ ID NO:105
84	GFYFPDYA SEQ ID NO:239	MRGWAYGGSA SEQ ID NO:240	EQRNKDYRYGQEGFGYSYGMDV SEQ ID NO:108	HFIANY SEQ ID NO:241	ESS SEQ ID NO:242	QQSHSPPVT SEQ ID NO:111
85	DFYFPDYA SEQ ID NO:243	IRGWAYGQAA SEQ ID NO:244	EQRGGDGRYSGDGFGYPYGMDV SEQ ID NO:113	HFIANY SEQ ID NO:241	QSW SEQ ID NO:245	QQSHSPPLS SEQ ID NO:115
86	DFYFPDYA SEQ ID NO:243	IRGWAYGQSA SEQ ID NO:246	EQRGANGRYGGDGFGYSYGMDV SEQ ID NO:117	HFIANY SEQ ID NO:241	ESS SEQ ID NO:242	QQSHSPPVS SEQ ID NO:119

表A4-抗HIV gp120 V3聚醣結合抗體之CDR (Honegger)						
Ab名稱	**VH – CDR1**	**VH – CDR2**	**VH – CDR3**	**VL – CDR1**	**VL – CDR2**	**VL – CDR3**
87	VSGASISDSY SEQ ID NO:247	VHKSGDTNYSPSLKSR SEQ ID NO:248	TLHGRRIYGIVAFN EWFTYFYMD SEQ ID NO:249	EKSLGSRA SEQ ID NO:250	NNQDRPSGIPER SEQ ID NO:251	WDSRVPTKW SEQ ID NO:252
88	VSGASISDSY SEQ ID NO:247	VHKSGDTNYNPSLKSR SEQ ID NO:253	TLHGRRIYGIVAFN EWFTYFYMD SEQ ID NO:249	EKSLGSRA SEQ ID NO:250	NNQDRPSGIPER SEQ ID NO:251	WDSRVPTKW SEQ ID NO:252

表A4-抗HIV gp120 V3聚醣結合抗體之CDR (Honegger)

Ab名稱	VH – CDR1	VH – CDR2	VH – CDR3	VL – CDR1	VL – CDR2	VL – CDR3
89	VSGDSMNNYY SEQ ID NO:254	ISDRESATYNPSLNSR SEQ ID NO:255	ARRGQRIYGVVSFG EFFYYYSMD SEQ ID NO:256	RQALGSRA SEQ ID NO:257	NNQDRPSGIPER SEQ ID NO:251	WDSRSGFSW SEQ ID NO:258
90	VSGGSISNYY SEQ ID NO:259	ISDRETTTYNPSLNSR SEQ ID NO:260	ARRGQRIYGVVSFG EFFYYYYMD SEQ ID NO:261	RQALGSRA SEQ ID NO:257	NNQDRPSGIPER SEQ ID NO:251	WDSRSGFSW SEQ ID NO:258
91	VSNGSVSGRF SEQ ID NO:262	FSDTDRSEYNPSLRSR SEQ ID NO:263	AQQGKRIYGIVSFG ELFYYYYMD SEQ ID NO:264	ERSRGSRA SEQ ID NO:265	NNQDRPAGVSER SEQ ID NO:266	WDSRSPISW SEQ ID NO:267
92	VSNGSVSGRF SEQ ID NO:262	FSDTDRSEYNPSLRSR SEQ ID NO:263	AQQGKRIYGIVSFG EFFYYYYMD SEQ ID NO:268	ERSRGSRA SEQ ID NO:265	NNQDRPAGVSER SEQ ID NO:266	WDSRSPISW SEQ ID NO:267
93	VSGASINDAY SEQ ID NO:269	VHHSGDTNYNPSLKRR SEQ ID NO:270	ALHGKRIYGIVALG ELFTYFYMD SEQ ID NO:271	KESIGSRA SEQ ID NO:272	NNQDRPAGVPER SEQ ID NO:273	YDARGGTNW SEQ ID NO:274
94	VSGTLVRDNY SEQ ID NO:275	VHDSGDTNYNPSLKSR SEQ ID NO:276	TKHGRRIYGVVAFK EWFTYFYMD SEQ ID NO:277	EESLGSRS SEQ ID NO:278	NNNDRPSGIPDR SEQ ID NO:279	WDSRRPTNW SEQ ID NO:280
95	VSGESTGACTYF SEQ ID NO:281	LSHCQSFWGSGWTFHNP SLKSR SEQ ID NO:282	FDGEVLVYNHWPKP AWVD SEQ ID NO:283	GTATNF SEQ ID NO:284	GVDKRPPGVPDR SEQ ID NO:285	LVGNWDV SEQ ID NO:286
96	VSGDSTAACDYF SEQ ID NO:287	LSHCAGYYNTGWTYHNP SLKSR SEQ ID NO:288	FDGEVLVYHDWPKP AWVD SEQ ID NO:289	GTSNRF SEQ ID NO:290	GVNKRPSGVPDR SEQ ID NO:291	LVGNWDV SEQ ID NO:286
97	VSGDSTAACDYF SEQ ID NO:287	LSHCAGYYNSGWTYHNP SLKSR SEQ ID NO:292	FGGDVLVYHDWPKP AWVD SEQ ID NO:293	GNINNF SEQ ID NO:294	GVNKRPSGVPDR SEQ ID NO:291	LAGNWDV SEQ ID NO:295
98	VSGDSTAACNSF SEQ ID NO:296	LSHCASYWNRGWTYHNP SLKSR	FGGEVLRYTDWPKP AWVD	GTSNNF	DVNKRPSGVPDR	LVGNWDV

表A4-抗HIV gp120 V3聚醣結合抗體之CDR (Honegger)

Ab名稱	VH - CDR1	VH - CDR2	VH - CDR3	VL - CDR1	VL - CDR2	VL - CDR3
		SEQ ID NO:297	SEQ ID NO:298	SEQ ID NO:299	SEQ ID NO:300	SEQ ID NO:286
99	VSGDSTAGCDYF SEQ ID NO:301	LSHCAGYYNTGWTYHNP SLKSR SEQ ID NO:298	FDGEVLVYNDWPKP AWVD SEQ ID NO:302	GTSNNF SEQ ID NO:299	GVNKRPSGVPDR SEQ ID NO:291	LVGNWDV SEQ ID NO:286
100	VSGESINTGHYY SEQ ID NO:303	IHYTTAVLHNPSLKSR SEQ ID NO:304	SGGDILYYYEWQKP HWFS SEQ ID NO:305	GTSSDIGGWNF SEQ ID NO:306	EVNKRPSGVPGR SEQ ID NO:307	LFGRWDV SEQ ID NO:308
101	VSGGSMRGTDWGE NDFH SEQ ID NO:309	IHWRGRTTHYKTSFRSR SEQ ID NO:310	HKYHDIFRVVPVAG WFD SEQ ID NO:311	ASQNVKNN SEQ ID NO:312	DASSRAGGIPDR SEQ ID NO:313	YEEWPR SEQ ID NO:314
102	ASGGSIRGGEWGD SDYH SEQ ID NO:315	IHWRGTTHYNAPFRGR SEQ ID NO:316	HKYHDIVMVVPIAG WFD SEQ ID NO:317	ASQSVKNN SEQ ID NO:318	DTSSRASGIPAR SEQ ID NO:319	YEEWPR SEQ ID NO:314
103	VSGDSIRGGEWGD KDYH SEQ ID NO:320	IHWRGTTHYKESLRRR SEQ ID NO:321	HRHHDVFMLVPIAG WFD SEQ ID NO:322	ASQNINKN SEQ ID NO:323	ETYSKIAAFPAR SEQ ID NO:324	YEEWPR SEQ ID NO:314
104	VSQDSRPSDHS SEQ ID NO:325	IHYNGATTYNPSLRSR SEQ ID NO:326	NAIRIYGVVALGEW FHYGMD SEQ ID NO:327	GAPLTSRF SEQ ID NO:328	RSSQRSSGWSGR SEQ ID NO:329	SDTSDSYK SEQ ID NO:330
105	VSNDSRPSDHS SEQ ID NO:331	IHYNGATTYNPSLRSR SEQ ID NO:326	NAIRIYGVVALGEW FHYGMD SEQ ID NO:327	GAPLTSRF SEQ ID NO:328	RSSQRSSGWSGR SEQ ID NO:329	SDTSDSYK SEQ ID NO:330
106	VFGDSRPSDHS SEQ ID NO:332	VHYNGDNTYNPSLRGR SEQ ID NO:333	NVIRVFGVISLGEW FHYGMD SEQ ID NO:334	GPPLASRY SEQ ID NO:335	RDRQFPSGVSGR SEQ ID NO:336	SDTSDSYK SEQ ID NO:330
107	VFGDSRPSDHS SEQ ID NO:332	VHYNGDTTYNPSLRGR SEQ ID NO:337	NVIRVFGVISLGEW FHYGMD SEQ ID NO:334	GPPLASRY SEQ ID NO:335	RDRQFPSGVSGR SEQ ID NO:336	SDTSDSYK SEQ ID NO:330

表A4-抗HIV gp120 V3聚醣結合抗體之CDR (Honegger)

Ab名稱	VH – CDR1	VH – CDR2	VH – CDR3	VL – CDR1	VL – CDR2	VL – CDR3
108	VSNDSRPSDHS SEQ ID NO:331	IHYNGATTYNPSLRSR SEQ ID NO:326	NAIRIYGVVALGEW FHYGMD SEQ ID NO:327	GAALTSRF SEQ ID NO:338	RTSQRSSGWSGR SEQ ID NO:339	SDTSDSYK SEQ ID NO:330
109	ISGDSRPSDHS SEQ ID NO:340	IHYGGDITYNPSLRSR SEQ ID NO:341	NVIRVFGVIALGEW FHYGMD SEQ ID NO:342	GPPLASRY SEQ ID NO:335	RDRQFSSGMSGR SEQ ID NO:343	SDINDSYK SEQ ID NO:344
110	ISGDSRPSDHS SEQ ID NO:340	IHYGGDITYNPSLRSR SEQ ID NO:341	NVIRVFGVIALGEW FHYGMD SEQ ID NO:342	GPPLASRY SEQ ID NO:335	RDRQFSSGISGR SEQ ID NO:345	SDTSDSFK SEQ ID NO:346
111	ISGDSRPSDHS SEQ ID NO:340	IHYGGDITYNPSLRSR SEQ ID NO:341	NVIRVFGVIALGEW FHYGMD SEQ ID NO:342	GPPLATRY SEQ ID NO:347	RDRQFSSGVSGR SEQ ID NO:348	SDTSDSYK SEQ ID NO:330
112	VFGDSRPSDHS SEQ ID NO:332	IHYNGDKTYNPSLRGR SEQ ID NO:349	NVIRVFGVISLGEW FHYGMD SEQ ID NO:334	GPPLASRY SEQ ID NO:335	RDRQFPSGVSGR SEQ ID NO:336	SDTSDSYK SEQ ID NO:330
113	ISGDSRPSDHS SEQ ID NO:340	IHYGGDITYNPSLRSR SEQ ID NO:341	NVIRVFGVIALGEW FHYGMD SEQ ID NO:342	GPPLASRY SEQ ID NO:335	RDRQFSSGISGR SEQ ID NO:345	SDNSDSFK SEQ ID NO:350
114	ASGFYFPDYA SEQ ID NO:351	MRGWAYGGSAQFAAFAV GK SEQ ID NO:352	EQRNKDYRYGQEGF GYSYGMD SEQ ID NO:353	ASHFIANY SEQ ID NO:354	ESSTLQRGVPSR SEQ ID NO:355	SHSPPV SEQ ID NO:356
115	AFDFYFPDYA SEQ ID NO:357	IRGWAYGQAAQYGKSAS GR SEQ ID NO:358	EQRGGDGRYSGDGF GYPYGMD SEQ ID NO:359	ASHFIANY SEQ ID NO:354	QSWTLNRGIPSR SEQ ID NO:360	SHSPPL SEQ ID NO:361
116	AFDFYFPDYA SEQ ID NO:357	IRGWAYGQSAQYGKSAS GR SEQ ID NO:362	EQRGANGRYGGDGF GYSYGMD SEQ ID NO:363	ASHFIANY SEQ ID NO:354	ESSTLNRGVPSR SEQ ID NO:364	SHSPPV SEQ ID NO:356

表B-抗HIV gp120 V3聚醣結合抗體之VH/VL

Ab名稱	SEQ ID NO	VH	SEQ ID NO	VL
117	365	QMQLQESGPGLVKPSETLSLTCSVSGASISDSYWSWI RRSPGKGLEWIGYVHKSGDTNYSPSLKSRVNLSLDTS KNQVSLSLVAATAADSGKYYCARTLHGRRIYGIVAFN EWFTYFYMDVWGNGTQVTVSS	366	SDISVAPGETARISCGEKSLGSRAVQWYQHRA GQAPSLIIYNNQDRPSGIPERFSGSPDSPFGT TATLTITSVEAGDEADYYCHIWDSRVPTKWVF GGGTTLTVL
118	367	QMQLQESGPGLVKPSETLSLTCSVSGASISDSYWSWI RRSPGKGLEWIGYVHKSGDTNYNPSLKSRVHLSLDTS KNQVSLSLTGVTAADSGKYYCARTLHGRRIYGIVAFN EWFTYFYMDVWGTGTQVTVSS	368	SDISVAPGETARISCGEKSLGSRAVQWYQHRA GQAPSLIIYNNQDRPSGIPERFSGSPDFRPGT TATLTITSVEAGDEADYYCHIWDSRVPTKWVF GGGTTLTVL
119	369	QMQLQESGPGLVKPSETLSLTCSVSGASISDSYWSWI RRSPGKGLEWIGYVHKSGDTNYNPSLKSRVHLSLDTS KNQVSLSLTGVTAADSGKYYCARTLHGRRIYGIVAFN EWFTYFYMDVWGTGTQVTVSS	370	SDISVAPGETARISCGEKSLGSRAVQWYQHRA GQAPSLIIYNNQDRPSGIPERFSGSPD**S**RPGT TATLTITSVEAGDEADYYCHIWDSRVPTKWVF GGGTTLTVL
120	371	QMQLQESGPGLVKPSETLSLTCSVSGASISDSYWSWI RQPPGKGLEWIGYVHKSGDTNYSPSLKSRVNLSLDTS KNQVSLSLSAATAADSGVYYCARTLHGRRIYGIVAFN EWFTYFYMDVWGNGTQVTVSS	372	SDISVAPGETARISCGEKSLGSRAVQWYQQRA GQAPSLIIYNNQDRPSGIPERFSGSPDSGFGT TATLTITSVEAGDEADYYCHIWDSRVPTKWVF GGGTTLTVL
121	373	QMQLQESGPGLVKPSETLSLTCSVSGASISDSYWSWI RRSPGKGLEWIGYVHKSGDTNYNPSLKSRVHLSLDTS KNQVSLSLTGVTAADSGKYYCARTLHGRRIYGIVAFN EWFTYFYMDVWGTGTQVTVSS	374	SDISVAPGETARISCGEKSLGSRAVQWYQHRA GQAPSLIIYNNQDRPSGIPERFSGSPDSRPGT TATLTITSVEAGDEADYYCHIWDSRVPTKWVF GGGTTLTVL
122	375	QVQLQESGPGLVKPSETLSVTCSVSGDSMNNYYWTWI RQSPGKGLEWIGYISDRESATYNPSLNSRVVISRDTS KNQLSLKLNSVTPADTAVYYCATARRGQRIYGVVSFG EFFYYYSMDVWGKGTTVTVSS	376	SYVRPLSVALGETARISCGRQALGSRAVQWYQ HRPGQAPILLIYNNQDRPSGIPERFSGTPDIN FGTRATLTISGVEAGDEADYYCHMWDSRSGFS WSFGGATRLTVL
123	377	QVQLQESGPGLVKPSETLSVTCSVSGDSMNNYYWTWI RQSPGKGLEWIGYISDRESATYNPSLNSRVTISRDTS KNQFSLKLNSVTPADTAVYYCARARRGQRIYGVVSFG EFFYYYSMDVWGKGTTVTVSS	378	SPVRPLSVALGETARISCGRQALGSRAVQWYQ HRPGQAPILLIYNNQDRPSGIPERFSGTPDIN FGTRATLTISGVEAGDEADYYCHMWDSRSGFS WSFGGATRLTVL

表B-抗HIV gp120 V3聚醣結合抗體之VH/VL

Ab名稱	SEQ ID NO	VH	SEQ ID NO	VL
124	379	QVQLQESGPGLVRPSETLSVTCIVSGGSISNYYWTWI RQSPGKGLEWIGYISDRETTYNPSLNSRAVISRDTS KNQLSLQLRSVTTADTAIYFCATARRGQRIYGVVSFG EFFYYYYMDVWGKGTAVTVSS	380	SYVSPLSVALGETARISCGRQALGSRAVQWYQ HKPGQAPILLIYNNQDRPSGIPERFSGTPDIN FGTTATLTISGVEVGDEADYYCHMWDSRSGFS WSFGGATRLTV
125	381	QVHLQESGPGLVTPSETLSLTCTVSNGSVSGRFWSWI RQSPGRGLEWIGYFSDTDRSEYNPSLRSRLTLSVDRS KNQLSLRLKSVTAADSATYYCARAQQGKRIYGIVSFG EFFYYYYMDAWGKGTPVTVSS	382	SLNPLSLAPGATAKIPCGERSRGSRAVQWYQQ KPGQAPTLIIYNNQDRPAGVSERFSGNPDVAI GVTATLTISRVEVGDEADYYCHYWDSRSPISW IFGGGTQLTVL
126	383	QVHLQESGPGLVTPSETLSLTCTVSNGSVSGRFWSWI RQSPGRGLEWIGYFSDTDRSEYNPSLRSRLTLSVDRS KNQLSLKLKSVTAADSATYYCARAQQGKRIYGIVSFG ELFYYYYMDAWGKGTPVTVSS	384	SLNPLSLAPGATAKIPCGERSRGSRAVQWYQQ KPGQAPTLIIYNNQDRPAGVSERFSGNPDVAI GVTATLTISRVEVGDEGDYYCHYWDSRSPISW IFAGGTQLTVL
127	385	QVHLQESGPGLVKPSETLSLTCNVSGTLVRDNYWSWI RQPLGKQPEWIGYVHDSGDTNYNPSLKSRVHLSLDKS KNLVSLRLTGVTAADSAIYYCATTKHGRRIYGVVAFK EWFTYFYMDVWGKGTSVTVSS	386	TFVSVAPGQTARITCGEESLGSRSVIWYQQRP GQAPSLIIYNNNDRPSGIPDRFSGSPGSTFGT TATLTITSVEAGDEADYYCHIWDSRRPTNWVF GEGTTLIVL
128	387	QLHLQESGPGLVKPPETLSLTCSVSGASINDAYWSWI RQSPGKRPEWVGYVHHSGDTNYNPSLKRRVTFSLDTA KNEVSLKLVDLTAADSATYFCARALHGKRIYGIVALG ELFTYFYMDVWGKGTAVTVSS	388	SSMSVSPGETAKISCGKESIGSRAVQWYQQKP GQPPSLIIYNNQDRPAGVPERFSASPDFRPGT TATLTITNVDAEDEADYYCHIYDARGGTNWVF DRGTTLTVL
129	389	QSQLQESGPRLVEASETLSLTCNVSGESTGACTYFWG WVRQAPGKGLEWIGSLSHCQSFWGSGWTFHNPSLKSR LTISLDTPKNQVFLKLTSLTAADTATYYCARFDGEVL VYNHWPKPAWVDLWGRGIPVTVSS	390	QSALTQPPSASGSPGQSITISCNGTATNFVSW YQQFPDKAPKLIIFGVDKRPPGVPDRFSGSRS GTTASLTVSRLQTDDEAVYYCGSLVGNWDVIF GGGTTLTVL
130	391	QPQLQESGPGLVEASETLSLTCTVSGDSTAACDYFWG WVRQPPGKGLEWIGGLSHCAGYYNTGWTYHNPSLKSR LTISLDTPKNQVFLKLNSVTAADTAIYYCARFDGEVL VYHDWPKPAWVDLWGRGTLVTVSS	392	QSALTQPPSASGSPGQSISISCTGTSNRFVSW YQQHPGKAPKLVIYGVNKRPSGVPDRFSGSKS GNTASLTVSGLQTDDEAVYYCSSLVGNWDVIF GGGTKLTVL

表B-抗HIV gp120 V3聚醣結合抗體之VH/VL

Ab名稱	SEQ ID NO	VH	SEQ ID NO	VL
131	393	QLQMQESGPGLVKPSETLSLSCTVSGDSIRGGEWGDK DYHWGWVRHSAGKGLEWIGSIHWRGTTHYKESLRRRV SMSIDTSRNWFSLRLASVTAADTAVYFCARHRHHDVF MLVPIAGWFDVWGPGVQVTVSS	394	EIVMTQSPDTLSVSPGETVTLSCRASQNINKN LAWYQYKPGQSPRLVIFETYSKIAAFPARFVA SGSGTEFTLTINNMQSEDVAVYYCQQYEEWPR TFGQGTKVDIK
132	395	QLQLQESGPGLVKPSETLSLTCTVSGGSMRGTDWGEN DFHYGWIRQSSAKGLEWIGSIHWRGRTTHYKTSFRSR ATLSIDTSNNRFSLTFSFVTAADTAVYYCARHKYHDI FRVVPVAGWFDPWGQGLLVTVSS	396	EIVMTQSPPTLSVSPGETATLSCRASQNVKNN LAWYQLKPGQAPRLLIFDASSRAGGIPDRFSG SGYGTDFTLTVNSVQSEDFGDYFCQQYEEWPR TFGQGTKVDIK
133	397	EVHLEESGPGLVRPSETLSLTCTASGGSIRGGEWGDS DYHWGWVRHSPEKGLEWIGSIHWRGTTHYNAPFRGRG RLSIDLSRNQFSLRLTSVTAEDTAVYYCVKHKYHDIV MVVPIAGWFDPWGQGLQVTVSS	398	EIMMTQSPAILSVSPGDRATLSCRASQSVKNN LAWYQKRPGQAPRLLIFDTSSRASGIPARFSG GGSGTEFTLTVNSMQSEDFATYYCQQYEEWPR TFGQGTKVEIK
134	399	QPQLQESGPGLVEASETLSLTCTVSGDSTAACDYFWG WVRQPPGKGLEWIGSLSHCAGYYNSGWTYHNPSLKSR LTISLDTPKNQVFLKLNSVTAADTAIYYCARFGGDVL VYHDWPKPAWVDLWGRGVLVTVSS	400	QSALTQPPSASGSPGQSITISCTGNINNFVSW YQQHPGKAPKLVIYGVNKRPSGVPDRFSGSKS GNAASLTVSGLQTDDEAVYYCGSLAGNWDVVF GGGTKLTVL
135	401	QPQLQESGPTLVEASETLSLTCAVSGDSTAACNSFWG WVRQPPGKGLEWVGSLSHCASYWNRGWTYHNPSLKSR LTLALDTPKNLVFLKLNSVTAADTATYYCARFGGEVL RYTDWPKPAWVDLWGRGTLVTVSS	402	QSALTQPPSASGSPGQSITISCTGTSNNFVSW YQQHAGKAPKLVIYDVNKRPSGVPDRFSGSKS GNTASLTVSGLQTDDEAVYYCGSLVGNWDVIF GGGTKLTVL
136	403	QPQLQESGPGLVEASETLSLTCTVSGDSTAGCDYFWG WVRQPPGKGLEWIGGLSHCAGYYNTGWTYHNPSLKSR LTISLDTPKNQVFLKLNSVTAADTAIYYCARFDGEVL VYNDWPKPAWVDLWGRGTLVTVSS	404	QSALTQPPSASGSPGQSITISCTGTSNNFVSW YQQHPAKAPKLVIYGVNKRPSGVPDRFSGSKS GNTASLTVSGLQTDDEAVYYCGSLVGNWDVIF GGGTKLTVL
137	405	QVQLQESGPGLVKPAETLSLTCSVSGESINTGHYYWG WVRQVPGKGLEWIGHIHYTTAVLHNPSLKSRLTIKIY TLRNQITLRLSNVTAADTAVYHCVRSGGDILYYYEWQ KPHWFSPWGPGIHVTVSS	406	QSALTQPPSASGSLGQSVTISCNGTSSDIGGW NFVSWYQQFPGRAPRLIIFEVNKRPSGVPGRF SGSKSGNSASLTVSGLQSDDEGQYFCSSLFGR WDVVFGGGTKLTVL

表B-抗HIV gp120 V3聚醣結合抗體之VH/VL

Ab名稱	SEQ ID NO	VH	SEQ ID NO	VL
138	407	QVQLRESGPGLVKPSETLSLSCTVSQDSRPSDHSWTW VRQSPGKALEWIGDIHYNGATTYNPSLRSRVRIELDQ SIPRFSLKMTSMTAADTGMYYCARNAIRIYGVVALGE WFHYGMDVWGQGTAVTVSS	408	WASSELTQPPSVSVSPGQTARITCSGAPLTSR FTYWYRQKPGQAPVLIISRSSQRSSGWSGRFS ASWSGTTVTLTIRGVQADDEADYYCQSSDTSD SYKMFGGGTKLTVL
139	409	QVQLRESGPGLVKPSETLSLSCTVSNDSRPSDHSWTW VRQSPGKALEWIGDIHYNGATTYNPSLRSRVRIELDQ SIPRFSLKMTSMTAADTGMYYCARNAIRIYGVVALGE WFHYGMDVWGQGTAVTVSS	410	SSELTQPPSVSVSPGQTARITCSGAPLTSRFT YWYRQKPGQAPVLIISRSSQRSSGWSGRFSAS WSGTTVTLTIRGVQADDEADYYCQSSDTSDSY KMFGGGTKLTVL
140	411	EVQLRESGPRLVKPSETLSLSCDVFGDSRPSDHSWTW VRQPPGKALEWIGDVHYNGDNTYNPSLRGRVKIDVDR STHRFSLTLKSLTAADTGIYFCARNVIRVFGVISLGE WFHYGMDVWGPGTAVIVSS	412	SSELTQAPSVSVSPGQTATIACSGPPLASRYT YWYRQKPGQAPVLIIFRDRQFPSGVSGRFSAS KSGTTATLTIRDVQVEDEGDYYCQSSDTSDSY KMFGGGTTLTVL
141	413	EVQLRESGPGLVKPSETLSLSCDVFGDSRPSDHSWTW VRQPPGKALEWIGDVHYNGDTTYNPSLRGRVKIDVDR STHRFSLTLNSLTAADTGIYFCARNVIRVFGVISLGE WFHYGMDVWGQGTAVTVSS	414	SSELTQAPSVSVSPGQTATIACSGPPLASRYT YWYRQKPGQAPVLIIFRDRQFPSGVSGRFSAS KSGTTATLTIRDVQVEDEGDYYCQSSDTSDSY KMFGGGTTLTVL
142	415	QVQLRESGPGLVKPSETLSLTCTVSNDSRPSDHSWTW VRQSPGKALEWIGDIHYNGATTYNPSLRSRVRIELDQ SIPRFSLKMTSMTAADTGMYYCARNAIRIYGVVALGE WFHYGMDVWGQGTAVTVSS	416	SSELTQPPSVSVSPGQTAKITCSGAALTSRFT YWYRQKPGQAPVLIISRTSQRSSGWSGRFSAS WSGTTVTLTIRGVQADDEGDYYCQSSDTSDSY KMFGGGTKLTVL
143	417	EVQLRESGPGLVKPSGNMALTCTISGDSRPSDHSWTW VRQSPGKALEWIGDIHYGGDITYNPSLRSRVKLEVDT STNRFFLKMTSLTVADTGIYFCARNVIRVFGVIALGE WFHYGMDVWGQGTAITVSP	418	SSELTQTPSVTVSPGETARIACSGPPLASRYC YWYRQKPGQAPVLIIFRDRQFSSGMSGRFASS HSGTTVTLTIRDVRVEDEADYYCQSSDINDSY KMFGGGTKVTVL
144	419	EVQLRESGPGLVKPSGNMALTCTISGDSRPSDHSWTW VRQSPGKTLEWIGDIHYGGDITYNPSLRSRVKLEVDT SSNRFFLKMTSLTVADTGIYFCARNVIRVFGVIALGE WFHYGMDVWGQGTAITVSP	420	SSELTQTASVTVSPGETARIACSGPPLASRYC YWYRQKPGQAPVLIIFRDRQFSSGISGRFSSS QSGTTVTLTIRDVRVEDEADYYCQSSDTSDSF KMFGGGTKLTVL

表B-抗HIV gp120 V3聚醣結合抗體之VH/VL				
Ab名稱	SEQ ID NO	VH	SEQ ID NO	VL
145	421	QVQLRESGPGLVKPSGNMALTCTISGDSRPSDHSWTWVRQSPGKALEWIGDIHYGGDITYNPSLRSRVELEVDRSTNRFFLKMTSLSVADTGMYFCARNVIRVFGVIALGEWFHYGMDVWGQGTAITVSP	422	SSELTQAPSVTVSPGDTARIACSGPPLATRYCYWYRQKSGQAPVLIIFRDRQFSSGVSGRFSSSQSGSTVTLTIRDVRVEDEADYYCQSSDTSDSYKMFGGGTKLTVL
146	423	QVQLRESGPGLVKPSETLSLSCDVFGDSRPSDHSWTWVRQPPGKALEWIGDIHYNGDKTYNPSLRGRVKIDVDRSTHRFSLTLNSLTAADTGMYFCARNVIRVFGVISLGEWFHYGMDVWGPGTAVTV	424	SSELTQAPSVSVSPGQTARIACSGPPLASRYTYWYRQKPGQAPVLIIFRDRQFPSGVSGRFSASKSGTTGTLTIRDVQAEDEGDYYCQSSDTSDSYKMFGGGTTLTVL
147	425	QVQLRESGPGLVKPSGNMALTCTISGDSRPSDHSWTWVRQSPGKALEWIGDIHYGGDITYNPSLRSRVKLEVDTSSNRFFLKMTSLTVADTGIYFCARNVIRVFGVIALGEWFHYGMDVWGQGTAITVSP	426	SSELTQAPSVTLSPGETARIACSGPPLASRYCYWYRQKPGQAPVLIIFRDRQFSSGISGRFSSSQSGTTVTLTIRDVRVEDEADYYCQSSDNSDSFKMFGGGTKLTVL
148	427	AEQLVESGGGLVPPGRSLRLSCSASGFYFPDYAMAWVRQAPGQGLQWVGFMRGWAYGGSAQFAAFAVGKFAISRDDGRNVVYLDVKNPTFEDTGVYFCAREQRNKDYRYGQEGFGYSYGMDVWGRGTTVVVST	428	DIHMTQSPVSLSASVGDRVTITCRASHFIANYVNWYQQKPGKAPTLLIFESSTLQRGVPSRFSAYGDGTEFTLSINTLQPEDFASYICQQSHSPPVTFGAGTRVDQK
149	429	EERLVESGGGLVPPGRSLRLSCSAFDFYFPDYAMAWVRQAPGKGLEWIGFIRGWAYGQAAQYGKSASGRMTISRDDSRRVVYLDIKSPIKEDTGAYFCAREQRGGDGRYSGDGFGYPYGMDVWGRGTMVTVSA	430	DILMTQSPVSLSASIGERITITCRASHFIANYVNWYQQRPGKAPKLLIFQSWTLNRGIPSRFSGYGDGTEFTLSISALQSEDFGTYICQQSHSPPLSFGGGTRVDQT
150	431	EERLVESGGGLVPPGRSLRLSCSAFDFYFPDYAMAWVRQAPGRALEWIGFIRGWAYGQSAQYGKSASGRMTISRDDSRRVVYLDIKSPTHEDTGVYFCAREQRGANGRYGGDGFGYSYGMDVWGRGTMVSVSA	432	DIQMTQSPFTLSASVGERVTITCRASHFIANYVNWYQQRPGRAPKLLIFESSTLNRGVPSRFSGSGDGTEFTLSISALQSEDFATYICQQSHSPPVSFGGGTRVDQT

【0032】 在一些實施例中，抗HIV gp120 V3聚醣結合抗體包含VH，其包含VH-CDR1、VH-CDR2、及VH-CDR3；及VL，其包含VL-CDR1、VL-CDR2、及第二VH-CDR3；其中VH-CDR1、VH-CDR2、VH-CDR3、VL-CDR1、VL-CDR2、及VH-CDR3包含下列所述之序列：SEQ ID NO: 7、8、9、10、11、及12；SEQ ID NO: 7、13、9、10、11、及12；SEQ ID NO: 14、15、16、17、11、及18；SEQ ID NO: 14、19、20、17、11、及18；SEQ ID NO: 21、22、23、24、25、及26；SEQ ID NO: 21、22、27、24、25、及26；SEQ ID NO: 28、29、30、31、32、及33；SEQ ID NO: 34、35、36、37、25、及38；SEQ ID NO: 39、40、41、42、43、及44；SEQ ID NO: 45、46、47、48、49、及50；SEQ ID NO: 45、51、52、53、49、及54；SEQ ID NO: 55、56、57、58、59、及44；SEQ ID NO: 60、46、61、58、49、及44；SEQ ID NO: 62、63、64、65、66、及67；SEQ ID NO: 68、69、70、71、72、及73；SEQ ID NO: 74、75、76、77、78、及73；SEQ ID NO: 79、80、81、82、83、及73；SEQ ID NO: 84、85、86、87、88、及89；SEQ ID NO: 84、90、91、92、93、及89；SEQ ID NO: 84、85、86、95、96、及89；SEQ ID NO: 84、97、98、99、100、及101；SEQ ID NO: 84、97、98、99、100、及102；SEQ ID NO: 84、97、98、103、100、及89；SEQ ID NO: 84、104、91、92、93、及89；SEQ ID NO: 84、97、98、99、100、及105；SEQ ID NO: 106、107、108、109、110、及111；SEQ ID NO: 106、112、113、109、114、及115或SEQ ID NO: 106、116、117、109、118、及119（根據Kabat之CDR）。

【0033】 在一些實施例中，抗HIV gp120 V3聚醣結合抗體包含VH，其包含VH-CDR1、VH-CDR2、及VH-CDR3；及VL，其包含VL-CDR1、VL-

CDR2、及第二VH-CDR3；其中VH-CDR1、VH-CDR2、VH-CDR3、VL-CDR1、VL-CDR2、及VH-CDR3包含下列所述之序列：SEQ ID NO: 120、121、9、10、11、及12；SEQ ID NO: 122、123、16、17、11、及18；SEQ ID NO: 124、125、20、17、11、及18；SEQ ID NO: 126、127、23、24、25、及26；SEQ ID NO: 126、127、27、24、25、及26；SEQ ID NO: 128、192、30、31、32、及33；SEQ ID NO: 130、131、36、37、25、及38；SEQ ID NO: 132、133、41、42、43、及44: SEQ ID NO: 134、135、47、48、49、及50；SEQ ID NO: 134、136、52、53、49、及54；SEQ ID NO: 137、56、57、58、59、及44；SEQ ID NO: 138、135、61、58、49、及44；SEQ ID NO: 139、140、64、65、66、及67；SEQ ID NO: 141、142、70、71、72、及71；SEQ ID NO: 143、144、76、77、78、及73；SEQ ID NO: 145、144、81、82、83、及73；SEQ ID NO: 146、147、86、87、88、及89；SEQ ID NO: 148、147、86、87、88、及89；SEQ ID NO: 149、150、91、92、93、及89；SEQ ID NO: 148、147、86、95、96、及89；SEQ ID NO: 149、151、98、99、100、及101；SEQ ID NO: 149、151、98、99、100、及102；SEQ ID NO: 149、151、98、103、100、及89；SEQ ID NO: 149、151、98、99、100、及105；SEQ ID NO: 152、153、108、109、110、及111；SEQ ID NO: 154、155、113、109、114、及115；或SEQ ID NO: 154、156、117、109、118、及119（根據Chothia之CDR）。

【0034】 在一些實施例中，抗HIV gp120 V3聚醣結合抗體包含VH，其包含VH-CDR1、VH-CDR2、及VH-CDR3；及VL，其包含VL-CDR1、VL-CDR2、及第二VH-CDR3；其中VH-CDR1、VH-CDR2、VH-CDR3、VL-CDR1、VL-CDR2、及VH-CDR3包含下列所述之序列：SEQ ID NO: 157、

158、159、160、161、及12；SEQ ID NO: 162、163、164、165、161、及18；SEQ ID NO: 162、163、166、165、161、及18；SEQ ID NO: 167、168、169、165、161、及18；SEQ ID NO: 170、171、172、173、161、及26；SEQ ID NO: 170、171、174、173、161、及26；SEQ ID NO: 175、176、177、178、161、及38；SEQ ID NO: 179、180、181、182、183、及33；SEQ ID NO: 184、185、186、187、188、及44；SEQ ID NO: 189、190、191、192、193、及50；SEQ ID NO: 189、194、195、196、193、及54；SEQ ID NO: 197、198、199、200、201、及44；SEQ ID NO: 202、203、204、200、193、及44；SEQ ID NO: 205、206、207、208、209、及67；SEQ ID NO: 210、211、212、213、214、及73；SEQ ID NO: 215、216、217、218、219、及73；SEQ ID NO: 220、216、221、222、223、及73；SEQ ID NO: 224、225、86、226、227、及89；SEQ ID NO: 228、225、86、226、227、及89；SEQ ID NO: 229、230、91、231、232、及89；SEQ ID NO: 229；233、91、231、232、及89；SEQ ID NO: 228、225、86、234、235、及89；SEQ ID NO: 229、236、98、231、232、及101；SEQ ID NO: 229、236、98、231、232、及102；SEQ ID NO: 229、236、98、237、232、及89；SEQ ID NO: 229、238、91、231、232、及89；SEQ ID NO: 229、236、98、231、232、及105；SEQ ID NO: 239、240、108、241、242、及111；SEQ ID NO: 243、244、113、241、245、及115；或SEQ ID NO: 243、246、117、241、242、及119（根據IMGT之CDR）。

【0035】 在一些實施例中，抗HIV gp120 V3聚醣結合抗體包含VH，其包含VH-CDR1、VH-CDR2、及VH-CDR3；及VL，其包含VL-CDR1、VL-CDR2、及第二VH-CDR3；其中VH-CDR1、VH-CDR2、VH-CDR3、VL-

CDR1、VL-CDR2、及VH-CDR3包含下列所述之序列：SEQ ID NO: 247、248、249、250、251、及252；SEQ ID NO: 247、253、249、250、251、及252；SEQ ID NO: 254、255、256、257、251、及258；SEQ ID NO: 259、260、261、257、251、及258；SEQ ID NO: 262、263、264、265、266、及267；SEQ ID NO: 262、263、268、265、266、及267；SEQ ID NO: 269、270、271、272、273、及274；SEQ ID NO: 275、276、277、278、279、及280；SEQ ID NO: 281、282、283、284、285、及286；SEQ ID NO: 287、288、289、290、291、及286；SEQ ID NO: 287、292、293、294、291、及295；SEQ ID NO: 296、297、298、299、300、及286；SEQ ID NO: 301、288、302、299、291、及286；SEQ ID NO: 303、304、305、306、307、及308；SEQ ID NO: 309、310、311、312、313、及314；SEQ ID NO: 315、316、317、318、319、及314；SEQ ID NO: 320、321、322、323、324、及314；SEQ ID NO: 325、326、327、328、329、及330；SEQ ID NO: 331、326、327、328、329、及330；SEQ ID NO: 332、333、334、335、336、及330；SEQ ID NO: 332、337、334、335、336、及330；SEQ ID NO: 331、326、327、338、339、及330；SEQ ID NO: 340、341、342、335、343、及344；SEQ ID NO: 340、341、342、335、345、346；SEQ ID NO: 340、341、342、347、348、及330；SEQ ID NO: 332、349、334、335、336、及330；SEQ ID NO: 340、341、342、335、345、及350；SEQ ID NO: 351、352、353、354、355、及356、及SEQ ID NO: 357、358、359、354、360、及361；或SEQ ID NO: 357、362、363、354、364、及356（根據Honegger之CDR）。

【0036】 表A1至表A4提供了可用於本文所述之方法中之抗HIV gp120 V3聚醣結合抗體之CDR序列的說明性實施例。

【0037】 在一些實施例中，抗HIV gp120 V3聚醣結合抗體包含VH及VL，其包含與分別如選自下列所述之胺基酸序列至少80%、至少85%、至少90%、至少91%、至少92%、至少93%、至少94%、至少95%、至少96%、至少97%、至少98%、至少99%、或100%同一的胺基酸序列：SEQ ID NO: 365及366；SEQ ID NO: 367及368；SEQ ID NO: 369及370；SEQ ID NO: 371及372；SEQ ID NO: 373及374；SEQ ID NO: 375及376；SEQ ID NO: 377及378；SEQ ID NO: 379及380；SEQ ID NO: 381及382；SEQ ID NO: 383及384；SEQ ID NO: 385及386；SEQ ID NO: 387及388；SEQ ID NO: 389及390；SEQ ID NO: 391及392；SEQ ID NO: 393及394；SEQ ID NO: 395及396；SEQ ID NO: 397及398；SEQ ID NO: 399及400；SEQ ID NO: 401及402；SEQ ID NO: 403及404；SEQ ID NO: 405及406；SEQ ID NO: 407及408；SEQ ID NO: 409及410；SEQ ID NO: 411及412；SEQ ID NO: 413及414；SEQ ID NO: 415及416；SEQ ID NO: 417及418；SEQ ID NO: 419及420；SEQ ID NO: 421及422；SEQ ID NO: 423及424；SEQ ID NO: 425及426；SEQ ID NO: 427及428；SEQ ID NO: 429及430；或SEQ ID NO: 431及432。表B提供了可用於本文所述之方法中之抗HIV gp120 V3聚醣結合抗體之可變域VH及VL序列的說明性實施例。

【0038】 在一些實施例中，抗HIV gp120 V3聚醣結合抗體係10-1074-LS。10-1074-LS之重鏈及輕鏈胺基酸序列在下文提供為SEQ ID NO: 433及434：

重鏈：

QVQLQESGPGLVKPSETLSVTCSVSGDSMNNYYWTWIRQSPGKGLEWIGYIS
DRESATYNPSLNSRVVISRDTSKNQLSLKLNSVTPADTAVYYCATARRGQRI
YGVVSFGEFFYYYSMDVWGKGTTVTVSSASTKGPSVFPLAPSSKSTSGGTAA
LGCLVKDYFPEPVTVSWNSGALTSGVHTFPAVLQSSGLYSLSSVVTVPSSSL
GTQTYICNVNHKPSNTKVDKKVEPKSCDKTHTCPPCPAPELLGGPSVFLFPPK
PKDTLMISRTPEVTCVVVDVSHEDPEVKFNWYVDGVEVHNAKTKPREEQY
NSTYRVVSVLTVLHQDWLNGKEYKCKVSNKALPAPIEKTISKAKGQPREPQ
VYTLPPSRDELTKNQVSLTCLVKGFYPSDIAVEWESNGQPENNYKTTPPVLD
SDGSFFLYSKLTVDKSRWQQGNVFSCSVLHEALHSHYTQKSLSLSPG (SEQ
ID NO: 433)

輕鏈：

SYVRPLSVALGETARISCGRQALGSRAVQWYQHRPGQAPILLIYNNQDRPSG
IPERFSGTPDINFGTRATLTISGVEAGDEADYYCHMWDSRSGFSWSFGGATR
LTVLGQPKAAPSVTLFPPSSEELQANKATLVCLISDFYPGAVTVAWKADSSP
VKAGVETTTPSKQSNNKYAASSYLSLTPEQWKSHRSYSCQVTHEGSTVEKT
VAPTECS (SEQ ID NO: 434)

c. 導向至HIV gp120之CD4bs區之抗體

【0039】 CD4結合位點(CD4bs)涉及位於gp120之β1-α1、環D、β20-β21（橋接片）、及β24-α5內之結構保守位點，此等位點判定CD4結合且參與CD4bs

結合抗體之表位(Qiao, *et al.*, *Antiviral Res*. 2016 Aug; 132:252-61)。gp120之CD4bs形成由涉及選自下列之一或多個胺基酸殘基之抗CD4bs抗體識別的構形表位：Thr278、Asp279、Ala281、Thr283、Asp368、Trp427、Glu460、Ser461、Glu462、Leu452、Leu453、及Arg476。胺基酸殘基及位置編號係參照HXB2亞型B HIV-1單離株，其對應於下列提供之NCBI Ref Seq No. NP_057856.1之殘基1至511。殘基Thr278、Asp279、Asn280、Ala281、Thr283、Asp368、Trp427、Leu452、Leu453、Gly459、Glu464、Ser465、Glu466、Ile467、Gly472、Gly473、及Arg476（其等可促成gp120 CD4bs）以粗體顯示且加底線：

MRVKEKYQHLWRWGWRWGTMLLGMLMICSATEKLWVTVYYGVPVWKEA TTTLFCASDAKAYDTEVHNVWATHACVPTDPNPQEVVLVNVTENFNMWKN DMVEQMHEDIISLWDQSLKPCVKLTPLCVSLKCTDLKNDTNTNSSSGRMIME KGEIKNCSFNISTSIRGKVQKEYAFFYKLDIIPIDNDTTSYKLTSCNTSVITQACP KVSFEPIPIHYCAPAGFAILKCNNKTFNGTGPCTNVSTVQCTHGIRPVVSTQLL LNGSLAEEEVVIRSVNF**TDNA**K**T**IIVQLNTSVEINCTRPNNNTRKRIRIQRGPG RAFVTIGKIGNMRQAHCNISRAKWNNTLKQIASKLREQFGNNKTIIFKQSSGG **D**PEIVTHSFNCGGEFFYCNSTQLFNSTWFNSTWSTEGSNNTEGSDTITLPCRIK QIINM**W**QKVGKAMYAPPISGQIRCSSNITG**LL**LTRDG**G**NSNN**ESEI**FRPG**GG**D M**R**DNWRSELYKYKVVKIEPLGVAPTKAKRRVVQREKR (SEQ ID NO: 435)。

【0040】 描繪促成gp120 CD4bs之胺基酸殘基之三維模型係提供於例如Canducci, et al., Retrovirology.2009 Jan 15; 6:4；Falkowska, et al., J Virol.2012 Apr; 86(8):4394-403；and Li, et al., J. Virol.2012 Oct; 86(20):11231–41；Gristick, et al., Nat Struct Mol Biol. 2016 Oct; 23(10):906-915；Kwon, et al., Nat

Struct Mol Biol. 2015 Jul; 22(7):522-31；Liu, et al., Nat Struct Mol Biol. 2017 Apr; 24(4):370-378；Chen, et al., Science.2009 Nov 20; 326(5956):1123-7、及 Lyumkis, et al., Science.2013 Dec 20; 342(6165):1484-90中。在一些實施例中，本文所述之抗體變體與抗CD4bs抗體GS-9723、GS-5423、b12、CH103、1NC9、12A12、VRC01、VRC07-523、N6、3BNC117、NIH45-46、及/或PGV04 (VRC-PG04)競爭結合至gp120 CD4bs。在一些實施例中，本文所述之抗體變體結合至與抗CD4bs抗體GS-9723、GS-5423（特羅帕單抗）、b12、CH103、1NC9、12A12、VRC01、VRC07-523、N6、3BNC117、NIH45-46、及/或PGV04 (VRC-PG04)結合之表位之重疊或相同表位。

【0041】 Gp120由HIV *env*基因編碼。*env*基因編碼約850個胺基酸之基因產物。初級*env*產物係蛋白質gp160，其在內質網中經細胞蛋白酶弗林蛋白酶(furin)裂解為gp120（約480個胺基酸）及gp41（約345個胺基酸）。

【0042】 下文提供了NCBI Ref Seq No. NP_057856.1中鑑別之HIV殖株之例示性gp160多肽之胺基酸序列（CD4bs以粗體顯示且加底線）：

MRVKEKYQHLWRWGWRWGTMLLGMLMICSATEKLWVTVYYGVPVWKE
ATTTLFCASDAKAYDTEVHNVWATHACVPTDPNPQEVVLVNVTENFNMW
KNDMVEQMHEDIISLWDQSLKPCVKLTPLCVSLKCTDLKNDTNTNSSSGRMI
MEKGEIKNCSFNISTSIRGKVQKEYAFFYKLDIIPIDNDTTSYKLTSCNTSVITQ
ACPKVSFEPIPIHYCAPAGFAILKCNNKTFNGTGPCTNVSTVQCTHGIRPVVST
QLLLNGSLAEEEVVIRSVNF**TDNA**K**T**IIVQLNTSVEINCTRPNNNTRKRIRIQR
GPGRAFVTIGKIGNMRQAHCNISRAKWNNTLKQIASKLREQFGNNKTIIFKQS
SGG**D**PEIVTHSFNCGGEFFYCNSTQLFNSTWFNSTWSTEGSNNTEGSDTITLP

CRIKQIINM**W**QKVGKAMYAPPISGQIRCSSNITG**LL**LTRDG**G**NSNN**ESEI**FRP G**GG**DM**R**DNWRSELYKYKVVKIEPLGVAPTKAKRRVVQREKRAVGIGALFL GFLGAAGSTMGAASMTLTVQARQLLSGIVQQQNNLLRAIEAQQHLLQLTV WGIKQLQARILAVERYLKDQQLLGIWGCSGKLICTTAVPWNASWSNKSLEQI WNHTTWMEWDREINNYTSLIHSLIEESQNQQEKNEQELLELDKWASLWNW FNITNWLWYIKLFIMIVGGLVGLRIVFAVLSIVNRVRQGYSPLSFQTHLPTPR GPDRPEGIEEEGGERDRDRSIRLVNGSLALIWDDLRSLCLFSYHRLRDLLLIVT RIVELLGRRGWEALKYWWNLLQYWSQELKNSAVSLLNATAIAVAEGTDRV IEVVQGACRAIRHIPRRIRQGLERILL (SEQ ID NO: 436)

【0043】 下文提供了HXB2亞型B HIV-1單離株（Genbank登錄號K0345；對應於NCBI Ref Seq No. NP_057856.1之殘基1-511）之例示性gp120多肽的胺基酸序列（CD4bs以粗體顯示且加底線）：

MRVKEKYQHLWRWGWRWGTMLLGMLMICSATEKLWVTVYYGVPVWKE ATTTLFCASDAKAYDTEVHNVWATHACVPTDPNPQEVVLVNVTENFNMW KNDMVEQMHEDIISLWDQSLKPCVKLTPLCVSLKCTDLKNDTNTNSSSGRMI MEKGEIKNCSFNISTSIRGKVQKEYAFFYKLDIIPIDNDTTSYKLTSCNTSVITQ ACPKVSFEPIPIHYCAPAGFAILKCNNKTFNGTGPCTNVSTVQCTHGIRPVVST QLLLNGSLAEEEVVIRSVNF**TDNA**K**T**IIVQLNTSVEINCTRPNNNTRKRIRIQR GPGRAFVTIGKIGNMRQAHCNISRAKWNNTLKQIASKLREQFGNNKTIIFKQS SGG**D**PEIVTHSFNCGGEFFYCNSTQLFNSTWFNSTWSTEGSNNTEGSDTITLP CRIKQIINM**W**QKVGKAMYAPPISGQIRCSSNITG**LL**LTRDG**G**NSNN**ESEI**FRP G**GG**DM**R**DNWRSELYKYKVVKIEPLGVAPTKAKRRVVQREKR (SEQ ID NO: 437)

【0044】 下文提供了例示性gp120多肽之胺基酸序列：

AEQLWVTVYYGVPVWREANTTLFCASDAKAYDTEVHNVWATHACVPTDP
NPQEVVMGNVTEDFNMWKNNMVEQMHEDIISLWDQSLKPCVKLTPLCVTL
HCTNVTISSTNGSTANVTMREEMKNCSFNTTTVIRDKIQKEYALFYKLDIVPI
EGKNTNTSYRLINCNTSVITQACPKVSFEPIPIHYCAPAGFAILKCNNKTFNGK
GPCRNVSTVQCTHGIKPVVSTQLLLNGSLAEEDIIIRSENF**TNNG**K**N**IIVQLKE
PVKINCTRPGNNTRRSINIGPGRAFYATGAIIGDIRKAHCNISTEQWNNTLTQI
VDKLREQFGNKTIIFNQSSGG**D**PEVVMHTFNCGGEFFYCNSTQLFNSTWFNN
GTSTWNSTADNITLPCRIKQVINM**W**QEVGKAMYAPPIRGQIDCSSNITG**LI**LT
RDG**G**SNSSQN**ET**FRPG**GG**NM**K**DNWRSELYKYKVVKIEPLGIAPTRAKRRV
VQREKR (SEQ ID NO: 438)。

【0045】 下文提供了另一例示性gp120多肽之胺基酸序列（參見bioafrica.net/proteomics/ENV-GP120prot.html）：

TEKLWVTVYYGVPVWKEATTTLFCASDAKAYDTEVHNVWATHACVPTDP
NPQEVVLVNVTENFNMWKNDMVEQMHEDIISLWDQSLKPCVKLTPLCVSL
KCTDLKNDTNTNSSSGRMIMEKGEIKNCSFNISTSIRGKVQKEYAFFYKLDIIP
IDNDTTSYKLTSCNTSVITQACPKVSFEPIPIHYCAPAGFAILKCNNKTFNGTG
PCTNVSTVQCTHGIRPVVSTQLLLNGSLAEEEVVIRSVNF**TDNA**K**T**IIVQLNT
SVEINCTRPNNNTRKRIRIQRGPGRAFVTIGKIGNMRQAHCNISRAKWNNTL
KQIASKLREQFGNNKTIIFKQSSGG**D**PEIVTHSFNCGGEFFYCNSTQLFNSTWF
NSTWSTEGSNNTEGSDTITLPCRIKQIINM**W**QKVGKAMYAPPISGQIRCSSNIT
G**LL**LTRDGGNSNN**ESEI**FRPG**GG**DM**R**DNWRSELYKYKVVKIEPLGVAPTK
AKRRVVQREKR (SEQ ID NO: 439)

【0046】 在本文所述之方法之某些實施例中，向對象投予結合至CD4bs區內的HIV gp120蛋白之抗體，例如gp120 CD4結合位點之表位或區域。在某些實施例中，所投予抗體結合至細胞表面上表現之HIV-1抗原且消除或殺滅感染細胞。

【0047】 結合至CD4bs中gp120而可用於本文中所述方法的說明性廣泛中和抗體包括（不限於）來自選自由下列所組成之群組的抗體：3BNC117、GS-9723、GS-5423、3BNC60、b12、F105、VRC01、VRC07、VRC07-523、VRC03、VRC06、VRC06b01 VRC08、VRC0801、NIH45-46、PGV04 (VRC-PG04)、CH103、44-VRC13.01、1NC9、12A12、N6、1-18、N49-P7、NC-Cow1、IOMA、CH235及CH235.12、N49P6、N49P7、N49P11、N49P9、及N60P25。

【0048】 表C1至表C4提供了靶向HIV gp120 CD4bs區之抗體之互補決定區(CDR)之說明性序列，該等序列可用於本文所述之方法中。表D提供了靶向HIV gp120 CD4bs區之抗體之VH及VL之說明性序列，該等序列可用於本文所述之方法中。

表C1-說明性抗HIV gp120 CD4bs抗體之CDR (Kabat)

Ab名稱	VH – CDR1	VH – CDR2	VH – CDR3	VL – CDR1	VL – CDR2	VL – CDR3
151	DYFIH SEQ ID NO:442	WINPKTGQPNNPRQFQG SEQ ID NO:443	QRSDYWDFDV SEQ ID NO:444	QANGYLN SEQ ID NO:445	DGSKLER SEQ ID NO:446	QVYEF SEQ ID NO:447
152	DHFIH SEQ ID NO:448	WINPKTGQPNNPRQFQG SEQ ID NO:443	QRSDFWDFDV SEQ ID NO:449	QANGYLN SEQ ID NO:445	DGSKLER SEQ ID NO:446	QVYEF SEQ ID NO:447
153	NCPIN SEQ ID NO:450	WMKPRGGAVSYARQLQG SEQ ID NO:451	GKYCTARDYYNWDFEH SEQ ID NO:452	RTSQYGSLA SEQ ID NO:453	SGSTRAA SEQ ID NO:454	QQYEF SEQ ID NO:455
154	NCPIN SEQ ID NO:450	WMKPRHGAVSYARQLQG SEQ ID NO:456	GKYCTARDYYNWDFEH SEQ ID NO:452	RTSQYGSLA SEQ ID NO:453	SGSTRAA SEQ ID NO:454	QQYEF SEQ ID NO:455
155	DCTLN SEQ ID NO:457	WLKPRGGAVNYARPLQ SEQ ID NO:458	GKNCDYNWDFEH SEQ ID NO:459	RTSQYGSLA SEQ ID NO:453	SGSTRAA SEQ ID NO:454	QQYEF SEQ ID NO:455
156	AHILF SEQ ID NO:460	WIKPQYGAVNFGGGFRD SEQ ID NO:461	DRSYGDSSWALDA SEQ ID NO:462	QTSQGVGSDLH SEQ ID NO:463	HTSSVED SEQ ID NO:464	QVLQF SEQ ID NO:465
157	DDDTFTKYWTH SEQ ID NO:466	VISPHFARPIYSYKFRD SEQ ID NO:467	DPFGDRAPHYNYHMDV SEQ ID NO:468	RASQGLDSSHLA SEQ ID NO:469	GTSNRAR SEQ ID NO:470	QRYGGTPIT SEQ ID NO:471
158	RTELIH SEQ ID NO:472	WVKTVTGAVNFGSPDFR SEQ ID NO:473	QKFYTGGQGWYFDL SEQ ID NO:474	TAASYGHMT SEQ ID NO:475	ATSKRAS SEQ ID NO:476	QQLEF SEQ ID NO:477

表C2-說明性抗HIV gp120 CD4bs抗體之CDR (Chothia)

Ab名稱	VH - CDR1	VH - CDR2	VH - CDR3	VL - CDR1	VL - CDR2	VL - CDR3
159	GYNIRDY SEQ ID NO:478	PKTG SEQ ID NO:479	RSDYWDFD SEQ ID NO:480	NGY SEQ ID NO:481	DGS SEQ ID NO:482	YE SEQ ID NO:483
160	GYKISDH SEQ ID NO:484	PKTG SEQ ID NO:479	RSDFWDFD SEQ ID NO:485	NGY SEQ ID NO:481	DGS SEQ ID NO:482	YE SEQ ID NO:483
161	GYEFINC SEQ ID NO:486	PRGG SEQ ID NO:487	KYCTARDYYNWDFE SEQ ID NO:488	SQYGS SEQ ID NO:489	SGS SEQ ID NO:490	YE SEQ ID NO:483
162	GYEFINC SEQ ID NO:486	PRHG SEQ ID NO:491	KYCTARDYYNWDFE SEQ ID NO:488	SQYGS SEQ ID NO:489	SGS SEQ ID NO:490	YE SEQ ID NO:483
163	GYEFIDC SEQ ID NO:492	PRGG SEQ ID NO:487	KNCDYNWDFE SEQ ID NO:493	SQYGS SEQ ID NO:489	SGS SEQ ID NO:490	YE SEQ ID NO:483
164	GYTFTAH SEQ ID NO:494	PQYG SEQ ID NO:495	R.SYGDSSWALD SEQ ID NO:496	SQGVGSD SEQ ID NO:497	HTS SEQ ID NO:498	LQ SEQ ID NO:499
165	DDPYTDDDTFTKY SEQ ID NO:500	PHFA SEQ ID NO:501	PFGDRAPHYNYHMD SEQ ID NO:502	SQGLDSSH SEQ ID NO:503	GTS SEQ ID NO:504	YGGTPI SEQ ID NO:505
166	EDIFERTE SEQ ID NO:506	TVTG SEQ ID NO:507	KFYTGGQGWYFD SEQ ID NO:508	ASYGH SEQ ID NO:509	ATS SEQ ID NO:510	LE SEQ ID NO:511

表C3-說明性抗HIV gp120 CD4bs抗體之CDR (IMGT)

Ab名稱	**VH – CDR1**	**VH – CDR2**	**VH – CDR3**	**VL – CDR1**	**VL – CDR2**	**VL – CDR3**
167	GYNIRDYF SEQ ID NO:512	INPKTGQP SEQ ID NO:513	ARQRSDYWDFDV SEQ ID NO:514	NGY SEQ ID NO:481	DGS SEQ ID NO:482	QVYEF SEQ ID NO:447
168	GYKISDHF SEQ ID NO:515	INPKTGQP SEQ ID NO:513	ARQRSDFWDFDV SEQ ID NO:516	NGY SEQ ID NO:481	DGS SEQ ID NO:482	QVYEF SEQ ID NO:447
169	GYEFINCP SEQ ID NO:517	MKPRGGAV SEQ ID NO:518	TRGKYCTARDYYNWDFEH SEQ ID NO:519	QYGS SEQ ID NO:520	SGS SEQ ID NO:490	QQYEF SEQ ID NO:455
170	GYEFINCP SEQ ID NO:517	MKPRHGAV SEQ ID NO:521	TRGKYCTARDYYNWDFEH SEQ ID NO:519	QYGS SEQ ID NO:520	SGS SEQ ID NO:490	QQYEF SEQ ID NO:455
171	GYEFIDCT SEQ ID NO:522	LKPRGGAV SEQ ID NO:523	TRGKNCDYNWDFEH SEQ ID NO:524	QYGS SEQ ID NO:520	SGS SEQ ID NO:490	QQYEF SEQ ID NO:455
172	GYTFTAHI SEQ ID NO:525	IKPQYGAV SEQ ID NO:526	ARDRSYGDSSWALDA SEQ ID NO:527	QGVGSD SEQ ID NO:528	HTS SEQ ID NO:498	QVLQF SEQ ID NO:465
173	DDPYTDDDTFTKYW SEQ ID NO:529	ISPHFARP SEQ ID NO:530	ARDPFGDRAPHYNYHMDV SEQ ID NO:531	QGLDSSH SEQ ID NO:532	GTS SEQ ID NO:504	QRYGGTPIT SEQ ID NO:471
174	EDIFERTEL SEQ ID NO:533	VKTVTGAV SEQ ID NO:534	ARQKFYTGGQGWYFDL SEQ ID NO:535	SYGH SEQ ID NO:536	ATS SEQ ID NO:510	QQLEF SEQ ID NO:477

表C4-說明性抗HIV gp120 CD4bs抗體之CDR (Honegger)

Ab名稱	VH - CDR1	VH - CDR2	VH - CDR3	VL - CDR1	VL - CDR2	VL - CDR3
175	ASGYNIRDYF SEQ ID NO:538	INPKTGQPNNPRQFQGR SEQ ID NO:539	QRSDYWDFD SEQ ID NO:540	ANGY SEQ ID NO:541	DGSKLERGVPSRF SEQ ID NO:542	YE SEQ ID NO:483
176	ASGYKISDHF SEQ ID NO:543	INPKTGQPNNPRQFQGR SEQ ID NO:539	QRSDFWDFD SEQ ID NO:544	ANGY SEQ ID NO:541	DGSKLERGVPAR SEQ ID NO:545	YE SEQ ID NO:483
177	ASGYEFINCP SEQ ID NO:546	MKPRGGAVSYARQLQGR SEQ ID NO:547	GKYCTARDYYNWDFE SEQ ID NO:548	TSQYGS SEQ ID NO:549	SGSTRAAGIPDR SEQ ID NO:550	YE SEQ ID NO:483
178	ASGYEFINCP SEQ ID NO:546	MKPRHGAVSYARQLQGR SEQ ID NO:551	GKYCTARDYYNWDFE SEQ ID NO:548	TSQYGS SEQ ID NO:549	SGSTRAAGIPDR SEQ ID NO:550	YE SEQ ID NO:483
179	ASGYEFIDCT SEQ ID NO:552	LKPRGGAVNYARPLQGR SEQ ID NO:553	GKNCDYNWDFE SEQ ID NO:554	TSQYGS SEQ ID NO:549	SGSTRAAGIPDR SEQ ID NO:550	YE SEQ ID NO:483
180	TSGYTFTAHI SEQ ID NO:555	IKPQYGAVNFGGGFRDR SEQ ID NO:556	DRSYGDSSWALD SEQ ID NO:557	TSQGVGSD SEQ ID NO:558	HTSSVEDGVPSR SEQ ID NO:559	LQ SEQ ID NO:499
181	ADDDPYTDDDTFTKYW SEQ ID NO:560	ISPHFARPIYSYKFRDR SEQ ID NO:561	DPFGDRAPHYNYHMD SEQ ID NO:562	ASQGLDSSH SEQ ID NO:563	GTSNRARGTPDR SEQ ID NO:564	YGGTPI SEQ ID NO:505
182	TSEDIFERTEL SEQ ID NO:565	VKTVTGAVNFGSPDFRQ SEQ ID NO:566	QKFYTGGQGWYFD SEQ ID NO:567	AASYGH SEQ ID NO:568	ATSKRASGIPDR SEQ ID NO:569	LE SEQ ID NO:511

表D-說明性抗HIV gp120 CD4bs抗體之VH/VL

Ab名稱	SEQ ID NO	VH	SEQ ID NO	VL
183	571	QVQLLQSGAAVTKPGASVRVSCEASGYNIRDYF IHWWRQAPGQGLQWVGWINPKTGQPNNPRQFQG RVSLTRHASWDFDTFSFYMDLKALRSDDTAVYF CARQRSDYWDFDVWGSGTQVTVSS	572	DIQMTQSPSSLSASVGDTVTITCQANGYLNWYQQR RGKAPKLLIYDGSKLERGVPSRFSGRRWGQEYNLT INNLQPEDIATYFCQVYEFVVPGTRLDLK
184	573	QVQLLQSGAAVTKPGASVRVSCEASGYNIRDYF IHWWRQAPGQGLQWVGWINPKTGQPNNPRQFQG RVSLTRHASFDFDTFSFYMDLKALRSDDTAVYF CARQRSDYWDFDVWGSGTQVTVSS	574	DIQMTQSPSSLSASVGDTATITCQANGYLNWYQQR RGKAPKLLIYDGSKLERGVPSRFSGRRWGQEYNLT INNLQPEDIATYFCQVYEFVVPGTRLDLK
185	575	QVHLSQSGAAVTKPGASVRVSCEASGYKISDHF IHWWRQAPGQGLQWVGWINPKTGQPNNPRQFQG RVSLTRQASWDFDTYSFYMDLKAVRSDDTAIYF CARQRSDFWDFDVWGSGTQVTVSS	576	DIQMTQSPSSLSARVGDTVTITCQANGYLNWYQQR RGKAPKLLIYDGSKLERGVPARFSGRRWGQEYNLT INNLQPEDVATYFCQVYEFIVPGTRLDLK
186	577	QVRLSQSGGQMKKPGDSMRISCRASGYEFINCP INWIRLAPGKRPEWMGWMKPRGGAVSYARQLQG RVTMTRDMYSETAFLELRSLTSDDTAVYFCTRG KYCTARDYYNWDFEHWGQGTPVTVSS	578	EIVLTQSPGTLSLSPGETAIISCRTSQYGSLAWYQ QRPGQAPRLVIYSGSTRAAGIPDRFSGSRWGPDYN LTISNLESGDFGVYYCQQYEFFGQGTKVQVDIK
187	579	QVRLSQSGGQMKKPGDSMRISCRASGYEFINCP INWIRLAPGKRPEWMGWMKPRHGAVSYARQLQG RVTMTRDMYSETAFLELRSLTSDDTAVYFCTRG KYCTARDYYNWDFEHWGQGTPVTVSS	580	SLTQSPGTLSLSPGETAIISCRTSQYGSLAWYQQR PGQAPRLVIYSGSTRAAGIPDRFSGSRWGPDYNLT ISNLESGDFGVYYCQQYEFFGQGTKVQVDIK
188	581	QVQLVQSGGQMKKPGESMRISCRASGYEFIDCT LNWIRLAPGKRPEWMGWLKPRGGAVNYARPLQG RVTMTRDVYSDTAFLELRSLTVDDTAVYFCTRG KNCDYNWDFEHWGRGTPVIVSS	582	EIVLTQSPGTLSLSPGETAIISCRTSQYGSLAWYQ QRPGQAPRLVIYSGSTRAAGIPDRFSGSRWGPDYN LTISNLESGDFGVYYCQQYEFFGQGTKVQVDIK
189	583	RAHLVQSGTAMKKPGASVRVSCQTSGYTFTAHI LFWFRQAPGRGLEWVGWIKPQYGAVNFGGGFRD RVTLTRDVYREIAYMDIRGLKPDDTAVYYCARD RSYGDSSWALDAWGQGTTVVVSA	584	YIHVTQSPSSLSVSIGDRVTINCQTSQGVGSDLHW YQHKPGRAPKLLIHHTSSVEDGVPSRFSGSGFHTS FNLTISDLQADDIATYYCQVLQFFGRGSRLHIK

表D-說明性抗HIV gp120 CD4bs抗體之VH/VL

Ab名稱	SEQ ID NO	VH	SEQ ID NO	VL
190	585	QGRLFQSGAEVKRPGASVRISCRADDDPYTDDDTFTKYWTHWIRQAPGQRPEWLGVISPHFARPIYSYKFRDRLTLTRDSSLTAVYLELKGLQPDDSGIYFCARDPFGDRAPHYNYHMDVWGGGTAVIVSS	586	EVVLTQSPAILSVSPGDRVILSCRASQGLDSSHLAWYRFKRGQIPTLVIFGTSNRARGTPDRFSGSGSGADFTLTISRVEPEDFATYYCQRYGGTPITFGGGTTLDKKRTVA
191	587	QVQLVQSGSGVKKPGASVRVSCWTSEDIFERTELIHWVRQAPGQGLEWIGWVKTVTGAVNFGSPDFRQRVSLTRDRDLFTAHMDIRGLTQGDTATYFCARQKFYTGGQGWYFDLWGRGTLIVVSS	588	EIVLTQSPGTLSLSPGETASLSCTAASYGHMTWYQKKPGQPPKLLIFATSKRASGIPDRFSGSQFGKQYTLTITRMEPEDFARYYCQQLEFFGQGTRLEIRRTVA

【0049】 在一些實施例中，抗HIV gp120 CD4bs結合抗體包含VH，其包含VH-CDR1、VH-CDR2、及VH-CDR3；及VL，其包含VL-CDR1、VL-CDR2、及第二VH-CDR3；其中VH-CDR1、VH-CDR2、VH-CDR3、VL-CDR1、VL-CDR2、及VH-CDR3包含下列所述之序列：SEQ ID NO: 442、443、444、445、446、及447；SEQ ID NO: 448、443、449、445、446、及447；SEQ ID NO: 450、451、452、453、454、及455；SEQ ID NO: 450、456、452、453、454、455；SEQ ID NO: 457、458、459、453、454、及455；SEQ ID NO: 460、461、462、463、464、及465；SEQ ID NO: 466、467、468、469、470、及471；或SEQ ID NO: 472、473、474、475、476、及477（根據Kabat之CDR）。

【0050】 在一些實施例中，抗HIV gp120 CD4bs結合抗體包含VH，其包含VH-CDR1、VH-CDR2、及VH-CDR3；及VL，其包含VL-CDR1、VL-CDR2、及第二VH-CDR3；其中VH-CDR1、VH-CDR2、VH-CDR3、VL-CDR1、VL-CDR2、及VH-CDR3包含下列所述之序列：SEQ ID NO: 478、479、480、481、482、及483；SEQ ID NO: 484、479、485、481、482、及483；SEQ ID NO: 486、487、488、489、490、及483；SEQ ID NO: 486、491、488、489、490、及483；SEQ ID NO: 492、487、493、489、490、及483；SEQ ID NO: 494、495、496、497、498、及499；SEQ ID NO: 500、501、502、503、504、及505；或SEQ ID NO: 506、507、508、509、510、及511（根據Chothia之CDR）。

【0051】 在一些實施例中，抗HIV gp120 CD4bs結合抗體包含VH，其包含VH-CDR1、VH-CDR2、及VH-CDR3；及VL，其包含VL-CDR1、VL-CDR2、及第二VH-CDR3；其中VH-CDR1、VH-CDR2、VH-CDR3、VL-CDR1、VL-CDR2、及VH-CDR3包含下列所述之序列：SEQ ID NO: 512、513、514、481、

482、及447；SEQ ID NO: 515、513、516、481、482、及447；SEQ ID NO: 517、518、519、520、490、及455；SEQ ID NO: 517、522、519、520、521、及455；SEQ ID NO:522、523、524、520、490、及455；SEQ ID NO: 525、526、527、528、498、及465；SEQ ID NO: 529、530、531、532、504、及471；SEQ ID NO: 533、534、535、536、510、及477（根據IMGT之CDR）。

【0052】 在一些實施例中，抗HIV gp120 CD4bs結合抗體包含VH，其包含VH-CDR1、VH-CDR2、及VH-CDR3；及VL，其包含VL-CDR1、VL-CDR2、及第二VH-CDR3；其中VH-CDR1、VH-CDR2、VH-CDR3、VL-CDR1、VL-CDR2、及VH-CDR3包含下列所述之序列：SEQ ID NO: 538、539、540、541、542、及483；SEQ ID NO: 543、539、544、541、545、及483；SEQ ID NO: 546、547、548、549、550、及483；SEQ ID NO: 546、551、548、549、550、及483；SEQ ID NO: 555、556、557、558、559、及499；SEQ ID NO: 560、561、562、563、564、及505；SEQ ID NO: 565、566、567、568、569、569、及511（根據Honegger之CDR）。

【0053】 在一些實施例中，抗HIV gp120 CD4bs結合抗體包含VH及VL，其包含與分別如選自下列所闡述之胺基酸序列至少80%、至少85%、至少90%、至少91%、至少92%、至少93%、至少94%、至少95%、至少96%、至少97%、至少98%、至少99%、或100%同一的胺基酸序列：SEQ ID NO: 571及572；SEQ ID NO: 573及574；SEQ ID NO: 575及576；SEQ ID NO: 577及578；SEQ ID NO: 579及580；SEQ ID NO:581及582；SEQ ID NO: 583及584；或SEQ ID NO:585及586；587及588。

【0054】 在一些實施例中，抗HIV gp120 CD4bs結合抗體係3BNC117-LS。3BNC117-LS之重鏈及輕鏈胺基酸序列在下文提供為SEQ ID NO: 589及590：

重鏈：

QVQLLQSGAAVTKPGASVRVSCEASGYNIRDYFIHWWRQAPGQGLQWVGWI
NPKTGQPNNPRQFQGRVSLTRHASWDFDTFSFYMDLKALRSDDTAVYFCAR
QRSDYWDFDVWGSGTQVTVSSASTKGPSVFPLAPSSKSTSGGTAALGCLVKD
YFPEPVTVSWNSGALTSGVHTFPAVLQSSGLYSLSSVVTVPSSSLGTQTYICNV
NHKPSNTKVDKKVEPKSCDKTHTCPPCPAPELLGGPSVFLFPPKPKDTLMISR
TPEVTCVVVDVSHEDPEVKFNWYVDGVEVHNAKTKPREEQYNSTYRVVSVL
TVLHQDWLNGKEYKCKVSNKALPAPIEKTISKAKGQPREPQVYTLPPSRDELT
KNQVSLTCLVKGFYPSDIAVEWESNGQPENNYKTTPPVLDSDGSFFLYSKLTV
DKSRWQQGNVFSCSVLHEALHSHYTQKSLSLSPG (SEQ ID NO: 589)

輕鏈：

DIQMTQSPSSLSASVGDTVTITCQANGYLNWYQQRRGKAPKLLIYDGSKLE
RGVPSRFSGRRWGQEYNLTINNLQPEDIATYFCQVYEFVVPGTRLDLKRTV
AAPSVFIFPPSDEQLKSGTASVVCLLNNFYPREAKVQWKVDNALQSGNSQE
SVTEQDSKDSTYSLSSTLTLSKADYEKHKVYACEVTHQGLSSPVTKSFNRG
EC (SEQ ID NO: 590)

d. 增加血清半衰期之Fc胺基酸取代

【0055】 在一些實施例中，抗HIV gp120 bNAb之Fc區或Fc域包含促進抗結合分子之血清半衰期增加的胺基酸修飾。已描述增加抗體半衰期之胺基酸取代。在一個實施例中，重鏈中之一或二者的Fc區或Fc域包含位置252（EU編號）的甲硫胺酸取代成酪胺酸、位置254（EU編號）的絲胺酸取代成蘇胺酸、及位置256（EU編號）的蘇胺酸取代成麩胺酸。見例如美國專利第7,658,921號。此種類型的突變體（命名為「YTE」）展現相對於野生型版本的相同抗體增加四倍半衰期(Dall'Acqua, *et al.*, J Biol Chem, 281: 23514-24 (2006)；Robbie, *et al.*, Antimicrob Agents Chemotherap., 57(12):6147-6153 (2013))。在某些實施例中，一或兩個重鏈之Fc區或Fc域包含IgG恆定域，其包含位置251至257、285至290、308至314、385至389、及428至436（EU編號）之胺基酸殘基的一、二、三、或更多個胺基酸取代。替代地，M428L及N434S（「LS」）胺基酸取代可增加多特異性抗原結合分子之藥物動力學半衰期。在其他實施例中，一或兩個重鏈之Fc區或Fc域包含M428L及N434S取代（EU編號）。在其他實施例中，一或兩個重鏈之Fc區或Fc域包含T250Q及M428L（EU編號）胺基酸取代，例如，如美國專利第7,217,797號及第7,217,798號中所描述。在其他實施例中，一或兩個重鏈之Fc區或Fc域包含H433K及N434F（EU編號）胺基酸取代，例如，如美國專利第8,163,881號中所描述。在其他實施例中，一或兩個重鏈之Fc區或Fc域包含T307Q/Q311V/A378V (DF215)或T256D/N286D/T307R/Q311V/A378V (DF228)（EU編號）胺基酸取代，例如，如美國公開案第2020-0277358號中所描述。在一些實施例中，一或兩個重鏈之Fc區或Fc域包含位置309之天冬胺酸、位置311之組胺酸、及位置434之絲胺酸(DHS)，例如，如美國專利第11,059,892號中所描述。

3. 排程方案

【0056】 一般而言，本發明方法藉由每年兩次共投予下列來治療或預防有需要之人類對象的HIV：有效量的bNAb，其結合至第三可變環(V3)及/或包含N332寡甘露糖聚醣之高甘露糖區塊內之gp120之表位，及有效量的bNAb，其結合至包含CD4結合位點(CD4bs)之gp120之表位，兩種bNAb均具有Fc胺基酸取代以延長血清半衰期。在各種實施例中，共投予之步調可係每六個月一次（亦即Q6M)、每24週一次（亦即Q24W)、每25週一次（亦即Q25W)、每26週一次（亦即Q26W）。

【0057】 「對象(subject)」、「個體(individual)」或「患者(patient)」係指任何哺乳動物，包括人類及非人類靈長類動物。在具體實施例中，哺乳動物係人類。

【0058】 「有效量(effective amount)」或「治療有效量(therapeutically effective amount)」係指抗體之量，當單獨或與另一治療劑組合投予至細胞、組織、或對象時，足以在對象中實現治療或有益結果。構成「有效量」之量將視抗體及其特定用途而變化，且亦可能視病況及其嚴重程度、投予方式、及待治療對象之年齡而變化，但可由所屬技術領域中具有通常知識者考慮其自身知識及本揭露常規地判定。治療有效劑量進一步係指抗體足以治療、預防或改善感染或疾病狀況或感染或疾病之進展的量，及足以實現此類病況之治療、治癒、預防或改善之速率提高的量。當施加至單獨投予之個別抗體時，治療有效劑量係指單獨活性成分。當施加至組合時，無論是組合投予、連續投予抑或同時投予，治療有效劑量係指產生治療效果之活性成分的組合量。在一些實施例

中，治療有效劑量允許在第二或後續投予時（例如在第一或先前投予之後6個月、24週、25週、或26週時）抗體之有效血液或血清濃度。

【0059】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣結合抗體及抗HIV gp120 CD4bs結合抗體各自以在下列範圍內之治療有效劑量量靜脈內投予：約500 mg至約3000 mg，例如約550 mg至約2900 mg、例如約600 mg至約2800 mg、例如約650 mg至約2700 mg、例如約700 mg至約2600 mg、例如約850 mg至約2550 mg。在一些實施例中，抗HIV gp120 V3聚醣結合抗體（例如，10-1074-LS）係以850 mg之劑量靜脈內投予。在一些實施例中，抗HIV gp120 V3聚醣結合抗體（例如，10-1074-LS）係以2550 mg之劑量靜脈內投予。在一些實施例中，抗HIV gp120 CD4bs結合抗體（例如，3BNC117-LS）係以1700 mg之劑量靜脈內投予。在一些實施例中，抗HIV gp120 CD4bs結合抗體（例如，3BNC117-LS）係以2550 mg之劑量靜脈內投予。在一些實施例中，抗HIV gp120 V3聚醣結合抗體（例如，10-1074-LS）係以2550 mg之劑量靜脈內投予，且抗HIV gp120 CD4bs結合抗體（例如，3BNC117-LS）係以2550 mg之劑量靜脈內投予。在一些實施例中，抗HIV gp120 V3聚醣結合抗體（例如，10-1074-LS）係以850 mg之劑量靜脈內投予，且抗HIV gp120 CD4bs結合抗體（例如，3BNC117-LS）係以2550 mg之劑量靜脈內投予。在一些實施例中，抗HIV gp120 V3聚醣結合抗體（例如，10-1074-LS）係以850 mg之劑量靜脈內投予，且抗HIV gp120 CD4bs結合抗體（例如，3BNC117-LS）係以1700 mg之劑量投予。在一些實施例中，抗HIV gp120 V3聚醣結合抗體（例如，10-1074-LS）係以850 mg之劑量靜脈內投予，且抗HIV gp120 CD4bs結合抗體（例如，3BNC117-LS）係以1275 mg之劑量投予。在一些實施例中，抗HIV gp120 V3聚醣結合抗體（例如，10-1074-

LS）係以10 mg/kg之劑量靜脈內投予，且抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體（例如，3BNC117-LS）係以30 mg/kg之劑量靜脈內投予。

【0060】 如本文所使用，「治療(treat/treating/treatment)」涵蓋治療患有所關注的疾病或病況之對象（例如哺乳動物，諸如人類）之所關注的疾病、損傷、或病況（例如，HIV-1感染），且包括：(i)抑制疾病、損傷、或病況之進展，亦即阻止其發展；(ii)減少或緩解疾病、損傷、或病況，亦即使疾病或病況消退；或(iii)緩解由疾病、損傷、或病況引起之症狀。如本文所使用，用語「疾病(disease)」、「病症(disorder)」、及「病況(condition)」可互換使用。如本文所使用，「抑制(inhibition)」、「治療(treatment/treating)」、及「改善(ameliorating)」可互換使用且係指例如穩定症狀、延長存活期、部分或完全改善症狀、及部分或完全根除病況、疾病、或病症。

【0061】 如本文所使用，「預防(prevent/prevention)」包括(i)預防或抑制疾病、損傷、或病況在對象中發生，尤其在該對象易患該病況但尚未診斷患有該病況時；或(ii)減少疾病、損傷、或病況在對象中發生之可能性。

【0062】 共投予包括並行投予以及投予單一劑量之如本文所述之抗HIV gp120 V3聚醣結合抗體及抗HIV gp120 CD4bs結合抗體。例如，如本文所述之抗HIV gp120 V3聚醣結合抗體及抗HIV gp120 CD4bs結合抗體可在投予彼此的同時或幾秒、幾分鐘、幾小時、或幾天內投予。在一些實施例中，單一劑量之本文所揭示之抗HIV gp120 V3聚醣結合抗體及抗HIV gp120 CD4bs結合抗體在彼此之幾小時內（例如1至12小時、1至24小時、1至36小時、1至48小時、1至60小時、1至72小時內）投予。

【0063】 在某些實施例中，如本文所述之抗HIV gp120 V3聚醣結合抗體及抗HIV gp120 CD4bs結合抗體係單獨地或以混合物的形式以用於同時投予至患者之單一劑型組合，例如以用於靜脈內、肌內或皮下投予之液體或懸浮液劑型組合。

【0064】 在某些實施例中，抗HIV gp120 V3聚醣結合抗體及抗HIV gp120 CD4bs結合抗體係單獨地或以混合物的形式調配為液體溶液或懸浮液，該液體溶液或懸浮液可選地含有可用於治療HIV的一或多種其他藥劑（例如HIV殼體抑制劑，例如利那卡帕韋）。在某些實施例中，液體溶液或懸浮液可含有另一種用於治療HIV之活性成分，該活性成分係諸如HIV蛋白酶抑制劑、HIV非核苷或非核苷酸反轉錄酶抑制劑、HIV核苷或核苷酸反轉錄酶抑制劑、HIV整合酶抑制劑、HIV非催化性部位（或異位）的整合酶抑制劑、藥物動力學增強劑、及其組合。

【0065】 在某些實施例中，此類液體溶液或懸浮液適合於每年兩次，例如每六個月一次（即Q6M)、每24週一次（即Q24W)、每25週一次（即Q25W)、每26週一次（即Q26W）投予。

【0066】 在一些實施例中，在10-1074-LS及3BNC117-LS之一或多次共投予之後，10-1074-LS及3BNC117-LS之血清濃度在第一時間點之後26週或在最近的共投予之後26週係至少10 μg/mL。

【0067】 在一些實施例中，在10-1074-LS及3BNC117-LS之一或多次共投予之後，HIV RNA之血清濃度在第一時間點之後26週或在最近的共投予之後26週係低於50個拷貝/mL。

4. 患者選擇

感染期

【0068】 在各種實施例中，人類對象係成人、幼年、或嬰兒。對象可有症狀（例如，病毒血症(viremic)）或無症狀（例如，急性感染或ART抑制）。在一些實施例中，人類對象受HIV急性感染或最近受HIV感染。在某些實施例中，對象未經血清轉化。在一些實施例中，該人類對象受HIV慢性感染。對象可接受或可不接受抗反轉錄病毒療法(ART)之方案。

【0069】 患者可分類為Fiebig第I至VI期，其係基於陽性HIV-1臨床診斷檢定的依序進展（經由PCR測得的病毒RNA、經由酶聯免疫吸附檢定(ELISA)測得的p24及p31病毒抗原）。p24抗原係病毒核心蛋白，其在上升期間（一旦HIV-1 RNA水平上升而高於10,000個拷貝/mL）與可偵測HIV抗體發展之前，暫時出現於血液中。在Fiebig第I期中，在上升之病毒血症期間，僅可偵測血液中的HIV-1 RNA。Fiebig第II期在約7天後開始，此時偵測p24抗原的測試結果變成陽性。在Fiebig第III期（在p24抗原測試結果變成陽性後約5天內）中，可用足夠靈敏的酶免疫檢定(EIA)（例如，第三代EIA）來偵測IgM抗HIV-1抗體。第III期一般發生於急性反轉錄病毒症狀開始後1至2週。Fiebig第IV期表示發展呈不確定性(indeterminate)的西方墨點測試，其發生於EIA測試顯示陽性結果後約3天。轉換為呈明確陽性的西方墨點測試，即Fiebig第V期，通常發生於另7天後，或初始感染後約1個月。HIV感染的Fiebig期係描述於例如Fiebig, *et al.*, AIDS.(2003) 17(13):1871-9；Cohen, *et al., J Infect Dis.*(2010) 202 Suppl 2:S270-7；及McMichael, *et al.*, *Nature Reviews Immunology* (2010) 10:11–23，

其全文特此以引用方式併入本文中以達所有目的。在一些實施例中，自具有下列之HIV感染的人類對象，評估生物樣本：Fiebig第IV期或更早期，例如Fiebig第I期、Fiebig第II期、Fiebig第III期、或Fiebig第IV期。在一些實施例中，自具有Fiebig第V期或Fiebig第VI期HIV感染的人類對象，評估生物樣本。

對象之HIV對一或兩種bNAb之敏感性

【0070】 在一些實施例中，該等方法進一步包含自對象獲得生物樣本（例如，血液、血清、血漿、精液、淋巴結）之步驟。在一些實施例中，該等方法需要接受HIV gp120胺基酸殘基的報告，該等HIV gp120胺基酸殘基存在於所關注之指稱位置處（例如，332及325處）以及選自由下列所組成之群組的一或多個胺基酸位置：63、179、320、及330，其中該等胺基酸位置係參照SEQ ID NO: 4。

【0071】 在各種實施例中，該等方法另外包含下列步驟：鑑別最可能受益於利用靶向HIV gp120之V3聚醣區的抗體及靶向HIV gp120之CD4bs的抗體中之一或二者之療法的患者。在一些實施例中，對象對靶向HIV gp120之V3聚醣區的抗體及靶向HIV gp120之CD4bs的抗體中之一或二者之敏感性在PhenoSense mAb檢定(Monogram)中經判定為bNAb之IC90係小於或等於(≤) 2 μg/mL。

HIV對抗gp120 V3聚醣抗體之敏感性

【0072】 在一些實施例中，藉由鑑別HIV gp120胺基酸殘基之接收感染患者之HIV物種的報告來鑑別患者，該等HIV gp120胺基酸殘基存在於所關注之指稱胺基酸位置處（例如，位置332及325處）以及選自由下列所組成之群組

的一或多個胺基酸位置：63、179、320、及330，其中該等胺基酸位置係參照SEQ ID NO: 4（同上，HXB2亞型B HIV-1單離株（GenBank登錄號K0345；對應於NCBI Ref Seq No. NP_057856.1之殘基1至511））。用於判定對象是否可能對抗HIV gp120 V3-聚醣抗體（包括10-1074-LS）敏感的檢定描述於例如WO 2020/236753中，其特此以全文引用之方式併入本文中。

【0073】 在一些實施例中，藉由進行一或多種檢定（例如多核苷酸或多肽定序）來鑑別患者，該一或多種檢定判定gp120之（多個）胺基酸序列或在感染患者之HIV物種的（多個）gp120蛋白之所關注之指稱胺基酸位置處存在的胺基酸殘基。可在多核苷酸或多肽水平下判定自對象獲得之gp120蛋白之全長或部分序列之鑑別。在一些實施例中，在多肽水平下判定存在於所關注之gp120殘基位置處的胺基酸。

【0074】 在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含N332聚醣、D325、及T63，其中該等胺基酸位置係參照SEQ ID NO: 4。

【0075】 在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含N332聚醣、D325、及L179，其中該等胺基酸位置係參照SEQ ID NO: 4。

【0076】 在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含N332聚醣、D325、及T320，其中該等胺基酸位置係參照SEQ ID NO: 4。

【0077】 在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含N332聚醣、D325、及H330，其中該等胺基酸位置係參照SEQ ID NO: 4。

【0078】 在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含N332聚醣、D325、T63、及L179，其中該等胺基酸位置係參照SEQ ID NO: 4。

【0079】 在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含N332聚醣、D325、T63、及T320，其中該等胺基酸位置係參照SEQ ID NO: 4。

【0080】 在一些實施例中，對象受HIV分支B病毒感染。在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含N332聚醣、D325、T63、及H330，其中該等胺基酸位置係參照SEQ ID NO: 4。在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含N332聚醣、D325、T63、L179、T320、及H330，其中該等胺基酸位置係參照SEQ ID NO: 4。

【0081】 在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含N332聚醣、D325、T320、及H330，其中該等胺基酸位置係參照SEQ ID NO: 4。

【0082】 在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含N332聚醣、D325、L179、T320、及H330，其中該等胺基酸位置係參照SEQ ID NO: 4。在一些實施例中，對象受HIV分支A病

毒及/或HIV分支C病毒感染。在一些實施例中，對象受HIV分支A病毒、分支B病毒、及/或HIV分支C病毒感染。

【0083】 在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含N332聚醣、D325、T63、L179、及T320，其中該等胺基酸位置係參照SEQ ID NO: 4。

【0084】 在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含N332聚醣、D325、T63、L179、及H330，其中該等胺基酸位置係參照SEQ ID NO: 4。

HIV對抗HIV gp120 CD4bs抗體之敏感性

【0085】 在一些實施例中，藉由鑑別HIV gp120胺基酸殘基之接收感染患者之HIV物種的報告來鑑別患者，該等HIV gp120胺基酸殘基存在於所關注之指稱胺基酸位置處（例如，位置201處）以及選自由下列所組成之群組的一或多個胺基酸位置：102、108、281、318、及353，其中該等胺基酸位置係參照SEQ ID NO: 439。在一些實施例中，藉由進行一或多種檢定（例如多核苷酸或多肽定序）來鑑別患者，該一或多種檢定判定gp120之（多個）胺基酸序列或在感染患者之HIV物種的（多個）gp120蛋白之所關注之指稱胺基酸位置處存在的胺基酸殘基。可在多核苷酸或多肽水平下判定自對象獲得之gp120蛋白之全長或部分序列之鑑別。在一些實施例中，在多肽水平下判定存在於所關注之gp120殘基位置處的胺基酸。用於判定對象是否可能對抗HIV gp120 CD4結合位點抗體（包括3BNC117-LS）敏感的檢定描述於例如WO 2022/103758中，其特此以全文引用之方式併入本文中。

【0086】 在各種實施例中，該等方法需要識別受表現gp120之HIV或HIV群感染的對象，該gp120包含I201及F353，其中該等胺基酸位置係參照SEQ ID NO:439。

【0087】 在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含I201、I108、及F353，其中該等胺基酸位置係參照SEQ ID NO: 439。

【0088】 在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含I201、I108、A281、及F353，其中該等胺基酸位置係參照SEQ ID NO: 439。

【0089】 在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含I201、E102、I108、A281、及F353，其中該等胺基酸位置係參照SEQ ID NO: 439。

【0090】 在各種實施例中，該等方法需要鑑別受表現gp120之HIV或HIV群感染的對象，該gp120包含I201、E102、I108、A281、Y318、及F353，其中該等胺基酸位置係參照SEQ ID NO: 439。

【0091】 在一些實施例中，對象受HIV分支（亦稱HIV亞型）B病毒感染。在一些實施例中，對象受HIV分支（亦稱HIV亞型）A病毒及/或HIV分支（亦稱HIV亞型）C病毒感染。在一些實施例中，對象受HIV分支（亦稱HIV亞型）A病毒、分支B病毒、及/或HIV分支（亦稱HIV亞型）C病毒感染。

判定所關注之gp120胺基酸

【0092】 判定對象的HIV gp120序列之胺基酸殘基，可以多核苷酸或多肽水平進行，該等胺基酸殘基係在所關注之指稱位置處（例如，332及325處）以及選自由下列所組成之群組的一或多個胺基酸位置：63、179、320、及330，其中該等胺基酸位置係參照SEQ ID NO:3。在多核苷酸水平下，可使用所屬技術領域中已知的方法，將自一或多個生物樣本單離之HIV RNA或前病毒(proviral) DNA定序。在一些實施例中，將自對象之二或更多個生物樣本單離之HIV RNA或前病毒DNA定序。在一些實施例中，該二或更多個生物樣本係自不同組織來源（例如，血液、周邊血液單核細胞、淋巴結、及/或精液）獲得。在一些實施例中，該二或更多個生物樣本係在不同時間點（例如，相隔1、2、3、4、5、6、7、或8週、相隔3、4、5、6、7、8、9、10、11、或12個月）獲得。

【0093】 如適當，可使用黏合並擴增HIV *env*編碼序列（特別是gp120的CD4bs區）之引子。在一些實施例中，可使用巢組引子。在各種實施例中，直接將RNA定序，或者可進行反轉錄酶聚合酶連鎖反應(reverse-transcriptase polymerase chain reaction, RT-PCR)。在一些實施例中，可進行桑格(Sanger)定序，例如在定序以判定CD4bs區中胺基酸殘基時，或者將來自Fiebig早期（例如，在Fiebig第III期之前，例如Fiebig第I或II期）疾病患者之樣本定序時。在各種實施例中，進行單一基因體擴增(single genome amplification, SGA)及定序。用於單一基因體擴增(SGA)及血漿HIV病毒體RNA定序之方法係描述於例如Salazar-Gonzalez, *et al.* (2008) *J Virol* 82:3952–3970；及Keele, *et al.*, *Proc Natl Acad Sci U S A.* (2008) 105(21):7552-7。應用SGA以判定HIV gp120序列中之胺基酸序列變異，以及可用於本文中所述方法者，係描述於例如Bar, *et al.*, *N Engl J Med.* (2016) 375(21):2037-2050；及Mendoza, *et al., Nature*.(2018)

561(7724):479-484。在各種實施例中，採用高通量、次世代定序(NGS)、大規模平行或深度定序技術，以將gp120（包括至少CD4bs區）定序，該gp120係來自單一患者或對象之一或多個生物樣本中的HIV物種群。在此類情況中，將編碼gp120之至少CD4bs區的多個核酸序列定序並比對。在一些實施例中，將全長gp120定序。可用於判定來自患者之一或多個生物樣本的HIV物種之gp120序列的NGS定序進行之說明性平台包括Illumina (Solexa) (illumina.com)、Ion torrent：質子/ PGM定序(thermofisher.com)、SOLiD (thermofisher.com)、及單分子即時(Single Molecule, Real-Time, SMRT)定序(Pacific Biosciences, pacb.com)。用於自患者單離及定序HIV gp120（至少包括CD4bs區）且可應用於本發明方法中之方法描述於例如*Shioda, et al., J Virol.*(1997) 71(7):4871-81；Colón, *et al.*, *J Virol Antivir Res.* (2015) 4(3). pii: 143 (PMID: 27358904)；Kafando, *et al., PLoS One.*(2017) 12(12):e0189999; Hebberecht, *et al., PLoS One.*(2018) 13(4):e0195679, Andrews, *et al.*, *Sci Rep.*(2018) 8(1):5743、及Landais, *et al. Immunity.*(2017) 47(5):990-1003。如適當，核酸序列之較短序列讀段（「contig」）可組裝成較長序列，其至少包括gp120之CD4bs區。可應用於本發明方法中之HIV基因體序列之contig組裝的方法描述於例如Huang, *et al.*, *Bioinformation.*(2018) 14(8):449-454；Hiener, *et al.*, *J Vis Exp.*(2018) Oct 16; (140). doi: 10.3791/58016；及Wymant, *et al.*, *Virus Evol.*(2018) May 18;4(1):vey007. doi: 10.1093/ve/vey007。

5. 組合療法

【0094】 在某些實施例中，提供了一種用於治療或預防患有或處於患有感染之風險的人類之HIV感染之方法，其包含向該人類投予治療有效量的如本文

所揭示之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體與治療有效量的一或多種（例如，一、二、三、四、一或二、一至三、或一至四種）額外治療劑之組合。在一個實施例中，提供了一種用於治療患有或處於患有感染之風險的人類之HIV感染之方法，其包含向該人類投予治療有效量的如本文所揭示之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體與治療有效量的一或多種（例如，一、二、三、四、一或二、一至三、或一至四種）額外治療劑之組合。

【0095】 在一個實施例中，提供了醫藥組成物，其包含如本文所揭示之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體與一或多種（例如，一、二、三、四、一或二、一至三、或一至四種）額外治療劑、及醫藥上可接受之載劑、稀釋劑、或賦形劑之組合。

【0096】 在某些實施例中，提供了用於治療HIV感染之方法，其包含向有需要之患者投予治療有效量的如本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體或其抗原結合片段與治療有效量的一或多種額外治療劑之組合，該一或多種額外治療劑適用於治療HIV感染。

【0097】 在某些實施例中，抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體或其抗原結合片段係與一、二、三、四、或更多種額外治療劑組合。在某些實施例中，抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體或其抗原結合片段係與兩種額外治療劑組合。在其他實施例中，抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體或其抗原結合片段係與三種額外治療劑組合。在其他實施例中，抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體或其抗原結合片段係與四種額外治療劑組合。一、二、三、四、或更多種額外治療劑

可係選自相同類別的治療劑（例如，一或多種抗HIV廣泛中和抗體）之不同治療劑，且/或其等可選自不同類別的治療劑。

HIV組合療法之投予

【0098】 在某些實施例中，如本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體或其抗原結合片段係與一或多種額外治療劑共投予。本文所揭示之抗HIV gp120 CD4bs結合抗體與一或多種額外治療劑之共投予一般係指同時或依序投予本文所揭示之抗HIV gp120 CD4bs結合抗體及一或多種額外治療劑，使得治療有效量的本文所揭示之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體及一或多種額外治療劑二者均存在於患者體內。當依序投予時，組合可在二或更多次投予中投予。

【0099】 共投予包括：並行投予以及投予單一劑量的如本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體或其抗原結合片段，其係在投予單一劑量的一或多種額外治療劑之前或之後。例如，可在投予一或多種額外治療劑的幾秒、幾分鐘、幾小時、或幾天內，投予如本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體或其抗原結合片段。在一些實施例中，首先投予單一劑量的本文所揭示之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體，接著在幾秒、幾分鐘、幾小時、或幾天內投予單一劑量的一或多種額外治療劑。替代地，首先投予單一劑量的一或多種額外治療劑，接著在幾秒、幾分鐘、幾小時、或幾天內投予單一劑量的本文所揭示之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體。在其他實施例中，首先投予單一劑量的本文所揭示之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體，

接著在經過幾小時（例如，1至12小時、1至24小時、1至36小時、1至48小時、1至60小時、1至72小時）的時段後投予單一劑量的一或多種額外治療劑。在又其他實施例中，首先投予單一劑量的一或多種額外治療劑，接著在經過幾小時（例如，1至12小時、1至24小時、1至36小時、1至48小時、1至60小時、1至72小時）的時段後投予單一劑量的本文所揭示之抗HIV gp120 CD4bs結合抗體。

【0100】 在某些實施例中，本文所揭示之抗HIV gp120 V3聚醣結合抗體及抗HIV gp120 CD4bs結合抗體係與一或多種額外治療劑，以用於同時投予至患者之單一劑型進一步組合，例如以用於口服、靜脈內、肌內、或皮下投予之固體、液體、或懸浮液劑型組合。

【0101】 在某些實施例中，血清半衰期延長的抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係調配為液體溶液或懸浮液，該液體溶液或懸浮液可選地含有可用於治療HIV的一或多種其他化合物。在某些實施例中，液體溶液或懸浮液可含有另一種用於治療HIV之活性成分，該活性成分係諸如HIV蛋白酶抑制劑、HIV非核苷或非核苷酸反轉錄酶抑制劑、HIV核苷或核苷酸反轉錄酶抑制劑、HIV整合酶抑制劑、HIV非催化性部位（或異位）的整合酶抑制劑、藥物動力學增強劑、及其組合。

【0102】 在某些實施例中，此類液體溶液或懸浮液適合於每年兩次，例如每六個月（Q6M)、每26週（Q26W)、每25週（Q25W)、每24週（Q24W）投予。

HIV組合療法

【0103】 在上述實施例中，額外治療劑可係抗HIV藥劑。可組合或共投予之說明性抗HIV劑包括但不限於第三抗HIV抗體、HIV蛋白酶抑制劑、HIV反轉錄酶非核苷或非核苷酸抑制劑、HIV反轉錄酶核苷或核苷酸抑制劑、HIV整合酶抑制劑、HIV非酶催化性部位（或異位）整合酶抑制劑、HIV進入抑制劑、HIV成熟抑制劑、HIV殼體抑制劑、核殼體蛋白7 (NCp7)抑制劑、HIV Tat或Rev抑制劑、Tat-TAR-P-TEFb抑制劑、免疫調節劑（例如免疫刺激劑）、免疫治療劑、抗體-藥物接合物、基因改質劑、基因編輯劑（諸如CRISPR/Cas9、鋅指核酸酶、歸巢核酸酶、合成核酸酶、TALEN）、細胞療法（諸如嵌合抗原受體T細胞、CAR-T、及經工程改造之T細胞受體、TCR-T、自體T細胞療法、經工程改造之B細胞、NK細胞）、潛伏期逆轉劑、基於免疫之療法、磷脂醯肌醇3-激酶(PI3K)抑制劑、HIV抗體、雙特異性抗體及「類抗體(antibody-like)」治療蛋白、HIV p17基質蛋白抑制劑、IL-13拮抗劑、肽基-脯胺醯基順-反異構酶A調節劑、蛋白二硫化物異構酶抑制劑、補體C5a受體拮抗劑、DNA甲基轉移酶抑制劑、脂肪酸合成酶抑制劑、HIV vif基因調節劑、Vif二聚化拮抗劑、HIV-1病毒感染性因子抑制劑、HIV-1 Nef調節劑、TNF α配體抑制劑、HIV Nef抑制劑、Hck酪胺酸激酶調節劑、混合譜系激酶3 (MLK-3)抑制劑、HIV-1剪接抑制劑、整合素拮抗劑、核蛋白抑制劑、剪接因子調節劑、含COMM域蛋白1調節劑、HIV核糖核酸酶H抑制劑、IFN拮抗劑、逆週期蛋白調節劑、CD3拮抗劑、CDK-4抑制劑、CDK-6抑制劑、CDK-9抑制劑、細胞色素P450 3抑制劑、CXCR4調節劑、樹突狀ICAM-3抓取非整合素1抑制劑、HIV GAG蛋白抑制劑、HIV POL蛋白抑制劑、補體因子H調節劑、泛素接合酶抑制劑、去氧胞苷激酶抑制劑、週期蛋白依賴性激酶抑制劑、HPK1 (MAP4K1)抑制劑、原蛋白

轉化酶PC9刺激劑、ATP依賴性RNA解螺旋酶DDX3X抑制劑、反轉錄酶引發複合體抑制劑、G6PD及NADH-氧化酶抑制劑、mTOR複合體1抑制劑、mTOR複合體2抑制劑、P-糖蛋白調節劑、RNA聚合酶調節劑、TAT蛋白抑制劑、脯胺醯基內肽酶抑制劑、磷脂酶A2抑制劑、藥物動力學增強劑、HIV基因療法、HIV疫苗、抗HIV肽、及其組合。

【0104】 在一些實施例中，額外治療劑係選自由下列所組成之群組：用於HIV之組合藥物、用於治療HIV之其他藥物、HIV蛋白酶抑制劑、HIV反轉錄酶抑制劑、HIV整合酶抑制劑、HIV非催化性部位（或異位）的整合酶抑制劑、HIV進入（融合）抑制劑、HIV成熟抑制劑、潛伏期逆轉劑、HIV殼體抑制劑、HIV Tat或Rev抑制劑、免疫調節劑（例如免疫刺激劑）、免疫治療劑、基於免疫之療法、PI3K抑制劑、HIV抗體、及雙特異性抗體、及「類抗體」治療蛋白、以及其組合。

【0105】 在一些實施例中，（多種）額外治療劑係選自HIV蛋白酶抑制劑、HIV非核苷或非核苷酸反轉錄酶抑制劑、HIV核苷或核苷酸反轉錄酶抑制劑、HIV整合酶抑制劑、HIV殼體抑制劑、gp41抑制劑、CXCR4抑制劑、gp120抑制劑、CCR5抑制劑、Nef抑制劑、潛伏期逆轉劑、HIV bNAb、TLR7、TLR8、及/或TLR9的促效劑、HIV疫苗、細胞介素、免疫檢查點抑制劑、FLT3配體、招募T細胞及NK細胞的雙特異性抗體、靶向HIV抗原的嵌合T細胞受體、藥物動力學增強劑、及用於治療HIV的其他藥物、及其組合。

【0106】 在一些實施例中，一或多種額外治療劑係選自多替拉韋(dolutegravir)、卡博特韋(cabotegravir)、伊司他韋(islatravir)、地瑞那韋

(darunavir)、比替拉韋(bictegravir)、艾法韋林(elsulfavirine)、利匹韋林(rilpivirine)、及利那卡帕韋(lenacapavir)、及其組合。

額外的抗HIV抗體

【0107】 在一些實施例中，本文所揭示之抗HIV gp120 V3聚醣結合抗體及抗HIV gp120 CD4bs結合抗體與一或多種額外抗HIV抗體進一步組合。在一些實施例中，一或多種額外抗體結合至選自由下列所組成之群組的gp120之表位或區域：(i)第二可變環(V2)及/或Env三聚體尖；(ii) gp120/gp41界面；或(iii) gp120之靜默面。前述由廣泛中和抗體結合之gp120之表位或區域係描述於例如McCoy, *Retrovirology* (2018) 15:70；Sok and Burton, *Nat Immunol*.2018 19(11):1179-1188；Possas, *et al., Expert Opin Ther Pat*. 2018 Jul; 28(7):551-560；及Stephenson及Barouch, *Curr HIV/AIDS Rep* (2016) 13:31–37，其全文出於所有目的特此以引用方式併入本文中。

【0108】 在一些實施例中，組合療法需要共投予抗HIV gp120 V3聚醣結合抗體及抗HIV gp120 CD4bs結合抗體、及一或多種額外抗HIV廣泛中和抗體或bNAb（亦即中和多種HIV-1病毒菌株之中和抗體）。各種bNAb係所屬技術領域中已知且可用來作為組合治療劑。使用額外說明性bNAb包括包含結合至選自由下列所組成之群組的gp120之表位或區域或與該表位或該區域競爭之VH及VL者：(i)第二可變環(V2)及/或Env三聚體尖；(ii) gp120/gp41界面；或(iii) gp120之靜默面。

【0109】 在一些實施例中，組合療法包括結合至第二可變環(V2)及/或Env三聚體尖中之gp120之表位或區域的抗體，且該抗體與選自由下列所組成之

群組的抗體之CDR及/或VH及VL區競爭或包含選自由下列所組成之群組的抗體之CDR及/或VH及VL區：PG9、PG16、PGC14、PGG14、PGT-142、PGT-143、PGT-144、PGT-145、CH01、CH59、PGDM1400、CAP256、CAP256-VRC26.08、CAP256-VRC26.09、CAP256-VRC26.25、PCT64-24E、及VRC38.01。

【0110】 在一些實施例中，組合療法包括結合至gp120/gp41界面中之gp120之表位或區域的抗體，且該抗體與選自由下列所組成之群組的抗體之CDR及/或VH及VL區競爭或包含選自由下列所組成之群組的抗體之CDR及/或VH及VL區：PGT-151、CAP248-2B、35O22、8ANC195、ACS202、VRC34、及VRC34.01。

【0111】 在一些實施例中，組合療法包括結合至gp120靜默面之表位或區域的抗體，且該抗體與抗體VRC-PG05之第二VH及VL區競爭或包含抗體VRC-PG05之第二VH及VL區。

【0112】 在一些實施例中，組合療法包括結合至近膜區(MPER)中之gp41之表位或區域的抗體，且該抗體與選自由下列所組成之群組的抗體之第二VH及VL區競爭或包含選自由下列所組成之群組的抗體之第二VH及VL區：10E8、10E8v4、10E8-5R-100cF、4E10、DH511.11P、2F5、7b2、及LN01。在一些實施例中，組合療法包括結合至跨膜蛋白gp41之不可變部位KLIC（「KLIC」，揭示為SEQ ID NO: 496）之表位或區域且與選殖株3人類單株抗體(Cl3hmAb)(Protheragen)之第二VH及VL區競爭或包含選殖株3人類單株抗體(Cl3hmAb)(Protheragen)之第二VH及VL區的抗體。參見例如Vanini, *et al.*, AIDS.(1993) 7(2):167-74。

【0113】 在一些實施例中，組合療法包括結合至gp41融合肽之表位或區域的抗體，且該抗體與選自由下列所組成之群組的抗體之第二VH及VL區競爭或包含選自由下列所組成之群組的抗體之第二VH及VL區：VRC34及ACS202。

【0114】 在一些實施例中，組合療法包括結合至HIV抗原之多特異性，例如雙特異性或三特異性抗體。HIV雙特異性及三特異性抗體之實例包括MGD014、B12BiTe、BiIA-SG、TMB-雙特異性、SAR-441236、VRC-01/PGDM-1400/10E8v4、10E8.4/iMab、及10E8v4/PGT121-VRC01。

【0115】 在投予之前，可改善bNAb以具有增強的類藥物性質、減少的免疫原性、增強的ADCC、及合適的藥物動力學性質。此類抗體顯示結合至病毒粒子或經感染之細胞表面表現之HIV封套糖蛋白，且介導直接病毒中和作用以及強效NK、單核球、及PBMC殺滅這些細胞。此性質允許抗體藉由中和病毒來治療HIV感染，且亦殺滅及消除感染個體的潛伏感染HIV之細胞，可能導致滅菌治癒HIV。

【0116】 在各種實施例中，所有在組合抗HIV抗體療法中投予之抗體可具有如上述之增加血清半衰期及/或增強效應活性之Fc及/或轉譯後修飾。

【0117】 在各種實施例中，抗HIV gp120 CD4bs結合抗體或抗原結合片段及可選地組合bNAb可在活體內遞送，例如經投予之mRNA或經工程改造之B細胞在活體內表現。活體內遞送bNAb之實例包括AAV8-VRC07；編碼抗HIV抗體VRC01之mRNA；及編碼3BNC117之經工程改造之B細胞(Hartweger *et al, J. Exp.Med*. 2019, 1301)。

HIV組合藥物

【0118】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與一、二、三、四、或更多種額外抗HIV治療劑組合。可共投予之抗HIV組合藥物之實例包括但不限於ATRIPLA®（依法韋侖(efavirenz)、反丁烯二酸替諾福韋二吡呋酯、及恩曲他濱(emtricitabine)）；COMPLERA®（EVIPLERA®；利匹韋林、反丁烯二酸替諾福韋二吡呋酯、及恩曲他濱）；STRIBILD®（埃替格韋、考比西他、反丁烯二酸替諾福韋二吡呋酯、及恩曲他濱）；TRUVADA®（反丁烯二酸替諾福韋二吡呋酯及恩曲他濱；TDF+FTC）；DESCOVY®（替諾福韋艾拉酚胺及恩曲他濱）；ODEFSEY®（替諾福韋艾拉酚胺、恩曲他濱、及利匹韋林）；GENVOYA®（替諾福韋艾拉酚胺、恩曲他濱、考比西他、及埃替格韋）；SYMTUZA®（地瑞那韋(darunavir)、半富馬酸替諾福韋艾拉酚胺、恩曲他濱、及考比司特）；依法韋侖、拉米夫定、及反丁烯二酸替諾福韋二吡呋酯；拉米夫定及反丁烯二酸替諾福韋二吡呋酯；替諾福韋及拉米夫定；替諾福韋艾拉酚胺及恩曲他濱；半反丁烯二酸替諾福韋艾拉酚胺及恩曲他濱；半反丁烯二酸替諾福韋艾拉酚胺、恩曲他濱、及利匹韋林；半反丁烯二酸替諾福韋艾拉酚胺、恩曲他濱、考比西他、及埃替格韋；替諾福韋類似物；COMBIVIR®（齊多夫定及拉米夫定；AZT+3TC）；EPZICOM®（LIVEXA®；硫酸阿巴卡韋及拉米夫定；ABC+3TC）；KALETRA®（ALUVIA®；洛匹那韋及利托那韋）；TRIUMEQ®（多替拉韋(dolutegravir)、阿巴卡韋、及拉米夫定）；BIKTARVY®（比替拉韋+恩曲他濱+替諾福韋艾拉酚胺）、DOVATO®（多替拉韋及拉米夫定）、TRIZIVIR®（硫酸阿巴卡韋、齊多夫定、及拉米夫定；ABC+AZT+3TC）；阿扎那韋及利托那韋(ATZ+RTV)；阿扎那韋及考比西他；硫酸阿扎那韋及考比西

他；硫酸阿扎那韋及利托那韋；PREZCOBIX®（地瑞那韋及考比西他）；多替拉韋及利匹韋林；多替拉韋及鹽酸利匹韋林；多替拉韋、硫酸阿巴卡韋、及拉米夫定；拉米夫定、奈韋拉平、及齊多夫定；雷特格韋及拉米夫定；多拉韋林、拉米夫定、及反丁烯二酸替諾福韋二吡呋酯；多拉韋林、拉米夫定、及替諾福韋二吡呋酯；多替拉韋+拉米夫定、拉米夫定+阿巴卡韋+齊多夫定、拉米夫定+阿巴卡韋、拉米夫定+反丁烯二酸替諾福韋二吡呋酯、拉米夫定+齊多夫定+奈韋拉平、洛匹那韋+利托那韋、洛匹那韋+利托那韋+阿巴卡韋+拉米夫定、洛匹那韋+利托那韋+齊多夫定+拉米夫定、替諾福韋+拉米夫定、ACC-008（ACC-007 +拉米夫定+反丁烯二酸替諾福韋二吡呋酯）、VM-1500 +恩曲他濱+替諾福韋二吡呋酯、及反丁烯二酸替諾福韋二吡呋酯+恩曲他濱+利匹韋林鹽酸鹽、洛匹那韋、利托那韋、齊多夫定、洛匹那韋+利托那韋+阿巴卡韋+拉米夫定、及拉米夫定；卡伯拉韋+利匹韋林；3-BNC117 +艾博韋地（艾法韋林；VM-1500）、VM-1500A、利那卡帕韋+伊司他韋（口服、注射用）、及雙目標HIV-1反轉錄酶/核殼體蛋白7抑制劑。

其他HIV藥物

【0119】 用於治療HIV之其他藥物之實例包括但不限於黑麴菌素C (aspernigrin C)、格瑪木因(Gamimune)、米特法林(metenkefalin)、那曲酮(naltrexone)、普拉斯汀(Prolastin)、REP 9、VSSP、H1病毒性、SB-728-T、1,5-二咖啡醯基奎尼酸、rHIV7-shl-TAR-CCR5RZ、AAV-eCD4-Ig基因療法、MazF基因療法、BlockAide、貝韋立馬(bevirimat)、ABBV-382、奧貝奇莫(obefazimod) (ABX-464)、AG-1105、APH-0812、APH0202、苔蘚蟲素-1

(bryostatin-1)、苔蘚蟲素-23、苔蘚蟲素類似物、SUW-133、BIT-225、BRII-732、BRII-778、Codivir、CYT-107、CS-TATI-1、氟-β-D-阿拉伯糖核酸(FANA)修飾之反義寡核苷酸、FX-101、格里菲斯辛(griffithsin)、HGTV-43、HPH-116、HRS-5685、HivCide-I、羥氯喹(hydroxychloroquine)、IMB-10035、IMO-3100、IND-02、JL-18008、LADAVRU、LLDT-8、MK-1376、MK-2048、MK-4250、MK-8507、MK-8558、伊司他韋(MK-8591)、NOV-205、OB-002H、ODE-Bn-TFV、PA-1050040 (PA-040)、PC-707、PGN-007、QF-036、S-648414、SCY-635、SB-9200、SCB-719、TR-452、TEV-90110、TEV-90112、TEV-90111、TEV-90113、RN-18、DIACC-1010、Fasnall、Immuglo、2-CLIPS肽、HRF-4467、血小板反應蛋白(thrombospondin)類似物、TBL-1004HI、VG-1177、xl-081、AVI-CO-004、rfhSP-D、[18F]-MC-225、URMC-099-C、RES-529、凡迪尼索(Verdinexor)、IMC-M113V、IML-106、抗病毒fc接合物(antiviral fc conjugate, AVC)、WP-1096、WP-1097、珈摩拉(Gammora)、ISR-CO48、ISR-48、ISR-49、MK-8527、大麻素、ENOB-HV-32、T-1144、VIR-576、尼帕莫韋(nipamovir)、Covimro、WP-1122、ZFP-362、及ABBV-1882。

HIV蛋白酶抑制劑

【0120】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與HIV蛋白酶抑制劑組合。HIV蛋白酶抑制劑之實例包括但不限於安普那韋(amprenavir)、阿紮那韋、貝卡那韋(brecanavir)、地瑞那韋(darunavir)、福沙那韋(fosamprenavir)、福沙那韋鈣、茚地那韋(indinavir)、硫酸茚地那韋、洛匹那韋(lopinavir)、奈非那韋(nelfinavir)、甲磺酸奈非那韋、利托

那韋、沙奎那韋(saquinavir)、甲磺酸沙奎那韋、替拉那韋(tipranavir)、ASC-09+利托那韋、AEBL-2、DG-17、艾盧諾那韋(elunonavir) (GS-1156)、TMB-657 (PPL-100)、T-169、BL-008、MK-8122、TMB-607、GRL-02031、及TMC-310911。HIV蛋白酶抑制劑之額外實例係描述於例如美國專利第10,294,234號及美國專利申請公開案第US2020030327號及第US2019210978號中。

HIV核糖核酸酶H抑制劑

【0121】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與HIV核糖核酸酶H抑制劑組合。可組合之HIV核糖核酸酶H抑制劑之實例包括但不限於NSC-727447。

HIV Nef抑制劑

【0122】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與HIV Nef抑制劑組合。可組合之HIV Nef抑制劑之實例包括但不限於FP-1。

HIV反轉錄酶抑制劑

【0123】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與非核苷或非核苷酸抑制劑組合。HIV非核苷或非核苷酸反轉錄酶抑制劑之實例包括但不限於達匹韋林(dapivirine)、地拉韋定(delavirdine)、甲磺酸地拉韋定、多拉韋林、二氟-聯苯-二芳基嘧啶(DAPY)、依法韋侖、依曲韋林(etravirine)、GS-5894、香菇多醣(lentinan)、奈韋拉平

(nevirapine)、利匹韋林、ACC-007、ACC-018、AIC-292、F-18、KM-023、PC-1005、M1-TFV、M2-TFV、VM-1500A-LAI、PF-3450074、艾法韋林（持續釋放型口服）、多拉韋林+伊司他韋（固定劑量組合/口服錠劑配方）、艾法韋林（長效注射型奈米懸浮液）、及艾法韋林(VM-1500)。

【0124】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與HIV核苷或核苷酸抑制劑組合。HIV核苷或核苷酸反轉錄酶抑制劑之實例包括但不限於阿德福韋(adefovir)、阿德福韋酯(adefovir dipivoxil)、阿茲夫定(azvudine)、恩曲他濱、替諾福韋、替諾福韋艾拉酚胺、反丁烯二酸替諾福韋艾拉酚胺、半反丁烯二酸替諾福韋艾拉酚胺、替諾福韋二吡呋酯、反丁烯二酸替諾福韋二吡呋酯、替諾福韋十八烷氧基乙基酯(AGX-1009)、反丁烯二酸艾米替諾福韋(HS-10234)、半反丁烯二酸替諾福韋二吡呋酯、VIDEX®及VIDEX EC®（地達諾新、ddl）、阿巴卡韋、硫酸阿巴卡韋、阿洛夫定(alovudine)、阿立他濱(apricitabine)、森沙戊定(censavudine)、地達諾新、艾夫他濱、非替那韋、氟沙定替酯(fosalvudine tidoxil)、CMX-157、達匹韋林、多拉韋林、依曲韋林、OCR-5753、乳清酸替諾福韋二吡呋酯、福齊夫定替酯(fozivudine tidoxil)、拉米夫定、福斯非茲(phosphazid)、司他夫定(stavudine)、紮西他濱(zalcitabine)、齊多夫定、羅法福韋艾他拉酚胺(rovafovir etalafenamide) (GS-9131)、GS-9148、GS-1614、GSK-4023991、MK-8504、伊司他韋、MK-8583、VM-2500、及KP-1461。

【0125】 HIV核苷或核苷酸反轉錄酶抑制劑之額外實例包括但不限於描述專利公開案US2007049754、US2016250215、US2016237062、

US2016251347、US2002119443、US2013065856、US2013090473、US2014221356、及WO04096286中者。

HIV整合酶抑制劑

【0126】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與HIV整合酶抑制劑組合。HIV整合酶抑制劑之實例包括但不限於埃替格韋、埃替格韋（緩釋微膠囊）、薑黃素、薑黃素衍生物、菊苣酸(chicoric acid)、菊苣酸衍生物、3,5-二咖啡醯奎寧酸、3,5-二咖啡醯奎寧酸衍生物、金黃三羧酸(aurintricarboxylic acid)、金黃三羧酸衍生物、咖啡酸苯乙酯、咖啡酸苯乙酯衍生物、酪胺酸磷酸化抑制劑(tyrphostin)、酪胺酸磷酸化抑制劑衍生物、槲皮素、槲皮素衍生物、雷特格韋、聚乙二醇化雷特格韋、多替拉韋、JTK-351、比替拉韋、AVX-15567、卡博特韋（長效注射用）、二酮喹啉-4-1衍生物、GS-1720、GS-6212、GS-1219、GS-3242、VH4524184、整合酶-LEDGF抑制劑、萊德金(ledgin)、M-522、M-532、MK-0536、NSC-310217、NSC-371056、NSC-48240、NSC-642710、NSC-699171、NSC-699172、NSC-699173、NSC-699174、S-365598、芪二磺酸(stilbenedisulfonic acid)、T169、STP-0404、VM-3500、XVIR-110、及ACC-017。

【0127】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與HIV非催化性部位（或異位）的整合酶抑制劑(NCINI)組合。HIV非催化性部位（或異位）的整合酶抑制劑(NCINI)之實例包括（不限於）CX-05045、CX-05168、及CX-14442。

殼體抑制劑

【0128】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與殼體抑制劑組合。可與本揭露之藥劑組合的殼體抑制劑之實例包括殼體聚合抑制劑或殼體破壞化合物、HIV核殼蛋白p7 (NCp7)抑制劑（諸如偶氮二甲醯胺）、HIV p24殼體蛋白抑制劑、利那卡帕韋(GS-6207)、VH4004280、VH4011499、GS-CA1、AVI-621、AVI-101、AVI-201、AVI-301、及AVI-CAN1-15系列、PF-3450074、及國際專利申請案公開號WO 2019/087016及美國專利第US2014/0221356、US2016/0016973、US2018/0051005、US2016/0108030號所述之化合物。

HIV病毒感染因子抑制劑

【0129】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與HIV病毒感染因子抑制劑組合。HIV病毒感染因子抑制劑之實例包括2-胺基-N-(2-甲氧基苯基)-6-((4-硝基苯基)硫基)苯甲醯胺衍生物及Irino-L。

HIV進入抑制劑

【0130】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與HIV進入抑制劑組合。HIV進入（融合）抑制劑之實例包括AAR-501、LBT-5001、賽尼克韋羅(cenicriviroc)、CCR5抑制劑、gp41抑制劑、CD4附著抑制劑、gp120抑制劑、gp160抑制劑、及CXCR4抑制劑。

【0131】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與CCR5抑制劑組合。CCR5抑制劑之實例包括阿普納維(aplaviroc)、維克維若(vicriviroc)、馬拉維若、馬拉維若（長效注射用奈米乳液）、森尼維若、勒隆利單抗(PRO-140)、艾達他韋(adaptavir) (RAP-101)、尼非韋羅(nifeviroc) (TD-0232)、抗GP120/CD4或CCR5雙特異性抗體、B-07、MB-66、多肽C25P、TD-0680、塞拉維若(thioraviroc)、及vMIP（海米普(Haimipu)）。

【0132】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與CXCR4抑制劑組合。CXCR4抑制劑之實例包括普樂沙福(plerixafor)、ALT-1188、N15肽、巴利沙福肽(balixafortide)、及vMIP（海米普）。

【0133】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與gp41抑制劑組合。gp41抑制劑之實例包括艾博韋他、恩夫韋地(enfuvirtide)、格里菲斯辛（gp41/gp120/gp160抑制劑）、BMS-986197、HIV-1融合抑制劑(P26-Bapc)、ITV-1、ITV-2、ITV-3、ITV-4、CPT-31、Cl3hmAb、利普韋他(lipovirtide)、PIE-12三聚體、及西夫韋他(sifuvirtide)。

【0134】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與CD4附著抑制劑組合。CD4附著抑制劑之實例包括伊巴利祖單抗及CADA類似物。

【0135】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與gp120抑制劑組合。gp120抑制劑之實例包括抗HIV殺微生物劑、Radha-108（瑞西普托(receptol)）3B3-PE38、BMS818251、

BanLec、基於皂土之奈米藥物、福斯特賽韋胺基丁三醇(fostemsavir tromethamine)、IQP-0831、VVX-004、及BMS-663068。

【0136】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與gp160抑制劑組合。可組合之gp160抑制劑之實例包括防己諾林鹼(fangchinoline)。

HIV成熟抑制劑

【0137】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與HIV成熟抑制劑組合。HIV成熟抑制劑之實例包括BMS-955176、GSK-3640254、VH-3739937 (GSK-3739937)、HRF-10071、及GSK-2838232。

潛伏期逆轉劑

【0138】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與HIV潛伏期逆轉劑組合。可與本文所述之一或多種多特異性抗原結合分子組合之潛伏期逆轉劑之實例包括IL-15受體促效劑（例如ALT-803；介白素15/Fc融合蛋白（例如XmAb24306）；重組介白素15（例如AM0015、NIZ-985）；聚乙二醇化IL-15（例如NKTR-255））；類鐸受體(TLR)促效劑（包括TLR7促效劑，例如維沙莫德(GS-9620)；TLR8促效劑，例如賽爾甘托莫德(GS-9688)；TLR9促效劑，例如勒托莫德(lefitolimod) (MGN-1703)）、組蛋白去乙醯酶(HDAC)抑制劑、蛋白酶體抑制劑諸如萬珂(velcade)、蛋白激酶C (PKC)活化子、Smyd2抑制劑、BET-布羅莫域4 (BRD4)

抑制劑（例如諸如ZL-0580、阿帕他隆(apabetalone)）、離子黴素、IAP拮抗劑（細胞凋亡蛋白抑制劑，諸如APG-1387、LBW-242）、SMAC擬似物（包括TL32711、LCL161、GDC-0917、HGS1029、謝維納潘(xevinapant)(AT-406)）、德比奧(Debio)-1143）、PMA、SAHA（辛二醯苯胺羥肟酸(suberanilohydroxamic acid)、或辛二醯基、苯胺、及羥肟酸）、NIZ-985、IL-15調節抗體、（包括IL-15、IL-15融合蛋白、及IL-15受體促效劑，例如ALT-803）、JQ1、二硫龍(disulfiram)、兩性黴素B (amphotericin B)、及泛素抑制劑諸如拉格唑拉(largazole)類似物、APH-0812、及GSK-343。PKC活化子之實例包括吲哚內醯胺(indolactam)、普羅斯坦(prostratin)、巨大戟醇(ingenol) B、及DAG-內酯。

類鐸受體(TLR)促效劑

【0139】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與類鐸受體(TLR)之促效劑組合，例如TLR1（NCBI基因ID：7096）、TLR2（NCBI基因ID：7097）、TLR3（NCBI基因ID：7098）、TLR4（NCBI基因ID：7099）、TLR5（NCBI基因ID：7100）、TLR6（NCBI基因ID：10333）、TLR7（NCBI基因ID：51284）、TLR8（NCBI基因ID：51311）、TLR9（NCBI基因ID：54106）、及/或TLR10（NCBI基因ID：81793）之促效劑。

【0140】 可與本文所述之一或多種多特異性抗原結合分子共投予或組合之例示性TLR7促效劑包括但不限於AL-034、DSP-0509、GS-9620（維沙莫德(vesatolimod)）、維沙莫德類似物、LHC-165、TMX-101（咪喹莫特

(imiquimod)）、GSK-2245035、雷西莫特(resiquimod)、DSR-6434、DSP-3025、IMO-4200、MCT-465、MEDI-9197、3M-051、SB-9922、3M-052、林托普(Limtop)、TMX-30X、TMX-202、RG-7863、RG-7854、RG-7795、及下列中所述之化合物：US20100143301 (Gilead Sciences)、US20110098248 (Gilead Sciences)、US20090047249 (Gilead Sciences)、US2010143301 (Gilead Sciences)、US20140045849 (Janssen)、US20140073642 (Janssen)、WO2014/056953 (Janssen)、WO2014/076221 (Janssen)、WO2014/128189 (Janssen)、US20140350031 (Janssen)、WO2014/023813 (Janssen)、US20080234251 (Array Biopharma)、US20080306050 (Array Biopharma)、US20100029585 (Ventirx Pharma)、US20110092485 (Ventirx Pharma)、US20110118235 (Ventirx Pharma)、US20120082658 (Ventirx Pharma)、US20120219615 (Ventirx Pharma)、US20140066432 (Ventirx Pharma)、US20140088085 (Ventirx Pharma)、US20140275167 (Novira Therapeutics)、及US20130251673 (Novira Therapeutics)。

【0141】　可共投予的TLR7/TLR8促效劑係NKTR-262、特拉莫德(telratolimod)、及BDB-001。

【0142】　可與本文所述之一或多種多特異性抗原結合分子共投予或組合之例示性TLR8促效劑之實例包括但不限於E-6887、IMO-4200、IMO-8400、IMO-9200、MCT-465、MEDI-9197、莫托莫特(motolimod)、雷西莫特、賽爾甘托莫德(GS-9688)、VTX-1463、VTX-763、3M-051、3M-052、及揭示於下列中之化合物：US2017071944 (Gilead Sciences)、US20140045849 (Janssen)、US20140073642 (Janssen)、WO2014/056953 (Janssen)、WO2014/076221

(Janssen)、WO2014/128189 (Janssen)、US20140350031 (Janssen)、WO2014/023813 (Janssen)、US20080234251 (Array Biopharma)、US20080306050 (Array Biopharma)、US20100029585 (Ventirx Pharma)、US20110092485 (Ventirx Pharma)、US20110118235 (Ventirx Pharma)、US20120082658 (Ventirx Pharma)、US20120219615 (Ventirx Pharma)、US20140066432 (Ventirx Pharma)、US20140088085 (Ventirx Pharma)、US20140275167 (Novira Therapeutics)、及US20130251673 (Novira Therapeutics)。

【0143】 可共投予的例示性TLR9促效劑包括但不限於AST-008、庫比莫德(cobitolimod)、CMP-001、IMO-2055、IMO-2125、利騰莫特(litenimod)、MGN-1601、BB-001、BB-006、IMO-3100、IMO-8400、IR-103、IMO-9200、阿托莫特(agatolimod)、DIMS-9054、DV-1079、DV-1179、AZD-1419、利福莫特(leftolimod) (MGN-1703)、CYT-003、CYT-003-QbG10、替索莫德(tilsotolimod)、及PUL-042。TLR3促效劑之實例包括瑞他立德(rintatolimod)、poly-ICLC、RIBOXXON®、Apoxxim、RIBOXXIM®、IPH-33、MCT-465、MCT-475、及ND-1.1。TLR4促效劑之實例包括：G-100及GSK-1795091。

組蛋白去乙醯酶(HDAC)抑制劑

【0144】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與組蛋白去乙醯酶之抑制劑組合，例如組蛋白去乙醯酶1、組蛋白去乙醯酶9（HDAC9、HD7、HD7b、HD9、HDAC、HDAC7、HDAC7B、HDAC9B、HDAC9FL、HDRP、MITR；基因ID：9734）。HDAC抑制劑之實例包括但不限於阿貝司他(abexinostat)、ACY-241、AR-42、BEBT-

908、貝林司他(belinostat)、CKD-581、CS-055 (HBI-8000)、CT-101、CUDC-907（非米司他(fimepinostat)）、恩替司他(entinostat)、吉韋司他(givinostat)、莫塞司他(mocetinostat)、帕比司他(panobinostat)、普拉司他(pracinostat)、奎西司他(quisinostat) (JNJ-26481585)、雷米諾他(resminostat)、瑞科司他(ricolinostat)、羅米地辛(romidepsin)、SHP-141、TMB-ADC、丙戊酸(VAL-001)、伏立諾他(vorinostat)、替諾斯汀(tinostamustine)、雷米諾他、及恩替司他。

細胞色素P450 3抑制劑

【0145】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與細胞色素P450 3抑制劑組合。細胞色素P450 3抑制劑之實例包括但不限於該些描述於美國專利第7,939,553號中者。

RNA聚合酶調節劑

【0146】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與RNA聚合酶調節劑組合。RNA聚合酶調節劑之實例包括但不限於該些描述於美國專利第10,065,958號及第8,008,264號中者。

週期蛋白依賴性激酶(CDK)抑制劑或拮抗劑

【0147】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與週期蛋白依賴性激酶(CDK)抑制劑或拮抗劑，例如週期蛋白依賴性激酶4（CDK4；NCBI基因ID：1019）、週期蛋白依賴性激酶6

（CDK6；NCBI基因ID：1021）、週期蛋白依賴性激酶9（CDK9；NCBI基因ID：1025）組合。在一些實施例中，CDK4/CDK6/CDK9抑制劑或拮抗劑係選自由下列所組成之群組：VS2-370。

干擾素基因刺激因子(STING)促效劑

【0148】 在一些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與干擾素基因刺激因子(STING)組合。在一些實施例中，STING受體促效劑或活化劑係選自由下列所組成之群組：ADU-S100 (MIW-815)、SB-11285、MK-1454、SR-8291、AdVCA0848、GSK-532、SYN-STING、MSA-1、SR-8291、5,6-二甲基吖酮-4-乙酸(DMXAA)、環狀-GAMP (cGAMP)、及環狀-二-AMP。

RIG-I促效劑

【0149】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與DExD/H盒解螺旋酶58（DDX58；又名RIG-I、RIG1、RIGI、RLR-1、SGMRT2；NCBI基因ID：23586）之促效劑組合。在一些實施例中，本文所述之藥劑係與RIG-I調節劑，諸如RGT-100、或NOD2調節劑，諸如SB-9200（又名GS 9992；伊納吉韋(inarigivir)）、及IR-103組合。例示性RIG-I促效劑係由Hemann, *et al.*, J Immunol May 1, 2016, 196 (1 Supplement) 76.1描述之KIN1148。額外RIG-I促效劑描述於例如Elion, *et al.*, Cancer Res. (2018) 78(21):6183-6195；及Liu, *et al.*, J Virol.(2016) 90(20):9406-19。RIG-I促效劑係可得自商業途徑例如Invivogen (invivogen.com)。

LAG-3及TIM-3抑制劑

【0150】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與抗TIM-3（又名A型肝炎病毒細胞性受體2（HAVCR2；NCBI基因ID：84868）抗體，諸如TSR-022、LY-3321367、MBG-453、INCAGN-2390組合。在一些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與抗-LAG-3（淋巴球活化）（NCBI基因ID：3902）抗體（諸如瑞拉單抗(relatlimab) (ONO-4482)、LAG-525、MK-4280、REGN-3767、INCAGN2385）組合。

基於免疫之療法

【0151】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與基於免疫之療法組合。基於免疫之療法之實例包括類鐸受體(TLR)調節劑，諸如TLR1、TLR2、TLR3、TLR4、TLR5、TLR6、TLR7、TLR8、TLR9、TLR10、TLR11、TLR12、及TLR13；程式性細胞死亡蛋白1 (PD-1)調節劑；程式性死亡配體1 (PD-L1)調節劑；IL-15調節劑（例如IL-15受體促效劑（例如ALT-803；介白素15/Fc融合蛋白（例如XmAb24306）；重組介白素15（例如AM0015、NIZ-985）；聚乙二醇化IL-15（例如NKTR-255））；DermaVir；介白素-7；必賴克瘧(plaquenil)（羥氯奎寧）；普留淨(proleukin)（阿地介白素(aldesleukin)，IL-2）；干擾素α；干擾素α-2b；干擾素α-n3；聚乙二醇化干擾素α；干擾素γ；羥基脲；黴酚酸酯(mycophenolate mofetil, MPA)及其酯衍生物黴酚酸酯(MMF)；利巴韋林(ribavirin)；聚合物聚乙

烯亞胺(PEI)；Gepon；IL-12；WF-10；VGV-1；MOR-22；BMS-936559；CYT-107、諾弗龍(normferon)、聚乙二醇化干擾素α-2a、聚乙二醇化干擾素α-2b、RPI-MN、STING調節劑、RIG-I調節劑、NOD2調節劑、SB-9200、及IR-103。

【0152】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與TLR促效劑組合。TLR促效劑之實例包括但不限於：維沙莫德(GS-9620)、利福莫特、替索莫德、瑞他立德、DSP-0509、AL-034、G-100、庫比莫德、AST-008、莫托莫特、GSK-1795091、GSK-2245035、VTX-1463、賽爾甘托莫德(GS-9688)、LHC-165、BDB-001、RG-7854、特拉莫德。

免疫檢查點受體蛋白調節劑

【0153】 在各種實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與抑制性免疫檢查點蛋白或受體之一或多種阻斷劑或抑制劑及/或與一或多種刺激性免疫檢查點蛋白或受體之一或多種刺激劑、活化劑、或促效劑組合。阻斷或抑制抑制性免疫檢查點可正向調節T細胞或NK細胞活化且預防經感染之細胞之免疫逃脫。活化或刺激刺激性免疫檢查點可放大免疫檢查點抑制劑在感染治療劑之效應。在各種實施例中，免疫檢查點蛋白或受體調控T細胞反應（例如綜述於Xu, et al., J Exp Clin Cancer Res. (2018) 37:110）。在各種實施例中，免疫檢查點蛋白或受體調節NK細胞反應（例如回顧於Davis, *et al*., Semin Immunol.(2017) 31:64–75及Chiossone, *et al*., Nat Rev Immunol.(2018) 18(11):671-688）。

【0154】 可與本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體組合之免疫檢查點蛋白或受體之實例包括但不限於CD27、CD70；CD40、CD40LG；CD47、CD48 (SLAMF2)、含跨膜及免疫球蛋白域2 (TMIGD2, CD28H)、CD84 (LY9B, SLAMF5)、CD96、CD160、MS4A1 (CD20)、CD244 (SLAMF4)；CD276 (B7H3)；含V-set域T細胞活化抑制子1 (VTCN1, B7H4)；V-set免疫調節受體(VSIR, B7H5, VISTA)；免疫球蛋白超家族成員11 (IGSF11, VSIG3)；自然殺手細胞細胞毒性受體3配體1 (NCR3LG1, B7H6)；HERV-H LTR關聯2 (HHLA2, B7H7)；可誘導T細胞共刺激劑(ICOS, CD278)；可誘導T細胞共刺激劑配體(ICOSLG, B7H2)；TNF受體超家族成員4 (TNFRSF4, OX40)；TNF超家族成員4 (TNFSF4, OX40L)；TNFRSF8 (CD30)、TNFSF8 (CD30L)；TNFRSF10A (CD261, DR4, TRAILR1)、TNFRSF9 (CD137)、TNFSF9 (CD137L)；TNFRSF10B (CD262, DR5, TRAILR2)、TNFRSF10 (TRAIL)；TNFRSF14 (HVEM, CD270)、TNFSF14 (HVEML)；CD272（B及T淋巴球相關(BTLA)）；TNFRSF17 (BCMA, CD269)、TNFSF13B (BAFF)；TNFRSF18 (GITR)、TNFSF18 (GITRL)；MHC第I型多肽相關序列A (MICA)；MHC第I型多肽相關序列B (MICB)；CD274 (CD274, PDL1, PD-L1)；程式性細胞死亡1 (PDCD1, PD1, PD-1)；細胞毒性T淋巴球相關蛋白4 (CTLA4, CD152)；CD80 (B7-1)、CD28；連接蛋白細胞黏附分子2 (NECTIN2, CD112)；CD226 (DNAM-1)；小兒麻痺病毒受體(PVR)細胞黏附分子(PVR, CD155)；含PVR相關免疫球蛋白域(PVRIG, CD112R)；具Ig及ITIM域之T細胞免疫受體(TIGIT)；含T細胞免疫球蛋白及黏蛋白域4 (TIMD4; TIM4)；A型肝炎病毒細胞性受體2 (HAVCR2, TIMD3, TIM3)；半乳糖凝集素9 (LGALS9)；淋巴球活化3

(LAG3, CD223)；信號傳導淋巴球性活化分子家族成員1 (SLAMF1, SLAM, CD150)；淋巴球抗原9 (LY9, CD229, SLAMF3)；SLAM家族成員6 (SLAMF6, CD352)；SLAM家族成員7 (SLAMF7, CD319)；UL16結合蛋白1 (ULBP1)；UL16結合蛋白2 (ULBP2)；UL16結合蛋白3 (ULBP3)；視黃酸早期轉錄物1E（RAET1E；ULBP4)；視黃酸早期轉錄物1G（RAET1G；ULBP5)；視黃酸早期轉錄物1L（RAET1L；ULBP6)；淋巴球活化3 (CD223)；殺手細胞免疫球蛋白樣受體、三個Ig域、及長細胞質尾1 (KIR, CD158E1)；殺手細胞凝集素樣受體C1 (KLRC1, NKG2A, CD159A)；殺手細胞凝集素樣受體K1 (KLRK1, NKG2D, CD314)；殺手細胞凝集素樣受體C2 (KLRC2, CD159c, NKG2C)；殺手細胞凝集素樣受體C3 (KLRC3, NKG2E)；殺手細胞凝集素樣受體C4 (KLRC4, NKG2F)；殺手細胞免疫球蛋白樣受體、二個Ig域、及長細胞質尾1 (KIR2DL1)；殺手細胞免疫球蛋白樣受體、二個Ig域、及長細胞質尾2 (KIR2DL2)；殺手細胞免疫球蛋白樣受體、二個Ig域、及長細胞質尾3 (KIR2DL3)；殺手細胞免疫球蛋白樣受體、三個Ig域、及長細胞質尾1 (KIR3DL1)；殺手細胞凝集素樣受體D1 (KLRD1)；及造血前驅細胞激酶1 (HPK1, MAP4K1)。

【0155】 在各種實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與一或多種T細胞抑制性免疫檢查點蛋白或受體的一或多種阻斷劑或抑制劑組合。例示性T細胞抑制性免疫檢查點蛋白或受體包括但不限於CD274 (CD274, PDL1, PD-L1)；程式性細胞死亡1配體2 (PDCD1LG2, PD-L2, CD273)；程式性細胞死亡1 (PDCD1, PD1, PD-1)；細胞毒性T淋巴球相關蛋白4 (CTLA4, CD152)；CD276 (B7H3)；含V-set域T細胞活化抑制子1

(VTCN1, B7H4)；V-set免疫調節受體(VSIR, B7H5, VISTA)；免疫球蛋白超家族成員11 (IGSF11, VSIG3)；TNFRSF14 (HVEM, CD270)、TNFSF14 (HVEML)；CD272（B及T淋巴球相關(BTLA)）；含PVR相關免疫球蛋白域(PVRIG, CD112R)；具Ig及ITIM域之T細胞免疫受體(TIGIT)；淋巴球活化3 (LAG3, CD223)；A型肝炎病毒細胞性受體2 (HAVCR2, TIMD3, TIM3)；半乳糖凝集素9 (LGALS9)；殺手細胞免疫球蛋白樣受體、三個Ig域、及長細胞質尾1 (KIR, CD158E1)；殺手細胞免疫球蛋白樣受體、二個Ig域、及長細胞質尾1 (KIR2DL1)；殺手細胞免疫球蛋白樣受體、二個Ig域、及長細胞質尾2 (KIR2DL2)；殺手細胞免疫球蛋白樣受體、二個Ig域、及長細胞質尾3 (KIR2DL3)；及殺手細胞免疫球蛋白樣受體、三個Ig域、及長細胞質尾1 (KIR3DL1)。在各種實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與一或多種T細胞刺激性免疫檢查點蛋白或受體之一或多種促效劑或活化劑組合。說明性T細胞刺激性免疫檢查點蛋白或受體包括但不限CD27、CD70；CD40、CD40LG；可誘導T細胞共刺激劑(ICOS, CD278)；可誘導T細胞共刺激劑配體(ICOSLG, B7H2)；TNF受體超家族成員4 (TNFRSF4, OX40)；TNF超家族成員4 (TNFSF4, OX40L)；TNFRSF9 (CD137)、TNFSF9 (CD137L)；TNFRSF18 (GITR)、TNFSF18 (GITRL)；CD80 (B7-1)、CD28；連接蛋白細胞黏附分子2 (NECTIN2, CD112)；CD226 (DNAM-1)；CD244 (2B4, SLAMF4)、小兒麻痺病毒受體(PVR)細胞黏附分子(PVR, CD155)。參見例如Xu, et al., J Exp Clin Cancer Res. (2018) 37:110。

【0156】 在各種實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與一或多種NK細胞抑制性免疫檢查點蛋白或受體之一

或多種阻斷劑或抑制劑組合。例示性NK細胞抑制性免疫檢查點蛋白或受體包括但不限於殺手細胞免疫球蛋白樣受體、三個Ig域、及長細胞質尾1 (KIR, CD158E1)；殺手細胞免疫球蛋白樣受體、二個Ig域、及長細胞質尾1 (KIR2DL1)；殺手細胞免疫球蛋白樣受體、二個Ig域、及長細胞質尾2 (KIR2DL2)；殺手細胞免疫球蛋白樣受體、二個Ig域、及長細胞質尾3 (KIR2DL3)；殺手細胞免疫球蛋白樣受體、三個Ig域、及長細胞質尾1 (KIR3DL1)；殺手細胞凝集素樣受體C1 (KLRC1, NKG2A, CD159A)；及殺手細胞凝集素樣受體D1 (KLRD1, CD94)。在各種實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與一或多種NK細胞刺激性免疫檢查點蛋白或受體之一或多種促效劑或活化劑組合。例示性NK細胞刺激性免疫檢查點蛋白或受體包括但不限CD16、CD226 (DNAM-1)；CD244 (2B4, SLAMF4)；殺手細胞凝集素樣受體K1 (KLRK1, NKG2D, CD314)；SLAM家族成員7 (SLAMF7)。參見例如Davis, *et al.*, Semin Immunol.(2017) 31:64–75；Fang, *et al.*, Semin Immunol.(2017) 31:37-54；及Chiossone, *et al.*, Nat Rev Immunol.(2018) 18(11):671-688。

【0157】 在一些實施例中，一或多種免疫檢查點抑制劑包含PD-L1 (CD274)、PD-1 (PDCD1)、或CTLA4之蛋白質（例如抗體或其片段、或抗體擬似物）抑制劑。在一些實施例中，一或多種免疫檢查點抑制劑包含PD-L1 (CD274)、PD-1 (PDCD1)、或CTLA4之小型有機分子抑制劑。

【0158】 可共投予的CTLA4抑制劑之實例包括但不限於易普利姆單抗(ipilimumab)、曲美木單抗(tremelimumab)、BMS-986218、AGEN1181、AGEN1884、BMS-986249、MK-1308、REGN-4659、ADU-1604、CS-1002、

BCD-145、APL-509、JS-007、BA-3071、ONC-392、AGEN-2041、JHL-1155、KN-044、CG-0161、ATOR-1144、PBI-5D3H5、BPI-002、及多特異性抑制劑FPT-155 (CTLA4/PD-L1/CD28)、PF-06936308 (PD-1/CTLA4)、MGD-019 (PD-1/CTLA4)、KN-046 (PD-1/CTLA4)、MEDI-5752 (CTLA4/PD-1)、XmAb-20717 (PD-1/CTLA4)、及AK-104 (CTLA4/PD-1)。

【0159】 可組合或共投予之程式性細胞死亡1（PDCD1；NCBI基因ID：5133；CD279、PD-1、PD1）之抑制劑之實例包括但不限於賽帕利單抗(zimberelimab) (AB122, GLS-010, WBP-3055)、帕博利珠單抗(pembrolizumab) (KEYTRUDA®, MK-3475, SCH900475)、納武單抗(nivolumab) (OPDIVO®, BMS-936558, MDX-1106)、西米普利單抗(cemiplimab)（LIBTAYO®；西米普利單抗-rwlc、REGN-2810）、皮地利珠單抗(pidilizumab) (CT-011)、AMG-404、MEDI0680 (AMP-514)、斯巴達珠單抗(spartalizumab) (PDR001)、緹勒珠單抗(tislelizumab) (BGB-A317)、特瑞普利單抗(toripalimab) (JS-001)、傑諾珠單抗(genolimzumab) (CBT-501, APL-501, GB 226)、SHR-1201、坎立珠單抗(camrelizumab) (SHR-1210)、信迪利單抗(sintilimab) (TYVYT®; IBI-308)、多斯利單抗(dostarlimab) (TSR-042, WBP-285)、拉立珠單抗(lambrolizumab) (MK-3475)；薩善利單抗(sasanlimab) (PF-06801591)、西利單抗(cetrelimab) (JNJ-63723283)、斯魯利單抗(serplulimab) (HLX-10)、瑞弗利單抗(retifanlimab) (MGA-012)、巴替利單抗(balstilimab) (AGEN2034)、帕洛利單抗(prolgolimab) (BCD 100)、布格利單抗(budigalimab) (ABBV-181)、沃普瑞單抗(vopratelimab) (JTX-4014)、AK-103 (HX-008)、AK-105、CS-1003、BI-754091、LZM-009、Sym-021、BAT-1306、PD1-PIK、太鐵立單抗(tebotelimab) (MGD013; PD-

1/LAG-3)、RO-7247669 (PD-1/LAG-3)、FS-118 (LAG-3/PD-L1)、RO-7121661 (PD-1/TIM-3)、RG7769 (PD-1/TIM-3)、PF-06936308 (PD-1/CTLA4)、MGD-019 (PD-1/CTLA4)、KN-046 (PD-1/CTLA4)、XmAb-20717 (PD-1/CTLA4)、AK-104 (CTLA4/PD-1)、及MEDI-5752 (CTLA4/PD-1)。在一些實施例中，第一及/或第二抗原結合域包含人類程序性細胞死亡1配體2 (PD-L2)之胞外域且結合至PD1（例如AMP-224）。

【0160】 可組合或共投予之CD274分子（NCBI基因ID：基因ID：29126；B7-H、B7H1、PD-L1）之抑制劑之實例包括但不限於阿特珠單抗(atezolizumab) (TECENTRIQ®)、艾維路單抗(avelumab) (BAVENCIO®；MSB0010718C)、恩弗利單抗(envafolimab) (ASC22)、德瓦魯單抗(durvalumab) (IMFINZI®; MEDI-4736)、BMS-936559 (MDX1105)、柯希利單抗(cosibelimab) (CK-301)、洛達利單抗(lodapolimab) (LY 3300054)、加利弗單抗(garivulimab) (BGB A333)、恩弗利單抗(KN035)、歐可利單抗(opucolimab) (HLX 20)、瑪奈利單抗(manelimab) (BCD 135)、CX-072、CBT-502 (TQB2450)、MSB-2311、SHR-1316、舒格利單抗(sugemalimab) (CS-1001; WBP3155)、A167 (KL-A167, HBM 9167)、STI-A1015 (IMC-001)、FAZ-053、BMS-936559 (MDX1105)、INCB086550、GEN-1046 (PD-L1/4-1BB)、FPT-155 (CTLA4/PD-L1/CD28)、M7824（PD-L1/TGFβ-EC域）、CA-170 (PD-L1/VISTA)、CDX-527 (CD27/PD-L1)、LY-3415244 (TIM-3/PDL1)、INBRX-105 (4-1BB/PDL1)、及GNS-1480 (PD-L1/EGFR)，且進一步包括經工程改造以表現靶向PD-L1之嵌合抗原受體(CAR)之人類衍生、同種異體、自然殺手細胞，諸如PD-L1 t-haNK。

【0161】 在一些實施例中，CD274或PDCD1之小分子抑制劑係選自由GS-4224、GS-4416、INCB086550、及MAX10181所組成之群組。在一些實施例中，CTLA4之小分子抑制劑包含BPI-002。

【0162】 在各種實施例中，如本文所述之抗體係與抗TIGIT抗體（諸如，多伐那利單抗(domvanalimab)、雷帕蘇塔單抗、維博利單抗、奧西伯利單抗、瑞利尤單抗、里韋戈斯托米格(rilvegostomig)、貝爾雷斯托圖格(belrestotug)、厄提吉利單抗(etigilimab)、BMS-986207、RG-6058、或AGEN-1307）組合。

TNF受體超家族(TNFRSF)成員促效劑或活化劑

【0163】 在各種實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與一或多個TNF受體超家族(TNFRSF)成員之促效劑組合，例如下列之一或多者的促效劑：TNFRSF1A（NCBI基因ID：7132）、TNFRSF1B（NCBI基因ID：7133）、TNFRSF4（OX40、CD134；NCBI基因ID：7293）、TNFRSF5（CD40；NCBI基因ID：958）、TNFRSF6（FAS，NCBI基因ID：355）、TNFRSF7（CD27，NCBI基因ID：939）、TNFRSF8（CD30，NCBI基因ID：943）、TNFRSF9（4-1BB、CD137，NCBI基因ID：3604）、TNFRSF10A（CD261、DR4、TRAILR1，NCBI基因ID：8797）、TNFRSF10B（CD262、DR5、TRAILR2，NCBI基因ID：8795）、TNFRSF10C（CD263、TRAILR3，NCBI基因ID：8794）、TNFRSF10D（CD264、TRAILR4，NCBI基因ID：8793）、TNFRSF11A（CD265、RANK，NCBI基因ID：8792）、TNFRSF11B（NCBI基因ID：4982）、TNFRSF12A（CD266，

NCBI基因ID：51330）、TNFRSF13B（CD267，NCBI基因ID：23495）、TNFRSF13C（CD268，NCBI基因ID：115650）、TNFRSF16（NGFR、CD271，NCBI基因ID：4804）、TNFRSF17（BCMA、CD269，NCBI基因ID：608）、TNFRSF18（GITR、CD357，NCBI基因ID：8784）、TNFRSF19（NCBI基因ID：55504）、TNFRSF21（CD358、DR6，NCBI基因ID：27242）、及TNFRSF25（DR3，NCBI基因ID：8718）。

【0164】 可共投予之抗TNFRSF4 (OX40)抗體之實例包括但不限於MEDI6469、MEDI6383、MEDI0562（塔伏利西單抗）、MOXR0916、PF-04518600、RG-7888、GSK-3174998、INCAGN1949、BMS-986178、GBR-8383、ABBV-368、及該些描述於WO2016179517、WO2017096179、WO2017096182、WO2017096281、及WO2018089628中者。

【0165】 可共投予的抗TNFRSF5 (CD40)抗體之實例包括但不限於：RG7876、SEA-CD40、APX-005M、及ABBV-428。

【0166】 在一些實施例中，共投予抗TNFRSF7 (CD27)抗體瓦里木單抗(varlilumab) (CDX-1127)。

【0167】 可共投予的抗TNFRSF9 (4-1BB, CD137)抗體之實例包括但不限於：烏瑞魯單抗(urelumab)、烏圖木單抗(utomilumab) (PF-05082566)、AGEN2373、與ADG-106。

【0168】 可共投予的抗TNFRSF18 (GITR)抗體之實例包括但不限於MEDI1873、FPA-154、INCAGN-1876、TRX-518、BMS-986156、MK-1248、GWN-323，以及該些描述於WO2017096179、WO2017096276、WO2017096189、及WO2018089628中者。在一些實施例中，共靶向TNFRSF4

(OX40)及TNFRSF18 (GITR)之抗體或其片段經共投予。此類抗體係描述於例如WO2017096179及WO2018089628。

介白素受體促效劑

【0169】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與介白素受體促效劑，諸如IL-2、IL-7、IL-15、IL-10、IL-12促效劑組合；IL-2受體促效劑之實例，諸如普留淨（阿地介白素，IL-2）；聚乙二醇化IL-2（例如NKTR-214）；IL-2之經修飾變體（例如，THOR-707）、貝培阿地白介素(bempegaldesleukin)、AIC-284、ALKS-4230、CUI-101、Neo-2/15；IL-15受體促效劑諸如ALT-803、NKTR-255、及hetIL-15、介白素15/Fc融合蛋白、AM-0015、NIZ-985、SO-C101、IL-15辛索林(Synthorin)（聚乙二醇化IL-15）、P-22339、及IL-15 -PD-1融合蛋白N-809；IL-7之實例包括CYT-107。

【0170】 可與本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體組合之干擾素受體促效劑之實例包括干擾素α；干擾素α-2b；干擾素α-n3；聚乙二醇化干擾素α；干擾素γ；Gepon；normferon、聚乙二醇化干擾素α-2a (peginterferon alfa-2a)、聚乙二醇化干擾素α-2b (peginterferon alfa-2b)、RPI-MN。

【0171】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與Flt3促效劑諸如GS-3583或CDX-301組合。

雙特異性及三特異性自然殺手(NK)細胞銜接器

【0172】 在各種實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與針對下列之雙特異性NK細胞銜接器(BiKE)或三特異性NK細胞銜接器(TriKE)（例如不具有Fc）或雙特異性抗體（例如具有Fc）組合：NK細胞活化受體（例如CD16A）、C型凝集素受體（CD94/NKG2C、NKG2D、NKG2E/H、及NKG2F）、天然細胞毒性受體（NKp30、NKp44、及NKp46）、殺手細胞C型凝集素樣受體（NKp65、NKp80）、Fc受體FcγR（其介導抗體依賴性細胞毒性）、SLAM家族受體（例如2B4、SLAM6、及SLAM7）、殺手細胞免疫球蛋白樣受體(KIR)（KIR-2DS及KIR-3DS）、DNAM-1、及CD137 (4-1BB)。可共投予的說明性抗CD16雙特異性抗體、BiKE、或TriKE包括AFM26 (BCMA/CD16A)及AFM-13 (CD16/CD30)。視情況，抗CD16結合雙特異性分子可具有或可不具有Fc。可共投予的說明性雙特異性NK細胞銜接器靶向CD16及如本文所述之一或多種HIV相關抗原。BiKE及TriKE係描述於例如Felices, *et al.*, Methods Mol Biol. (2016) 1441:333–346；Fang, *et al.*, Semin Immunol.(2017) 31:37-54。三特異性NK細胞銜接器(TRiKE)之實例包括OXS-3550、HIV-TriKE、及CD16-IL-15-B7H3 TriKe。

吲哚胺-吡咯-2,3-二加氧酶(IDO1)抑制劑

【0173】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與吲哚胺2,3-二加氧酶1（IDO1；NCBI基因ID：3620）之抑制劑組合。IDO1抑制劑之實例包括但不限於BLV-0801、依波斯他(epacadostat)、F-001287、GBV-1012、GBV-1028、GDC-0919、吲哚莫德(indoximod)、NKTR-218、基於NLG-919之疫苗、PF-06840003、哌喃萘醌衍生

物(SN-35837)、雷米司他、SBLK-200802、BMS-986205、及shIDO-ST、EOS-200271、KHK-2455、LY-3381916。

磷脂醯肌醇3-激酶(PI3K)抑制劑

【0174】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與PI3K抑制劑組合。PI3K抑制劑之實例包括艾代拉里斯(idelalisib)、艾培昔布(alpelisib)、布帕昔布(buparlisib)、CAI乳清酸鹽、考班昔布(copanlisib)、杜維昔布(duvelisib)、吉達昔布(gedatolisib)、來那替尼(neratinib)、帕努昔布(panulisib)、哌立福新(perifosine)、皮克昔布(pictilisib)、皮拉昔布(pilaralisib)、甲磺酸普喹替尼(puquitinib mesylate)、瑞戈替布(rigosertib)、瑞戈替布鈉、索諾昔布(sonolisib)、泰尼昔布(taselisib)、AMG-319、AZD-8186、BAY-1082439、CLR-1401、CLR-457、CUDC-907、DS-7423、EN-3342、GSK-2126458、GSK-2269577、GSK-2636771、INCB-040093、LY-3023414、MLN-1117、PQR-309、RG-7666、RP-6530、RV-1729、SAR-245409、SAR-260301、SF-1126、TGR-1202、UCB-5857、VS-5584、XL-765、及ZSTK-474。

α-4/β-7拮抗劑

【0175】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與α-4/β-7拮抗劑組合。整合素α-4/β-7拮抗劑之實例包括PTG-100、TRK-170、阿布里單抗(abrilumab)、艾托珠單抗(etrolizumab)、卡洛斯特(carotegrast)甲基、及維多珠單抗(vedolizumab)。

HPK1/MAP4K1抑制劑

【0176】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與有絲分裂原活化蛋白激酶激酶激酶激酶1（MAP4K1，又名造血前驅細胞激酶1 (HPK1)；NCBI基因ID：11184）組合。HPK1抑制劑之實例包括但不限於ZYF-0272及ZYF-0057。

藥物動力學增強劑

【0177】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與藥物動力學增強劑組合。藥物動力學增強劑之實例包括考比西他及利托那韋。

額外治療劑

【0178】 額外治療劑之實例包括揭示於下列中之化合物：WO 2004/096286 (Gilead Sciences)；WO 2006/015261 (Gilead Sciences)；WO 2006/110157 (Gilead Sciences)；WO 2012/003497 (Gilead Sciences)；WO 2012/003498 (Gilead Sciences)；WO 2012/145728 (Gilead Sciences)；WO 2013/006738 (Gilead Sciences)；WO 2013/159064 (Gilead Sciences)；WO 2014/100323 (Gilead Sciences)、US 2013/0165489 (University of Pennsylvania)、US 2014/0221378 (Japan Tobacco)、US 2014/0221380 (Japan Tobacco)；WO 2009/062285 (Boehringer Ingelheim)；WO 2010/130034 (Boehringer Ingelheim)；

WO 2013/006792 (Pharma Resources)、US 20140221356 (Gilead Sciences)、US 20100143301 (Gilead Sciences)、及WO 2013/091096 (Boehringer Ingelheim)。

HIV組合療法

【0179】 在一具體實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與一、二、三、四、或更多種選自下列之額外治療劑組合：ATRIPLA®（依法韋侖、反丁烯二酸替諾福韋二吡呋酯、及恩曲他濱）；BIKTARVY®（比替拉韋+恩曲他濱+替諾福韋艾拉酚胺）、COMPLERA®（EVIPLERA®；利匹韋林、反丁烯二酸替諾福韋二吡呋酯、及恩曲他濱）；STRIBILD®（埃替格韋、考比西他、反丁烯二酸替諾福韋二吡呋酯、及恩曲他濱）；TRUVADA®（反丁烯二酸替諾福韋二吡呋酯及恩曲他濱；TDF +FTC）；DESCOVY®（替諾福韋艾拉酚胺及恩曲他濱）；ODEFSEY®（替諾福韋艾拉酚胺、恩曲他濱、及利匹韋林）；GENVOYA®（替諾福韋艾拉酚胺、恩曲他濱、考比西他、及埃替格韋）；阿德福韋；阿德福韋酯；考比西他；恩曲他濱；替諾福韋；替諾福韋二吡呋酯；反丁烯二酸替諾福韋二吡呋酯；替諾福韋艾拉酚胺；半反丁烯二酸替諾福韋艾拉酚胺；TRIUMEQ®（多替拉韋(dolutegravir)、阿巴卡韋、及拉米夫定）；多替拉韋、硫酸阿巴卡韋、及拉米夫定；雷特格韋；雷特格韋及拉米夫定；馬拉韋羅；恩夫韋地；ALUVIA®（KALETRA®；洛匹那韋及利托那韋）；COMBIVIR®（齊多夫定及拉米夫定；AZT+3TC）；EPZICOM®（LIVEXA®；硫酸阿巴卡韋及拉米夫定；ABC+3TC）；TRIZIVIR®（硫酸阿巴卡韋、齊多夫定、及拉米夫定；ABC+AZT+3TC）；利匹韋林；鹽酸利匹韋林；硫酸阿扎那韋及考比西

他；阿扎那韋及考比西他；地瑞那韋及考比西他；阿扎那韋；硫酸阿扎那韋；多替拉韋；埃替格韋；利托那韋；硫酸阿扎那韋及利托那韋；地瑞那韋；拉米夫定；普拉斯汀；福沙那韋；福沙那韋鈣依法韋侖；依曲韋林；奈非那韋；甲磺酸奈非那韋；干擾素；地達諾新；司他夫定；茚地那韋；硫酸茚地那韋；替諾福韋及拉米夫定；齊多夫定；奈韋拉平；沙奎那韋；甲磺酸沙奎那韋；阿地介白素；扎西他濱；替拉那韋；安普那韋；地拉韋啶；甲磺酸地拉韋啶；Radha-108（瑞西普托）；拉米夫定及反丁烯二酸替諾福韋二吡呋酯；依法韋侖、拉米夫定、及反丁烯二酸替諾福韋二吡呋酯；福斯非茲；拉米夫定、奈韋拉平、及齊多夫定；阿巴卡韋；及硫酸阿巴卡韋。

【0180】　所屬技術領域中具有通常知識者將理解，以上列出之額外治療劑可被包括在超過一個以上列出之類型中。特定類型並不意圖限制列出在該些類型中之該些化合物之功能性。

【0181】　在一具體實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與下列組合：HIV核苷或核苷酸反轉錄酶抑制劑、及HIV非核苷反轉錄酶抑制劑。在另一具體實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與下列組合：HIV核苷或核苷酸反轉錄酶抑制劑、及HIV蛋白酶抑制化合物。在一額外實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與下列組合：HIV核苷或核苷酸反轉錄酶抑制劑、HIV非核苷反轉錄酶抑制劑、及藥物動力學增強劑。在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與下列組合：至少一種HIV核苷反轉錄酶抑制劑、整合酶抑制劑、及藥

物動力學增強劑。在另一實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與兩種HIV核苷或核苷酸反轉錄酶抑制劑組合。

【0182】 在一具體實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與下列組合：硫酸阿巴卡韋、替諾福韋、替諾福韋二吡呋酯、反丁烯二酸替諾福韋二吡呋酯、半反丁烯二酸替諾福韋二吡呋酯、替諾福韋艾拉酚胺、或半反丁烯二酸替諾福韋艾拉酚胺。

【0183】 在一具體實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與下列組合：替諾福韋、替諾福韋二吡呋酯、反丁烯二酸替諾福韋二吡呋酯、替諾福韋艾拉酚胺、或半反丁烯二酸替諾福韋艾拉酚胺。

【0184】 在一具體實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與第一額外治療劑及第二額外治療劑組合，該第一額外治療劑係選自由硫酸阿巴卡韋、替諾福韋、替諾福韋二吡呋酯、反丁烯二酸替諾福韋二吡呋酯、替諾福韋艾拉酚胺、或半反丁烯二酸替諾福韋艾拉酚胺所組成之群組，該第二額外治療劑係選自由恩曲他濱及拉米夫定所組成之群組。

【0185】 在一具體實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與第一額外治療劑及第二額外治療劑組合，該第一額外治療劑係選自由替諾福韋、替諾福韋二吡呋酯、反丁烯二酸替諾福韋二吡呋酯、替諾福韋艾拉酚胺、或半反丁烯二酸替諾福韋艾拉酚胺所組成之群組，其中該第二額外治療劑係恩曲他濱。

【0186】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與一或多種額外治療劑組合，其治療有效劑量係在例

如1 mg至50 mg、75 mg、100 mg、150 mg、200 mg、250 mg、300 mg、400 mg、500 mg、1000 mg、或1500 mg範圍內的抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體或抗原結合片段。在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與一或多種額外治療劑組合，其治療有效劑量係在例如約0.1 mg/kg至約0.5 mg/kg、1 mg/kg、2 mg/kg、3 mg/kg、4 mg/kg、5 mg/kg、8 mg/kg、10 mg/kg、15 mg/kg、20 mg/kg、25 mg/kg、30 mg/kg、35 mg/kg、40 mg/kg、45 mg/kg、或50 mg/kg範圍內的抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體或抗原結合片段。在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與一或多種額外治療劑組合，其治療有效劑量係在例如約5 mg至約10 mg、20 mg、25 mg、50 mg、100 mg、125 mg、150 mg、250 mg、300 mg、500 mg、1000 mg、或1500 mg範圍內的抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體或抗原結合片段。

【0187】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與5至30 mg的反丁烯二酸替諾福韋艾拉酚胺、半反丁烯二酸替諾福韋艾拉酚胺、或替諾福韋艾拉酚胺、及200 mg的恩曲他濱組合。在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與5至10、5至15、5至20、5至25、25至30、20至30、15至30、或10至30 mg的反丁烯二酸替諾福韋艾拉酚胺、半反丁烯二酸替諾福韋艾拉酚胺、或替諾福韋艾拉酚胺、及200 mg的恩曲他濱組合。在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與10 mg的反丁烯二酸替諾福韋艾拉酚胺、半反丁烯二酸替諾福韋艾拉酚胺、或替諾福韋艾拉酚胺、及200 mg

的恩曲他濱組合。在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與25 mg的反丁烯二酸替諾福韋艾拉酚胺、半反丁烯二酸替諾福韋艾拉酚胺、或替諾福韋艾拉酚胺、及200 mg的恩曲他濱組合。

【0188】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與200至400 mg的反丁烯二酸替諾福韋二吡呋酯、半反丁烯二酸替諾福韋二吡呋酯、或替諾福韋二吡呋酯、及200 mg的恩曲他濱組合。在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與200至250、200至300、200至350、250至350、250至400、350至400、300至400、或250至400 mg的反丁烯二酸替諾福韋二吡呋酯、半反丁烯二酸替諾福韋二吡呋酯、或替諾福韋二吡呋酯、及200 mg的恩曲他濱組合。在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與300 mg的反丁烯二酸替諾福韋二吡呋酯、半反丁烯二酸替諾福韋二吡呋酯、或替諾福韋二吡呋酯、及200 mg的恩曲他濱組合。抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體可與本文所提供之藥劑以任何劑量（例如1 mg至500 mg的抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體）組合，如同劑量之各組合具體地且個別地列出一樣。

長效HIV抑制劑

【0189】 在一些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體可與長效HIV抑制劑共投予。在各種實施例中，長效HIV抑制劑可每年兩次，例如每6個月（Q6M)、每24週（Q24W)、每25週（Q25W)、每26週（Q26W）共投予。可組合或共投予之長效HIV抑制劑之實

例包括但不限於：長效殼體抑制劑，例如利那卡帕韋；長效整合酶抑制劑，例如長效比替拉韋(GS-9883)、GS-6212、卡博特韋長效(long-acting, LA)、長效雷特格韋(long-acting raltegravir, RAL)；長效NRTI，例如EFdA/MK-8591（4-乙炔基-2-氟-2-去氧腺苷；伊司他韋）植入物、反丁烯二酸替諾福韋艾拉酚胺(TAF)植入物、可注射羅法福韋艾他拉酚胺(GS-9131)；長效NNRTI，例如GS-5894、長效達匹韋林(DPV)、長效利匹韋林(RPV)、艾法韋林；亦VM-1500 LAI、馬拉維若(LAI)、及長效多替拉韋、(RPV)。長效抗HIV藥物綜述於Singh, *et al*., *Pharmaceuticals* (2019) 12:62。

HIV疫苗

【0190】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與HIV疫苗組合。HIV疫苗之實例包括肽疫苗、重組次單元蛋白疫苗、活載體疫苗、DNA疫苗、HIV MAG DNA疫苗、CD4衍生肽疫苗、疫苗組合、腺病毒載體疫苗（例如Ad5、Ad26、或Ad35）、猴(simian)腺病毒（黑猩猩、大猩猩、恆河猴，即rhAd）、腺相關病毒載體疫苗、黑猩猩腺病毒疫苗（例如ChAdOX1、ChAd68、ChAd3、ChAd63、ChAd83、ChAd155、ChAd157、Pan5、Pan6、Pan7、Pan9)、基於柯沙奇病毒之疫苗、基於腸病毒之疫苗、大猩猩腺病毒疫苗、基於慢病毒載體之疫苗、二區段或三區段之基於沙狀病毒之疫苗（例如LCMV、皮欽德）、基於三聚體之HIV-1疫苗、基於麻疹病毒之疫苗、基於黃病毒載體之疫苗、基於菸草嵌紋病毒載體之疫苗、基於水痘帶狀疱疹病毒之疫苗、基於人類副流感病毒3 (PIV3)之疫苗、基於痘病毒之疫苗（經修飾之痘瘡病毒安卡拉(Ankara) (MVA)、正痘病毒衍生

NYVAC、及禽痘病毒衍生ALVAC（金絲雀痘病毒）株）；基於雞痘病毒之疫苗、基於棒狀病毒之疫苗諸如水皰性口炎病毒(Vesicular stomatitis virus, VSV)及馬拉巴病毒(marabavirus)、基於重組人類CMV (rhCMV)之疫苗、基於α病毒之疫苗，諸如semliki森林病毒、委內瑞拉馬腦炎病毒(venezuelan equine encephalitis virus)、及辛得比斯病毒(sindbis virus)（參見例如Lauer, *et al.*, *Clin Vaccine Immunol.*(2017) 24(1): e00298-16)；LNP調配之基於mRNA之治療性疫苗；及LNP調配之自我複製RNA/自我擴增RNA疫苗。

【0191】 HIV疫苗之實例包括但不限於AAVLP-HIV疫苗、AdC6-HIVgp140、AE-298p、抗CD40.Env-gp140疫苗、Ad4-EnvC150、BG505 SOSIP.664 gp140佐劑疫苗、BG505 SOSIP.GT1.1 gp140佐劑疫苗、ChAdOx1.tHIVconsv1疫苗、CMV-MVA三重疫苗、ChAdOx1.HTI、Chimigen HIV疫苗、ConM SOSIP.v7 gp140、rgp120 (AIDSVAX)、ALVAC HIV (vCP1521)/AIDSVAX B/E (gp120) (RV144)、單體gp120 HIV-1亞型C疫苗、MPER-656脂質體次單元疫苗、Remune、ITV-1、Contre Vir、Ad5-ENVA-48、DCVax-001 (CDX-2401)、Vacc-4x、Vacc-C5、VAC-3S、多分支DNA重組腺病毒-5 (rAd5)、rAd5 gag-pol env A/B/C疫苗、Pennvax-G、Pennvax-GP、Pennvax-G/MVA-CMDR、HIV-TriMix-mRNA疫苗、HIV-LAMP-vax、Ad35、Ad35-GRIN、NAcGM3/VSSP ISA-51、聚-ICLC佐劑疫苗、TatImmune、GTU-multiHIV (FIT-06)、ChAdV63.HIVconsv、gp140[delta]V2.TV1+MF-59、rVSVIN HIV-1 gag疫苗、SeV-EnvF、SeV-Gag疫苗、AT-20、DNK-4、ad35-Grin/ENV、TBC-M4、HIVAX、HIVAX-2、基於N123-VRC-34.01誘導表位之HIV疫苗、NYVAC-HIV-PT1、NYVAC-HIV-PT4、DNA-HIV-PT123、rAAV1-

PG9DP、GOVX-B11、GOVX-B21、GOVX-C55、TVI-HIV-1、Ad-4 (Ad4-env Clade C+Ad4-mGag)、Paxvax、EN41-UGR7C、EN41-FPA2、ENOB-HV-11、ENOB-HV-12、exoVACC、PreVaxTat、AE-H、MYM-V101、CombiHIVvac、ADVAX、MYM-V201、MVA-CMDR、MagaVax、DNA-Ad5 gag/pol/nef/nev (HVTN505)、MVATG-17401、ETV-01、CDX-1401、表現SCaVII之DNA及Sev載體疫苗、rcAD26.MOS1.HIV-Env、Ad26.Mod.HIV疫苗、Ad26.Mod.HIV + MVA鑲嵌疫苗+ gp140、AGS-004、AVX-101、AVX-201、PEP-6409、SAV-001、ThV-01、TL-01、TUTI-16、VGX-3300、VIR-1111、IHV-001、及病毒樣粒子疫苗，諸如偽病毒粒子疫苗、CombiVICHvac、LFn-p24 B/C融合疫苗、基於GTU之DNA疫苗、HIV gag/pol/nef/env DNA疫苗、抗TAT HIV疫苗、接合物多肽疫苗、樹突細胞疫苗（諸如DermaVir）、基於gag之DNA疫苗、GI-2010、gp41 HIV-1疫苗、HIV疫苗（PIKA佐劑）、I i-key/MHC第II型表位雜交肽疫苗、ITV-2、ITV-3、ITV-4、LIPO-5、多分支Env疫苗、MVA疫苗、Pennvax-GP、pp71缺乏HCMV載體HIV gag疫苗、重組肽疫苗（HIV感染）、NCI、rgp160 HIV疫苗、RNActive HIV疫苗、SCB-703、Tat Oyi疫苗、TBC-M4、治療性HIV疫苗、UBI HIV gp120、Vacc-4x +羅米地辛、變體gp120多肽疫苗、rAd5 gag-pol env A/B/C疫苗、DNA.HTI及MVA.HTI、MVA.tHIVconsv3、MVA.tHIVconsv4、VRC-HIVDNA016-00-VP + VRC-HIVADV014-00-VP、INO-6145、JNJ-9220、gp145 C.6980；基於eOD-GT8 60mer之疫苗、PD-201401、env (A, B, C, A/E)/gag (C) DNA疫苗、gp120 (A,B,C,A/E)蛋白疫苗、PDPHV-201401、Ad4-EnvCN54、EnvSeq-1 Envs HIV-1疫苗（GLA-SE佐劑）、HIV p24gag初免-加強質體DNA疫苗、刺激HIV-1 iglb12中和VRC-01抗體之抗CD4疫

苗、基於沙狀病毒載體之疫苗(Vaxwave, TheraT)、MVA-BN HIV-1疫苗方案、基於mRNA之疫苗、VPI-211、HIV ANTI-CD40.ENV GP140、HIV ANTI-CD40.HIV5PEP、多聚體HIV gp120疫苗TBL-1203HI、CH505 TF chTrimer、CD40.HIVRI.Env疫苗、VRC-HIVRGP096-00-VP、Drep-HIV-PT-1、BG505 MD39.3 mRNA、BG505 MD39.3 gp151 CD4KO mRNA、BG505 MD39.3 gp151 mRNA、mRNA-1644、mRNA-1547、mRNA-1574、及描述於WO2021011544及WO2022155258中之抗HIV疫苗。

生育控制（避孕）組合療法

【0192】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與生育控制或避孕方案組合。用於生育控制（避孕）之治療劑包括乙酸環丙孕酮、去氧孕烯(desogestrel)、地諾孕素(dienogest)、屈螺酮(drospirenone)、戊酸雌二醇(estradiol valerate)、乙炔基雌二醇(ethinyl Estradiol)、炔諾醇(ethynodiol)、依託孕烯(etonogestrel)、左甲基四氫葉酸鹽(levomefolate)、左炔諾孕酮(levonorgestrel)、利奈孕醇(lynestrenol)、乙酸甲羥助孕酮(medroxyprogesterone acetate)、美雌醇(mestranol)、美服培酮(mifepristone)、米索前列醇(misoprostol)、乙酸諾美孕酮(nomegestrol acetate)、甲基孕酮(norelgestromin)、炔諾酮(norethindrone)、異炔諾酮(noretynodrel)、諾孕酯(norgestimate)、奧美昔芬(ormeloxifene)、乙酸烯諾孕酮(segestersone acetate)、乙酸烏利司他(ulipristal acetate)、及其任何組合。

基因療法及細胞療法

【0193】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與基因或細胞療法方案組合。基因療法及細胞療法包括但不限於靜默基因之基因修飾；直接殺滅經感染之細胞之基因方法；輸注免疫細胞，其經設計以置換患者自身的大部分免疫系統，以增強對受感染細胞的免疫反應、或活化患者自身的免疫系統以殺滅受感染細胞、或找到並殺滅受感染細胞；修飾細胞活性之基因方法以進一步改變針對感染之內源性免疫反應性。細胞療法之實例包括LB-1903、ENOB-HV-01、ENOB-HV-21、ENOB-HV-31、GOVX-B01、過度表現ALDH1的HSPC（LV-800，HIV感染）、AGT103-T、及基於SupT1細胞之療法。樹突細胞療法之實例包括AGS-004。CCR5基因編輯劑包括但不限於SB-728T及SB-728-HSPC。CCR5基因抑制劑包括Cal-1及慢病毒載體CCR5 shRNA/TRIM5α/TAR誘餌轉導自體CD34陽性造血祖細胞（HIV感染/HIV相關淋巴瘤）。在一些實施例中，將C34-CCR5/C34-CXCR4表現性之CD4陽性T細胞與一或多種多特異性抗原結合分子共投予。在一些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與AGT-103轉導自體T細胞療法或AAV-eCD4-Ig基因療法共投予。

基因編輯器

【0194】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與基因編輯器（例如HIV靶向基因編輯器）組合。在各種實施例中，基因體編輯系統可選自由下列所組成之群組：CRISPR/Cas9複合物、鋅指核酸酶複合物、TALEN複合物、歸巢內核酸酶複合物、及大範圍核

酸酶(meganuclease)複合物。說明性HIV靶向CRISPR/Cas9系統包括但不限於EBT-101及XVIR-TAT。

CAR-T細胞療法

【0195】 在一些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體可與免疫效應細胞群共投予，該等免疫效應細胞經工程改造以表現嵌合抗原受體(CAR)，其中CAR包含HIV抗原結合域。HIV抗原包括HIV套膜蛋白或其部分、gp120或其部分、gp120上之CD4結合部位、gp120上之CD4誘導結合部位、gp120上之N聚醣、gp120之V2、gp41上之近膜區。免疫效應細胞係T細胞或NK細胞。在一些實施例中，T細胞係CD4+ T細胞、CD8+ T細胞、或其組合。細胞可為自體或同種異體。HIV CAR-T之實例包括A-1801、A-1902、可轉換CAR-T、VC-CAR-T、CMV-N6-CART、抗HIV duoCAR-T、抗Env duoCAR T、抗CD4 CART細胞療法、CD4 CAR+C34-CXCR4+CCR5 ZFN T細胞、雙重抗CD4 CART-T細胞療法（CD4 CAR+C34-CXCR4 T細胞）、抗CD4 MicAbody抗體+抗MicAbody CAR T細胞療法（iNKG2D CAR，HIV感染）、GP-120 CAR-T療法、經基因工程改造以表現CD4 CAR及C46肽之自體造血幹細胞。

TCR-T細胞療法

【0196】 在某些實施例中，本文所述之抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體係與TCR-T細胞群組合。TCR-T細胞經工程改造以靶向存在於病毒感染細胞之表面上之HIV衍生的肽，例如IMC-M113V，即具有TCR

結合域及第二抗原結合域之TCR雙特異性，該TCR結合域靶向衍生自HIV感染細胞之表面上的HLA*A02呈遞之Gag蛋白之肽，該第二抗原結合域靶向CD3。

6. 套組

【0197】 進一步提供了套組，該等套組包含一或多個單一劑量的結合HIV gp120 V3聚醣之第一抗體及結合HIV gp120 CD4bs之第二抗體，其中第一抗體及第二抗體具有延長血清半衰期的胺基酸取代，且第一抗體及第二抗體經調配用於每年兩次（例如，每6個月(Q6M)、每26週(Q26W)、每25週(Q25W)、或每24週(Q24W)）投予。

【0198】 在某些實施例中，套組包含如本文所述之抗HIV gp120 V3聚醣結合抗體及抗HIV gp120 CD4bs結合抗體係單獨地或以混合物的形式以用於同時投予至患者之單一劑型組合，例如以用於靜脈內、肌內或皮下投予之液體或懸浮液劑型組合。

【0199】 在一些實施例中，結合HIV gp120 V3聚醣之第一抗體及結合HIV gp120 CD4bs之第二抗體之單一劑量係獨立地在約500 mg至約3000 mg，例如約550 mg至約2900 mg、例如約600 mg至約2800 mg、例如約650 mg至約2700 mg、例如約700 mg至約2600 mg、例如約850 mg至約2550 mg範圍內。在一些實施例中，抗HIV gp120 V3聚醣結合抗體（例如，10-1074-LS）之單一劑量係850 mg。在一些實施例中，抗HIV gp120 V3聚醣結合抗體（例如，10-1074-LS）之單一劑量係2550 mg。在一些實施例中，抗HIV gp120 CD4bs結合抗體（例如，3BNC117-LS）之單一劑量係2550 mg。在一些實施例中，抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體（例如，3BNC117-LS）之單一劑

量均係1700 mg。在一些實施例中，抗HIV gp120 V3聚醣及抗HIV gp120 CD4bs結合抗體（例如，3BNC117-LS）之單一劑量均係2550 mg。在一些實施例中，抗HIV gp120 V3聚醣結合抗體（例如，10-1074-LS）之單一劑量係850 mg，且抗HIV gp120 CD4bs結合抗體（例如，3BNC117-LS）之單一劑量係2550 mg。在一些實施例中，抗HIV gp120 V3聚醣結合抗體（例如，10-1074-LS）之單一劑量係850 mg，且抗HIV gp120 CD4bs結合抗體（例如，3BNC117-LS）之單一劑量係1700 mg。在一些實施例中，抗HIV gp120 V3聚醣結合抗體（例如，10-1074-LS）之單一劑量係850 mg，且抗HIV gp120 CD4bs結合抗體（例如，3BNC117-LS）之單一劑量係1275 mg。

【0200】 在一些實施例中，套組進一步包含一或多個單一劑量的長效抗HIV藥物。在一些實施例中，一或多種長效HIV藥物係選自長效殼體抑制劑、長效整合酶股轉移抑制劑(INSTI)、長效非核苷反轉錄酶抑制劑(NNRTI)、長效核苷反轉錄酶抑制劑(NRTI)、及長效蛋白酶抑制劑(PI)。在一些實施例中，長效殼體抑制劑包含利那卡帕韋。在一些實施例中，利那卡帕韋之單一劑量係在300 mg至1000 mg範圍內，例如300 mg、600 mg、900 mg、927 mg。如適當時，單一劑量的利那卡帕韋可經調配用於口服、皮下或靜脈內投予。在一些實施例中，長效INSTI係選自比替拉韋、雷特格韋、埃替格韋、多替拉韋、及卡博特韋。在一些實施例中，長效NNRTI係選自利匹韋林、艾法韋林、多拉韋林、及GS-5894。在一些實施例中，長效NRTI係選自伊司他韋及其前藥、替諾福韋艾拉酚胺(tenofovir alafenamide, TAF)及替諾福韋之前藥、羅法福韋艾他拉酚胺、及GS-1614。在一些實施例中，長效蛋白酶抑制劑係選自阿扎那韋、利托那韋、地瑞那韋、GS-1156及GS-1156之前藥、及其組合。

【0201】 在一個實施例中，套組包含一或多種醫藥包裝或一或多個容器（例如，小瓶、安瓿、預載注射器），其含有本文所述之醫藥組成物之成分中之一或多者，諸如本文所述之抗HIV gp120 V3聚醣結合抗體及抗HIV gp120 CD4bs結合抗體。在一些情況下，套組含有本文所述之醫藥組成物。在一個實施例中，提供了套組，其包含本文所述之抗HIV gp120 V3聚醣結合抗體及抗HIV gp120 CD4bs結合抗體或其醫藥組成物與一或多種（例如，一、二、三、四、一或二、一至三、或一至四種）額外治療劑（諸如上文揭示之彼等治療劑）之組合。

【0202】 可選地與此類（多個）容器相關聯的可為主管機關規範藥品或生物藥品製造、使用、或販售之指定形式標示，該標示反映主管機關核准製造、使用、或販售以供人類使用。

實例

【0203】 提供下列實例說明，但不限制主張之發明。

實例1

Ph1b研究：長效廣泛中和抗體

與利那卡帕韋之組合之26W的主要結果

【0204】 GS-US-536-5816（ClinicalTrials.gov上之NCT04811040）為隨機分組、盲法、概念驗證(POC)第1b期研究，以在患有HIV-1感染的成人，通過口服ART獲得病毒學抑制（HIV-1 RNA < 50個拷貝數/mL），評估下列之長

效方案之單一劑量之安全性及功效：利那卡帕韋、特羅帕單抗(GS 5423; 3BNC117-LS; TAB)及津利維單抗(GS 2872; 10-1074-LS; ZAB)。

給藥

【0205】 參與者是通過ART治療後經HIV病毒學抑制≥2年（HIV-1 RNA < 50個拷貝/mL）的成人，藉由HIV前病毒DNA表型對兩種bNAb敏感(PhenoSense mAb IC90 ≤2ug/mL, Monogram Biosciences)，研究開始時CD4最低值≥350，且CD4計數≥500。基於GS 2872之劑量（IV投予10 mg/kg或30 mg/kg），將提供書面同意且符合所有資格標準之參與者以1:1之比隨機分組至2個治療組中之一者。所有參與者在第1天及第2天接受GS-5423 (30 mg/kg IV)及口服利那卡帕韋600 mg，且在第1天皮下接受注射利那卡帕韋927 mg。每4週對參與者進行一次血漿HIV-1 RNA臨床監測，直至第26周達到主要終點。主要終點為安全性；次要終點包括FDA快照分析之病毒學結果。

【0206】 在3BNC117-LS (NCT03254277)之首次人類研究中，39名接受在3至30 mg/kg (IV)範圍內、或150或300 mg (SC)劑量之單一劑量的3BNC117-LS；5名參與者接受安慰劑。43名入組之參與者中有5名在給藥後4週內報告了5例設定記錄(solicited)不良事件(adverse event, AE)，均為1級嚴重程度：投予部位之壓痛(2%)、頭痛(2%)、不適/疲勞(2%)、及噁心(4%)。此外，43名入組之參與者中有28名報告了48例非設定記錄AE，且報告的事件中之29例(58%)發生在試驗藥品(investigational product, IP)投予後4週內。在報告的事件中，9例(17%)係2級嚴重程度，且2例(4%)係3級嚴重程度：蛋白尿及蜂窩性組織炎，需要IV抗生素），1例係4級嚴重程度（低血鉀症）。一名參與者因右頸動脈血栓

繼發的短暫性腦缺血發作入院。進一步評估揭露可能導致血栓事件之血管解剖異常。此嚴重AE被視為與IP無關。最常報告的AE係與上呼吸道感染(14%)、噁心(4%)、及暈眩(4%)相關的彼等AE。

【0207】 在10-1074-LS (NCT03554408)之首次人類研究中，入組之77名參與者：27名參與者接受在3至30 mg/kg (IV, n=15)範圍內、或140或280 mg (SC, n=12)劑量之單一劑量的10-1074-LS；12名額外的參與者接受10-1074-LS與3BNC117-LS之組合之單一SC注射，且18名接受3次抗體混合物之重複的SC注射（每12週）；10名參與者接受10-1074-LS及3BNC117-LS之單一靜脈輸注，各抗體之劑量係30 mg/kg。剩餘10名參與者接受安慰劑。截至2020年7月，77名入組之參與者中有15名報告了20例設定記錄AE，均為1級嚴重程度：投予部位之紅斑/皮膚變色(8%)、疼痛(4%)、及硬結(2%)、頭痛(4%)、發熱(4%)、不適/疲勞(3%)、及肌痛(1%)。此外，46名參與者報告了86例非設定記錄AE。在86例AE中，29例(33.7%)發生在IP投予後4週內。在報告的非設定記錄AE中，10例(11.6%)係2級嚴重程度，且8例報告的事件(9.3%)係3級嚴重程度：腎結石(1%)、血壓升高(4%)、血紅蛋白降低(1%)、蛋白尿(1%)、及左側無力增加(1%)。在IP投予當天經歷暫時性3級血壓升高之3名參與者具有高血壓病史。最常見的AE係與上呼吸道感染(25%)、局部肌肉骨骼疼痛(8%)、及胃腸炎症狀(8%)相關的彼等AE。

NCT04811040 Ph1b研究概述

【0208】 參與者在第1天接受研究藥物之前1天中止其背景口服ART方案。在124名經過篩選的參與者中，55名對兩種bNAb均敏感，21名經隨機分

組，20名接受了完整的研究方案。中位數年齡係44歲(IQR 34, 51)；14%係女性；14%黑人，14%亞洲人，33%西班牙裔/拉丁裔；中位數CD4計數係909 (IQR 687, 1270)。

【0209】 在第26週，所有參與者恢復其背景口服ART基線方案（或由研究者選擇之相容方案），且在第38週及第52週返回診所進行訪視。

【0210】 大約20名參與者係在主要群組中。患有HIV-1之成人，在篩選前無病毒學失敗(virologic failure, VF)史或抗反轉錄病毒藥物抗性、CD4最低值≥ 350個細胞/μL，接受第一線ART至少2年，且證明病毒學抑制（HIV-1 RNA < 50個拷貝/mL）至少18個月，願意為試驗策略修改其ART方案。研究之示意圖係提供於圖1中。

【0211】 21名參與者經入組至主要群組且隨機分組，20名參與者接受完整研究方案（各治療組10名），一名參與者接受口服利那卡帕韋且在完成給藥程序之前撤回同意。參與者之中位數年齡係44歲（範圍25至61），18名(86%)出生時係男性，均係HIV-1 RNA <50個拷貝/mL且CD4計數>500個細胞/μL。表1總結了入組之參與者人口統計及基線特徵。

【0212】 特羅帕維單抗(TAB)、津利維單抗(ZAB)、及利那卡帕韋(LEN)的治療濃度維持至第26週。這些結果描繪於圖1B。

表1–入組之參與者人口統計及基線特徵

		LEN + TAB + ZAB 10 mg/kg (N = 11)	**LEN + TAB + ZAB 30 mg/kg (N = 10)**	**總計 N = 21**
年齡，中位數（範圍）		46（31 至 61）	37（25 至 59）	44（25 至 61）

出生時性別，n	男性	11	7	18
	女性	0	3	3
種族，n	亞洲人	2	1	3
	黑人	1	2	3
	白人	7	5	12
	其他	1	2	3
西班牙裔或拉丁裔，n		4	3	7
重量(kg)，中位數（範圍）		90.2（58.9 至 150.0）	92.9（60.2 至 143.0）	90.2（58.9 至 150.0）
身體質量指數(kg/m^2)，中位數（範圍）		30.2（21.6 至 42.9）	30.2（21.6 至 54.1）	30.2（21.6 至 54.1）
CD4 細胞計數（每 mL），中位數（範圍）		778（547 至 1391）	1024（667 至 1644）	909（547 至 1644）
基線 ART 之持續時間（年），中位數（範圍）		3.6（2.4 至 4.8）	2.6（2.0 至 5.5）	2.6（2.0 至 5.5）
自 HIV 診斷之時間（年），中位數（範圍）		12.4（6.4 至 26.3）	5.3（2.6 至 22.4）	8.2（2.6 至 26.3）

【0213】 根據FDA快照演算法在第26週之主要終點評估功效。第1組中之一名參與者在第16週確認HIV RNA ≥50個拷貝/mL（155個拷貝/mL，確認之524個拷貝/mL）且用重新起始基線ART重新抑制；第2組中之一名參與者在第12週撤回同意（具有HIV-1 RNA < 50個拷貝/mL）。18/20 (90%)參與者在第26週時具有HIV-1 RNA < 50個拷貝/mL。主要功效結果總結於表2及圖1C中。

表2-如美國FDA定義之快照演算法在第26週時所判定之功效

	LEN + GS-5423 + GS-2872 10 mg/kg	**LEN + GS-5423 + GS-2872 30 mg/kg**
	(N=10)	(N=10)
HIV-1 RNA ≥50 個拷貝/mL，N (% [95% CI])	1^ (10%, [0.3%, 44.5%])	0

HIV-1 RNA <50 個拷貝/mL，N (% [95% CI])	9 (90%, [55.5%, 99.7%])	9 (90%, [55.5%, 99.7%])
由於其他原因[$]停止研究藥物及最後可用的HIV-1 RNA <50 個拷貝/mL	0	1 (10%)[*]

^抗性測試待定
*第12週後退出研究
$除了AE/死亡或缺乏功效以外的原因

【0214】 無治療出現的嚴重不良事件，無導致研究藥物或研究之中止的治療出現的不良事件，且無死亡。最常見的治療中出現的不良事件是與皮下注射利那卡帕韋(LEN)相關的注射部位反應（17/20名患者或85%）。兩名參與者具有3級AE：一名患有注射部位蜂窩性織炎，一名患有LEN注射部位的注射部位紅斑。LEN + GS-5423（特羅帕單抗）+ GS-2872（津利維單抗）的組合在選定的經病毒學抑制的HIV感染者中具有良好的耐受性和高效力持續6個月。此等結果與LEN + GS-5423（特羅帕單抗）+ GS-2872（津利維單抗）組合通過每年兩次給藥提供長效治療HIV的結論一致。

實例2

模型化以判定允許每年兩次投予之平穩給藥

【0215】 在此實例中，吾人執行群體PK(popPK)模型化及模擬以預測GS-5423（特羅帕單抗）及GS-2872（津利維單抗）在基於體重的給藥及不同劑量的平穩給藥下之PK概況，且將其等與目標有效水平進行比較，以判定患有HIV之成人每6個月給藥之GS-5423及GS-2872之最佳劑量範圍。

方法

【0216】 PK資料來自GS-5423（特羅帕單抗；3BNC117-LS；TAB）及GS-2872（津利維單抗；10-1074-LS；ZAB）獲自四項針對病毒血症或病毒抑制的PWH的臨床研究（TAB：n=34；ZAB：n=36）單獨接受單一靜脈內注射TAB (30 mg/kg)及/或ZAB（10或30 mg/kg）或與LEN組合或不組合的患者，研究包括YCO-0946 (NCT03254277)及YCO-0971 (NCT03554408)。使用經驗證的Mesa Scale Discovery-電化學發光免疫檢定測量TAB及ZAB血清濃度。開發二隔室群體PK模型以描述在HIV-及HIV+參與者中IV及SC投予之後GS-5423及GS-2872之PK資料。參見oel S. Owen, Jill Fiedler-Kelly,「Introduction to Population Pharmacokinetic / Pharmacodynamic Analysis with Nonlinear Mixed Effects Models」, Wiley; 1st edition, 2014 (ISBN: 9780470582299)。使用非線性混合效應模型化開發TAB及ZAB之PopPK模型。進行共變量分析以識別對GS-5423及GS-2872的PK參數的顯著共變量，包括體重、人口統計學影響、基線特徵、組合方案、及疾病狀態。模擬群體PK模型以預測GS-5423及GS-2872在每6個月IV投予30或10 mg/kg的體重標準化劑量或等效平穩劑量之後的PK概況。進行模型模擬以預測與基於重量之給藥之後TAB及ZAB的濃度。假定體重之分布與先前對接受抗反轉錄病毒療法之病毒學上受到抑制的患有HIV之成人（平均體重係85 kg）之研究一致。

結果

【0217】 基於四項臨床研究（包括YCO-0946及YCO-0971）之資料之PK模型化之模擬顯示，預期固定劑量為2550 mg或850 mg的GS-5423或GS-2872會產生分別與30 mg/kg或10 mg/kg的基於體重之劑量類似的暴露，其中PK可變性

無明顯增加（圖3A至圖3D）。因此，鑒於在正在進行的研究GS-US-536-5816及先前對HIV+參與者之研究中，高達30 mg/kg之GS-5423及GS-2872單獨或組合係良好耐受的，預期在具有HIV感染之成人中，對於GS-5423及GS-2872二者，高達2550 mg之劑量IV均係安全的。

【0218】 兩隔室PopPK模型充分描述PWH中的GS-5423 (TAB)及GS-2872 (ZAB) PK資料。體重增加與TAB及ZAB兩者的分布體積及清除率增加相關。與基線時受到抑制的患者相比，病毒血症患者的TAB及ZAB清除率顯著增加。模型模擬表明，根據最近成人PWH第3期HIV研究中的體重分布，2550 mg的固定劑量將導致TAB及ZAB與30 mg/kg相似的暴露，平均體重約為85公斤。

【0219】 先前對接受分析治療中斷之HIV+參與者中之各抗體之非LS形式之研究(Mendoza, *et al.*, *Nature*.(2018) 561(7724):479-484及Gaebler, *et al.*, *Nature* (2022) 606(7913):368-374)表明，當兩種抗體之血清濃度均高於10 μg/mL時，通常可維持病毒學抑制。基於PK模擬，預期1700 mg GS-5423或850 mg GS-2872在給藥後6個月（26週）內，對象中之99%至100%之濃度維持在高於10 μg/mL（圖4A至圖4B，表3）。因此，預期每6個月IV給予1700至2550 mg GS-5423及850至2550 mg GS-2872之劑量範圍對於兩種bNAb係有效且安全的劑量範圍。

表3

每6個月IV投予GS-5423及GS-2872後，在第26週時高於10 μg/mL之患者之預測百分比

	GS-5423		GS-2872	
	2550 mg	1700 mg	2550 mg	850 mg
在第 26 週時高於 10 μg/mL 之%患者	100%	99%	100%	100%

實例3

抗HIV抗體之治療濃度評估

3BNC117/特羅帕單抗及10-1074/津利維單抗通過PK-PD模型化及HIV治癒研究中之清除持續時間之預測

【0220】 3BNC117及10-1074已被證明可引起患有HIV之人的病毒血症迅速下降，並在分析治療中斷(ATI)期間延遲經抑制的患有HIV之人的病毒反彈時間(Caskey, *et al*. Nature. 2015;522:487-491; Caskey, *et al*. Nat Med. 2017;23:185-191; Scheid, *et al*. Nature. 2016;535:556-560; Mendoza, *et al*. Nature. 2018;561:479-484; Bar-On, *et al*. Nat Med. 2018;24:1701-1707; Gaebler, *et al*. Nature. 2022;606:368-374)。3BNC117/TAB及10-1074/ZAB的組合與免疫調節劑一起，正在研究其消除HIV貯庫並引起患有HIV之人長期緩解的潛力。然而，由於其強效病毒中和效應，在ATI之前的清除持續時間不足，可能會混淆HIV治愈研究中病毒學反彈時間的療效評估。本研究的目的是通過PK-PD病毒動力學模型來表徵這些bNAb的藥物動力學(PK)及藥物動力學-藥效動力學(PK-PD)關係，並預測HIV治愈研究中TAB/ZAB所需的清除時間長度，以便在ATI期間評估治療後病毒控制。

方法

【0221】 群體PK及PK-PD模型是使用非線性混合效應模型化方法開發的，該方法基於血清bNAb濃度及/或病毒動態資料，這些資料來自患有HIV之

人的6項功效研究，及3BNC117/TAB (GS-5423)及/或10-1074/ZAB (GS-2872)的3項PK研究（表4）。

表4 -包括在PK-PD模型化中之研究

研究	化合物（劑量）	參與者	功效評估	用於 PK 之 N	用於 PD 之 N
NCT02018510	3BNC117 (1, 3, 10, 30 mg/kg IV)	HIV 陰性		22	-
		抑制 PWH		16	-
		病毒血症 PWH	病毒抑制	17	17
NCT02511990	10-1074 (3, 10, 30 mg/kg IV)	HIV 陰性		14	-
		抑制 PWH		3	-
		病毒血症 PWH	病毒抑制	15	15
NCT02446847	3BNC117 (30 mg/kg IV)	抑制 PWH	ATI 期間病毒反彈	15	14
NCT02824536	3BNC117 + 10-1074 (3+3, 10+10 mg/kg IV)	HIV 陰性	-	18	-
NCT02825797	3BNC117 + 10-1074 (30+30 mg/kg IV)	病毒血症 PWH	病毒抑制	7	-
		抑制 PWH	ATI 期間病毒反彈	21	13
NCT03526848	3BNC117 + 10-1074 (30+30 mg/kg IV)	抑制 PWH	ATI 期間病毒反彈	26	22
NCT03254277	TAB (30 mg/kg IV, 150 或 300 mg SC)	HIV 陰性	-	15	-
		抑制 PWH	-	3	-
NCT03554408	單獨 ZAB（3, 10, 30 mg/kg IV, 140 或 280 SC） TAB + ZAB (30+30 mg/kg IV, 150-300 + 60-280 mg SC)	HIV 陰性	-	57	-
		抑制 PWH	-	10	-
NCT04250636	TAB + ZAB (30+30 mg/kg IV)	病毒血症 PWH	病毒抑制	6	6

【0222】 bNAb濃度藉由ELISA檢定進行測量，NCT03526848研究除外(Gaebler, et al. Nature. 2022;606:368-374)。對於此研究，將藉由TZM-bl檢定測

量的濃度(Sarzotti-Kelsoe, et al. J Immunol Methods. 2014;409:131-146)使用基於來自研究NCT02825797之資料校準的對數線性相關模型轉換至ELISA資料(Mendoza, et al. Nature. 2018;561:479-484; Bar-On Y, et al. Nat Med. 2018;24:1701-1707)，並使用兩種方法量測PK。藉由2隔室線性PK模型來模型化bNAb之PK資料。使用逐步向前添加(α = 0.01)及向後消除(α = 0.001)方法測試共變量（人口統計學、疾病狀態、組合治療）。PK-PD模型使用邏輯增長函數描述病毒複製，使用一級動力學描述病毒消除，並使用非線性飽和(Emax)模型描述bNAb濃度及病毒消除率之間的關係。對每種bNAb敏感或耐藥的不同病毒群體進行模型化，以捕獲經治療之參與者的耐藥選擇機制（圖5）。依序擬合PK及PK-PD模型。使用標準診斷圖及視覺預測檢查進行模型評估。執行模擬以預測在TAB/ZAB給藥後不同長度的清除週期之後的ATI期間的病毒反彈的PK及動力學。使用Phoenix®NLME進行模型化。使用R軟體進行模擬及繪製。

結果

【0223】 *PK*模型化藉由線性2隔室PK模型描述3BNC117、10-1074、TAB、及ZAB之PK資料（圖6）。對於3BNC117及10-1074，評估半衰期在無HIV之人中最長，其次是經抑制的患有HIV之人，而患有HIV病毒血症之人的半衰期最短（圖7）。對於TAB及ZAB，評估半衰期比3BNC117及10-1074長，在無HIV之人及經抑制的患有HIV之人之間相似（TAB及ZAB分別為62天及79天），而在患有HIV之病毒血症之人中則更短（TAB及ZAB分別為46天及55天）（圖7）。

【0224】 *PK-PD*模型化PK-PD模型充分描述患有HIV病毒血症之人單獨使用不同劑量的3BNC117、10-1074，及組合使用3BNC117、10-1074的bNAb治療，以及與TAB及ZAB組合治療後的病毒抑制動力學（圖8）。該模型描述單獨使用3BNC117或與10-1074組合使用的bNAb治療後ATI期間病毒反彈的時間（圖9）。3BNC117/TAB及10-1074/ZAB的50%最大藥效(EC_{50})對應的評估平均血清濃度分別為25.4及32.2 μg/mL，對應的EC_{20}分別為6.35及8.06 μg/mL（表5）。

表5-關鍵PK-PD模型參數評估值

參數	均值	95% CI	%CV
$EC_{50,\ 3BNC117\ 或\ TAB}$, μg/mL[a]	25.4	(19.6-32.9)	162
$EC_{50,\ 10\text{-}1074\ 或\ ZAB}$, μg/mL[b]	32.2	(10.1-102.8	79.5
病毒複製速率常數，kg，天$^{-1}$	0.441	(0.414-0.468)	24.5
病毒消除速率常數，$k_{del,\ 3BNC117\ 或\ TAB}$，天$^{-1}$	0.507	(0.476-0.538)	-
病毒消除速率常數、$k_{\ del,\ 10\text{-}1074\ 或\ ZAB}$，天$^{-1}$	0.799	(0.609-0.990)	-

CI，信賴區間；CV，變異係數；EC_{20}，達到最大藥效20%的濃度；EC_{50}，達到最大藥效50%的濃度；PD，藥效動力學；PK，藥物動力學；TAB，特羅帕單抗；ZAB，津利維單抗。[a]對應於平均值(95%CI) EC_{20}值為6.35 (4.90-8.22)μg/mL。[b]對應於平均(95%CI) EC20值為8.06 (2.53-25.7) μg/mL。

【0225】 *PK-PD*刺激。在單一劑量TAB及ZAB靜脈內投予後≥ 48週的清除期後PK-PD模擬預測，這些bNAb的病毒中和作用對ATI期間病毒反彈時間的影響極小（圖10）。在單一劑量30 mg/kg TAB及10 mg/kg ZAB靜脈內投予後，預測兩種bNAb濃度將在相似的時間內降至低於其體內EC50，並隨後保持相對於EC50相似的水平，從而最大限度地降低任一bNAb功能性單一療法產生之耐藥性的風險。在第48週時，預測超過90%的參與者的兩種bNAb濃度均低於EC50（圖11）。

實例4

具有HIV-1感染之經病毒學抑制的成人中之特羅帕單抗(GS-5423)及津利維單抗(GS-2872)與殼體抑制劑利那卡帕韋(LEN)組合之第2期研究

【0226】 研究設計：GS-US-539-5939（ClinicalTrials.gov上之NCT05729568）為第2期、隨機分組、開放標籤、主動控制、多中心研究，用於評估殼體抑制劑利那卡帕韋(LEN)、特羅帕單抗(GS-5423)、及津利維單抗(GS-2872)之長效組合方案之安全性及功效。該研究將包括大約125名符合所有資格標準之根據方案定義的標準對兩種bNAb均具有敏感性之參與者，且將以2:2:1之比例不分層隨機分組為治療組1、2、及3。臨床試驗研究示意圖描繪於圖12中。

【0227】 參與者將在第1天接受最後一劑之基線口服抗反轉錄病毒療法(ART)，隨機分組為治療組1及2之參與者將在第1天投予完整研究方案之後停止其等基線ART方案（皮下可注射LEN，口服LEN 600 mg，及靜脈內(IV)輸注GS-5423及GS-2872），且將在第2天自行投予口服LEN 600 mg。治療組3中之參與者將依規定繼續其等基線口服ARV方案直至第52週。在第26週時，隨機分組為治療組1及2之參與者將接受研究藥物（可注射LEN及IV輸注GS-5423及GS-2872）。所有治療組中之所有參與者將在第4、12、24、26、38、50、及52週返回研究中心進行訪視。

【0228】 在第52週時，將治療組1及2中之參與者接受LEN、GS 5423、GS-2872之研究方案且完成研究追蹤直至第52週，且血漿水平為HIV RNA小於(<) 50個拷貝/mL之參與者將入組至研究擴展階段。選擇不參與或無資格參與擴展階段之參與者將恢復其等基線ART方案（或由研究者選擇之適當方案），

且在第52週後的30、90、及180天時返回進行研究追蹤。隨機分組為治療組3之參與者，如果在整個研究之隨機分組階段完成研究追蹤直至第52週，且血漿水平為HIV-1 RNA < 50個拷貝/mL，則將每26週接受LEN、GS-5423、及GS-2872之研究方案。GS-5423及GS-2872之劑量將在初步分析時判定。治療組3中在初步分析之前達至第52週之參與者將接受治療組2指定的劑量之研究方案，直至完成初步分析及劑量選擇（除非治療組2回應於資料監測委員會(data monitoring committee, DMC)進行修改）。治療組3中在第52週之後未接受研究方案之參與者將返回進行30天追蹤。

【0229】 將召開獨立DMC以在兩次規劃中期分析下審查安全性及功效資料：大約前50%之入組的參與者已完成其等第12及26週訪視或提前停止研究藥物。此外，若任何群組之任何LEN + bNAb治療組中之四名或更多名參與者在所有參與者達至第26週之前經歷病毒學反彈(virologic rebound, VR)，則可召開臨時(*ad hoc*)DMC會議以評估資料。

【0230】 **病毒學失敗(Virologic Failure, VF)**：如下文所定義，經歷病毒學反彈(VR)之參與者將被視為處於病毒學失敗之情況，且可接受抗性分析。

【0231】 **病毒學反彈**：符合下列標準之參與者將視為具有VR：

- 在第 1 天之後的任何訪視，HIV-1 RNA ≥ 50 個拷貝/mL 之反彈，隨後在下列排程或未排程訪視下確認，或
- 在研究藥物中止時 HIV-1 RNA ≥ 50 個拷貝/mL 之任何參與者

【0232】 若在所有參與者達至第26週之前對功效進行上述排程或ad-hoc期中DMC分析（基於第12、26週之病毒學失敗(VF)，亦即血漿水平為HIV-1 RNA大於或等於(≥) 50個拷貝/mL、或病毒學反彈越過無效邊界（即治療差異之

95%信賴區間(confidence interval, CI)之下限（治療組1或組2 –保持基線方案(Baseline Regimen, SBR)），比例為VF > 0），則DMC可建議放棄較低劑量組。中止給藥組之決策將由發起者進行。

【0233】 **目標群體：**患有HIV-1之成人，在篩選前至少12個月接受ART，且表現出病毒學抑制（HIV-1 RNA < 50個拷貝/mL），且符合對bNAb之敏感性之方案標準。

【0234】 **介入持續時間：**隨機分組階段長達52週，且擴展階段長達104週。

表6

測試產品、劑量、及投予模式

治療組	藥物		第 1 天	第 2 天	第 26 週
1	負荷	LEN	600 mg PO*	600 mg PO	
	維持	LEN	927 mg SC		927 mg SC
		GS-5423	2550 mg IV		2500 mg IV
		GS-2872	2550 mg IV		2550 mg IV
2	負荷	LEN	600 mg PO	600 mg PO	
	維持	LEN	927 mg SC		927 mg SC
		GS-5423	1700 mg IV		1700 mg IV
		GS-2872	850 mg IV		850 mg IV

*PO =經口(Per Os)，口服投予；SC =皮下；IV =靜脈內

【0235】 **統計方法：**主要功效終點係如藉由FDA定義之快照演算法定義的，在第26週時HIV-1 RNA ≥ 50個拷貝/mL之參與者比例。95% CI將使用無條件確切方法構築。功效終點將藉由Fisher確切測試在治療組之間進行比較。如藉由US FDA定義之快照演算法判定的，將使用與主要功效終點相同的方法分

析在第52週時HIV 1 RNA ≥ 50個拷貝/mL之參與者比例及在第26及52週時HIV-1 RNA < 50個拷貝/mL之參與者比例。

【0236】 CD4+ T細胞計數相對於基線之變化將由使用描述性統計之治療進行概述。將比較2個治療群組之間CD4+ T細胞計數相對於基線之變化之差異。

【0237】 治療出現的不良事件(AE)、嚴重不良事件(SAE)、及引起研究藥物永久停藥之不良事件將由治療組、系統器官類別(SOC)、及使用目前版本的監管活動醫學詞典(Medical Dictionary for Regulatory Activities, MedDRA)之較佳用語進行概述。實驗室結果及相對於所選實驗室測試之基線值之變化將由治療組及訪視進行概述。治療出現的實驗室異常之發生率將由治療組進行概述。生命體徵及心電圖資料將由治療組進行概述。

【0238】 如適當，將列出GS-5423、GS-2872、及LEN（及代謝物，如適當）之血清濃度或PK參數，且將各分析物使用描述性統計由治療組進行概述。

表7

目的及終點

主要目的	**主要終點**
• 評估研究方案之功效，如藉由在第 26 週時具有病毒學反彈（HIV-1 RNA ≥50 個拷貝/mL）之參與者之比例判定的	• 在第 26 週時 HIV-1 RNA ≥ 50 個拷貝/mL 之參與者之比例，如藉由美國(US)食品及藥物管理局(Food and Drug Administration, FDA)定義之快照演算法判定的
次要目的	**次要終點**
• 評估研究方案之功效，如藉由在第 52 週時具有病毒學反彈（HIV-1 RNA ≥50 個拷貝/mL）之參與者之比例判定的	• 在第 52 週時 HIV-1 RNA ≥ 50 個拷貝/mL 之參與者之比例，如藉由 US FDA 定義之快照演算法判定的
• 評估研究方案之功效，如藉由在第 26 及 52 週時維持病毒學抑制（HIV-1 RNA < 50 個拷貝/mL）之參與者之比例判定的	• 在第 26 及 52 週時 HIV-1 RNA < 50 個拷貝/mL 之參與者之比例，如藉由 US FDA 定義之快照演算法判定的

• 評估第 26 及 52 週時之 CD4+ T 細胞計數 • 評估研究方案在第 26 及 52 週時之安全性及耐受性 • 評估 GS-5423、GS-2872、及利那卡帕韋(LEN)之藥物動力學(PK) • 評估 GS-5423 及 GS-2872 之免疫原性	• 在第 26 及 52 週時 CD4+ T 細胞計數中相對於基線之變化 • 經歷治療出現的不良事件(TEAE)之參與者之比例 • 如適當，GS-5423、GS-2872、及 LEN 之 PK 參數：AUC_{0-t}、AUC_{last}、$t_{1/2}$、C_{max}、T_{max} • 直至第 26 及 52 週發展抗 GS-5423 及/或抗 GS-2872 抗體之參與者之比例
探索目的	**探索終點**
• 評估研究治療期間病毒抗性之出現 • 評估 HIV 病毒庫(reservoir)之變化 • 評估每 6 個月 bNAb/LEN 治療對患者報告的結果之影響	• 直至第 52 週治療引發的對研究藥物之病毒抗性 • 周邊血液單核細胞(peripheral blood mononuclear cell, PBMC)中之 HIV-1 病毒貯庫相對於基線之變化 • HIV-TSQ 及治療偏好調查

【0239】 應瞭解本文所述之實例及實施例僅用於說明性之目的，並且根據該等實例及實施例之各式修飾或變化將為所屬領域中具有通常知識者所推知且應被納入本申請案之精神與範圍及隨附之權利要求的範疇內。所有在本文中引用之出版物、專利及專利申請案全文出於所有目的特此以引用方式併入本文中。

【符號說明】

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【發明申請專利範圍】

【請求項1】一種抗體用於製備在有需要之人類個體治療或預防HIV之醫藥品之用途，其中該抗體係(i)第一抗體，其與結合至第三可變環(V3)及/或包含N332寡甘露糖聚醣之高甘露糖區塊內之gp120之表位的VH及VL區競爭或包含該等VH及VL區，或(ii)第二抗體，其與結合至包含CD4結合位點(CD4bs)之gp120之表位的VH及VL區競爭或包含該等VH及VL區，其中該第一抗體及該第二抗體均包含Fc胺基酸取代以延長血清半衰期，該治療或預防包含：

a) 在第一時間點共投予有效量的該第一抗體及有效量的該第二抗體；及

b) 在該第一時間點之後至少約 24 週，例如至少約 25 週，例如至少約 26 週的第二時間點共投予有效量之該第一抗體及有效量之該第二抗體。

【請求項2】如請求項1之用途，其中該第一抗體及該第二抗體包含Fc區，該Fc區在所示位置（依據EU索引編號）包含下列胺基酸：

(i) 位置 252 之酪胺酸、位置 254 之蘇胺酸及位置 256 之麩胺酸(YTE)；

(ii) 位置 428 之白胺酸及位置 434 之絲胺酸(LS)；

(iii) 位置 433 之離胺酸及位置 434 之苯丙胺酸；

(iv) 位置 250 之麩醯胺酸及位置 428 之白胺酸(QL)；

(v) 位置 307 之麩醯胺酸、位置 311 之纈胺酸及位置 378 之纈胺酸(DF215)；

(vi) 位置 256 之天冬胺酸、位置 286 之天冬胺酸、位置 307 之精胺酸、位置 311 之纈胺酸及位置 378 之纈胺酸(DF228)；或

(vii) 位置 309 之天冬胺酸、位置 311 之組胺酸及位置 434 之絲胺酸(DHS)。

【請求項3】如請求項1之用途，其中該第一抗體與選自下列的抗體之VH區及VL區競爭或包含該VH區及該VL區：10-1074-LS（GS-2872；津利維單抗

(zinlirvimab)）、10-1074、10-1074-J、GS-9722、GS-9721、PGT-121、PGT-121.66、PGT-121.414、PGT-122、PGT-123、PGT-124、PGT-125、PGT-126、PGT-128、PGT-130、PGT-133、PGT-134、PGT-135、PGT-136、PGT-137、PGT-138、PGT-139、VRC24、2G12、BG18、354BG8、354BG18、354BG42、354BG33、354BG129、354BG188、354BG411、354BG426、DH270.1、DH270.6、PGDM12、VRC41.01、PGDM21、PCDN-33A、BF520.1及VRC29.03；且該第二抗體與選自下列的抗體之VH及VL區競爭或包含該VH區及該VL區：3BNC117-LS（GS-5423；特羅帕單抗(teropavimab)）、3BNC117、GS-9723、3BNC60、b12、F105、VRC01、VRC07、VRC07-523、VRC03、VRC06、VRC06b01 VRC08、VRC0801、NIH45-46、PGV04 (VRC-PG04)；CH103、44-VRC13.01、1NC9、12A12、N6、1-18、N49-P7、NC-Cow1、IOMA、CH235及CH235.12、N49P6、N49P7、N49P11、N49P9及N60P25。

【請求項4】如請求項1之用途，其中該第一抗體與10-1074之VH及VL區競爭或包含10-1074之VH及VL區，且該第二抗體與3BNC117之VH及VL區競爭或包含3BNC117之VH及VL區。

【請求項5】如請求項1之用途，其中該第一抗體包含10-1074-LS（又名津利維單抗；GS-2872），且該第二抗體包含3BNC117-LS（又名特羅帕單抗；GS-5423）。

【請求項6】如請求項1之用途，其中該第一抗體及該第二抗體係每6個月(Q6M)共投予。

【請求項7】如請求項1之用途，其中該第一抗體及該第二抗體係每24週(Q24W)共投予。

【請求項8】如請求項1之用途，其中該第一抗體及該第二抗體係每25週(Q25W)共投予。

【請求項9】如請求項1之用途，其中該第一抗體及該第二抗體係每26週(Q26W)共投予。

【請求項10】如請求項1之用途，其中該第一抗體及該第二抗體獨立地以在約500 mg至約3000 mg，例如約550 mg至約2900 mg、例如約600 mg至約2800 mg、例如約650 mg至約2700 mg、例如約700 mg至約2600 mg、例如約850 mg至約2550 mg範圍內的劑量靜脈內投予。

【請求項11】如請求項1之用途，其中該第一抗體係以2550 mg之劑量靜脈內投予，且該第二抗體係以2550 mg之劑量靜脈內投予。

【請求項12】如請求項1之用途，其中該第一抗體係以850 mg之劑量靜脈內投予，且該第二抗體係以1275 mg之劑量靜脈內投予。

【請求項13】如請求項1之用途，其中該第一抗體係以850 mg之劑量靜脈內投予，且該第二抗體係以1700 mg之劑量靜脈內投予。

【請求項14】如請求項1之用途，其中該第一抗體係以850 mg之劑量靜脈內投予，且該第二抗體係以2550 mg之劑量靜脈內投予。

【請求項15】如請求項1之用途，其中該治療或預防進一步包含共投予一或多種長效HIV藥物。

【請求項16】如請求項15之用途，其中該一或多種長效HIV藥物係選自長效殼體抑制劑、長效整合酶股轉移抑制劑(INSTI)、長效非核苷反轉錄酶抑制劑(NNRTI)、長效核苷反轉錄酶抑制劑(NRTI)及長效蛋白酶抑制劑(PI)。

【請求項17】如請求項16之用途，其中該一或多種長效HIV藥物包含長效殼體抑制劑。

【請求項18】如請求項16之用途，其中該長效殼體抑制劑係選自利那卡帕韋(lenacapavir)、VH4004280及VH4011499。

【請求項19】如請求項16之用途，其中該長效殼體抑制劑包含利那卡帕韋。

【請求項20】如請求項18之用途，其中該利那卡帕韋係以在300 mg至1000 mg範圍內的劑量投予。

【請求項21】如請求項19之用途，其中該利那卡帕韋係口服或皮下投予。

【請求項22】如請求項16之用途，其中該長效INSTI係選自比替拉韋(bictegravir)、雷特格韋(raltegravir)、埃替格韋(elvitegravir)、多替拉韋(dolutegravir)、卡博特韋(cabotegravir)、GS-1720、GS-6212、GS-1219、GS-3242及VH4524184。

【請求項23】如請求項16之用途，其中該長效NNRTI係選自利匹韋林(rilpivirine)、艾法韋林(elsulfavirine)、多拉韋林(doravirine)及GS-5894。

【請求項24】如請求項16之用途，其中該長效NRTI係選自伊司他韋(islatravir)及其前藥、替諾福韋艾拉酚胺(tenofovir alafenamide, TAF)及替諾福韋之前藥、羅法福韋艾他拉酚胺(rovafovir etalafenamide)及GS-1614。

【請求項25】如請求項16之用途，其中該長效蛋白酶抑制劑係選自阿扎那韋(atazanavir)、利托那韋(ritonavir)、地瑞那韋(darunavir)、GS-1156及GS-1156之前藥、及其組合。

【請求項26】如請求項1至25中任一項之用途，其中該治療或預防進一步包含判定該個體之HIV對該第一抗體及該第二抗體中之一或二者之敏感性。

【請求項27】如請求項1至25中任一項之用途，其中該個體經歷過大量治療(heavily treatment experienced, HTE)。

【請求項28】如請求項1至25中任一項之用途，其中該個體對下列之一或多者具有抗性或無反應：整合酶股轉移抑制劑(INSTI)、非核苷反轉錄酶抑制劑(NNRTI)、核苷反轉錄酶抑制劑(NRTI)及蛋白酶抑制劑(PI)。

【請求項29】如請求項1至25中任一項之用途，其中該個體係具有病毒血症的(viremic)。

【請求項30】如請求項1至25中任一項之用途，其中該個體係經病毒學抑制的。

【請求項31】如請求項1至25中任一項之用途，其中該個體正接受抗反轉錄病毒療法(antiretroviral therapy, ART)。

【請求項32】如請求項1至25中任一項之用途，其中抗反轉錄病毒療法(ART)係在投予該第一抗體及該第二抗體之前中止。

【請求項33】如請求項1至25中任一項之用途，其中該個體受急性HIV感染。

【請求項34】如請求項33之用途，其中個體具有Fiebig第IV期或更早期HIV感染。

【請求項35】如請求項34之用途，其中該個體未經血清轉化。

【請求項36】如請求項1至25中任一項之用途，其中該個體最近受HIV感染。

【請求項37】如請求項36之用途，其中該醫藥品係用於投予具有Fiebig第V期或Fiebig第VI期HIV感染的個體。

【請求項38】如請求項1至25中任一項之用途，其中該個體受慢性HIV感染。

【請求項39】如請求項1至25中任一項之用途，其中該個體受HIV分支B病毒感染。

【請求項40】一種10-1074-LS（津利維單抗；GS-2872）或3BNC117-LS（特羅帕單抗；(GS-5423)）用於製備在有需要之人類個體治療或預防HIV之醫藥品之用途，其中該治療或預防包含：

a) 在第一時間點共投予(i)有效量的 10-1074-LS 及(ii)有效量的 3BNC117-LS；及

b) 在該第一時間點之後至少約 24 週，例如至少約 25 週，例如至少約 26 週的第二時間點共投予有效量之 10-1074-LS 及有效量之 3BNC117-LS。

【請求項41】如請求項40之用途，其中該10-1074-LS及該3BNC117-LS係每6個月(Q6M)共投予。

【請求項42】如請求項40之用途，其中該10-1074-LS及該3BNC117-LS係每24週(Q24W)共投予。

【請求項43】如請求項40之用途，其中該10-1074-LS及該3BNC117-LS係每25週(Q25W)共投予。

【請求項44】如請求項40之用途，其中該10-1074-LS及該3BNC117-LS係每26週(Q26W)共投予。

【請求項45】如請求項40至44中任一項之用途，其中該10-1074-LS及該3BNC117-LS係在1年內共投予2次。

【請求項46】如請求項40至44中任一項之用途，其中該10-1074-LS及該3BNC117-LS係在2年內共投予4次。

【請求項47】如請求項40至44中任一項之用途，其中該10-1074-LS及該3BNC117-LS係在3年內共投予6次。

【請求項48】如請求項40至44中任一項之用途，其中該10-1074-LS及該3BNC117-LS係在4年內共投予8次。

【請求項49】如請求項40至44中任一項之用途，其中該10-1074-LS係以30 mg/kg之劑量靜脈內投予，且該3BNC117-LS係以30 mg/kg之劑量靜脈內投予。

【請求項50】如請求項40至44中任一項之用途，其中該10-1074-LS係以10 mg/kg之劑量靜脈內投予，且該3BNC117-LS係以30 mg/kg之劑量靜脈內投予。

【請求項51】如請求項40至44中任一項之用途，其中該10-1074-LS及該3BNC117獨立地以在約500 mg至約3000 mg，例如約550 mg至約2900 mg、例如約600 mg至約2800 mg、例如約650 mg至約2700 mg、例如約700 mg至約2600 mg、例如約850 mg至約2550 mg範圍內的劑量靜脈內投予。

【請求項52】如請求項51之用途，其中該10-1074-LS係以2550 mg之劑量靜脈內投予，且該3BNC117-LS係以2550 mg之劑量靜脈內投予。

【請求項53】如請求項51之用途，其中該10-1074-LS係以850 mg之劑量靜脈內投予，且該3BNC117-LS係以1275 mg之劑量靜脈內投予。

【請求項54】如請求項51之用途，其中該10-1074-LS係以850 mg之劑量靜脈內投予，且該3BNC117-LS係以1700 mg之劑量靜脈內投予。

【請求項55】如請求項51之用途，其中該10-1074-LS係以850 mg之劑量靜脈內投予，且該3BNC117-LS係以2550 mg之劑量靜脈內投予。

【請求項56】如請求項40至44中任一項之用途，其中在該第一時間點之後26週，該10-1074-LS及該3BNC117-LS之血清濃度係至少10 μg/mL。

【請求項57】如請求項40至44中任一項之用途，其中在該第一時間點之後26週，HIV RNA之血漿或血清濃度係低於50個拷貝/mL。

【請求項58】如請求項40至44中任一項之用途，其中該治療或預防進一步包含共投予一或多種長效HIV藥物。

【請求項59】如請求項58之用途，其中該一或多種長效HIV藥物係選自長效殼體抑制劑、長效整合酶股轉移抑制劑(INSTI)、長效非核苷反轉錄酶抑制劑(NNRTI)、長效核苷反轉錄酶抑制劑(NRTI)及長效蛋白酶抑制劑(PI)。

【請求項60】如請求項59之用途，其中該長效殼體抑制劑係選自利那卡帕韋、VH4004280及VH4011499。

【請求項61】如請求項59之用途，其中該長效殼體抑制劑包含利那卡帕韋。

【請求項62】如請求項61之用途，其中該利那卡帕韋係以在300 mg至1000 mg範圍內的劑量投予。

【請求項63】如請求項61之用途，其中該利那卡帕韋係口服或皮下投予。

【請求項64】如請求項59之用途，其中該長效INSTI係選自比替拉韋、雷特格韋、埃替格韋、多替拉韋、卡博特韋、GS-1720、GS-6212、GS-1219、GS-3242及VH4524184。

【請求項65】如請求項59之用途，其中該長效NNRTI係選自利匹韋林、艾法韋林、多拉韋林及GS-5894。

【請求項66】如請求項59之用途，其中該長效NRTI係選自伊司他韋及其前藥、替諾福韋艾拉酚胺(TAF)及替諾福韋之前藥、羅法福韋艾他拉酚胺及GS-1614。

【請求項67】如請求項59之用途，其中該長效蛋白酶抑制劑係選自阿扎那韋、利托那韋、地瑞那韋、GS-1156及GS-1156之前藥及其組合。

【請求項68】如請求項40至44中任一項之用途，其中該治療或預防進一步包含判定該個體之HIV對10-1074-LS及3BNC117-LS中之一或二者之敏感性。

【請求項69】如請求項40至44中任一項之用途，其中該個體經歷過大量治療(HTE)。

【請求項70】如請求項40至44中任一項之用途，其中該個體對下列之一或多者具有抗性或無反應：整合酶股轉移抑制劑(INSTI)、非核苷反轉錄酶抑制劑(NNRTI)、核苷反轉錄酶抑制劑(NRTI)及蛋白酶抑制劑(PI)。

【請求項71】如請求項40至44中任一項之用途，其中該個體係具有病毒血症的。

【請求項72】如請求項40至44中任一項之用途，其中該個體係經病毒學抑制的。

【請求項73】如請求項40至44中任一項之用途，其中該個體正接受抗反轉錄病毒療法(ART)。

【請求項74】如請求項40至44中任一項之用途，其中抗反轉錄病毒療法(ART)已在投予10-1074-LS及3BNC117-LS之前中止。

【請求項75】如請求項40至44中任一項之用途，其中該個體受急性HIV感染。

【請求項76】如請求項75之用途，其中該個體具有Fiebig第IV期或更早期HIV感染。

【請求項77】如請求項76之用途，其中該個體未經血清轉化。

【請求項78】如請求項40至44中任一項之用途，其中該個體最近受HIV感染。

【請求項79】如請求項78之用途，其中該醫藥品係用於投予具有Fiebig第V期或Fiebig第VI期HIV感染的個體。

【請求項80】如請求項40至44中任一項之用途，其中該個體受慢性HIV感染。

【請求項81】如請求項40至44中任一項之用途，其中該個體受HIV分支B病毒感染。

【請求項82】一種套組，其包含一或多個單一劑量的結合HIV gp120 V3聚醣之第一抗體及結合HIV gp120 CD4bs之第二抗體，其中該第一抗體及該第二抗體具有延長血清半衰期的胺基酸取代，且其中該第一抗體及該第二抗體經調配用於每年兩次（例如，每6個月(Q6M)、每26週(Q26W)、每25週(Q25W)或每24週(Q24W)）投予。

【請求項83】如請求項82之套組，其中該第一抗體及該第二抗體之該等單一劑量係獨立地在約500 mg至約3000 mg，例如約550 mg至約2900 mg、例如約600 mg至約2800 mg、例如約650 mg至約2700 mg、例如約700 mg至約2600 mg、例如約850 mg至約2550 mg範圍內。

【請求項84】一種套組，其包含一或多個單一劑量之3BNC117-LS（特羅帕單抗）及10-1074-LS（津利維單抗），其中該3BNC117-LS（特羅帕單抗）及該10-1074-LS（津利維單抗）經調配用於每年兩次（例如，每6個月(Q6M)、每26週(Q26W)、每25週(Q25W)或每24週(Q24W)）投予。

【請求項85】如請求項84之套組，其中10-1074-LS及3BNC117-LS之該等單一劑量係獨立地在約500 mg至約3000 mg，例如約550 mg至約2900 mg、例如約600 mg至約2800 mg、例如約650 mg至約2700 mg、例如約700 mg至約2600 mg、例如約850 mg至約2550 mg範圍內。

【請求項86】如請求項85之套組，其中10-1074-LS之該一或多個單一劑量係2550 mg，且3BNC117-LS之該一或多個單一劑量係2550 mg。

【請求項87】如請求項85之套組，其中10-1074-LS之該一或多個單一劑量係850 mg，且3BNC117-LS之該一或多個單一劑量係1275 mg。

【請求項88】如請求項85之套組，其中10-1074-LS之該一或多個單一劑量係850 mg，且3BNC117-LS之該一或多個單一劑量係1700 mg。

【請求項89】如請求項85之套組，其中10-1074-LS之該一或多個單一劑量係850 mg，且3BNC117-LS之該一或多個單一劑量係2550 mg。

【請求項90】如請求項84至89中任一項之套組，其中該10-1074-LS及該3BNC117-LS經調配用於靜脈內投予。

【請求項91】如請求項82至89中任一項之套組，其中該一或多個單一劑量包含於一或多個容器中。

【請求項92】如請求項91之套組，其中該一或多個容器係選自小瓶、安瓿及預載注射器。

【請求項93】如請求項82至89中任一項之套組，其進一步包含一或多個單一劑量的一或多種長效HIV藥物。

【請求項94】如請求項93之套組，其中該一或多個單一劑量的一或多種長效HIV藥物係選自長效殼體抑制劑、長效整合酶股轉移抑制劑(INSTI)、長效非核苷反轉錄酶抑制劑(NNRTI)、長效核苷反轉錄酶抑制劑(NRTI)及長效蛋白酶抑制劑(PI)。

【請求項95】如請求項94之套組，其中該長效殼體抑制劑係選自利那卡帕韋、VH4004280及VH4011499。

【請求項96】如請求項94之套組，其中該長效殼體抑制劑包含利那卡帕韋。

【請求項97】如請求項96之套組，其中利那卡帕韋之該單一劑量係在300 mg至1000 mg範圍內。

【請求項98】如請求項96之套組，其中該利那卡帕韋經調配用於口服或皮下投予。

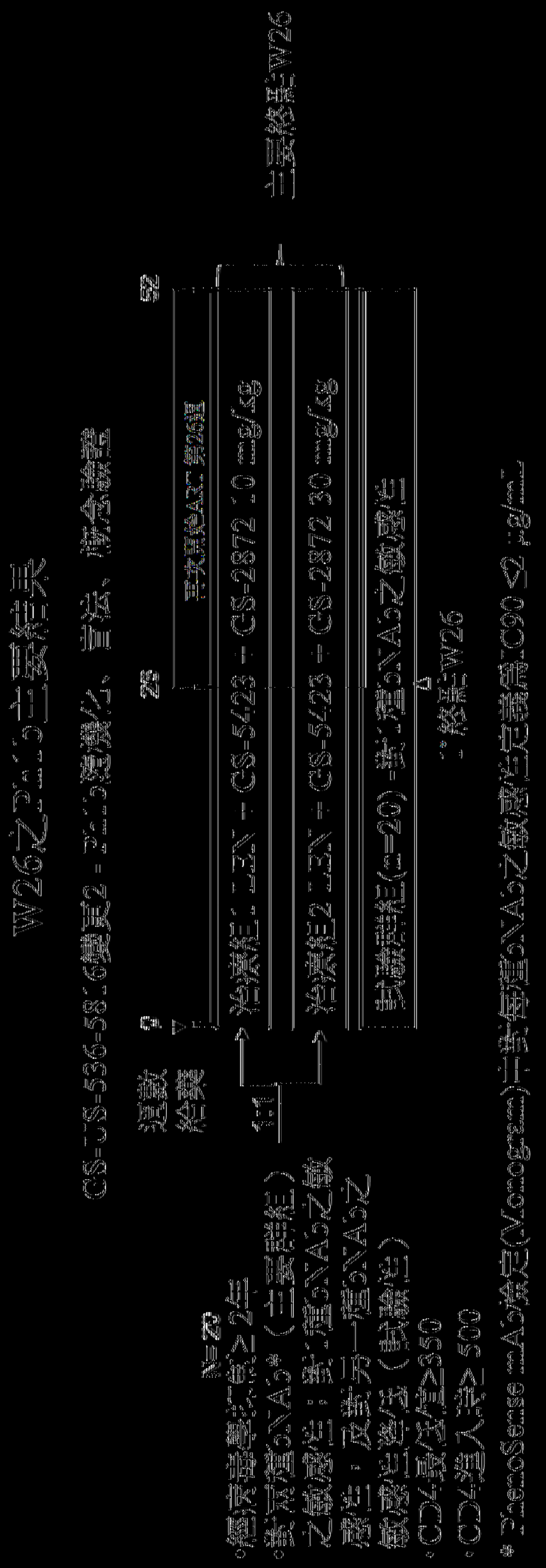
【請求項99】如請求項94之套組，其中該長效INSTI係選自比替拉韋、雷特格韋、埃替格韋、多替拉韋、卡博特韋、GS-1720、GS-6212、GS-1219、GS-3242及VH4524184。

【請求項100】如請求項94之套組，其中該長效NNRTI係選自利匹韋林、艾法韋林、多拉韋林及GS-5894。

【請求項101】如請求項94之套組，其中該長效NRTI係選自伊司他韋及其前藥、替諾福韋艾拉酚胺(TAF)及替諾福韋之前藥、羅法福韋艾他拉酚胺及GS-1614。

【請求項102】如請求項94之套組，其中該長效蛋白酶抑制劑係選自阿扎那韋、利托那韋、地瑞那韋、GS-1156及GS-1156之前藥及其組合。

【發明圖式】


W26之Ph1b主要結果
GS-US-536-5816變更2 - Ph1b隨機化、盲法、概念驗證
週數
給藥
0
26
52
再次開始ART 第26週
N= 20
•經病毒學抑制≥ 2年
•對兩種bNAb*（主要群組）之敏感性；對1種bNAb之敏感性，及對另一種bNAb之敏感性降低（試驗性）
•CD4最低值≥350
•CD4進入時≥ 500
1:1
治療組1 LEN + GS-5423 + GS-2872 10 mg/kg
治療組2 LEN + GS-5423 + GS-2872 30 mg/kg
試驗群組(n=20) -對1種bNAb之敏感性
主要終點W26
1°終點W26
* PhenoSense mAb檢定(Monogram)中對每種bNAb之敏感性定義為IC90 ≤2 µg/mL

【圖1A】

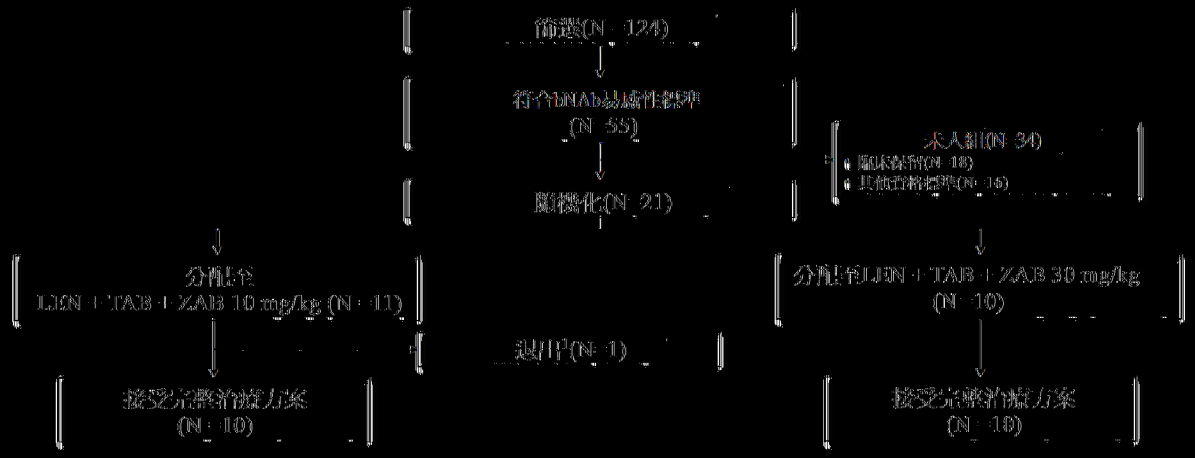
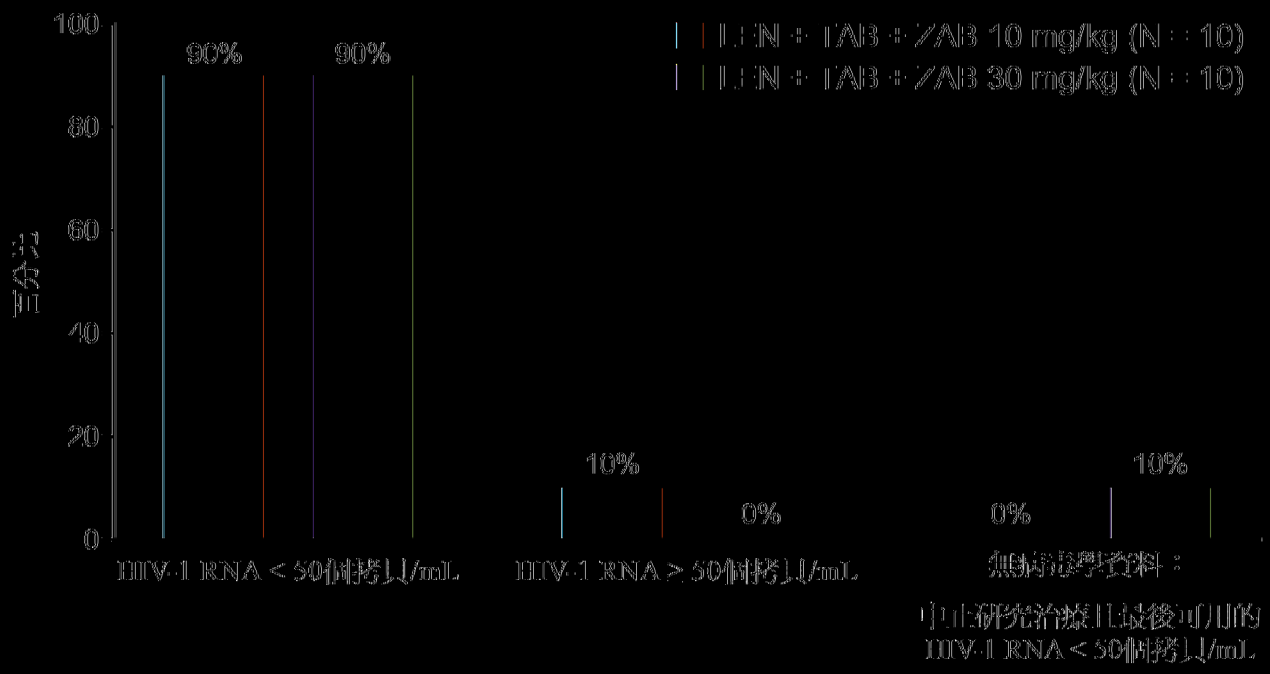

篩選(N=124)
符合HNAb以外條件評估(N=55)
隨機化(N=21)
未入組(N=34)
篩選失敗(N=18)
其他原因中止(N=16)
分配至LEN+TAB+ZAB 10 mg/kg (N=11)
退出(N=1)
分配至LEN+TAB+ZAB 30 mg/kg (N=10)
接受治療治療方案 (N=10)
接受治療治療方案 (N=10)

圖1B


100
80
60
40
20
0
90%
90%
10%
0%
0%
10%
LEN + FAB + ZAB 10 mg/kg (N = 10)
LEN + FAB + ZAB 30 mg/kg (N = 10)
HIV-1 RNA < 50個拷貝/mL
HIV-1 RNA > 50個拷貝/mL
無病態學資料：
中止研究治療日後可用的
HIV-1 RNA < 50個拷貝/mL

(圖1C)

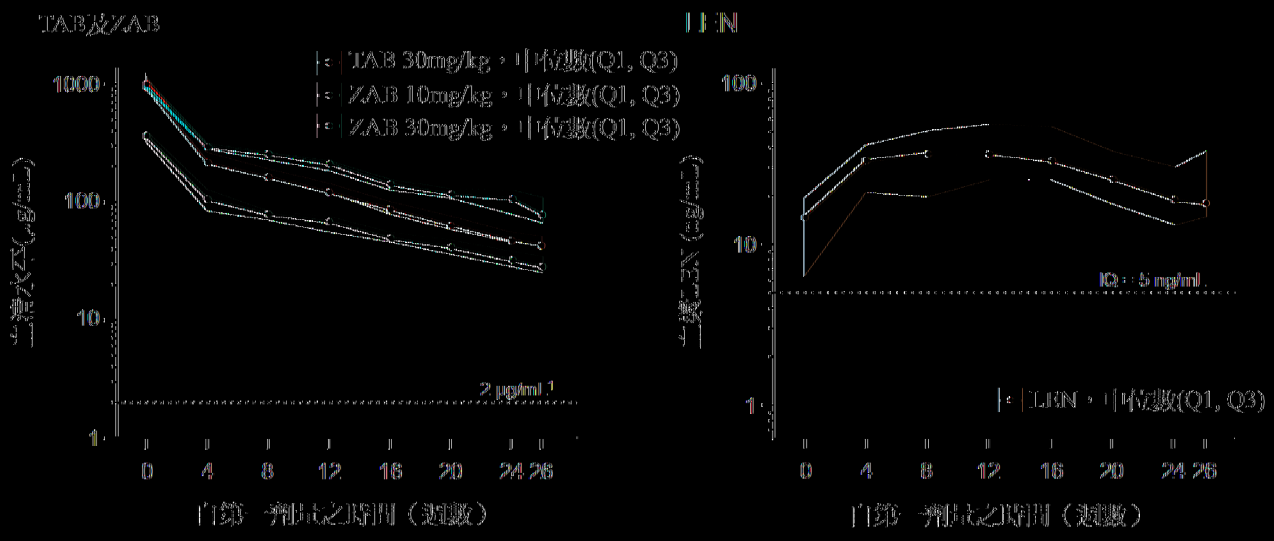
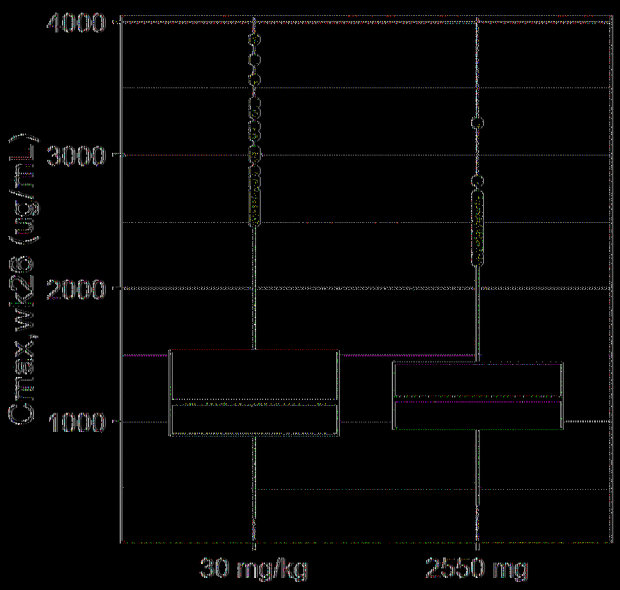
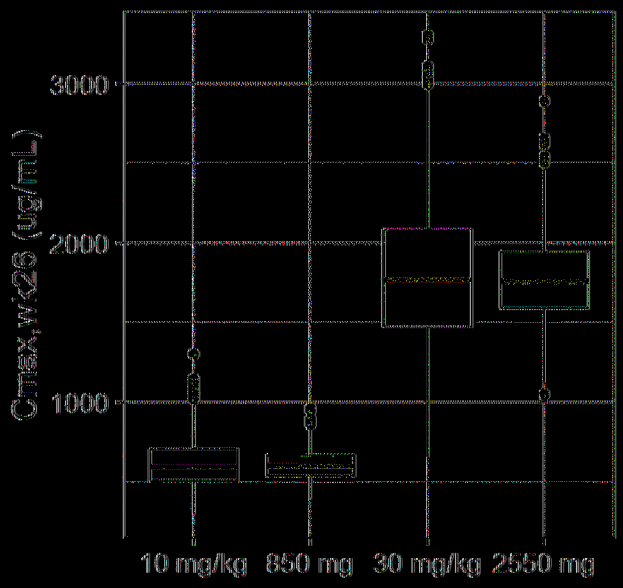

TAB及ZAB
TAB 30mg/kg，中位數(Q1, Q3)
ZAB 10mg/kg，中位數(Q1, Q3)
ZAB 30mg/kg，中位數(Q1, Q3)
1000
100
10
1
2 μg/ml
0
4
8
12
16
20
24 26
自第一劑起之時間（週數）
LEN
100
10
1
10 ng/ml
LEN，中位數(Q1, Q3)
0
4
8
12
16
20
24 26
自第一劑起之時間（週數）

圖2



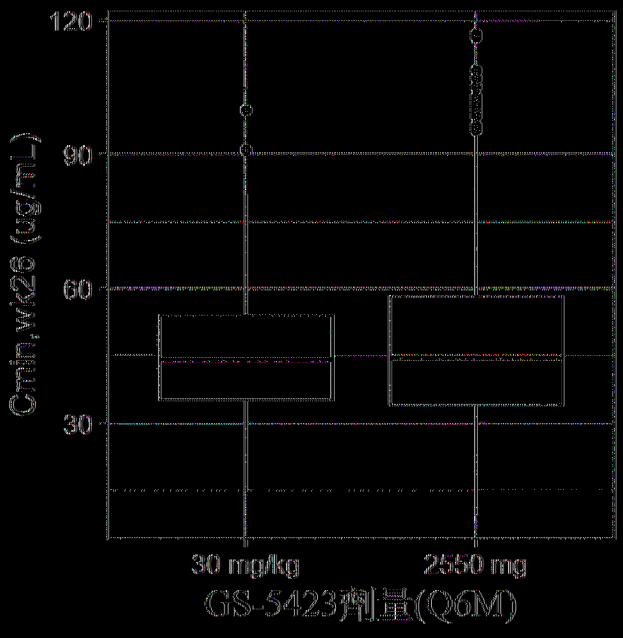
GS-5423劑量(Q6M)

|(與3A)|

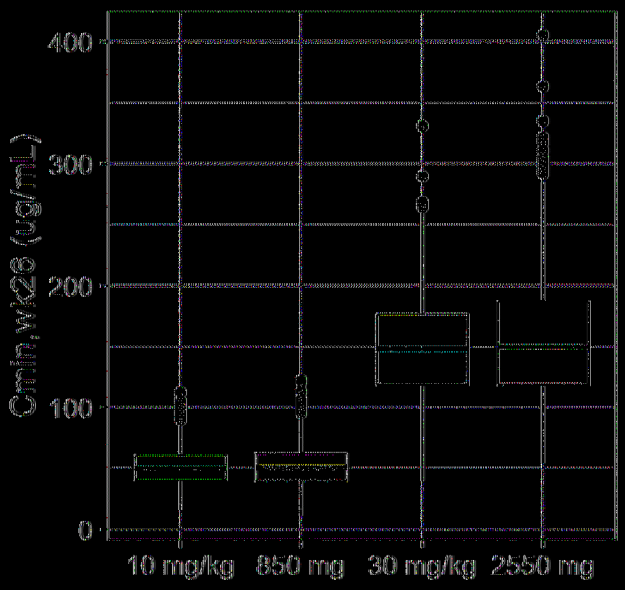


GS-2872劑量(Q6M)

(圖3B)



|(圖3C)|



GS-2872劑量(Q6M)

|(共3D)|

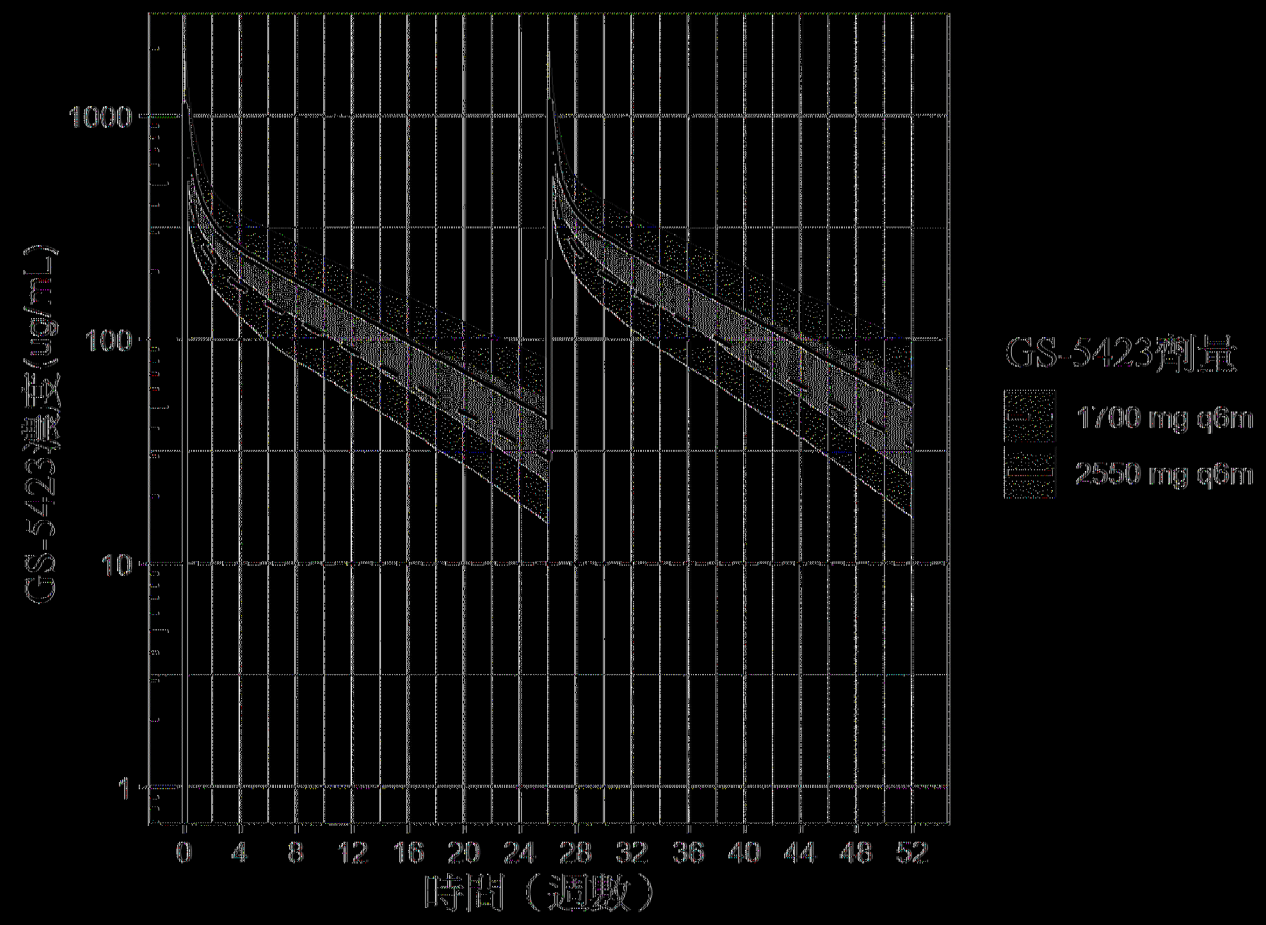
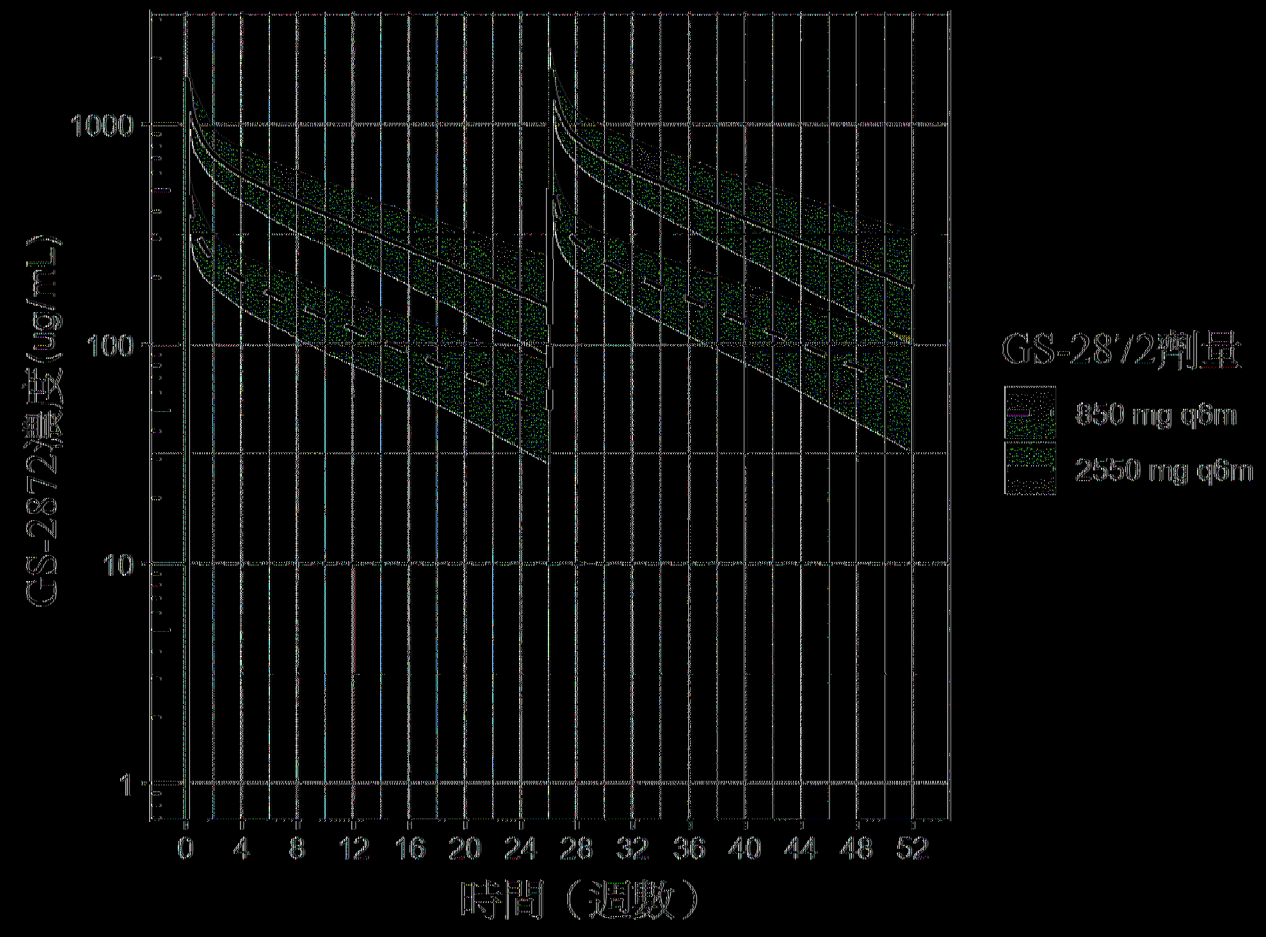
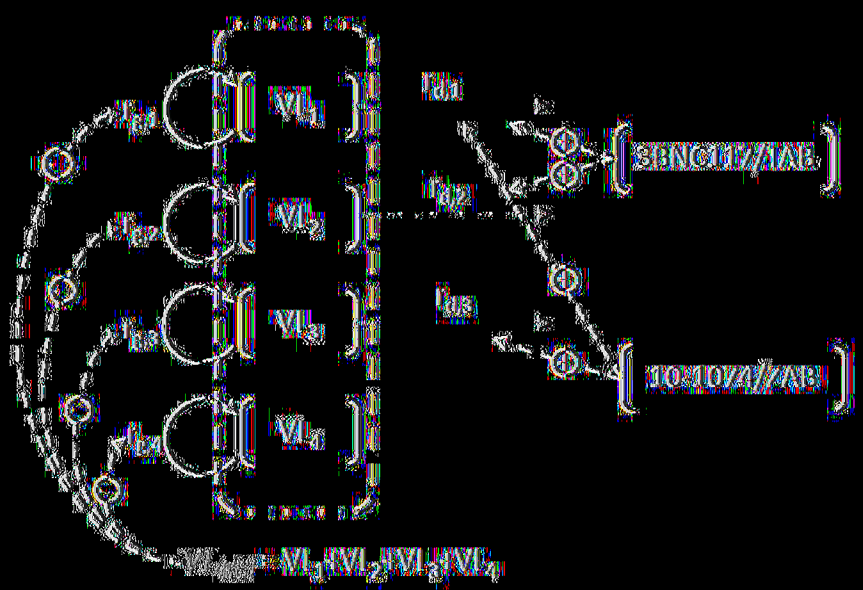

1000
100
10
1
GS-5423血漿濃度 (ng/mL)
0
4
8
12
16
20
24
28
32
36
40
44
48
52
時間（週數）
GS-5423劑量
1700 mg q6m
2550 mg q6m

圖4A


GS-2872血漿濃度（ng/mL）
1000
100
10
1
0
4
8
12
16
20
24
28
32
36
40
44
48
52
時間（週數）
GS-2872劑量
850 mg q6m
2550 mg q6m

[圖4B]



$$\frac{dV_{in}}{dt} = \gamma_{in} + \gamma_{out}$$

$$\gamma_{out} = k_{out} \times \left(1 - \frac{V_{in}}{V_{in,max}}\right) \times V_{in}$$

$$V_{in}(0) = V_{in,0} \times f_1$$

$$(i = 1, \ldots, 4)$$

$$\gamma_{in} = \frac{k_{in,max} \times C_1}{C_2 / C_{in,half} + C_2 / C_{in,max} + 1} \times V_{in}$$

$$\gamma_{out} = \frac{k_{out,max} \times C_1}{C_2 / C_{out,half} + 1} \times V_{in}$$

$$k_{in,max} = \frac{k_{out,max} \times C_2}{C_2 / C_{out,half} + 1} \times V_{in}$$

圖(圖5)

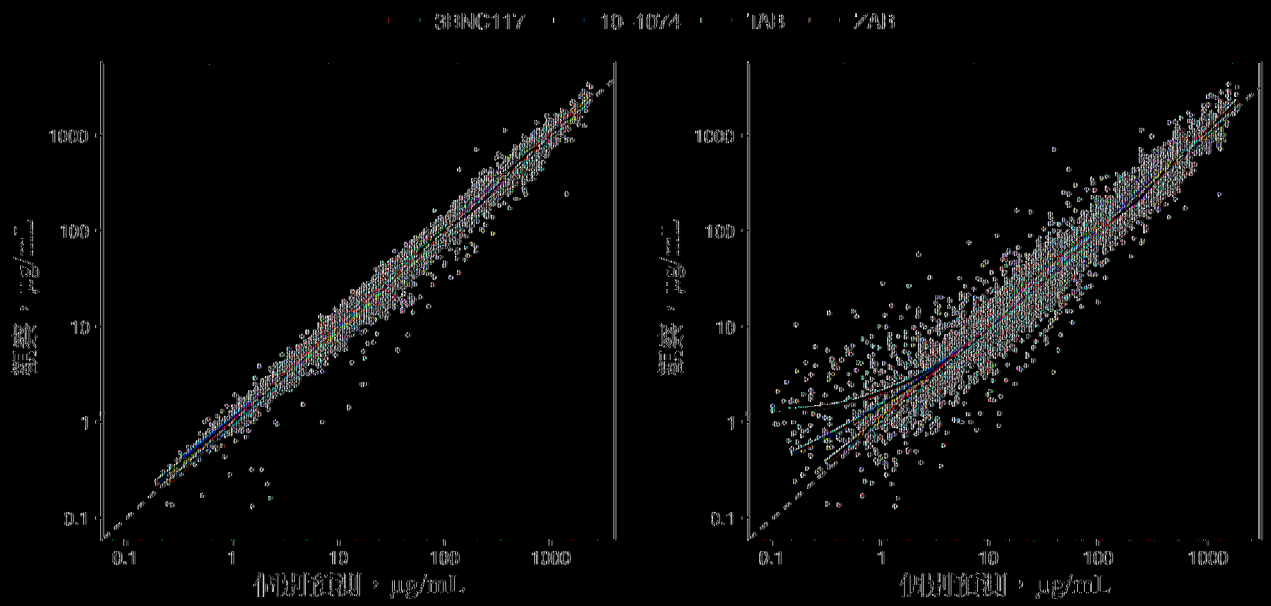
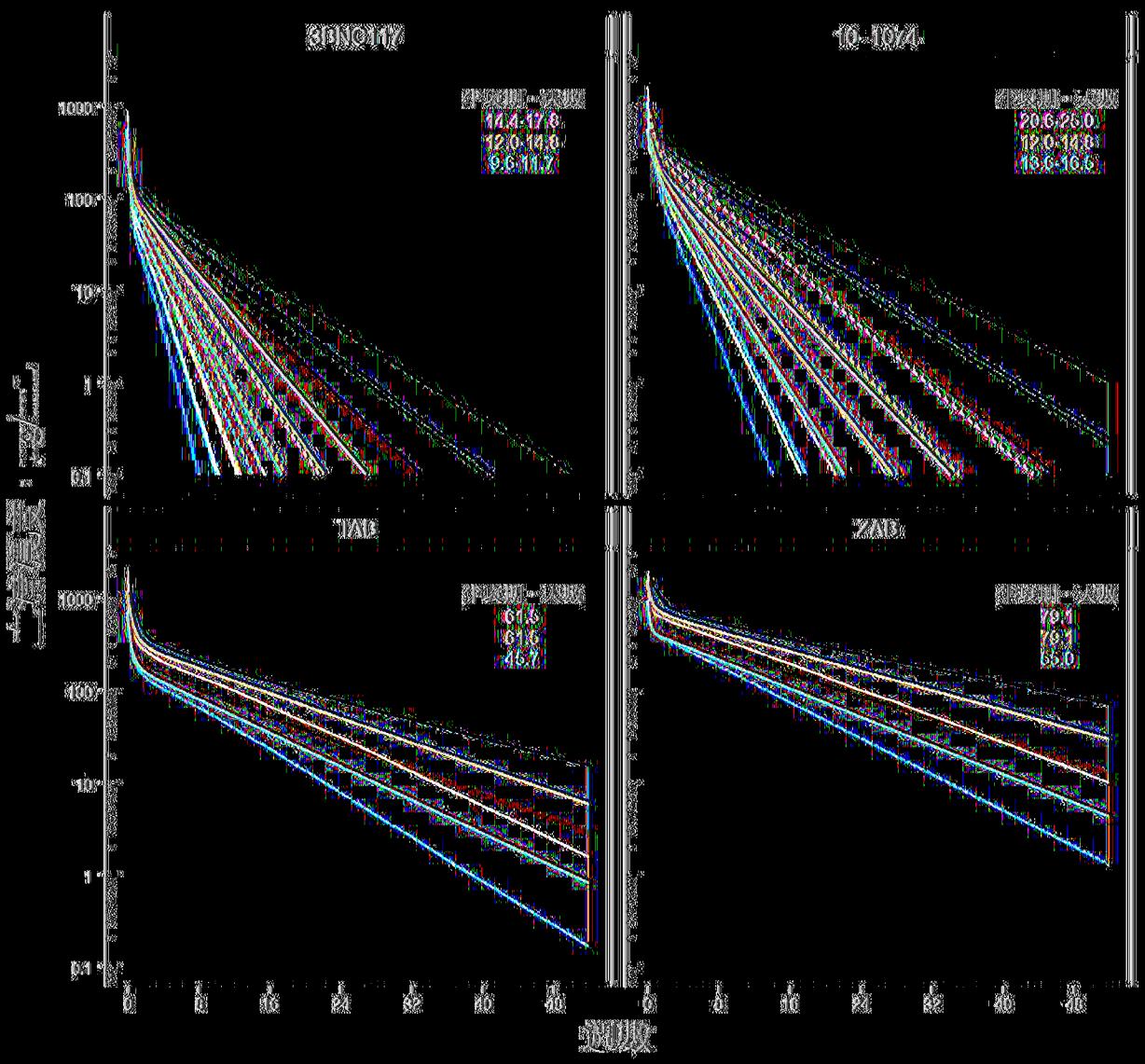

3BNC117
10-1074
PAB
ZAB
1000
100
10
1
0.1
0.1
1
10
100
1000
偵測濃度，μg/mL
偵測濃度，μg/mL

圖6


3B1C117
10~1024
14.4-17.8
12.0-14.8
9.6-11.7
20.6-25.0
12.0-14.8
13.6-16.6
1000
100
10
1
0.1
61.8
61.8
45.7
79.1
79.1
65.0
0
8
16
24
32
40
48
時間

[(圖7)]

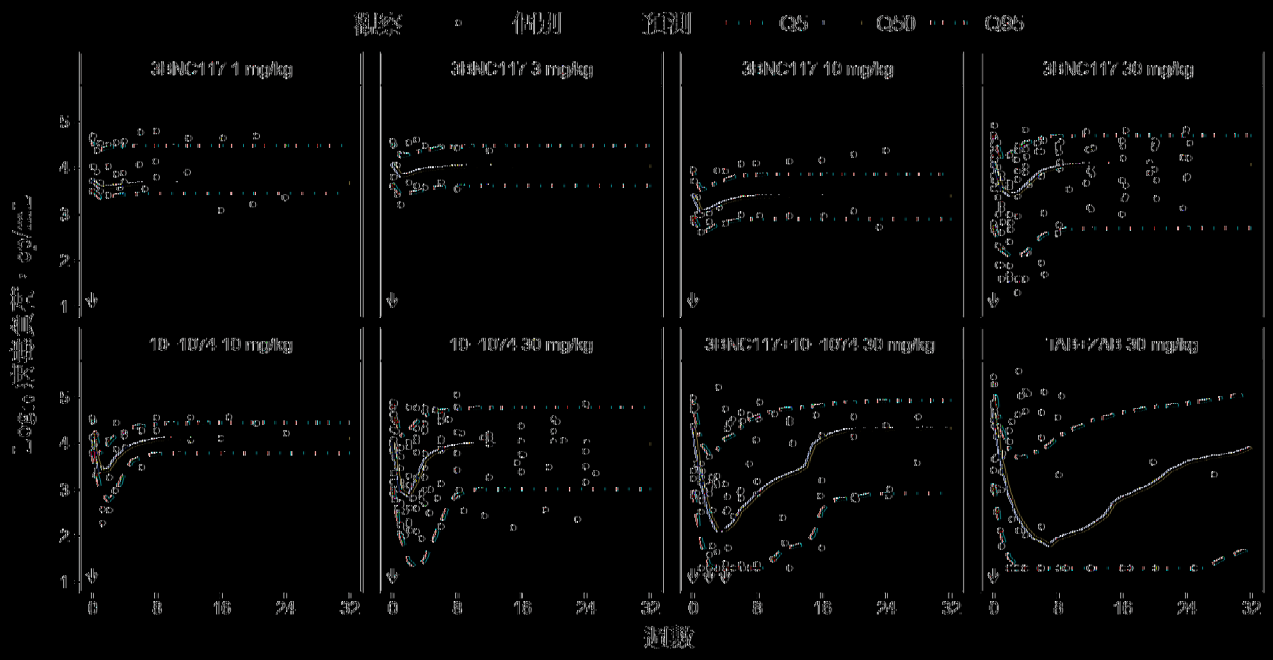

觀察
個別
預測
Q5
Q50
Q95
3BNC117 1 mg/kg
3BNC117 3 mg/kg
3BNC117 10 mg/kg
3BNC117 30 mg/kg
10-1074 10 mg/kg
10-1074 30 mg/kg
3BNC117+10-1074 30 mg/kg
TAB-VAR 30 mg/kg
log10(病毒量, 拷貝/毫升)
週數

圖8

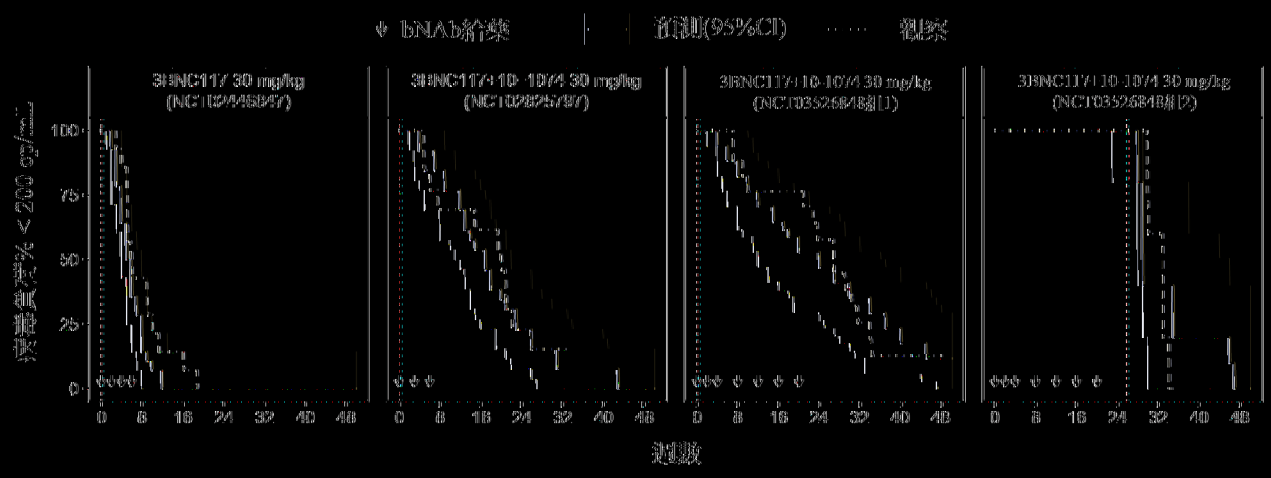

bNAb給藥
預測(95%CI)
觀察
3BNC117 30 mg/kg
(NCT02445847)
3BNC117+10-1074 30 mg/kg
(NCT02825797)
3BNC117+10-1074 30 mg/kg
(NCT03526848組1)
3BNC117+10-1074 30 mg/kg
(NCT03526848組2)
病毒載量≥200 c/mL (%)
100
75
50
25
0
0
8
16
24
32
40
48
週數

圖9

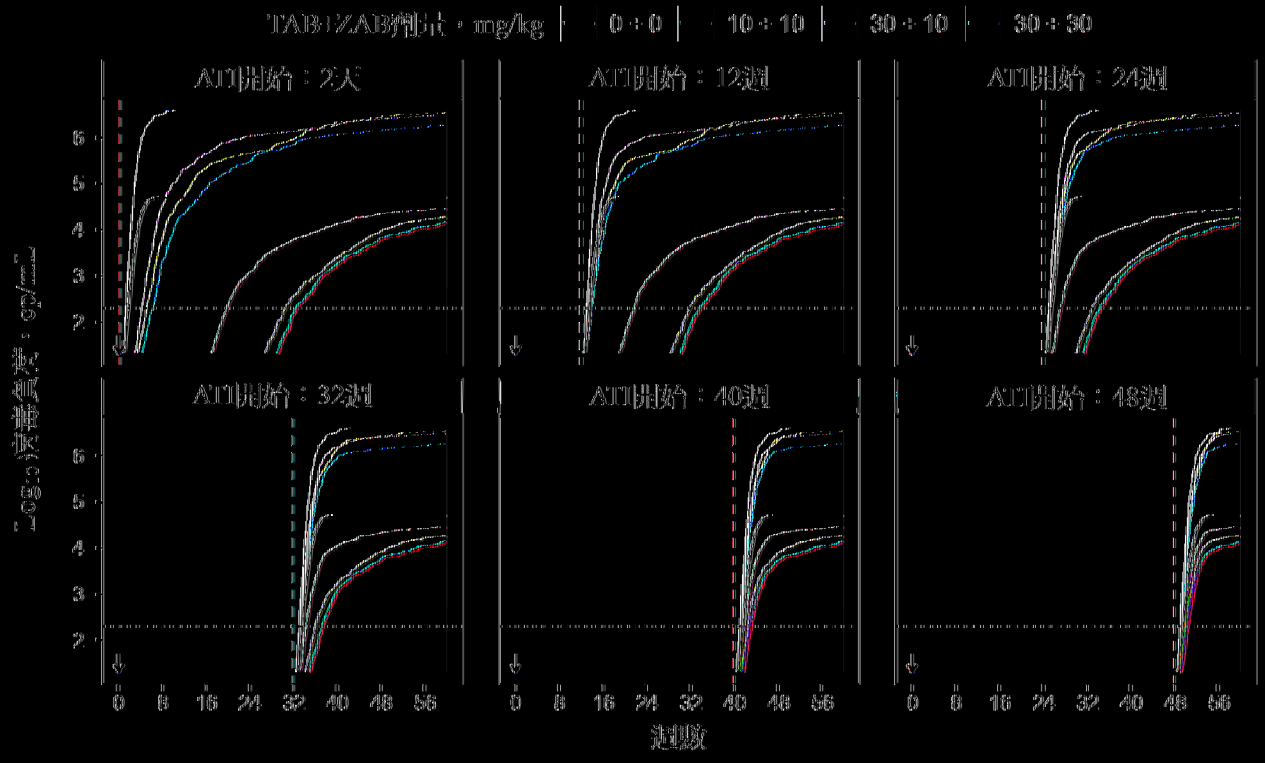

TAB/ZAB開始：mg/kg
0＋0
10＋10
30＋10
30＋30
ATI開始：2天
ATI開始：12週
ATI開始：24週
ATI開始：32週
ATI開始：40週
ATI開始：48週
HBV DNA（log10 copies/mL）
2
3
4
5
6
0
8
16
24
32
40
48
56
週數

圖10

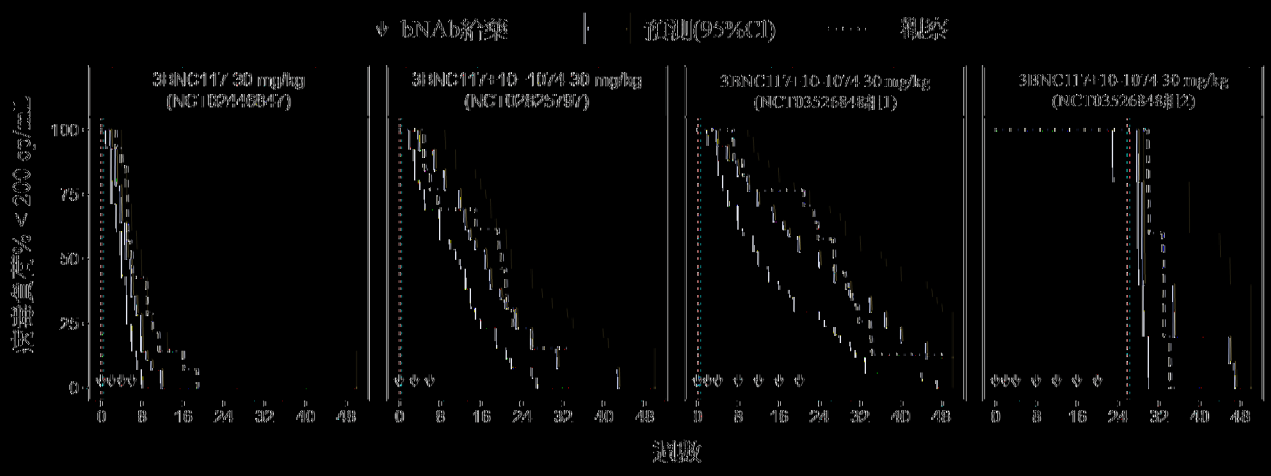

bNAb給藥
預測(95%CI)
觀察
3BNC117 30 mg/kg
(NCT02484847)
3BNC117+10-1074 30 mg/kg
(NCT02825758)
3BNC117+10-1074 30 mg/kg
(NCT03526848組1)
3BNC117+10-1074 30 mg/kg
(NCT03526848組2)
病毒載量 (log10 copies/mL)
100
75
50
25
0
0
8
16
24
32
40
48
週數

圖11)

第2世代方式：
32-US 536-939-燒蝕ノ、真放置構
0
26
52
78
…秒数
冷蔵庫1：
EV一日航本 - 927 ㎝ SO ℃6 ㎝
CS-5423 2550 ㎝ -CS-2872 2550 ㎝ -7V ℃6 ㎝
冷蔵庫2：
EV一日航本 - 927 ㎝ SO ℃6 ㎝
CS-5423 700 ㎝ -CS-2872 850 ㎝ -7V ℃6 ㎝
冷蔵庫3
保冷ケース用方式（参考）
1：冷蔵庫
2：冷蔵庫
2. ZeroSense ™Ab抗体(Nomogram Biosciences)：先端ゲノム・プロテオミクス解析を基盤とするAb之特異性と高親和性 V2 .μg/mL
3：主治AV12カプセル：冷蔵庫庫内専用ケース、左右方向ガイド入り、三ヨコ方式を採用
次之参照：冷蔵庫方式之詳細

|(圖12)|