ボラシデニブ　クエン酸水和物

医薬品製造販売承認申請書添付資料

第 1 部（モジュール 1）

1.9　一般的名称に係る文書

日本セルヴィエ株式会社

目次

1. JAN 3
2. INN 3

1. JAN

令和 6 年 9 月 30 日付医薬薬審発 0930 第 4 号により以下のとおり通知された。
一般的名称：（日本名）ボラシデニブ　クエン酸水和物
（英名）Vorasidenib Citric Acid Hydrate

当該通知を別添 1 として添付する。

2. INN

WHO Drug Information, Vol.32, No.1, 2018, List 79 に、以下のとおり収載された。
rINN：vorasidenib

当該リストを別添 2 として添付する。

別添1

写

医薬薬審発 0930 第４号
令 和 ６ 年 ９ 月 30 日

各都道府県衛生主管部（局）長　殿

厚生労働省医薬局医薬品審査管理課長
（　　公　　印　　省　　略　　）

医薬品の一般的名称について

標記については、「医薬品の一般的名称の取扱いについて（平成 18 年３月 31 日薬食発第 0331001 号厚生労働省医薬食品局長通知）」等により取り扱っているところです。今般、我が国における医薬品の一般的名称（以下「JAN」という。）について、新たに別添のとおり定めたので、御了知の上、貴管下関係業者に周知方よろしく御配慮願います。

（参照）
「日本医薬品一般的名称データベース」https://jpdb.nihs.go.jp/jan/
（別添の情報のうち、JAN 以外の最新の情報は、当該データベースの情報で対応することとしています。）

（別表１）INN との整合性が図られる可能性のあるもの
（平成 18 年 3 月 31 日薬食審査発第 0331001 号厚生労働省医薬食品局審査管理課長通知に示す別表１）

登録番号 305-7-A1
JAN（日本名）：シパビバルト（遺伝子組換え）
JAN（英　名）：Sipavibart (Genetical Recombination)

アミノ酸配列及びジスルフィド結合

H 鎖

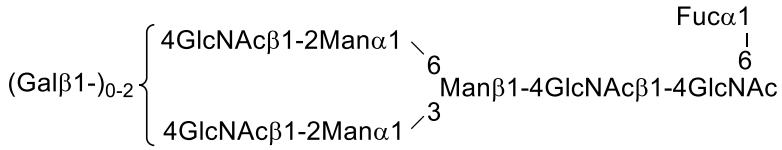
```
EVQLVESGGG LVQPGRSLRL SCAASGFPFD DYAIHWVRLA PGKGLEWVSS  50
ISWDSGSIGY ADSVKGRFTI SRDNAKNSLY LQMNSLRAED TALYYCAKGA 100
FPGYSSGWYY GLEVWGQGTT VTVSSASTKG PSVFPLAPSS KSTSGGTAAL 150
GCLVKDYFPE PVTVSWNSGA LTSGVHTFPA VLQSSGLYSL SSVVTVPSSS 200
LGTQTYICNV NHKPSNTKVD KRVEPKSCDK THTCPPCPAP EFEGGPSVFL 250
FPPKPKDTLY ITREPEVTCV VVDVSHEDPE VKFNWYVDGV EVHNAKTKPR 300
EEQYNSTYRV VSVLTVLHQD WLNGKEYKCK VSNKALPASI EKTISKAKGQ 350
PREPQVYTLP PSREEMTKNQ VSLTCLVKGF YPSDIAVEWE SNGQPENNYK 400
TTPPVLDSDG SFFLYSKLTV DKSRWQQGNV FSCSVMHEAL HNHYTQKSLS 450
LSPGK                                                   455
```

L 鎖

```
QSVVTQPPSA SGSLGQSVTI SCTGTSSDVG GYNYVSWYQQ HPGKAPKLMI  50
FEVSKRPSGV PDRFSGSKSG NTASLTVSGL QAEDEADYYC SSYAGNKGVF 100
GGGTKLTVLG QPKAAPSVTL FPPSSEELQA NKATLVCLIS DFYPGAVTVA 150
WKADSSPVKA GVETTTPSKQ SNNKYAASSY LSLTPEQWKS HRSYSCQVTH 200
EGSTVEKTVA PTECS                                        215
```

H 鎖 E1，L 鎖 Q1：部分的ピログルタミン酸；H 鎖 N305：糖鎖結合；H 鎖 K455：部分的プロセシング
H 鎖 C228 – L 鎖 C214，H 鎖 C234 – H 鎖 C234，H 鎖 C237 – H 鎖 C237：ジスルフィド結合

主な糖鎖の推定構造



$C_{6430}H_{9880}N_{1704}O_{2022}S_{40}$（タンパク質部分，4 本鎖）
H 鎖　$C_{2227}H_{3412}N_{588}O_{683}S_{14}$
L 鎖　$C_{988}H_{1532}N_{264}O_{328}S_{6}$

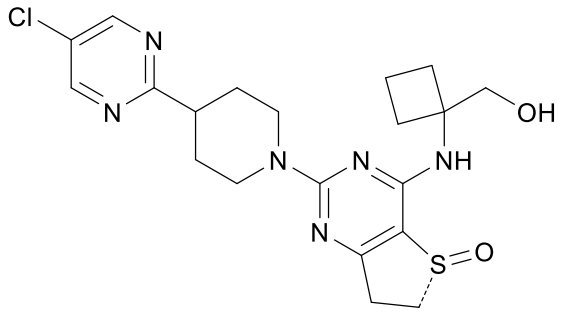
シパビバルトは，遺伝子組換え抗SARS-CoV-2スパイクタンパク質モノクローナル抗体であり，ヒトIgG1に由来し，H鎖の6個のアミノ酸残基が置換（L242F，L243E，M260Y，S262T，T264E，P339S）されている．シパビバルトは，CHO細胞により産生される．シパビバルトは，455個のアミノ酸残基からなるH鎖（γ1鎖）2本及び215個のアミノ酸残基からなるL鎖（λ鎖）2本で構成される糖タンパク質（分子量：約148,000）である．

Sipavibart is a recombinant anti-SARS-CoV-2 spike protein monoclonal antibody derived from human IgG1, in which amino acid residues in the H-chain are substituted at 6 positions (L242F, L243E, M260Y, S262T, T264E, P339S). Sipavibart is produced in CHO cells. Sipavibart is a glycoprotein (molecular weight: ca. 148,000) composed of 2 H-chains (γ1-chains) consisting of 455 amino acid residues each and 2 L-chains (λ-chains) consisting of 215 amino acid residues each.

登録番号 305-7-A2

JAN（日本名）：ネランドミラスト

JAN（英　名）：Nerandomilast



$C_{20}H_{25}ClN_6O_2S$

(5*R*)-2-[4-(5-クロロピリミジン-2-イル)ピペリジン-1-イル]-4-{[1-(ヒドロキシメチル)シクロブチル]アミノ}-6,7-ジヒドロ-5*H*-5λ⁴-チエノ[3,2-*d*]ピリミジン-5-オン

(5*R*)-2-[4-(5-Chloropyrimidin-2-yl)piperidin-1-yl]-4-{[1-(hydroxymethyl)cyclobutyl]amino}-6,7-dihydro-5*H*-5λ⁴-thieno[3,2-*d*]pyrimidin-5-one

（別表２）INN に収載された品目の我が国における医薬品一般的名称
（平成 18 年 3 月 31 日薬食審査発第 0331001 号厚生労働省医薬食品局審査管理課長通知に示す別表２）

登録番号 305-6-B16
JAN（日本名）：シベプレンリマブ（遺伝子組換え）
JAN（英　名）：Sibeprenlimab (Genetical Recombination)

アミノ酸配列及びジスルフィド結合

H 鎖

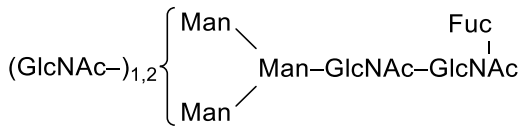
```
QVQLVQSGAE  VKKPGASVKV  SCKASGYTFT  DYTIHWVRQA  TGQGLEWMGW   50
IYPLRGSINY  AQKFQGRVTM  TADKSISTVY  MELSSLRSED  TAVYFCARHG  100
AYYSNAFDYW  GQGTLVTVSS  ASTKGPSVFP  LAPCSRSTSE  STAALGCLVK  150
DYFPEPVTVS  WNSGALTSGV  HTFPAVLQSS  GLYSLSSVVT  VPSSNFGTQT  200
YTCNVDHKPS  NTKVDKTVER  KCCVECPPCP  APPVAGPSVF  LFPPKPKDTL  250
MISRTPEVTC  VVVDVSHEDP  EVQFNWYVDG  VEVHNAKTKP  REEQFNSTFR  300
VVSVLTVVHQ  DWLNGKEYKC  KVSNKGLPAP  IEKTISKTKG  QPREPQVYTL  350
PPSREEMTKN  QVSLTCLVKG  FYPSDIAVEW  ESNGQPENNY  KTTPPMLDSD  400
GSFFLYSKLT  VDKSRWQQGN  VFSCSVMHEA  LHNHYTQKSL  SLSPGK       446
```

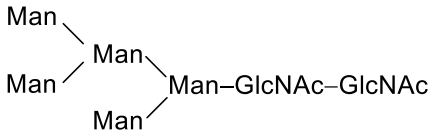
L 鎖

```
EIVMTQSPAT  LSVSPGERAT  LSCRASESVD  NDGIRFLHWY  QQKPGQAPRL   50
LIYRASTRAT  GIPARFSGSG  SRTEFTLTIS  SLQSEDFAVY  YCQQSNKDPY  100
TFGGGTKVEI  KRTVAAPSVF  IFPPSDEQLK  SGTASVVCLL  NNFYPREAKV  150
QWKVDNALQS  GNSQESVTEQ  DSKDSTYSLS  STLTLSKADY  EKHKVYACEV  200
THQGLSSPVT  KSFNRGEC                                       218
```

H 鎖 Q1：ピログルタミン酸；H 鎖 N296：糖鎖結合；H 鎖 K446：部分的プロセシング
H 鎖 C134 – L 鎖 C218，H 鎖 C222 – H 鎖 C222，H 鎖 C223 – H 鎖 C223，H 鎖 C226 – H 鎖 C226，H 鎖 C229 – H 鎖 C229：ジスルフィド結合

主な糖鎖の推定構造





$C_{6488}H_{10008}N_{1744}O_{2016}S_{52}$（タンパク質部分，4 本鎖）
H 鎖　$C_{2195}H_{3373}N_{581}O_{668}S_{20}$
L 鎖　$C_{1049}H_{1637}N_{291}O_{340}S_{6}$

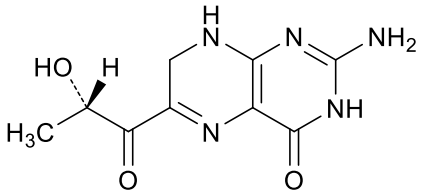
シベプレンリマブは，遺伝子組換え抗 APRIL（a proliferation-inducing ligand）モノクローナル抗体であり，その相補性決定部はマウス抗体に由来し，その他はヒト IgG2 に由来する．シベプレンリマブは，CHO 細胞により産生される．シベプレンリマブは，446 個のアミノ酸残基からなる H 鎖（γ2 鎖）2 本及び 218 個のアミノ酸残基からなる L 鎖（κ 鎖）2 本で構成される糖タンパク質（分子量：約 149,000）である．

Sibeprenlimab is a recombinant anti-APRIL (a proliferation-inducing ligand) monoclonal antibody whose complementarity-determining regions are derived from mouse antibody and other regions are derived from human IgG2. Sibeprenlimab is produced in CHO cells. Sibeprenlimab is a glycoprotein (molecular weight: ca. 149,000) composed of 2 H-chains (γ2-chains) consisting of 446 amino acid residues each and 2 L-chains (κ-chains) consisting of 218 amino acid residues each.

登録番号 305-6-B17

JAN（日本名）：セピアプテリン

JAN（英　名）：Sepiapterin



$C_9H_{11}N_5O_3$

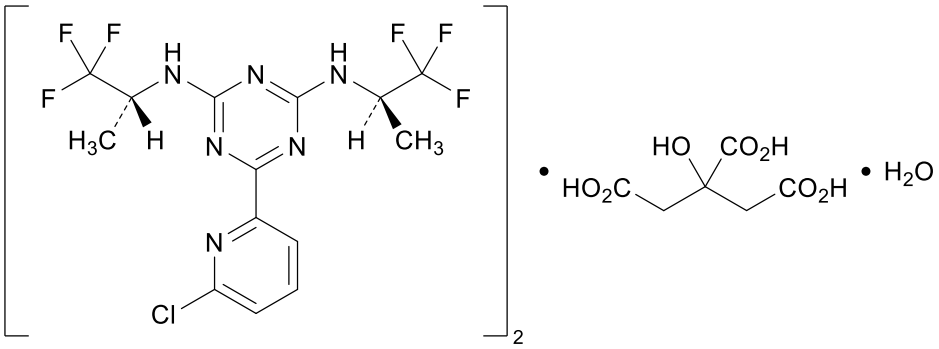
2-アミノ-6-[(2*S*)-2-ヒドロキシプロパノイル]-7,8-ジヒドロプテリジン-4(3*H*)-オン

2-Amino-6-[(2*S*)-2-hydroxypropanoyl]-7,8-dihydropteridin-4(3*H*)-one

登録番号 305-7-B1

JAN（日本名）：ボラシデニブ　クエン酸水和物

JAN（英　名）：Vorasidenib Citric Acid Hydrate



$(C_{14}H_{13}ClF_6N_6)_2 \cdot C_6H_8O_7 \cdot H_2O$

6-(6-クロロピリジン-2-イル)-*N*^{2},*N*^{4}-ビス[(2*R*)-1,1,1-トリフルオロプロパン-2-イル]-1,3,5-トリアジン-2,4-ジアミン　ヘミクエン酸　ヘミ水和物

6-(6-Chloropyridin-2-yl)-*N*^{2},*N*^{4}-bis[(2*R*)-1,1,1-trifluoropropan-2-yl]-1,3,5-triazine-2,4-diamine hemicitric acid hemihydrate

登録番号 305-7-B2

JAN（日本名）：タグラキソフスプ（遺伝子組換え）

JAN（英　名）：Tagraxofusp (Genetical Recombination)

アミノ酸配列及びジスルフィド結合



$C_{2553}H_{4022}N_{692}O_{798}S_{16}$

タグラキソフスプは，N 末端がメチオニル化された遺伝子組換え融合タンパク質であり，2～389 番目，390～391 番目及び 392～524 番目は，それぞれジフテリア毒素の 33～420 番目のアミノ酸残基，リンカー及びヒトインターロイキン-3 に相当する．タグラキソフスプは，*Escherichia coli* により産生される．タグラキソフスプは，524 個のアミノ酸残基からなるタンパク質である．

Tagraxofusp is a recombinant N-terminal methionylated fusion protein, whose amino acid residues at positions 2 – 389, 390 – 391, and 392 – 524 correspond to amino acid residues at positions 33 – 420 of diphtheria toxin, a linker, and human interleukin-3, respectively. Tagraxofusp is produced in *Escherichia coli*. Tagraxofusp is a protein consisting of 524 amino acid residues.

登録番号 305-7-B4

JAN（日本名）：レチファンリマブ（遺伝子組換え）

JAN（英　名）：Retifanlimab (Genetical Recombination)

アミノ酸配列及びジスルフィド結合

H 鎖

```
QVQLVQSGAE VKKPGASVKV SCKASGYSFT SYWMNWVRQA PGQGLEWIGV   50
IHPSDSETWL DQKFKDRVTI TVDKSTSTAY MELSSLRSED TAVYYCAREH  100
YGTSPFAYWG QGTLVTVSSA STKGPSVFPL APCSRSTSES TAALGCLVKD  150
YFPEPVTVSW NSGALTSGVH TFPAVLQSSG LYSLSSVVTV PSSSLGTKTY  200
TCNVDHKPSN TKVDKRVESK YGPPCPPCPA PEFLGGPSVF LFPPKPKDTL  250
MISRTPEVTC VVVDVSQEDP EVQFNWYVDG VEVHNAKTKP REEQFNSTYR  300
VVSVLTVLHQ DWLNGKEYKC KVSNKGLPSS IEKTISKAKG QPREPQVYTL  350
PPSQEEMTKN QVSLTCLVKG FYPSDIAVEW ESNGQPENNY KTTPPVLDSD  400
GSFFLYSRLT VDKSRWQEGN VFSCSVMHEA LHNHYTQKSL SLSLG       445
```

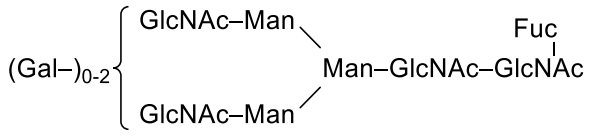
L 鎖

```
EIVLTQSPAT LSLSPGERAT LSCRASESVD NYGMSFMNWF QQKPGQPPKL   50
LIHAASNQGS GVPSRFSGSG SGTDFTLTIS SLEPEDFAVY FCQQSKEVPY  100
TFGGGTKVEI KRTVAAPSVF IFPPSDEQLK SGTASVVCLL NNFYPREAKV  150
QWKVDNALQS GNSQESVTEQ DSKDSTYSLS STLTLSKADY EKHKVYACEV  200
THQGLSSPVT KSFNRGEC                                     218
```

H 鎖 Q1：部分的ピログルタミン酸；H 鎖 N296：糖鎖結合

H 鎖 C133 – L 鎖 C218，H 鎖 C225 – H 鎖 C225，H 鎖 C228 – H 鎖 C228：ジスルフィド結合

主な糖鎖の推定構造



$C_{6456}H_{9934}N_{1702}O_{2032}S_{46}$（タンパク質部分，4 本鎖）

H 鎖　$C_{2188}H_{3361}N_{573}O_{677}S_{16}$

L 鎖　$C_{1040}H_{1610}N_{278}O_{339}S_{7}$

レチファンリマブは，遺伝子組換え抗 PD-1 モノクローナル抗体であり，その相補性決定部はマウス抗体に由来し，その他はヒト IgG4 に由来する．H 鎖の 1 つのアミノ酸残基が置換（S227P）され，C 末端の K446

は除去されている．レチファンリマブは，CHO 細胞により産生される．レチファンリマブは，445 個のアミノ酸残基からなる H 鎖（γ4 鎖）2 本及び 218 個のアミノ酸残基からなる L 鎖（κ 鎖）2 本で構成される糖タンパク質（分子量：約 148,000）である．

Retifanlimab is a recombinant anti-PD-1 monoclonal antibody whose complementarity-determining regions are derived from mouse antibody and other regions are derived from human IgG4. In the H-chain, the amino acid residue is substituted at 1 position (S227P), and K446 at the C-terminus is deleted. Retifanlimab is produced in CHO cells. Retifanlimab is a glycoprotein (molecular weight: ca. 148,000) composed of 2 H-chains (γ4-chains) consisting of 445 amino acid residues each and 2 L-chains (κ-chains) consisting of 218 amino acid residues each.

※　JAN 以外の情報は、参考として掲載しました。

International Nonproprietary Names for Pharmaceutical Substances (INN)

RECOMMENDED International Nonproprietary Names: List 79

Notice is hereby given that, in accordance with paragraph 7 of the Procedure for the Selection of Recommended International Nonproprietary Names for Pharmaceutical Substances [*Off. Rec. Wld Health Org.*, 1955, **60**, 3 (Resolution EB15.R7); 1969, **173**, 10 (Resolution EB43.R9); Resolution EB115.R4 (EB115/2005/REC/1)], the following names are selected as Recommended International Nonproprietary Names. The inclusion of a name in the lists of Recommended International Nonproprietary Names does not imply any recommendation of the use of the substance in medicine or pharmacy.
Lists of Proposed (1–117) and Recommended (1–78) International Nonproprietary Names can be found in *Cumulative List No. 17, 2017* (available in CD-ROM only).

Dénominations communes internationales des Substances pharmaceutiques (DCI)

Dénominations communes internationales RECOMMANDÉES: Liste 79

Il est notifié que, conformément aux dispositions du paragraphe 7 de la Procédure à suivre en vue du choix de Dénominations communes internationales recommandées pour les Substances pharmaceutiques [*Actes off. Org. mond. Santé*, 1955, **60**, 3 (résolution EB15.R7); 1969, **173**, 10 (résolution EB43.R9); résolution EB115.R4 (EB115/2005/REC/1)] les dénominations ci-dessous sont choisies par l'Organisation mondiale de la Santé en tant que dénominations communes internationales recommandées. L'inclusion d'une dénomination dans les listes de DCI recommandées n'implique aucune recommandation en vue de l'utilisation de la substance correspondante en médecine ou en pharmacie.
On trouvera d'autres listes de Dénominations communes internationales proposées (1–117) et recommandées (1–78) dans la *Liste récapitulative No. 17, 2017* (disponible sur CD-ROM seulement).

Denominaciones Comunes Internacionales para las Sustancias Farmacéuticas (DCI)

Denominaciones Comunes Internacionales RECOMENDADAS: Lista 79

De conformidad con lo que dispone el párrafo 7 del Procedimiento de Selección de Denominaciones Comunes Internacionales Recomendadas para las Sustancias Farmacéuticas [*Act. Of. Mund. Salud*, 1955, **60**, 3 (Resolución EB15.R7); 1969, **173**, 10 (Resolución EB43.R9); Résolution EB115.R4 (EB115/2005/REC/1) EB115.R4 (EB115/2005/REC/1)], se comunica por el presente anuncio que las denominaciones que a continuación se expresan han sido seleccionadas como Denominaciones Comunes Internacionales Recomendadas. La inclusión de una denominación en las listas de las Denominaciones Comunes Recomendadas no supone recomendación alguna en favor del empleo de la sustancia respectiva en medicina o en farmacia.
Las listas de Denominaciones Comunes Internacionales Propuestas (1–117) y Recomendadas (1–78) se encuentran reunidas en *Cumulative List No. 17, 2017* (disponible sólo en CD-ROM).

Latin, English, French, Spanish: *Recommended INN* *DCI Recommandée* *DCI Recomendada*	*Chemical name or description; Molecular formula; Graphic formula* *Nom chimique ou description; Formule brute; Formule développée* *Nombre químico o descripción; Fórmula molecular; Fórmula desarrollada*

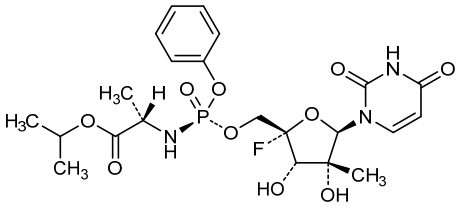
adafosbuvirum

adafosbuvir — propan-2-yl *N*-[(*P*$^{5'}$*S*)-4'-fluoro-2'-*C*-methyl-*P*-*O*-phenyl-5'-uridylyl]-L-alaninate

adafosbuvir — *N*-[(*P*$^{5'}$*S*)-4'-fluoro-2'-*C*-méthyl-*P*-*O*-phényl-5'-uridylyl]-L-alaninate de propan-2-yle

adafosbuvir — *N*-[(*P*$^{5'}$*S*)-4'-fluoro-2'-*C*-metil-*P*-*O*-fenil-5'-uridilil]-L-alaninato de propan-2-ilo

$C_{22}H_{29}FN_3O_{10}P$



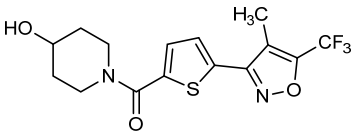
adarigilinum

adarigiline — (4-hydroxypiperidin-1-yl){5-[4-methyl-5-(trifluoromethyl)-1,2-oxazol-3-yl]thiophen-2-yl}methanone

adarigiline — (4-hydroxypipéridin-1-yl){5-[4-méthyl-5-(trifluorométhyl)-1,2-oxazol-3-yl]thiophén-2-yl}methanone

adarigilina — (4-hidroxipiperidin-1-il){5-[4-metil-5-(trifluoromethil)-1,2-oxazol-3-il]tiofeno-2-il}metanona

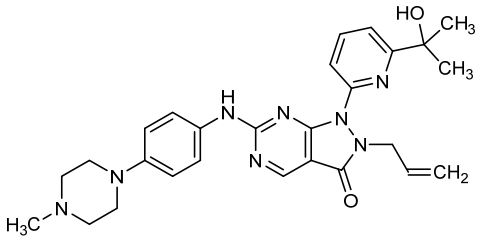
$C_{15}H_{15}F_3N_2O_3S$



adavosertibum

adavosertib	1-[6-(2-hydroxypropan-2-yl)pyridin-2-yl]-6-[4-(4-methylpiperazin-1-yl)anilino]-2-(prop-2-en-1-yl)-1,2-dihydro-3*H*-pyrazolo[3,4-*d*]pyrimidin-3-one
adavosertib	1-[6-(2-hydroxypropan-2-yl)pyridin-2-yl]-6-[4-(4-méthylpipérazin-1-yl)anilino]-2-(prop-2-én-1-yl)-1,2-dihydro-3*H*-pyrazolo[3,4-*d*]pyrimidin-3-one
adavosertib	1-[6-(2-hidroxipropan-2-il)piridin-2-il]-6-[4-(4-metilpiperazin-1-il)anilino]-2-(prop-2-en-1-il)-1,2-dihidro-3*H*-pirazolo[3,4-*d*]pirimidin-3-ona

$C_{27}H_{32}N_8O_2$



adimlecleucelum

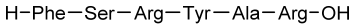
adimlecleucel	Human culture enriched allogenic Cytomegalovirus-specific cytotoxic T cells (CMV-CTL) for cell-based therapy. Cells are isolated from blood of CMV seropositive healthy human donors. CMV-CTLs exhibit human leukocyte antigen (HLA)-restricted cytotoxic activity against CMV+ cells in allogeneic hematopoietic cell or solid organ transplant patients with CMV infection.
adimlecleucel	Lymphocytes T cytotoxiques spécifiques du cytomégalovirus (CMV-CTL), allogéniques, humains, enrichis en culture pour thérapie cellulaire. Les cellules sont isolées à partir du sang de donneurs humains sains séropositifs au CMV. Les CMV-CTL montrent une activité cytotoxique restreinte à l'antigène leucocytaire humain (HLA) contre les cellules CMV+ chez des patients transplantés avec des cellules hématopoïétiques allogéniques ou avec un organe solide, et souffrants d'une infection à CMV.
adimlecleucel	Linfocitos T citotóxicos específicos del virus de Citomegalovirus (CMV-CTL), alogénicos, humanos, enriquecidos en cultivo para terapia celular. Las células están asiladas a partir de sangre de donantes humanos sanos seropositivo para CMV. Los CMV-CTLs muestran actividad citotóxica restringida por HLA contra células CMV+ en pacientes trasplantados con células hematopoyéticas alogénicas u órgano sólido con infección por CMV.

alirinetidum
alirinetide — L-phenylalanyl-L-seryl-L-arginyl-L-tyrosyl-L-alanyl-L-arginine

alirinétide — L-phénylalanyl-L-séryl-L-arginyl-L-tyrosyl-L-alanyl-L-arginine

alirinetida — L-fenilalanil-L-seril-L-arginil-L-tirosil-L-alanil-L-arginina

$C_{36}H_{54}N_{12}O_9$

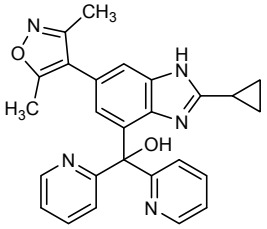


alobresibum
alobresib — [2-cyclopropyl-6-(3,5-dimethyl-1,2-oxazol-4-yl)-1*H*-benzimidazol-4-yl]di(pyridin-2-yl)methanol

alobrésib — [2-cyclopropyl-6-(3,5-diméthyl-1,2-oxazol-4-yl)-1*H*-benzimidazol-4-yl]di(pyridin-2-yl)méthanol

alobresib — [2-ciclopropil-6-(3,5-dimetil-1,2-oxazol-4-il)-1*H*-benzimidazol-4-il]di(piridin-2-il)metanol

$C_{26}H_{23}N_5O_2$

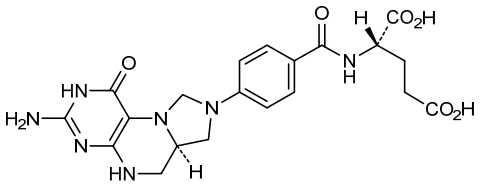


arfolitixorinum
arfolitixorin — *N*-{4-[(6a*R*)-3-amino-1-oxo-1,2,5,6,6a,7-hexahydroimidazo[1,5-*f*]pteridin-8(9*H*)-yl]benzoyl}-L-glutamic acid

arfolitixorine — acide *N*-{4-[(6a*R*)-3-amino-1-oxo-1,2,5,6,6a,7-hexahydroimidazo[1,5-*f*]ptéridin-8(9*H*)-yl]benzoyl}-L-glutamique

arfolitixorina — ácido *N*-{4-[(6a*R*)-3-amino-1-oxo-1,2,5,6,6a,7-hexahidroimidazo[1,5-*f*]pteridin-8(9*H*)-il]benzoil}-L-glutámico

$C_{20}H_{23}N_7O_6$



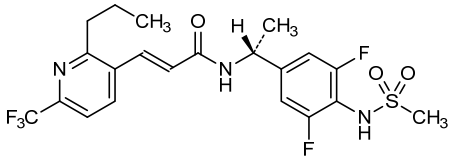
asivatrepum

asivatrep — (2*E*)-*N*-{(1*R*)-1-[3,5-difluoro-4-(methanesulfonamido)phenyl]ethyl}-3-[2-propyl-6-(trifluoromethyl)pyridin-3-yl]prop-2-enamide

asivatrep — (2*E*)-*N*-{(1*R*)-1-[3,5-difluoro-4-(méthanesulfonamido)phényl]éthyl}-3-[2-propyl-6-(trifluorométhyl)pyridin-3-yl]prop-2-énamide

asivatrep — (2*E*)-*N*-{(1*R*)-1-[3,5-difluoro-4-(metanosulfonamido)fenil]etil}-3-[2-propil-6-(trifluorometil)piridin-3-il]prop-2-enamida

$C_{21}H_{22}F_5N_3O_3S$



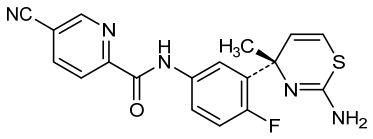
atabecestatum

atabecestat — *N*-{3-[(4*S*)-2-amino-4-methyl-4*H*-1,3-thiazin-4-yl]-4-fluorophenyl}-5-cyanopyridine-2-carboxamide

atabécestat — *N*-{3-[(4*S*)-2-amino-4-méthyl-4*H*-1,3-thiazin-4-yl]-4-fluorophényl}-5-cyanopyridine-2-carboxamide

atabecestat — *N*-{3-[(4*S*)-2-amino-4-metil-4*H*-1,3-tiazin-4-il]-4-fluorofenil}-5-cianopiridina-2-carboxamida

$C_{18}H_{14}FN_5OS$



atidortoxumabum #

atidortoxumab — immunoglobulin G1-kappa, anti-[*Staphylococcus aureus* alpha toxin (AT, alpha-hemolysin, alpha-HL, hly, hla) and bi-component leukocidins (HlgAB, HlgCB, LukED, and LukSF (Panton-Valentine leukocidin, PVL)], *Homo sapiens* monoclonal antibody;
gamma1 heavy chain (1-448) [*Homo sapiens* VH (IGHV4-38-2*01 (92.90%) -(IGHD) -IGHJ6*03) [9.7.12] (1-119) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (216) (120-217), hinge (218-232), CH2 (233-342), CH3 D12 (358), L14 (360) (343-447), CHS K2>del (448)) (120-448)], (222-214')-disulfide with kappa light chain (1'-214') [*Homo sapiens* V-KAPPA (IGKV1-12*01 (95.80%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (228-228":231-231")-bisdisulfide

atidortoxumab

immunoglobuline G1-kappa, anti-[*Staphylococcus aureus* toxine alpha (AT, hémolysine alpha, HL-alpha, hly, hla) et leucocidines à deux composants (HlgAB, HlgCB, LukED, LukSF (leucocidine de Panton-Valentine, PVL)], *Homo sapiens* anticorps monoclonal;
chaîne lourde gamma1 (1-448) [*Homo sapiens* VH (IGHV4-38-2*01 (92.90%) -(IGHD) -IGHJ6*03) [9.7.12] (1-119) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (216) (120-217), charnière (218-232), CH2 (233-342), CH3 D12 (358), L14 (360) (343-447), CHS K2>del (448)) (120-448)], (222-214')-disulfure avec la chaîne légère (1'-214') [*Homo sapiens* V-KAPPA (IGKV1-12*01 (95.80%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (228-228":231-231")-bisdisulfure

atidortoxumab

inmunoglobulina G1-kappa, anti-[*Staphylococcus aureus* toxina alfa (AT, hemolisina alfa, HL-alfa, hly, hla) y leucocidinas con dos componentes (HlgAB, HlgCB, LukED, LukSF (Panton-Valentine leukocidina, PVL)], *Homo sapiens* anticuerpo monoclonal;
cadena pesada gamma1 (1-448) [*Homo sapiens* VH (IGHV4-38-2*01 (92.90%) -(IGHD) -IGHJ6*03) [9.7.12] (1-119) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (216) (120-217), bisagra (218-232), CH2 (233-342), CH3 D12 (358), L14 (360) (343-447), CHS K2>del (448)) (120-448)], (222-214')-disulfuro con la cadena ligera (1'-214') [*Homo sapiens* V-KAPPA (IGKV1-12*01 (95.80%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (228-228":231-231")-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLQESGPG LVRPSETLSL TCAVSGYSIS SGMGWGWIRQ PPGKGLEWIG  50
SIDQRGSTYY NPSLKSRVTI SVDTSKNQFS LKLSSVTAAD TAVYYCARDA 100
GHAVDMDVWG KGTTVTVSSA STKGPSVFPL APSSKSTSGG TAALGCLVKD 150
YFPEPVTVSW NSGALTSGVH TFPAVLQSSG LYSLSSVVTV PSSSLGTQTY 200
ICNVNHKPSN TKVDKKVEPK SCDKTHTCPP CPAPELLGGP SVFLFPPKPK 250
DTLMISRTPE VTCVVVDVSH EDPEVKFNWY VDGVEVHNAK TKPREEQYNS 300
TYRVVSVLTV LHQDWLNGKE YKCKVSNKAL PAPIEKTISK AKGQPREPQV 350
YTLPPSRDEL TKNQVSLTCL VKGFYPSDIA VEWESNGQPE NNYKTTPPVL 400
DSDGSFFLYS KLTVDKSRWQ QGNVFSCSVM HEALHNHYTQ KSLSLSPG   448
```

Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS VSASVGDRVT ITCRASQGIS RWLAWYQQKP GKAPKLLIYA  50
ASSLQSGVPS RFSGSGSGTD FTLTISSLQP EDFATYYCQQ GYVFPLTFGG 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 146-202 263-323 369-427
22"-96" 146"-202" 263"-323" 369"-427"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (h 5-CL 126) 222-214' 222"-214'"
Inter-H-H (h 11, h 14) 228-228" 231-231"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
299, 299"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados
G0F 46%, G1F 39.9%

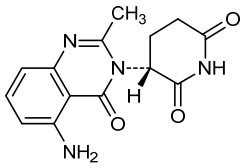
avadomidum

avadomide — *rac*-(3*R*)-3-(5-amino-2-methyl-4-oxoquinazolin-3(4*H*)-yl)piperidine-2,6-dione

avadomide — *rac*-(3*R*)-3-(5-amino-2-méthyl-4-oxoquinazolin-3(4*H*)-yl)pipéridine-2,6-dione

avadomida — *rac*-(3*R*)-3-(5-amino-2-metil-4-oxoquinazolin-3(4*H*)-il)piperidina-2,6-diona

$C_{14}H_{14}N_4O_3$



and enantiomer
et énantiomère
y enantiómero

avalglucosidasum alfa #

avalglucosidase alfa — mutated human acid α-glucosidase produced in Chinese hamster ovary (CHO) cells, glycoform alfa, conjugated to a synthetic branched hexasaccharide containing two terminal mannose-6-phosphate (M6P), via aminooxy linkers;

[His^{143}>Arg,Arg^{167}>His,Val^{724}>Ile]prepro-lysosomal α-glucosidase (EC=3.2.1.20) (human) (57-952)-peptide, expressed in CHO cells, glycoform alfa, with 5~9 sialyl end groups of glycan residues being oxidized and chemically modified to 5-acetamido-3,5,7-trideoxy-7-[(*E*)-(2-oxo-2-{2-[4-({*O*-(6-*O*-phosphono-α-D-mannopyranosyl)-(1→2)-*O*-α-D-mannopyranosyl-(1→6)-*O*-α-D-mannopyranosyl-(1→6)-*O*-[*O*-(6-*O*-phosphono-α-D-mannopyranosyl)-(1→2)-*O*-α-D-mannopyranosyl-(1→3)]-β-D-mannopyranosyl}oxy)butanoyl]hydrazinyl}ethoxy)imino]-β-L-*arabino*-2-heptulo-2,6-pyranosylonic acid groups

avalglucosidase alfa — α-glucosidase acide humaine modifiée, produite dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa, liée à un hexasaccharide de synthèse dont les résidus terminaux sont deux mannose-6-phosphates via un groupe aminoxy;

[His^{143}>Arg,Arg^{167}>His,Val^{724}>Ile]prépro-α-glucosidase lysosomale (EC=3.2.1.20) (humaine) (57-952)-peptide, exprimé dans des cellules CHO, glycoforme alfa: 5~9 résidus sialyl terminaux sont oxidés et chimiquement modifiés en acide 5-acétamido-3,5,7-tridésoxy-7-[(*E*)-(2-oxo-2-{2-[4-({*O*-(6-*O*-phosphono-α-D-mannopyranosyl)-(1→2)-*O*-α-D-mannopyranosyl-(1→6)-*O*-α-D-mannopyranosyl-(1→6)-*O*-[*O*-(6-*O*-phosphono-α-D-mannopyranosyl)-(1→2)-*O*-α-D-mannopyranosyl-(1→3)]-β-D-mannopyranosyl}oxy)butanoyl]hydrazinyl}éthoxy)imino]-β-L-*arabino*-2-heptulo-2,6-pyranosylonique

avalglucosidasa alfa

α-glucosidasa ácida humana modificada, producida en las células ováricas de hamster chino (CHO), glicoforma alfa, conjugada con un glicano hexasacarídico sintético que contiene dos manosa-6-fosfatos (M6Ps) terminales, vía un grupo aminoxi;

[His^{143}>Arg,Arg^{167}>His,Val^{724}>Ile]prepro-α-glucosidasa lisosomal (EC=3.2.1.20) (humana) (57-952)-péptido, expresada en las células CHO, glicoforma alfa: con los 5~9 restos sialil terminales están oxidados y químicamente modificados en ácido 5-acetamido-3,5,7-tridesoxi-7-[(*E*)-(2-oxo-2-{2-[4-({*O*-(6-*O*-fosfono-α-D-manopiranosil)-(1→2)-*O*-α-D-manopiranosil-(1→6)-*O*-α-D-manopiranosil-(1→6)-*O*-[*O*-(6-*O*-fosfono-α-D-manopiranosil)-(1→2)-*O*-α-D-manopiranosil-(1→3)]-β-D-manopiranosil}oxi)butanoil]hidrazinil}etoxi)imino]-β-L-*arabino*-2-heptulo-2,6-piranosilónico

Sequence / Séquence / Secuencia

```
QQGASRPGPR DAQAHPGRPR AVPTQCDVPP NSRFDCAPDK AITQEQCEAR  50
GCCYIPAKQG LQGAQMGQPW CFFPPSYPSY KLENLSSSEM GYTATLTRTT 100
PTFFPKDILT LRLDVMMETE NRLHFTIKDP ANRRYEVPLE TPRVHSRAPS 150
PLYSVEFSEE PFGVIVHRQL DGRVLLNTTV APLFFADQFL QLSTSLPSQY 200
ITGLAEHLSP LMLSTSWTRI TLWNRDLAPT PGANLYGSHP FYLALEDGGS 250
AHGVFLLNSN AMDVVLQPSP ALSWRSTGGI LDVYIFLGPE PKSVVQQYLD 300
VVGYPFMPPY WGLGFHLCRW GYSSTAITRQ VVENMTRAHF PLDVQWNDLD 350
YMDSRRDFTF NKDGFRDFPA MVQELHQGGR RYMMIVDPAI SSSGPAGSYR 400
PYDEGLRRGV FITNETGQPL IGKVWPGSTA FPDFTNPTAL AWWEDMVAEF 450
HDQVPFDGMW IDMNEPSNFI RGSEDGCPNN ELENPPYVPG VVGGTLQAAT 500
ICASSHQFLS THYNLHNLYG LTEAIASHRA LVKARGTRPF VISRSTFAGH 550
GRYAGHWTGD VWSSWEQLAS SVPEILQFNL LGVPLVGADV CGFLGNTSEE 600
LCVRWTQLGA FYPFMRNHNS LLSLPQEPYS FSEPAQQAMR KALTLRYALL 650
PHLYTLFHQA HVAGETVARP LFLEFPKDSS TWTVDHQLLW GEALLITPVL 700
QAGKAEVTGY FPLGTWYDLQ TVPIEALGSL PPPPAAPREP AIHSEGQWVT 750
LPAPLDTINV HLRAGYIIPL QGPGLTTTES RQQPMALAVA LTKGGEARGE 800
LFWDDGESLE VLERGAYTQV IFLARNNTIV NELVRVTSEG AGLQLQKVTV 850
LGVATAPQQV LSNGVPVSNF TYSPDTKVLD ICVSLLMGEQ FLVSWC     896
```

Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
26-53 36-52 47-71 477-502 591-602 882-896

Glycosylation sites (N) / Sites de glycosylation (N) / Posiciones de glicosilación (N)
Asn-84 Asn-177 Asn-334 Asn-414 Asn-596 Asn-826 Asn-869

Methionine S-oxide / S-Oxyde de méthionine / S-Óxido de metionina (~50 %)
Met-66 Met-90 Met-116 Met-117

avapritinibum

avapritinib

(1*S*)-1-(4-fluorophenyl)-1-(2-{4-[6-(1-methyl-1*H*-pyrazol-4-yl)pyrrolo[2,1-*f*][1,2,4]triazin-4-yl]piperazin-1-yl}pyrimidin-5-yl)ethan-1-amine

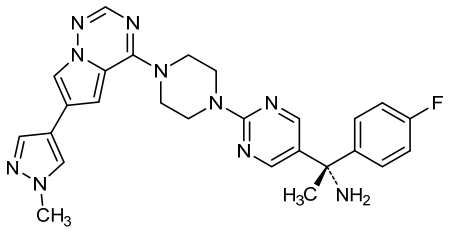
avapritinib

(1*S*)-1-(4-fluorophényl)-1-(2-{4-[6-(1-méthyl-1*H*-pyrazol-4-yl)pyrrolo[2,1-*f*][1,2,4]triazin-4-yl]pipérazin-1-yl}pyrimidin-5-yl)éthan-1-amine

avapritinib

(1*S*)-1-(4-fluorofenil)-1-(2-{4-[6-(1-metil-1*H*-pirazol-4-il)pirrolo[2,1-*f*][1,2,4]triazin-4-il]piperazin-1-il}pirimidin-5-il)etan-1-amina

$C_{26}H_{27}FN_{10}$



axicabtagenum ciloleucelum #

axicabtagene ciloleucel

human culture expanded genetically modified autologous T cells for cell-based gene therapy. Cells are derived from isolated blood of the patient and are transduced with non-replicative retroviral vector encoding the FMC63 anti-CD19 single chain variable fragment (scFv) CD28/CD3zeta chimeric antigen receptor (FMC63-28Z CAR). Cells exhibit anti-tumoral activity in patients with CD19-expressing B cell malignancies.

axicabtagène ciloleucel

Lymphocytes T humains autologues en culture d'expansion et modifiés génétiquement pour thérapie génique avec cellules. Les cellules sont dérivées du sang prélévé chez le patient et sont transduites avec un vecteur rétroviral non-répliquant codant pour le récepteur de l'antigène chimérique FMC63 anti-CD-19 fragment de la chaîne simple de la région variable de l'anticorps (scFv) CD28/CD3zêta (FMC63-28Z CAR). Les cellules montrent une activité anti-tumorale chez les patients présentant des lymphocytes B malins exprimant le CD19.

axicabtagén ciloleucel

Linfocitos T autólogos, humanos, expandidos en cultivo y modificados genéticamente, para terapia génica con células. Las células se derivan a partir de sangre aislada del paciente y están transducidas con un vector retroviral no replicativo que codifica para el receptor de antígenos quimérico FMC63 anti-CD19 fragmento de cadena simple de la región variable del anticuerpo (scFv) CD28/CD3zeta (FMC63-28Z CAR). Las células muestran actividad anti-tumoral en pacientes con malignidades de linfocitos B que expresan CD19.

beinaglutidum

beinaglutide

human glucagon-like peptide-1 (7-36)-peptide (GLP-1-(7-36))

béinaglutide

peptide 1 semblable au glucagon humain (7-36) (GLP-1-(7-36))

beinaglutida

péptido tipo 1 similar al glucagón humano (7-36) (GLP-1-(7-36))

$C_{149}H_{225}N_{39}O_{46}$

HAEGTFTSDV SSYLEGQAAK EFIAWLVKGR 30

bemarituzumabum #

bemarituzumab	immunoglobulin G1-kappa, anti-[*Homo sapiens* FGFR2 (fibroblast growth factor receptor 2, keratinocyte growth factor receptor, KGFR, bacteria-expressed kinase, BEK, craniofacial dysostosis I, CFDI, Jackson-Weiss syndrome, JWS, CD332) isoform b (FGFR2b)], humanized monoclonal antibody; gamma1 heavy chain (1-444) [humanized VH (*Homo sapiens* IGHV1-46*01 (80.60%) -(IGHD) -IGHJ4*01) [8.8.7] (1-114) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (211) (115-212), hinge (213-227), CH2 (228-337), CH3 E12 (353), M14 (355) (338-442), CHS (443-444)) (115-444)], (217-214')-disulfide with kappa light chain (1'-214') [humanized V-KAPPA (*Homo sapiens* IGKV1-33*01 (85.30%) -IGKJ2*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (223-223'':226-226'')-bisdisulfide
bémarituzumab	immunoglobuline G1-kappa, anti-[*Homo sapiens* FGFR2 (récepteur 2 du facteur de croissance des fibroblastes, récepteur du facteur de croissance des kératinocytes, KGFR, kinase exprimée dans des bactéries, BEK, dysostose craniofaciale I, CFDI, syndrome de Jackson-Weiss, JWS, CD332) isoforme b (FGFR2b)], anticorps monoclonal humanisé; chaîne lourde gamma1 (1-444) [VH humanisé (*Homo sapiens* IGHV1-46*01 (80.60%) -(IGHD) -IGHJ4*01) [8.8.7] (1-114) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (211) (115-212), charnière (213-227), CH2 (228-337), CH3 E12 (353), M14 (355) (338-442), CHS (443-444)) (115-444)], (217-214')-disulfure avec la chaîne légère (1'-214') [V-KAPPA humanisé (*Homo sapiens* IGKV1-33*01 (85.30%) -IGKJ2*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (223-223'':226-226'')-bisdisulfure
bemarituzumab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* FGFR2 (receptor 2 del factor de crecimiento de fibroblastos, receptor del factor de crecimiento de keratinocitos, KGFR, kinasa expresada en bacterias, BEK, disostosa craneofacial I, CFDI, síndrome de Jackson-Weiss, JWS, CD332) isoforma b (FGFR2b)], anticuerpo monoclonal humanizado; cadena pesada gamma1 (1-444) [VH humanizado (*Homo sapiens* IGHV1-46*01 (80.60%) -(IGHD) -IGHJ4*01) [8.8.7] (1-114) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (211) (115-212), bisagra (213-227), CH2 (228-337), CH3 E12 (353), M14 (355) (338-442), CHS (443-444)) (115-444)], (217-214')-disulfuro con la cadena ligera (1'-214') [V-KAPPA humanizado (*Homo sapiens* IGKV1-33*01 (85.30%) -IGKJ2*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (223-223'':226-226'')-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGSSVKV SCKASGYIFT TYNVHWVRQA PGQGLEWIGS  50
IYPDNGDTSY NQNFKGRATI TADKSTSTAY MELSSLRSED TAVYYCARGD 100
FAYWGQGTLV TVSSASTKGP SVFPLAPSSK STSGGTAALG CLVKDYFPEP 150
VTVSWNSGAL TSGVHTFPAV LQSSGLYSLS SVVTVPSSSL GTQTYICNVN 200
HKPSNTKVDK RVEPKSCDKT HTCPPCPAPE LLGGPSVFLF PPKPKDTLMI 250
SRTPEVTCVV VDVSHEDPEV KFNWYVDGVE VHNAKTKPRE EQYNSTYRVV 300
SVLTVLHQDW LNGKEYKCKV SNKALPAPIE KTISKAKGQP REPQVYTLPP 350
SREEMTKNQV SLTCLVKGFY PSDIAVEWES NGQPENNYKT TPPVLDSDGS 400
FFLYSKLTVD KSRWQQGNVF SCSVMHEALH NHYTQKSLSL SPGK       444
```

Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS LSASVGDRVT ITCKASQGVS NDVAWYQQKP GKAPKLLIYS  50
ASYRYTGVPS RFSGSGSGTD FTFTISSLQP EDIATYYCQQ HSTTPYTFGQ 100
GTKLEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 141-197 258-318 364-422
22"-96" 141"-197" 258"-318" 364"-422"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (h 5-CL 126) 217-214' 217"-214'"
Inter-H-H (h 11, h 14) 223-223" 226-226"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
294, 294"
Afucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes afucosylés / glicanos de tipo CHO biantenarios complejos afucosilados

bemcentinibum
bemcentinib

1-(6,7-dihydro-5*H*-benzo[6,7]cyclohepta[1,2-*c*]pyridazin-3-yl)-N^3-[(7*S*)-7-(pyrrolidin-1-yl)-6,7,8,9-tetrahydro-5*H*-benzo[7]annulen-2-yl]-1*H*-1,2,4-triazole-3,5-diamine

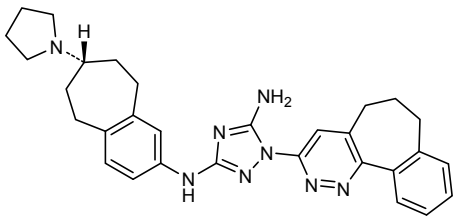
bemcentinib

1-(6,7-dihydro-5*H*-benzo[6,7]cyclohepta[1,2-*c*]pyridazin-3-yl)-N^3-[(7*S*)-7-(pyrrolidin-1-yl)-6,7,8,9-tétrahydro-5*H*-benzo[7]annulén-2-yl]-1*H*-1,2,4-triazole-3,5-diamine

bemcentinib

1-(6,7-dihidro-5*H*-benzo[6,7]ciclohepta[1,2-*c*]piridazin-3-il)-N^3-[(7*S*)-7-(pirrolidin-1-il)-6,7,8,9-tetrahidro-5*H*-benzo[7]anulen-2-il]-1*H*-1,2,4-triazol-3,5-diamina

$C_{30}H_{34}N_8$



berdazimerum natricum
berdazimer sodium

polysodium poly[{[3-(methylamino)propyl]silasesquioxane}-*co*-{[3-(1-methyl-2-nitroso-2-oxidohydrazin-1-yl)propyl]silasesquioxane}-*co*-silicate (1:3:6 x)], partially hydrolysed (Si : OH ~ 10 : 5)

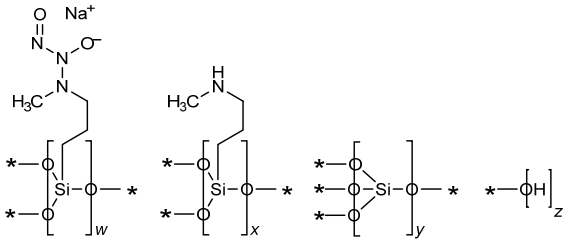
berdazimère sodique

poly[{[3-(méthylamino)propyl]silasesquioxane}-*co*-{[3-(1-méthyl-2-nitroso-2-oxidohydrazin-1-yl)propyl]silasesquioxane}-*co*-silicate (1:3:6 x)] polysodique, partiellement hydrolysé (Si : OH ~ 10 : 5)

berdazímero de sodio

poli[{[3-(metilamino)propil]silasesquioxano}-*co*-{[3-(1-metil-2-nitroso-2-oxidohidrazin-1-il)propil]silasesquioxano}-*co*-silicato (1:3:6 x)] polisódico, parcialmente hidrolizado (Si : OH ~ 10 : 5)

$[(C_4\ H_9\ N_3\ Na\ O_{3.5}\ Si)_3\ (C_4\ H_{10}\ N\ O_{1.5}\ Si)\ (Si\ O_2)_6\ (H\ O_{0.5})_5]_{0.1n}$



w : *x* : *y* : *z* = 3 : 1 :6 : ~5

berlimatoxumabum #

berlimatoxumab

immunoglobulin G1-kappa, anti-[*Staphylococcus aureus* LukGH (LukAB) bi-component leukocidin], *Homo sapiens* monoclonal antibody;
gamma1 heavy chain (1-448) [*Homo sapiens* VH (IGHV4-39*01 (94.90%) -(IGHD) -IGHJ6*04) [10.7.11] (1-119) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (216) (120-217), hinge (218-232), CH2 (233-342), CH3 D12 (358), L14 (360) (343-447), CHS K2>del (448)) (120-448)], (222-214')-disulfide with kappa light chain (1'-214') [*Homo sapiens* V-KAPPA (IGKV1-39*01 (94.70%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (228-228":231-231")-bisdisulfide

berlimatoxumab

immunoglobuline G1-kappa, anti-[*Staphylococcus aureus* LukGH (Luk AB) leucocidine à deux composants], *Homo sapiens* anticorps monoclonal;
chaîne lourde gamma1 (1-448) [*Homo sapiens* VH (IGHV4-39*01 (94.90%) -(IGHD) -IGHJ6*04) [10.7.11] (1-119) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (216) (CH1 (120-217), charnière (218-232), CH2 (233-342), CH3 D12 (358), L14 (360) (343-447), CHS K2>del (448)) (120-448)], (222-214')-disulfure avec la chaîne légère (1'-214') [*Homo sapiens* V-KAPPA (IGKV1-39*01 (94.70%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (228-228":231-231")-bisdisulfure

berlimatoxumab

inmunoglobulina G1-kappa, anti-[*Staphylococcus aureus* LukGH (Luk AB) leucocidina con dos componentes], *Homo sapiens* anticuerpo monoclonal;
cadena pesada gamma1 (1-448) [*Homo sapiens* VH (IGHV4-39*01 (94.90%) -(IGHD) -IGHJ6*04) [10.7.11] (1-119) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (216) (CH1 (120-217), bisagra(218-232), CH2 (233-342), CH3 D12 (358), L14 (360) (343-447), CHS K2>del (448)) (120-448)], (222-214')-disulfuro con la cadena ligera (1'-214') [*Homo sapiens* V-KAPPA (IGKV1-39*01 (94.70%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (228-228":231-231")-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
ELQLQESGPG LVKPSETLSL TCTVSGGSIS SGSYYWDWIR QPPGKGLEWI  50
GNIYKSGSTY YNPSLKSRVT ISVDTSKNQF SLKLSSVTAA DTAVYYCARE 100
RGMHYMDVWG KGTTVTVSSA STKGPSVFPL APSSKSTSGG TAALGCLVKD 150
YFPEPVTVSW NSGALTSGVH TFPAVLQSSG LYSLSSVVTV PSSSLGTQTY 200
ICNVNHKPSN TKVDKKVEPK SCDKTHTCPP CPAPELLGGP SVFLFPPKPK 250
DTLMISRTPE VTCVVVDVSH EDPEVKFNWY VDGVEVHNAK TKPREEQYNS 300
TYRVVSVLTV LHQDWLNGKE YKCKVSNKAL PAPIEKTISK AKGQPREPQV 350
YTLPPSRDEL TKNQVSLTCL VKGFYPSDIA VEWESNGQPE NNYKTTPPVL 400
DSDGSFFLYS KLTVDKSRWQ QGNVFSCSVM HEALHNHYTQ KSLSLSPG   448
```

Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS LSASVGDRVT ITCRASQSIN SYLNWYQQKP GKAPKLLIYA  50
ASSLQSGVPS RFSGSGSGTD FTLTISSLQP EDFATYYCQQ QFDPPFTFGG 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-97 146-202 263-323 369-427
22"-97" 146"-202" 263"-323" 369"-427"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (h 5-CL 126) 222-214' 222"-214'"
Inter-H-H (h 11, h 14) 228-228" 231-231"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
299, 299"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados
G0F 42.5%, G1F 39.8%

berzosertibum

berzosertib

3-(3-{4-[(methylamino)methyl]phenyl}-1,2-oxazol-5-yl)-5-[4-(propane-2-sulfonyl)phenyl]pyrazin-2-amine

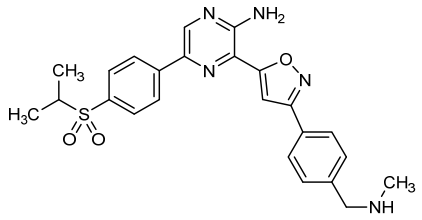
berzosertib

3-(3-{4-[(méthylamino)méthyl]phényl}-1,2-oxazol-5-yl)-5-[4-(propane-2-sulfonyl)phenyl]pyrazin-2-amine

berzosertib

3-(3-{4-[(metilamino)metil]fenil}-1,2-oxazol-5-il)-5-[4-(propano-2-sulfonil)fenil]pirazin-2-amina

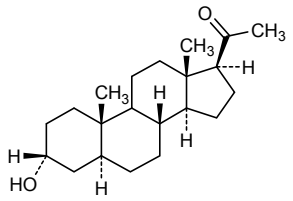
$C_{24}H_{25}N_5O_3S$



brexanolonum

brexanolone	3α-hydroxy-5α-pregnan-20-one
brexanolone	3α-hydroxy-5α-prègnan-20-one
brexanolona	3α-hidroxi-5α-pregnano-20-ona

$C_{21}H_{34}O_2$



camidanlumabum #

camidanlumab	immunoglobulin G1-kappa, anti-[*Homo sapiens* IL2RA (interleukin 2 receptor alpha subunit, IL-2RA, TAC, p55, CD25)], *Homo sapiens* monoclonal antibody; gamma1 heavy chain (1-445) [*Homo sapiens* VH (IGHV1-69*02 (94.90%) -(IGHD) -IGHJ4*01) [8.8.8] (1-115) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (212) (116-213), hinge (214-228), CH2 229-338), CH3 E12 (354), M14 (356) (339-443), CHS (444-445)) (116-445)], (218-214')-disulfide with kappa light chain (1'-214') [*Homo sapiens* V-KAPPA (IGKV3-20*01 (99.00%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (224-224'':227-227'')-bisdisulfide
camidanlumab	immunoglobuline G1-kappa, anti-[*Homo sapiens* IL2RA (sous-unité alpha du récepteur de l'interleukine 2, IL-2RA, TAC, p55, CD25)], *Homo sapiens* anticorps monoclonal; chaîne lourde gamma1 (1-445) [*Homo sapiens* VH (IGHV1-69*02 (94.90%) -(IGHD) -IGHJ4*01) [8.8.8] (1-115) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (212) (116-213), charnière (214-228), CH2 (229-338), CH3 E12 (354), M14 (356) (339-443), CHS (444-445)) (116-445)], (218-214')-disulfure avec la chaîne légère (1'-214') [*Homo sapiens* V-KAPPA (IGKV3-20*01 (99.00%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (224-224'':227-227'')-bisdisulfure
camidanlumab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* IL2RA (subunidad alfa del receptor de la interleukina 2, IL-2RA, TAC, p55, CD25)], *Homo sapiens* anticuerpo monoclonal; cadena pesada gamma1 (1-445) [*Homo sapiens* VH (IGHV1-69*02 (94.90%) -(IGHD) -IGHJ4*01) [8.8.8] (1-115) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (212) (116-213), bisagra (214-228), CH2 (229-338), CH3 E12 (354), M14 (356) (339-443), CHS (444-445)) (116-445)], (218-214')-disulfuro con la cadena ligera

(1'-214') [*Homo sapiens* V-KAPPA (IGKV3-20*01 (99.00%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (224-224":227-227")-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGSSVKV SCKASGGTFS RYIINWVRQA PGQGLEWMGR  50
IIPILGVENY AQKFQGRVTI TADKSTSTAY MELSSLRSED TAVYYCARKD 100
WFDYWGQGTL VTVSSASTKG PSVFPLAPSS KSTSGGTAAL GCLVKDYFPE 150
PVTVSWNSGA LTSGVHTFPA VLQSSGLYSL SSVVTVPSSS LGTQTYICNV 200
NHKPSNTKVD KRVEPKSCDK THTCPPCPAP ELLGGPSVFL FPPKPKDTLM 250
ISRTPEVTCV VVDVSHEDPE VKFNWYVDGV EVHNAKTKPR EEQYNSTYRV 300
VSVLTVLHQD WLNGKEYKCK VSNKALPAPI EKTISKAKGQ PREPQVYTLP 350
PSREEMTKNQ VSLTCLVKGF YPSDIAVEWE SNGQPENNYK TTPPVLDSDG 400
SFFLYSKLTV DKSRWQQGNV FSCSVMHEAL HNHYTQKSLS LSPGK      445
```

Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPGT LSLSPGERAT LSCRASQSVS SYLAWYQQKP GQAPRLLIYG  50
ASSRATGIPD RFSGSGSGTD FTLTISRLEP EDFAVYYCQQ YGSSPLTFGG 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 142-198 259-319 365-423
22"-96" 142"-198" 259"-319" 365"-423"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (h 5-CL 126) 218-214' 218"-214'"
Inter-H-H (h 11, h 14) 224-224" 227-227"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
295, 295"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

camidanlumabum tesirinum #

camidanlumab tesirine

immunoglobulin G1-kappa, anti-[*Homo sapiens* IL2RA (interleukin 2 receptor alpha subunit, IL-2RA, TAC, p55, CD25)], *Homo sapiens* monoclonal antibody conjugated to the pyrrolobenzodiazepine (PBD) dimer SCX;
gamma1 heavy chain (1-445) [*Homo sapiens* VH (IGHV1-69*02 (94.90%) -(IGHD) -IGHJ4*01) [8.8.8] (1-115) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (212) (116-213), hinge (214-228), CH2 (229-338), CH3 E12 (354), M14 (356) (339-443), CHS (444-445)) (116-445)], (218-214')-disulfide with kappa light chain (1'-214') [*Homo sapiens* V-KAPPA (IGKV3-20*01 (99.00%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (224-224":227-227")-bisdisulfide; conjugated, on an average of 2 cysteines, to the pyrrolobenzodiazepine (PBD) dimer SCX, via a cleavable (valine-alanine dipeptide as cathepsine B cleavage site) maleimide type linker containing a spacer PEG (n=8)
For the *tesirine* part, please refer to the prop.INN List 113, published in *the WHO Drug Information, Vol.29, No.2, 2015.*

camidanlumab tésirine

immunoglobuline G1-kappa, anti-[*Homo sapiens* IL2RA (sous-unité alpha du récepteur de l'interleukine 2, IL-2RA, TAC, p55, CD25)], *Homo sapiens* anticorps monoclonal conjugué au dimère de pyrrolobenzodiazépine (PDB) SCX;

chaîne lourde gamma1 (1-445) [*Homo sapiens* VH (IGHV1-69*02 (94.90%) -(IGHD) -IGHJ4*01) [8.8.8] (1-115) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (212) (116-213), charnière (214-228), CH2 (229-338), CH3 E12 (354), M14 (356) (339-443), CHS (444-445)) (116-445)], (218-214')-disulfure avec la chaîne légère (1'-214') [*Homo sapiens* V-KAPPA (IGKV3-20*01 (99.00%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (224-224'':227-227'')-bisdisulfure; conjugué, sur 2 cystéines en moyenne, au dimère de pyrrolobenzodiazépine (PBD) SCX, via un linker clivable (dipeptide valine-alanine clivable par la cathepsine B) de type maléimide et comprenant un espaceur PEG (n=8).
Pour la partie *tésirine*, veuillez vous référer à la Liste 113 des DCI prop, publiée dans le *WHO Drug Information, Vol.29, No.2, 2015.*

camidanlumab tesirina

inmunoglobulina G1-kappa, anti-[*Homo sapiens* IL2RA (subunidad alfa del receptor de la interleukina 2, IL-2RA, TAC, p55, CD25)], *Homo sapiens* anticuerpo monoclonal conjugado con el dímero de pirrolobenzodiazepina (PDB) SCX;
cadena pesada gamma1 (1-445) [*Homo sapiens* VH (IGHV1-69*02 (94.90%) -(IGHD) -IGHJ4*01) [8.8.8] (1-115) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (212) (116-213), bisagra (214-228), CH2 (229-338), CH3 E12 (354), M14 (356) (339-443), CHS (444-445)) (116-445)], (218-214')-disulfuro con la cadena ligera (1'-214') [*Homo sapiens* V-KAPPA (IGKV3-20*01 (99.00%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (224-224'':227-227'')-bisdisulfuro; conjugado, en una media de 2 cisteínas, al dímero de pirrolobenzodiazepina (PBD) SCX, mediante un espaciador escindible (dipéptido valina-alanina escindible por la catepsina B) de tipo maleimida que comprende un espaciador PEG (n=8)
Para la fracción *tesirina* se puede referir a la Lista 113 de DCI prop., publicada en el *WHO Drug Information, Vol.29, No.2, 2015.*

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGSSVKV SCKASGGTFS RYIINWVRQA PGQGLEWMGR  50
IIPILGVENY AQKFQGRVTI TADKSTSTAY MELSSLRSED TAVYYCARKD 100
WFDYWGQGTL VTVSSASTKG PSVFPLAPSS KSTSGGTAAL GCLVKDYFPE 150
PVTVSWNSGA LTSGVHTFPA VLQSSGLYSL SSVVTVPSSS LGTQTYICNV 200
NHKPSNTKVD KRVEPKSCDK THTCPPCPAP ELLGGPSVFL FPPKPKDTLM 250
ISRTPEVTCV VVDVSHEDPE VKFNWYVDGV EVHNAKTKPR EEQYNSTYRV 300
VSVLTVLHQD WLNGKEYKCK VSNKALPAPI EKTISKAKGQ PREPQVYTLP 350
PSREEMTKNQ VSLTCLVKGF YPSDIAVEWE SNGQPENNYK TTPPVLDSDG 400
SFFLYSKLTV DKSRWQQGNV FSCSVMHEAL HNHYTQKSLS LSPGK      445
```

Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPGT LSLSPGERAT LSCRASQSVS SYLAWYQQKP GQAPRLLIYG  50
ASSRATGIPD RFSGSGSGTD FTLTISRLEP EDFAVYYCQQ YGSSPLTFGG 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 142-198 259-319 365-423
22"-96" 142"-198" 259"-319" 365"-423"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (h 5-CL 126) * 218-214' 218"-214'"
Inter-H-H (h 11, h 14) * 224-224" 227-227"
*One or two of the inter-chain disulfide bridges are not present, an average of 2 cysteinyl being conjugated each via a thioether bond to a drug linker.
*Un ou deux des ponts disulfures inter-chaînes ne sont pas présents, 2 cystéinyl en moyenne étant chacun conjugué via une liaison thioéther à un linker-principe actif.
*Faltan uno o dos puentes disulfuro inter-catenarios, una media de 2 cisteinil están conjugados con sendos enlaces tioéter, a conectores de principio activo.

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
295, 295"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

canerpaturevum #

canerpaturev — Replication-competent, spontaneously occurring mutant of Herpes Simplex Virus type 1 (HSV-1) with a number of deletions and insertions in the genome, resulting in the lack of functional expression of UL43, UL49.5, UL55 and UL56.

canerpaturev — mutant spontané de Virus Herpes Simplex type 1 (HSV-1) capable de se répliquer, avec un nombre de délétions et d'insertions dans le génome, résultant en l'absence de l'expression fonctionnelle des gènes UL43, UL49.5, UL55et UL56.

canerpaturev — Virus Herpes Simplex tipo 1 (HSV-1) competente de replicación, mutado espontáneamente, con un número de deleciones e inserciones en el genoma que dan como resultado la ausencia de expresión functional de los genes UL43, UL49.5, UL55 y UL56.

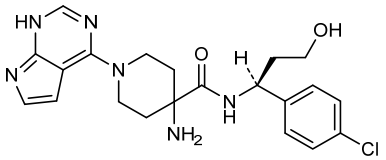
capivasertibum

capivasertib — 4-amino-*N*-[(1*S*)-1-(4-chlorophenyl)-3-hydroxypropyl]-1-(1*H*-pyrrolo[2,3-*d*]pyrimidin-4-yl)piperidine-4-carboxamide

capivasertib — 4-amino-*N*-[(1*S*)-1-(4-chlorophényl)-3-hydroxypropyl]-1-(1*H*-pyrrolo[2,3-*d*]pyrimidin-4-yl)pipéridine-4-carboxamide

capivasertib — 4-amino-*N*-[(1*S*)-1-(4-clorofenil)-3-hidroxipropil]-1-(1*H*-pirrolo[2,3-*d*]pirimidin-4-il)piperidina-4-carboxamida

$C_{21}H_{25}ClN_6O_2$



cobomarsenum

cobomarsen — *all-P-ambo*-5-methyl-2'-*O*,4'-*C*-methylene-*P*-thiocytidylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-5-methyl-2'-*O*,4'-*C*-methylene-*P*-thiocytidylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-5-methyl-2'-*O*,4'-*C*-methylene-*P*-thiouridylyl-(3'→5')-5-methyl-2'-*O*,4'-*C*-methylene-*P*-thiouridylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-2'-*O*,4'-*C*-methylene-*P*-thioguanylyl-(3'→5')-2'-deoxy-*P*-thiocytidylyl-(3'→5')-2'-*O*,4'-*C*-methylene-*P*-thioadenylyl-(3'→5')-5-methyl-2'-*O*,4'-*C*-methylene-*P*-thiouridylyl-(3'→5')-5-methyl-2'-*O*,4'-*C*-methylene-*P*-thiouridylyl-(3'→5')-2'-*O*,4'-*C*-methyleneadenosine

cobomarsen

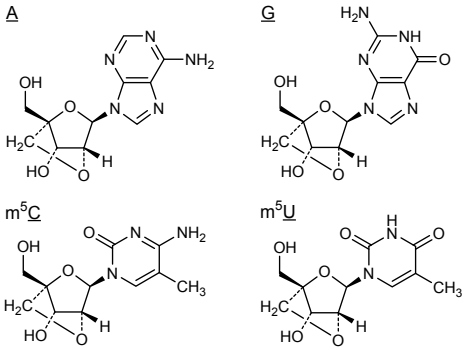
tout-P-ambo-5-méthyl-2'-*O*,4'-*C*-méthylène-*P*-thiocytidylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-5-méthyl-2'-*O*,4'-*C*-méthylène-*P*-thiocytidylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-5-méthyl-2'-*O*,4'-*C*-méthylène-*P*-thiouridylyl-(3'→5')-5-méthyl-2'-*O*,4'-*C*-méthylène-*P*-thiouridylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-2'-*O*,4'-*C*-méthylène-*P*-thioguanylyl-(3'→5')-2'-désoxy-*P*-thiocytidylyl-(3'→5')-2'-*O*,4'-*C*-méthylène-*P*-thioadénylyl-(3'→5')-5-méthyl-2'-*O*,4'-*C*-méthylène-*P*-thiouridylyl-(3'→5')-5-méthyl-2'-*O*,4'-*C*-méthylène-*P*-thiouridylyl-(3'→5')-2'-*O*,4'-*C*-méthylèneadénosine

cobomarsén

todo-P-ambo-5-metil-2'-*O*,4'-*C*-metileno-*P*-tiocitidilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-5-metil-2'-*O*,4'-*C*-metileno-*P*-tiocitidilil-(3'→5')-2'-desoxi-*P*-tioguanilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-5-metil-2'-*O*,4'-*C*-metileno-*P*-tiouridilil-(3'→5')-5-metil-2'-*O*,4'-*C*-metileno-*P*-tiouridilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-2'-*O*,4'-*C*-metileno-*P*-tioguanilil-(3'→5')-2'-desoxi-*P*-tiocitidilil-(3'→5')-2'-*O*,4'-*C*-metileno-*P*-tioadenilil-(3'→5')-5-metil-2'-*O*,4'-*C*-metileno-*P*-tiouridilil-(3'→5')-5-metil-2'-*O*,4'-*C*-metileno-*P*-tiouridilil-(3'→5')-2'-*O*,4'-*C*-metileneadenosina

$C_{148}H_{177}N_{52}O_{77}P_{13}S_{13}$

(3'-5')(*P*-thio)(m^{5}C-dA-m^{5}C-dG-dA-m^{5}U-m^{5}U-dA-G-dC-A-m^{5}U-m^{5}U-A)



dX : 2'-deoxy-X / dX : 2'-désoxy-X / dX: 2'-desoxi-X

cofetuzumabum #
cofetuzumab

immunoglobulin G1-kappa, anti-[*Homo sapiens* PTK7 (protein tyrosine kinase 7, colon carcinoma kinase 4, CCK4) extracellular domain], humanized monoclonal antibody; gamma1 heavy chain (1-448) [humanized VH (*Homo sapiens* IGHV1-3*01 (81.60%) -(IGHD) -IGHJ4*01) [8.8.12] (1-119) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (216) (120-217), hinge (218-232), CH2 (233-342), CH3 D12 (358), L14 (360) (343-447), CHS K>del (448)) (120-448)], (222-218')-disulfide with kappa light chain (1'-218') [humanized V-KAPPA (*Homo sapiens* IGKV3-11*01 (83.80%) -IGKJ4*01) [10.3.9] (1'-111') -*Homo sapiens* IGKC*01, Km3 A45.1 (157), V101 (195) (112'-218')]; dimer (228-228":231-231")-bisdisulfide

cofétuzumab	immunoglobuline G1-kappa, anti-[*Homo sapiens* PTK7 (protéine tyrosine kinase 7, kinase du cancer du côlon, CCK4) domaine extracellulaire], anticorps monoclonal humanisé; chaîne lourde gamma1 (1-448) [VH humanisé (*Homo sapiens* IGHV1-3*01 (81.60%) -(IGHD) -IGHJ4*01) [8.8.12] (1-119) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (216) (120-217), charnière (218-232), CH2 (233-342), CH3 D12 (358), L14 (360) (343-447), CHS K>del (448)) (120-448)], (222-218')-disulfure avec la chaîne légère kappa (1'-218') [V-KAPPA humanisé (*Homo sapiens* IGKV3-11*01 (83.80%) -IGKJ4*01) [10.3.9] (1'-111') -*Homo sapiens* IGKC*01, Km3 A45.1 (157), V101 (195) (112'-218')]; dimère (228-228":231-231")-bisdisulfure
cofetuzumab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* PTK7 (proteína tirosina kinasa 7, kinasa del cáncer de colon, CCK4) dominio extracelular], anticuerpo monoclonal humanizado; cadena pesada gamma1 (1-448) [VH humanizado (*Homo sapiens* IGHV1-3*01 (81.60%) -(IGHD) -IGHJ4*01) [8.8.12] (1-119) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (216) (120-217), bisagra (218-232), CH2 (233-342), CH3 D12 (358), L14 (360) (343-447), CHS K>del (448)) (120-448)], (222-218')-disulfuro con la cadena ligera kappa (1'-218') [V-KAPPA humanizado (*Homo sapiens* IGKV3-11*01 (83.80%) -IGKJ4*01) [10.3.9] (1'-111') -*Homo sapiens* IGKC*01, Km3 A45.1 (157), V101 (195) (112'-218')]; dímero (228-228":231-231")-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGPE VKKPGASVKV SCKASGYTFT DYAVHWVRQA PGKRLEWIGV  50
ISTYNDYTYN NQDFKGRVTM TRDTSASTAY MELSRLRSED TAVYYCARGN 100
SYFYALDYWG QGTSVTVSSA STKGPSVFPL APSSKSTSGG TAALGCLVKD 150
YFPEPVTVSW NSGALTSGVH TFPAVLQSSG LYSLSSVVTV PSSSLGTQTY 200
ICNVNHKPSN TKVDKKVEPK SCDKTHTCPP CPAPELLGGP SVFLFPPKPK 250
DTLMISRTPE VTCVVVDVSH EDPEVKFNWY VDGVEVHNAK TKPREEQYNS 300
TYRVVSVLTV LHQDWLNGKE YKCKVSNKAL PAPIEKTISK AKGQPREPQV 350
YTLPPSRDEL TKNQVSLTCL VKGFYPSDIA VEWESNGQPE NNYKTTPPVL 400
DSDGSFFLYS KLTVDKSRWQ QGNVFSCSVM HEALHNHYTQ KSLSLSPG   448
```

Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPAT LSLSPGERAT LSCRASESVD SYGKSFMHWY QQKPGQAPRL  50
LIYRASNLES GIPARFSGSG SGTDFTLTIS SLEPEDFAVY YCQQSNEDPW 100
TFGGGTKLEI KRTVAAPSVF IFPPSDEQLK SGTASVVCLL NNFYPREAKV 150
QWKVDNALQS GNSQESVTEQ DSKDSTYSLS STLTLSKADY EKHKVYACEV 200
THQGLSSPVT KSFNRGEC                                    218
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 146-202 263-323 369-427
22"-96" 146"-202" 263"-323" 369"-427"
Intra-L (C23-C104) 23'-92' 138'-198'
23'"-92'" 138'"-198'"
Inter-H-L (h 5-CL 126) 222-218' 222"-218'"
Inter-H-H (h 11, h 14) 228-228" 231-231"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
299, 299"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados.

cofetuzumabum pelidotinum #

cofetuzumab pelidotin	immunoglobulin G1-kappa, anti-[*Homo sapiens* PTK7 (protein tyrosine kinase 7, colon carcinoma kinase 4, CCK4) extracellular domain], humanized monoclonal antibody, conjugated to auristatin-0101; gamma1 heavy chain (1-448) [humanized VH (*Homo sapiens* IGHV1-3*01 (81.60%) -(IGHD) -IGHJ4*01) [8.8.12] (1-119) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (216) (120-217), hinge (218-232), CH2 (233-342), CH3 D12 (358), L14 (360) (343-447), CHS K>del (448)) (120-448)], (222-218')-disulfide with kappa light chain (1'-218') [humanized V-KAPPA (*Homo sapiens* IGKV3-11*01 (83.80%) -IGKJ4*01) [10.3.9] (1'-111') -*Homo sapiens* IGKC*01, Km3 A45.1 (157), V101 (195) (112'-218')]; dimer (228-228":231-231")-bisdisulfide; conjugated, on an average of 4 cysteinyl, to auristatin-0101 (Aur0101), via a cleavable maleimidocaproyl-valyl-citrullinyl-*p*-aminobenzyloxycarbonyl (mc-val-cit-PABC) type linker
cofétuzumab pélidotine	immunoglobuline G1-kappa, anti-[*Homo sapiens* PTK7 (protéine tyrosine kinase 7, kinase du cancer du côlon, CCK4) domaine extracellulaire], anticorps monoclonal humanisé, conjugué à l'auristatine-0101; chaîne lourde gamma1 (1-448) [VH humanisé (*Homo sapiens* IGHV1-3*01 (81.60%) -(IGHD) -IGHJ4*01) [8.8.12] (1-119) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (216) (120-217), charnière (218-232), CH2 (233-342), CH3 D12 (358), L14 (360) (343-447), CHS K>del (448)) (120-448)], (222-218')-disulfure avec la chaîne légère kappa (1'-218') [V-KAPPA humanisé (*Homo sapiens* IGKV3-11*01 (83.80%) -IGKJ4*01) [10.3.9] (1'-111') -*Homo sapiens* IGKC*01, Km3 A45.1 (157), V101 (195) (112'-218')]; dimère (228-228":231-231")-bisdisulfure; conjugué, sur 4 cystéinyl en moyenne, à l'auristatine-0101 (Aur0101), via un linker clivable de type maléimidocaproyl-valyl-citrullinyl-*p*-aminobenzyloxycarbonyl (mc-val-cit-PABC)
cofetuzumab pelidotina	inmunoglobulina G1-kappa, anti-[*Homo sapiens* PTK7 (proteína tirosina kinasa 7, kinasa de cáncer de colon, CCK4) dominio extracelular], anticuerpo monoclonal humanizado, conjugado con la auristatina-0101; cadena pesada gamma1 (1-448) [VH humanizado (*Homo sapiens* IGHV1-3*01 (81.60%) -(IGHD) -IGHJ4*01) [8.8.12] (1-119) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (216) (120-217), bisagra (218-232), CH2 (233-342), CH3 D12 (358), L14 (360) (343-447), CHS K>del (448)) (120-448)], (222-218')-disulfuro con la cadena ligera kappa (1'-218') [V-KAPPA humanizado (*Homo sapiens* IGKV3-11*01 (83.80%) -IGKJ4*01) [10.3.9] (1'-111') -*Homo sapiens* IGKC*01, Km3 A45.1 (157), V101 (195) (112'-218')]; dímero (228-228":231-231")-bisdisulfuro; conjugado, en una media de 3 a 4 restos cisteinil, con la auristatina-0101 (Aur0101), mediante un conector escindible de tipo maleimidocaproil-valil-citrulinil-*p*-aminobenziloxicarbonil (mc-val-cit-PABC)

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGPE VKKPGASVKV SCKASGYTFT DYAVHWVRQA PGKRLEWIGV  50
ISTYNDYTYN NQDFKGRVTM TRDTSASTAY MELSRLRSED TAVYYCARGN 100
SYFYALDYWG QGTSVTVSSA STKGPSVFPL APSSKSTSGG TAALGCLVKD 150
YFPEPVTVSW NSGALTSGVH TFPAVLQSSG LYSLSSVVTV PSSSLGTQTY 200
ICNVNHKPSN TKVDKKVEPK SCDKTHTCPP CPAPELLGGP SVFLFPPKPK 250
DTLMISRTPE VTCVVVDVSH EDPEVKFNWY VDGVEVHNAK TKPREEQYNS 300
TYRVVSVLTV LHQDWLNGKE YKCKVSNKAL PAPIEKTISK AKGQPREPQV 350
YTLPPSRDEL TKNQVSLTCL VKGFYPSDIA VEWESNGQPE NNYKTTPPVL 400
DSDGSFFLYS KLTVDKSRWQ QGNVFSCSVM HEALHNHYTQ KSLSLSPG   448
```

Light chain / Chaîne légère / Cadena ligera

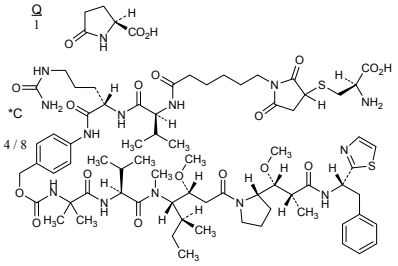
```
EIVLTQSPAT LSLSPGERAT LSCRASESVD SYGKSFMHWY QQKPGQAPRL  50
LIYRASNLES GIPARFSGSG SGTDFTLTIS SLEPEDFAVY YCQQSNEDPW 100
TFGGGTKLEI KRTVAAPSVF IFPPSDEQLK SGTASVVCLL NNFYPREAKV 150
QWKVDNALQS GNSQESVTEQ DSKDSTYSLS STLTLSKADY EKHKVYACEV 200
THQGLSSPVT KSFNRGEC                                    218
```

Post-translational modifications

Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro

Intra-H (C23-C104) 22-96 146-202 263-323 369-427
22"-96" 146"-202" 263"-323" 369"-427"
Intra-L (C23-C104) 23'-92' 138'-198'
23'"-92'" 138'"-198'"
Inter-H-L (h 5-CL 126) * 222-218' 222"-218'"
Inter-H-H (h 11, h 14) * 228-228" 231-231"

Modified residues / résidus modifiés / restos modificados



N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación

H CH2 N84.4:
299, 299"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados.

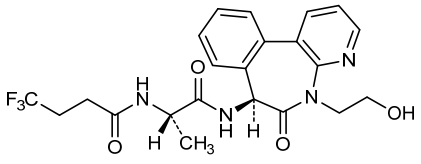
crenigacestatum

crenigacestat — 4,4,4-trifluoro-*N*-[(2*S*)-1-{[(7*S*)-5-(2-hydroxyethyl)-6-oxo-6,7-dihydro-5*H*-pyrido[3,2-*a*][3]benzoxazepin-7-yl]amino}-1-oxopropan-2-yl]butanamide

crénigacestat — 4,4,4-trifluoro-*N*-[(2*S*)-1-{[(7*S*)-5-(2-hydroxyéthyl)-6-oxo-6,7-dihydro-5*H*-pyrido[3,2-*a*][3]benzoxazépin-7-yl]amino}-1-oxopropan-2-yl]butanamide

crenigacestat — 4,4,4-trifluoro-*N*-[(2*S*)-1-{[(7*S*)-5-(2-hidroxietil)-6-oxo-6,7-dihidro-5*H*-pirido[3,2-*a*][3]benzoxazepin-7-il]amino}-1-oxopropan-2-il]butanamida

$C_{22}H_{23}F_3N_4O_4$



danvatirsenum

danvatirsen

all-P-ambo-2'-*O*,4'-*C*-[(1*S*)-ethane-1,1-diyl]-5-methyl-*P*-thiocytidylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-ethane-1,1-diyl]-5-methyl-*P*-thiouridylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-ethane-1,1-diyl]-*P*-thioadenylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-deoxy-5-methyl-*P*-thiocytidylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-ethane-1,1-diyl]-*P*-thioadenylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-ethane-1,1-diyl]-*P*-thioguanylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-ethane-1,1-diyl]-5-methylcytidine

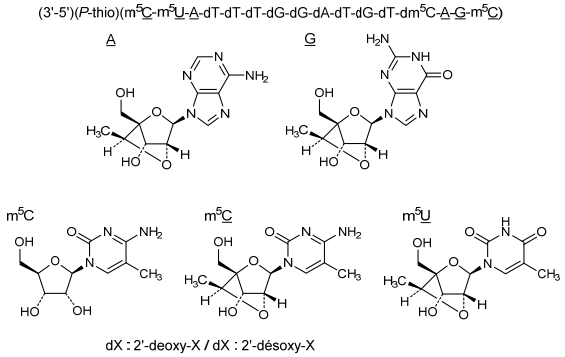
danvatirsen

tout-P-ambo-2'-*O*,4'-*C*-[(1*S*)-éthane-1,1-diyl]-5-méthyl-*P*-thiocytidylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-éthane-1,1-diyl]-5-méthyl-*P*-thiouridylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-éthane-1,1-diyl]-*P*-thioadénylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-désoxy-5-méthyl-*P*-thiocytidylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-éthane-1,1-diyl]-*P*-thioadénylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-éthane-1,1-diyl]-*P*-thioguanylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-éthane-1,1-diyl]-5-méthylcytidine

danvatirsén

todo-P-ambo-2'-*O*,4'-*C*-[(1*S*)-etano-1,1-diil]-5-metil-*P*-tiocitidilil-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-etano-1,1-diil]-5-metil-*P*-tiouridilil-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-etano-1,1-diil]-*P*-tioadenilil-(3'→5')-*P*-tiotimidilil-(3'→5')-*P*-tiotimidilil-(3'→5')-*P*-tiotimidilil-(3'→5')-2'-desoxi-*P*-tioguanilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-*P*-tiotimidilil-(3'→5')-2'-desoxi-*P*-tioguanilil-(3'→5')-*P*-tiotimidilil-(3'→5')-2'-desoxi-5-metil-*P*-tiocitidilil-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-etano-1,1-diil]-*P*-tioadenilil-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-etano-1,1-diil]-*P*-tioguanilil-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-etano-1,1-diil]-5-metilcitidina

$C_{172}H_{217}N_{56}O_{88}P_{15}S_{15}$



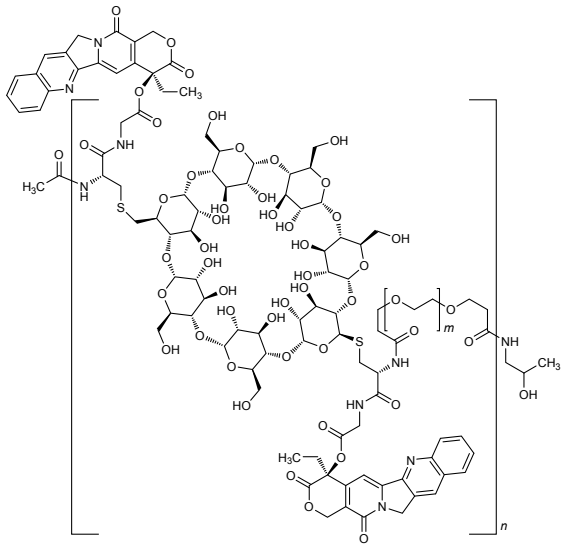
darvadstrocelum

darvadstrocel	Human culture expanded allogeneic adipose stromal progenitor cells (eASC) for cell-based therapy. Cells are derived from isolated adipose tissue of healthy living donors. eASC express cell surface markers CD29, CD73, CD90 and CD105 and are capable to express factors such as vascular endothelial growth factor (VEGF), transforming growth factor-beta 1 (TGF-β1), interleukin-6 (IL-6), matrix metalloproteinase inhibitor-1 (TIMP-1), and interferon-gamma (IFN-γ) inducible indoleamine 2,3-dioxygenase (IDO).
darvadstrocel	Cellules progénitrices humainesallogéniques du stroma adipeux (eASC), en culture d'expansion, pour thérapie à base de cellules. Les cellules sont dérivées d'un tissu adipeux isolé à partir de donneurs vivants sains. Les eASC expriment les marqueurs de surface CD29, CD73, CD90 et CD105 et sont capables d'exprimer les facteurs comme le facteur de croissance de l'endothélium vasculaire (VEGF), le facteur de croissance transformant beta 1 (TGF-β1), l'interleukine 6 (IL-6), l'inhibiteur tissulaire des métalloprotéases 1 (TIMP-1) et l'indoléamine 2,3-dioxygénase (IDO) induite par l'interféron gamma (IFN-γ).
darvadstrocel	Células progenitoras del estroma adiposo alogénicas, humanas, expandidas en cultivo (eASC) para terapia celular. Las células se derivan a partir tejido adiposo aislado de donantes sanos vivos. Las eASC expresan los marcadores de superficie CD29, CD73, CD90 y CD105, y pueden expresar factores como el factor de crecimiento del endotelio vascular (VEGF), factor transformador del crecimiento beta 1 (TGF- β1), interleukina 6 (IL-6), inhibidor de metaloproteinasa de la matriz 1 (TIMP-1), e indoleamina 2,3- dioxigenasa (IDO) inducible por interferón gamma (IFN-γ) .

davamotecanum pegadexamerum

davamotecan pegadexamer	α-acetyl-ω-{[(2*RS*)-2-hydroxypropyl]amino}poly[({bis[(4*S*)-4-ethyl-3,14-dioxo-3,4,12,14-tetrahydro-1*H*-pyrano[3',4':6,7]indolizino[1,2-b]quinolin-4-yl] *S,S'*-(6^{I},6^{IV}-dideoxycyclomaltoheptaose-6^{I},6^{IV}-diyl)bis(L-cysteinylglycinate)}-*N*$^{2.1}$,N$^{2.1'}$-diyl)(1-oxopropane-1,3-diyl)poly(oxyethylene)oxy(3-oxopropane-1,3-diyl)]
davamotécan pégadexamère	α-acétyl-ω-{[(2*RS*)-2-hydroxypropyl]amino}poly[({bis[(4*S*)-4-éthyl-3,14-dioxo-3,4,12,14-tétrahydro-1*H*-pyrano[3',4':6,7]indolizino[1,2-b]quinolin-4-yl] *S,S'*-(6^{I},6^{IV}-didésoxycyclomaltoheptaose-6^{I},6^{IV}-diyl)bis(L-cystéinylglycinate)}-*N*$^{2.1}$,N$^{2.1'}$-diyl)(1-oxopropane-1,3-diyl)poly(oxyéthylène)oxy(3-oxopropane-1,3-diyl)]
davamotecán pegadexámero	α-acetil-ω-{[(2*RS*)-2-hidroxipropil]amino}poli[({bis[(4*S*)-4-etil-3,14-dioxo-3,4,12,14-tetrahidro-1*H*-pirano[3',4':6,7]indolizino[1,2-b]quinolin-4-il] *S,S'*-(6^{I},6^{IV}-didesoxiciclomaltoheptaosa-6^{I},6^{IV}-diil)bis(L-cisteinilglicinato)}-*N*$^{2.1}$,N$^{2.1'}$-diil)(1-oxopropano-1,3-diil)poli(oxietileno)oxi(3-oxopropano-1,3-diil)]

C_2H_3O-($C_{252}H_{428}N_8O_{125}S_2$)$_n$-$C_3H_8NO$



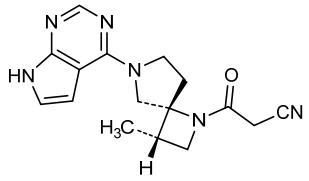
delgocitinibum

delgocitinib — 3-[(3*S*,4*R*)-3-methyl-6-(7*H*-pyrrolo[2,3-*d*]pyrimidin-4-yl)-1,6-diazaspiro[3.4]octan-1-yl]-3-oxopropanenitrile

delgocitinib — 3-[(3*S*,4*R*)-3-méthyl-6-(7*H*-pyrrolo[2,3-*d*]pyrimidin-4-yl)-1,6-diazaspiro[3.4]octan-1-yl]-3-oxopropanenitrile

delgocitinib — 3-[(3*S*,4*R*)-3-metil-6-(7*H*-pirrolo[2,3-*d*]pirimidin-4-il)-1,6-diazaspiro[3.4]octan-1-il]-3-oxopropanenitrilo

$C_{16}H_{18}N_6O$



demplatinum pegraglumerum

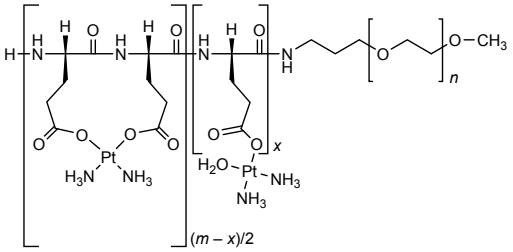
demplatin pegraglumer — {[α-{3-[α-*N*-hydropoly(L-glutamyl-κ*O*^{5})$_m$-ω-amino]propyl}-ω-methoxypoly(oxyethane-1,2-diyl)$_n$]polyato}poly[*cis*-(*SP*-4)-aquadiammineplatinum(II)/*cis*-(*SP*-4)-diammineplatinum(II) (x:y)], with m ~ 40, n ~ 268, x ~ 8, (m+x)/2 = 24

demplatine pégraglumère — {[α-{3-[α-*N*-hydropoly(L-glutamyl-κ*O*^{5})$_m$-ω-amino]propyl}-ω-méthoxypoly(oxyéthane-1,2-diyl)$_n$]polyato}poly[*cis*-(*SP*-4)-aquadiammineplatine(II)/*cis*-(*SP*-4)-diammineplatine(II) (x:y)], avec m ~ 40, n ~ 268, x ~ 8, (m+x)/2 = 24

demplatino pegraglúmero

{[α-{3-[α-*N*-hidropoli(L-glutamil-κO^5)$_m$-ω-amino]propil}-ω-metoxipoli(oxietano-1,2-diil)$_n$]poliato}poli[*cis*-(*SP*-4)-aquadiammineplatino(II)/*cis*-(*SP*-4)-diammineplatino(II)] (x:y)], con m ~ 40, n ~ 268, x ~ 8, (m+x)/2 = 24

$C_4H_{11}NO(C_5H_6NO_3)_m(CH_2CH_2O)_n(H_6N_2Pt)_{(m+x)/2}(H2O)_x$



m ~ 40, *n* ~ 268, *x* ~ 8, (*m* + *x*)/2 = 24

desidustatum

desidustat

N-[1-(cyclopropylmethoxy)-4-hydroxy-2-oxo-1,2-dihydroquinoline-3-carbonyl]glycine

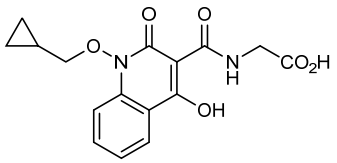
désidustat

N-[1-(cyclopropylméthoxy)-4-hydroxy-2-oxo-1,2-dihydroquinoléine-3-carbonyl]glycine

desidustat

N-[1-(ciclopropilmetoxi)-4-hidroxi-2-oxo-1,2-dihidroquinoleína-3-carbonil]glicina

$C_{16}H_{16}N_2O_6$



desmetramadolum

desmetramadol

rac-3-{(1*R*,2*R*)-2-[(dimethylamino)methyl]-1-hydroxycyclohexyl}phenol

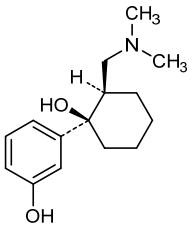
desmétramadol

rac-3-{(1*R*,2*R*)-2-[(diméthylamino)méthyl]-1-hydroxycyclohexyl}phénol

desmetramadol

rac-3-{(1*R*,2*R*)-2-[(dimetilamino)metil]-1-hidroxiciclohexil}fenol

$C_{15}H_{23}NO_2$



and enantiomer
et énantiomère
y enantiómero

efepoetinum alfa #

efepoetin alfa

human erythropoietin (epoetin alfa) fused to a hybrid human immunoglobulin (Ig), consisting of the Fc fragment of the IgG4 fused to the hinge and amino-terminus of the IgD heavy chain isotype 2, produced in Chinese hamster ovary (CHO) cells, glycoform alfa;

[human erythropoietin (EPO) (1-166)]-[immunoglobulin heavy chain delta (IGHD) isoform 2 constant region (133-170)-peptide (C-terminal hinge region and N-terminal CH2 domain) (167-204)]-[immunoglobulin heavy chain gamma 4 (IGHG4) constant region (121-327)-peptide (CH2 and CH3 domains) (205-411)]-fusion protein, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

éfépoétine alfa

érythropoïétine humaine (époétine alfa) fusionée à une immunoglobuline (Ig) humaine hybride, consistant en un fragment Fc de l'IgG4 fusionné à la région charnière et à la chaîne lourde isotoype 2 de l'IgD sur la partie N-terminale, produite par des cellules ovariennes de hamster chinois (CHO), glycoforme alfa;

[érythropoïétine humaine (EPO) (1-166)]-[région constante de la chaîne lourde delta de l'immunoglobuline (IGHD) isoforme 2 (133-170)-peptide (région charnière C-terminale et domaine CH2 N-terminal) (167-204)]-[région constante de la chaîne lourde de l'immunoglobuline gamma 4 (IGHG4) (121-327)-peptide (domaines CH2 et CH3) (205-411)]- protéine de fusion, produite par des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

efepoetina alfa

eritropoyetina humana (epoetina alfa) fusionada con una inmunoglobulina (Ig) humana híbrida, consistente en un fragmento Fc de la IgG4 fusionada con la región bisagra y con la cadena pesada isótopo 2 de la IgD sobre la parte N-terminal, producia por las células ováricas de hamster chino (CHO), glicoforma alfa;

[eritropoyetina humana (EPO) (1-166)]-[región constante de la cadena pesada delta de la inmunoglobulina (IGHD) isoforma 2 (133-170)-péptido (región bisagra C-terminal y dominio CH2 N-terminal) (167-204)]-[región constante de la cadena pesada de la inmunoglobulina gamma 4 (IGHG4) (121-327)-péptido (dominios CH2 y CH3) (205-411)]- proteína de fusión, producida por las células ováricas de hamster chinos (CHO), glicoforma alfa

Monomer sequence / Séquence du monomère / Secuencia del monómero

```
APPRLICDSR VLERYLLEAK EAENITTGCA EHCSLNENIT VPDTKVNFYA 50
WKRMEVGQQA VEVWQGLALL SEAVLRGQAL LVNSSQPWEP LQLHVDKAVS 100
GLRSLTTLLR ALGAQKEAIS PPDAASAAPL RTITADTFRK LFRVYSNFLR 150
GKLKLYTGEA CRTGDRRNTG RGGEEKKKEK EKEEQEERET KTPECPSHTQ 200
PLGVFLFPPK PKDTLMISRT PEVTCVVVDV SQEDPEVQFN WYVDGVEVHN 250
AKTKPREEQF NSTYRVVSVL TVLHQDWLNG KEYKCKVSNK GLPSSIEKTI 300
SKAKGQPREP QVYTLPPSQE EMTKNQVSLT CLVKGFYPSD IAVEWESNGQ 350
PENNYKTTPP VLDSDGSFFL YSRLTVDKSR WQEGNVFSCS VMHEALHNHY 400
TQKSLSLSLG K                                          411
```

Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro

Intra-chain disulfide bridges: 7-161 29-33 225-285 331-389
7'-161' 29'-33' 225'-285' 331'-389'

Inter-chain disulfide bridges: 195-195'

Glycosylation sites (N) / Sites de glycosylation (N) / Posiciones de glicosilación (N)

Asn-24 Asn-38 Asn-83 Asn-261

Glycosylation sites (O) / Sites de glycosylation (O) / Posiciones de glicosilación (O)

Ser-126

efizonerimodum alfa #

efizonerimod alfa

modified human immunoglobulin G4 Fc fragment fused to tumor necrosis factor receptor-associated factor TRAF2 (human C-C domain fragment) and to the CD252 antigen (human extracellular domain fragment), hexamer, produced in Chinese hamster ovary (CHO) cells, glycoform alfa;

modified human immunoglobulin G4 Fc fragment (1-229) [*Homo sapiens* IGHG4*01 del-CH1, [10-proline (S>P)]hinge] fusion protein with human TNF receptor-associated factor2 (TRAF2)-(310-349)-peptide (230-269) fusion protein with des-(1-50)-human tumor necrosis factor ligand superfamily member4 (TNFSF4, also known as CD252 or OX40L) (270-402), produced in Chinese hamster ovary (CHO) cells, non-covalent trimer of (8-8',11-11')-bisdisulfide dimers, glycoform alfa

éfizonérimod alfa

fragment Fc modifié de l'immunoglobuline G4 humaine, fusionné au facteur associé au récepteur du facteur de nécrose tumorale TRAF2 (fragment du domaine C-C humain) et à l'antigène CD252 (fragment du domaine extracellulaire humain), héxamère, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa;

fragment Fc modifié de l'immunoglobuline G4 humaine (1-229)[*Homo sapiens* IGHG4*01 del-CH1, [10-proline (S>P)]charnière] protéine de fusion avec le facteur 2 associé au récepteur du TNF humain (TRAF2)-(310-349)-peptide (230-269) protéine de fusion avec le dès-(1-50)-membre 4 de la superfamille des ligands du facteur de nécrose tumorale humain (TNFSF4, CD252, OX40L) (270-402), produit dans des cellules ovariennes de hamster chinois (CHO), trimère non-covalent de dimères (8-8',11-11')-bisdisulfure, glycoforme alfa

efizonerimod alfa

fragmento Fc modificado de la inmunoglobulina G4 humana, fusionada con el factor asociado al receptor del factor de necrosis tumoral TRAF2 (fragmento del dominio C-C humano) y al antígeno CD252 (fragmento del dominio extracelular humano), hexámero, producido en las células ováricas de hámsters chinos (CHO), glicoforma alfa;

fragmento Fc modificado de la inmunoglobulina G4 humana (1-229)[*Homo sapiens* IGHG4*01 del-CH1, [10-prolina (S>P)]bisagra] proteína de fusión con el factor 2 asociado al receptor del TNF humano (TRAF2)-(310-349)-péptido (230-269) proteína de fusión con el des-(1-50)- miembro 4 de la superfamilia de los ligandos del factor de necrosis tumoral humano (TNFSF4, CD252, OX40L) (270-402), producido en las células ováricas de hámster chino (CHO), trímero no-covalente de dímeros (8-8',11-11')-bisdisulfuro, glicoforma alfa

Monomer sequence / Séquence du monomère / Secuencia del monómero

```
ESKYGPPCPP CPAPEFLGGP SVFLFPPKPK DTLMISRTPE VTCVVVDVSQ 50
EDPEVQFNWY VDGVEVHNAK TKPREEQFNS TYRVVSVLTV LHQDWLNGKE 100
YKCKVSNKGL PSSIEKTISK AKGQPREPQV YTLPPSQEEM TKNQVSLTCL 150
VKGFYPSDIA VEWESNGQPE NNYKTTPPVL DSDGSFFLYS RLTVDKSRWQ 200
EGNVFSCSVM HEALHNHYTQ KSLSLSLGKD QDKIEALSSK VQQLERSIGL 250
KDLAMADLEQ KVLEMEASTQ VSHRYPRIQS IKVQFTEYKK EKGFILTSQK 300
EDEIMKVQNN SVIINCDGFY LISLKGYFSQ EVNISLHYQK DEEPLFQLKK 350
VRSVNSLMVA SLTYKDKVYL NVTTDNTSLD DFHVNGGELI LIHQNPGEFC 400
VL                                                    402
```

Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro

8-8' 11-11' 43-103 149-207 316-400

Glycosylation sites (N) / Sites de glycosylation (N) / Posiciones de glicosilación (N)

Asn-79 Asn-309 Asn-333 Asn-371 Asn-376

eflenograstimum alfa #

eflenograstim alfa	human granulocyte-colony stimulating factor (G-CSF) fused to a hybrid human immunoglobulin consisting of the Fc fragment of the IgG4 fused to the hinge region and amino-terminus of the IgD heavy chain isotype 2, produced in Chinese hamster ovary (CHO) cells, glycoform alfa; [human granulocyte-colony stimulating factor (G-CSF) short isoform (1-174)]-[immunoglobulin heavy chain delta (IGHD) constant region isoform 2 (133-170)-peptide (C-terminal hinge and N-terminal CH2 domains) (175-212)]-[immunoglobulin heavy chain gamma 4 (IGHG4) constant region (121-327)-peptide (CH2 and CH3 domains) (213-419)]-fusion protein, (203-203')-disulfide dimer, produced in Chinese hamster ovary (CHO) cells, glycoform alfa
éflénograstim alfa	facteur stimulant les colonies de granulocytes humain (G-CSF) fusionné à une immunoglobuline (Ig) humaine hybride, consistant en un fragment Fc de l'IgG4 fusionné à la région charnière et à la chaîne lourde isotoype 2 de l'IgD sur la partie N-terminale, produite par des cellules ovariennes de hamsters chinois (CHO), glycoforme alfa; [facteur stimulant les colonies de granulocytes humain (G-CSF) isoforme courte (1-174)]-[région constante de la chaîne lourde delta de l'immunoglobuline (IGHD) isoforme 2 (133-170)-peptide (région charnière C-terminale et domaine CH2 N-terminal) (175-212)]-[région constante de la chaîne lourde de l'immunoglobuline gamma 4 (IGHG4) (121-327)-peptide (domaines CH2 et CH3) (213-419)]-protéine de fusion, (203-203')-disulfide dimère, produite par des cellules ovariennes de hamsters chinois (CHO), glycoforme alfa
eflenograstim alfa	factor estimulante de las colonias de granulocitos humanos (G-CSF) fusionado con una inmunoglobulina (Ig) humana híbrida, consistente en un fragmento Fc de la IgG4 fusionado con la región bisagra y con la cadena pesada isótopo 2 de la IgD sobre la parte N-terminal, producido por las células ováricas de hamster chino (CHO), glicoforma alfa; [factor estimulante de las colonias de granulocitos humanos (G-CSF) isoforma corta (1-174)]-[región constante de la cadena pesada delta de la inmunoglobulina (IGHD) isoforma 2 (133-170)-péptido (región bisagra C-terminal y dominio CH2 N-terminal) (175-212)]-[región constante de la cadena pesada de la inmunoglobulina gamma 4 (IGHG4) (121-327)-péptido (dominios CH2 y CH3) (213-419)]-proteína de fusión, (203-203')-disulfuro dímero, producido por las células ováricas de hamster chino (CHO), glicoforma alfa

Monomer sequence / Séquence du monomère / Secuencia del monómero

```
TPLGPASSLP QSFLLKCLEQ VRKIQGDGAA LQEKLCATYK LCHPEELVLL 50
GHSLGIPWAP LSSCPSQALQ LAGCLSQLHS GLFLYQGLLQ ALEGISPELG 100
PTLDTLQLDV ADFATTIWQQ MEELGMAPAL QPTQGAMPAF ASAFQRRAGG 150
VLVASHLQSF LEVSYRVLRH LAQPRNTGRG GEEKKKEKEK EEQEERETKT 200
PECPSHTQPL GVFLFPPKPK DTLMISRTPE VTCVVVDVSQ EDPEVQFNWY 250
VDGVEVHNAK TKPREEQFNS TYRVVSVLTV LHQDWLNGKE YKCKVSNKGL 300
PSSIEKTISK AKGQPREPQV YTLPPSQEEM TKNQVSLTCL VKGFYPSDIA 350
VEWESNGQPE NNYKTTPPVL DSDGSFFLYS RLTVDKSRWQ EGNVFSCSVM 400
HEALHNHYTQ KSLSLSLGK                                  419
```

Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro

Intra-chain disulfide bridges: 36-42 64-74 233-293 339-397
36'-42' 64'-74' 233'-293' 339'-397'

Inter-chain disulfide bridges: 203-203'

Glycosylation sites (N) / Sites de glycosylation (N) / Posiciones de glicosilación (N)
Asn-269

Glycosylation sites (O) / Sites de glycosylation (O) / Posiciones de glicosilación (O)
Thr-133

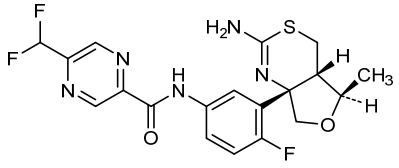
elenbecestatum

elenbecestat — *N*-{3-[(4a*S*,5*R*,7a*S*)-2-amino-5-methyl-4a,5-dihydro-4*H*-furo[3,4-*d*][1,3]thiazin-7a(7*H*)-yl]-4-fluorophenyl}-5-(difluoromethyl)pyrazine-2-carboxamide

élenbécestat — *N*-{3-[(4a*S*,5*R*,7a*S*)-2-amino-5-méthyl-4a,5-dihydro-4*H*-furo[3,4-*d*][1,3]thiazin-7a(7*H*)-yl]-4-fluorophényl}-5-(difluorométhyl)pyrazine-2-carboxamide

elenbecestat — *N*-{3-[(4a*S*,5*R*,7a*S*)-2-amino-5-metil-4a,5-dihidro-4*H*-furo[3,4-*d*][1,3]tiazin-7a(7*H*)-il]-4-fluorofenil}-5-(difluorometil)pirazina-2-carboxamida

$C_{19}H_{18}F_3N_5O_2S$



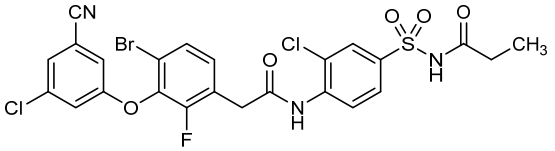
elsulfavirinum

elsulfavirine — *N*-(4-{2-[4-bromo-3-(3-chloro-5-cyanophenoxy)-2-fluorophenyl]acetamido}-3-chlorobenzenesulfonyl)propanamide

elsulfavirine — *N*-(4-{2-[4-bromo-3-(3-chloro-5-cyanophénoxy)-2-fluorophényl]acétamido}-3-chlorobenzènesulfonyl)propanamide

elsulfavirina — *N*-(4-{2-[4-bromo-3-(3-cloro-5-cianofenoxi)-2-fluorofenil]acetamido}-3-clorobencenosulfonil)propanamida

$C_{24}H_{17}BrCl_2FN_3O_5S$



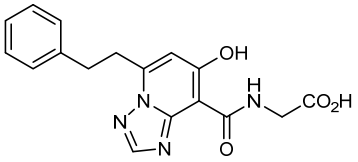
emiplacelum

emiplacel	human culture expanded allogenic adherent mesenchymal-like stromal cells for cell-based therapy. Cells are derived of maternal origin from isolated placentae of healthy donors following a cesarean section. Cells express cell surface markers CD29, CD73, and CD105 and exhibit immunomodulatory, pro-angiogenic and muscle regeneration effects.
émiplacel	cellules mésenchymales adhérentes humaines allogéniques semblables au stroma, en culture d'expansion, pour thérapie cellulaire. Les cellules d'origine maternelle sont obtenues à partir du placenta de donneuses saines et vivantes suivant une césarienne. Les cellules expriment les marqueurs de surface CD29, CD73, and CD105 et montrent des propriétés immunomodulatrices et des effets pro-angiogéniques.
emiplacel	células adherentes mesenquimales similares al estroma alogénicas, humanas, expandidas en cultivo para terapia celular. Las células de origén maternal se derivan a partir de la placenta de donantes sanos vivos tras una sección por cesárea. Las células expresan los marcadores de superficie CD29, CD73 y D105, y muestran efectos inmunomoduladores y angiogénicos

enarodustatum

enarodustat	*N*-[7-hydroxy-5-(2-phenylethyl)[1,2,4]triazolo[1,5-*a*]pyridine-8-carbonyl]glycine
énarodustat	*N*-[7-hydroxy-5-(2-phényléthyl)[1,2,4]triazolo[1,5-*a*]pyridine-8-carbonyl]glycine
enarodustat	*N*-[7-hidroxi-5-(2-feniletil)[1,2,4]triazolo[1,5-*a*]piridina-8-carbonil]glicina

$C_{17}H_{16}N_4O_4$



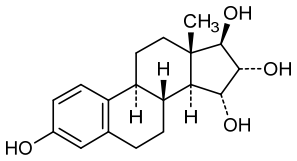
estetrolum

estetrol — estra-1,3,5(10)-triene-3,15α,16α,17β-tetrol

estétrol — estra-1,3,5(10)-triène-3,15α,16α,17β-tétrol

estetrol — estra-1,3,5(10)-trieno-3,15α,16α,17β-tetrol

$C_{18}H_{24}N_4$



exebacasum #

exebacase — *Streptococcus suis* bacteriophage-derived lysin**,** produced in *Escherichia coli*;

des-Met[1]-phage lysin (endolysin, lysozyme, murein hydrolase, EC 3.2.1.17) of *Streptococcus suis phage* φ891591 (PlySs2), produced in *Escherichia coli*

exébacase — lysine dérivée du bactériophage *Streptococcus suis***,** produite par *Escherichia coli;*

lysine du dès-Mét[1]-phage *Streptococcus suis* φ891591 (PlySs2) (endolysine, lysozyme, muréine hydrolase, EC 3.2.1.17), produite par *Escherichia coli*

exebacasa — lisina derivada del bacteriófago *Streptococcus suis***,** producido por *Escherichia coli;*

lisina del des-Met[1]-fago *Streptococcus suis* φ891591 (PlySs2) (endolisina, lisozima, mureína hidrolasa, EC 3.2.1.17), producida por *Escherichia coli*

Sequence / Séquence / Secuencia

```
TTVNEALNNV RAQVGSGVSV GNGECYALAS WYERMISPDA TVGLGAGVGW 50
VSGAIGDTIS AKNIGSSYNW QANGWTVSTS GPFKAGQIVT LGATPGNPYG 100
HVVIVEAVDG DRLTILEQNY GGKRYPVRNY YSAASYRQQV VHYITPPGTV 150
AQSAPNLAGS RSYRETGTMT VTVDALNVRR APNTSGEIVA VYKRGESFDY 200
DTVIIDVNGY VWVSYIGGSG KRNYVATGAT KDGKRFGNAW GTFK       244
```

fenebrutinibum

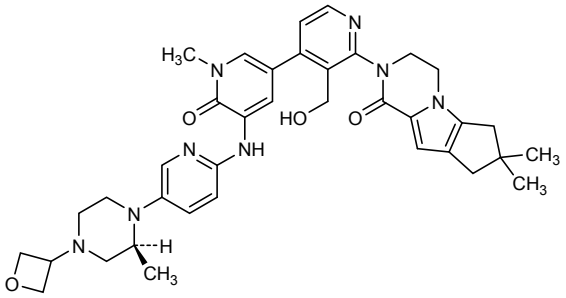
fenebrutinib — (6[2]*S*)-2[3]-(hydroxymethyl)-1[7],1[7],3[1],6[2]-tetramethyl-1[3],1[4],1[7],1[8]-tetrahydro-4-aza-1(2)-cyclopenta[4,5]pyrrolo[1,2-*a*]pyrazina-6(1,4)-piperazina-2(2,4),3(3,5),5(2,5)-tripyridina-7(3)-oxetanaheptaphane-1[1](1[6]*H*),3[6](3[1]*H*)-dione

fénébrutinib — (6[2]*S*)-2[3]-(hydroxyméthyl)-1[7],1[7],3[1],6[2]-tétraméthyl-1[3],1[4],1[7],1[8]-tétrahydro-4-aza-1(2)-cyclopenta[4,5]pyrrolo[1,2-*a*]pyrazina-6(1,4)-pipérazina-2(2,4),3(3,5),5(2,5)-tripyridina-7(3)-oxétanaheptaphane-1[1](1[6]*H*),3[6](3[1]*H*)-dione

fenebrutinib

(6^{2}*S*)-2^{3}-(hidroximetil)-1^{7},1^{7},3^{1},6^{2}-tetrametil-1^{3},1^{4},1^{7},1^{8}-tetrahidro-4-aza-1(2)-ciclopenta[4,5]pirrolo[1,2-*a*]pirazina-6(1,4)-piperazina-2(2,4),3(3,5),5(2,5)-tripiridina-7(3)-oxetanaheptafano-1^{1}(1^{6}*H*),3^{6}(3^{1}*H*)-diona

$C_{37}H_{44}N_8O_4$



firibastatum

firibastat

4,4'-disulfanediylbis[(3*S*)-3-aminobutane-1-sulfonic] acid

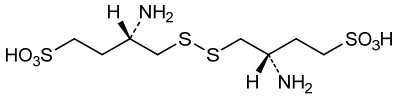
firibastat

acide 4,4'-disulfanediylbis[(3*S*)-3-aminobutane-1-sulfonique]

firibastat

ácido 4,4'-disulfanodiilbis[(3*S*)-3-aminobutano-1-sulfónico]

$C_8H_{20}N_2O_6S_4$



foligluraxum

foliglurax

N-{6-[3-(morpholin-4-yl)propyl]-2-(thieno[3,2-*c*]pyridin-6-yl)-4*H*-1-benzopyran-4-ylidene}hydroxylamine

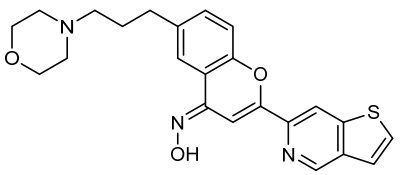
foliglurax

N-{6-[3-(morpholin-4-yl)propyl]-2-(thiéno[3,2-*c*]pyridin-6-yl)-4*H*-1-benzopyran-4-ylidène}hydroxylamine

foliglurax

N-{6-[3-(morfolin-4-il)propil]-2-(tieno[3,2-*c*]piridin-6-il)-4*H*-1-benzopiran-4-ilideno}hidroxilamina

$C_{23}H_{23}N_3O_3S$



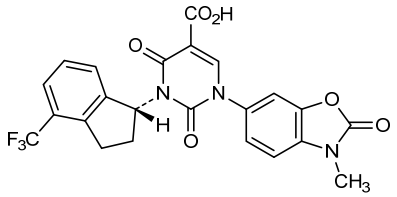
fulacimstatum

fulacimstat — 1-(3-methyl-2-oxo-2,3-dihydro-1,3-benzoxazol-6-yl)-2,4-dioxo-3-[(1*R*)-4-(trifluoromethyl)-2,3-dihydro-1*H*-inden-1-yl]-1,2,3,4-tetrahydropyrimidine-5-carboxylic acid

fulacimstat — acide 1-(3-méthyl-2-oxo-2,3-dihydro-1,3-benzoxazol-6-yl)-2,4-dioxo-3-[(1*R*)-4-(trifluorométhyl)-2,3-dihydro-1*H*-indén-1-yl]-1,2,3,4-tétrahydropyrimidine-5-carboxylique

fulacimstat — ácido 1-(3-metil-2-oxo-2,3-dihidro-1,3-benzoxazol-6-il)-2,4-dioxo-3-[(1*R*)-4-(trifluorometil)-2,3-dihidro-1*H*-inden-1-il]-1,2,3,4-tetrahidropirimidina-5-carboxílico

$C_{23}H_{16}F_3N_3O_6$



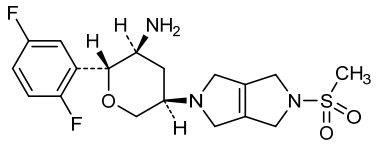
garvagliptinum

garvagliptin — (2*R*,3*S*,5*R*)-2-(2,5-difluorophenyl)-5-[5-(methanesulfonyl)-3,4,5,6-tetrahydropyrrolo[3,4-*c*]pyrrol-2(1*H*)-yl]oxan-3-amine

garvagliptine — (2*R*,3*S*,5*R*)-2-(2,5-difluorophényl)-5-[5-(méthanesulfonyl)-3,4,5,6-tétrahydropyrrolo[3,4-*c*]pyrrol-2(1*H*)-yl]oxan-3-amine

garvagliptina — (2*R*,3*S*,5*R*)-2-(2,5-difluorofenil)-5-[5-(metanosulfonil)-3,4,5,6-tetrahidropirrolo[3,4-*c*]pirrol-2(1*H*)-il]oxan-3-amina

$C_{18}H_{23}F_2N_3O_3S$



gimsilumabum #

gimsilumab — immunoglobulin G1-kappa, anti-[*Homo sapiens* CSF2 (colony stimulating factor 2 (granulocyte-macrophage), granulocyte-macrophage colony stimulating factor, GM-CSF)], *Homo sapiens* monoclonal antibody;
gamma1 heavy chain (1-451) [*Homo sapiens* VH (IGHV3-74*03 (84.70%) -(IGHD) -IGHJ4*01, L123>P (116) [8.8.14] (1-121) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (218) (122-219), hinge (220-234), CH2 (235-344), CH3 D12 (360), L14 (362), M107>V (432) (345-449), CHS (450-451)) (122-451)], (224-214')-disulfide with kappa light chain (1'-214') [*Homo sapiens* V-KAPPA (IGKV3-15*01 (89.50%) -IGKJ2*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (159), V101 (197) (108'-214')]; dimer (230-230'':233-233'')-bisdisulfide

gimsilumab

immunoglobuline G1-kappa, anti-[*Homo sapiens* CSF2 (facteur 2 stimulant de colonies (granulocyte-macrophage), facteur stimulant des colonies de granulocytes et macrophages, GM-CSF)], *Homo sapiens* anticorps monoclonal;
chaîne lourde gamma1 (1-451) [*Homo sapiens* VH (IGHV3-74*03 (84.70%) -(IGHD) -IGHJ4*01, L123>P (116) [8.8.14] (1-121) -*Homo sapiens* IGHG1*01 G1m17,1 (CH1 K120 (218) (CH1 (122-219), charnière (220-234), CH2 (235-344), CH3 D12 (360), L14 (362), M107>V (432) (345-449), CHS (450-451)) (122-451)], (224-214')-disulfure avec la chaîne légère (1'-214') [*Homo sapiens* V-KAPPA (IGKV3-15*01 (89.50%) -IGKJ2*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (159), V101 (197) (108'-214')]; dimère (230-230'':233-233'')-bisdisulfure

gimsilumab

inmunoglobulina G1-kappa, anti-[*Homo sapiens* CSF2 (factor 2 estimulante de colonias (granulocito-macrófago), factor estimulante de colonias de granulocitos y macrófagos, GM-CSF)], *Homo sapiens* anticuerpo monoclonal;
cadena pesada gamma1 (1-451) [*Homo sapiens* VH (IGHV3-74*03 (84.70%) -(IGHD) -IGHJ4*01, L123>P (116) [8.8.14] (1-121) -*Homo sapiens* IGHG1*01 G1m17,1 (CH1 K120 (218) (CH1 (122-219), bisagra (220-234), CH2 (235-344), CH3 D12 (360), L14 (362), M107>V (432) (345-449), CHS (450-451)) (122-451)], (224-214')-disulfuro con la cadena ligera (1'-214') [*Homo sapiens* V-KAPPA (IGKV3-15*01 (89.50%) -IGKJ2*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (159), V101 (197) (108'-214')]; dímero (230-230'':233-233'')-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVESGGG LVQPGGSLRL SCAASGFTFS RHWMHWLRQV PGKGPVWVSR  50
INGAGTSITY ADSVRGRFTI SRDNANNTLF LQMNSLRADD TALYFCARAN 100
SVWFRGLFDY WGQGTPVTVS SASTKGPSVF PLAPSSKSTS GGTAALGCLV 150
KDYFPEPVTV SWNSGALTSG VHTFPAVLQS SGLYSLSSVV TVPSSSLGTQ 200
TYICNVNHKP SNTKVDKKVE PKSCDKTHTC PPCPAPELLG GPSVFLFPPK 250
PKDTLMISRT PEVTCVVVDV SHEDPEVKFN WYVDGVEVHN AKTKPREEQY 300
NSTYRVVSVL TVLHQDWLNG KEYKCKVSNK ALPAPIEKTI SKAKGQPREP 350
QVYTLPPSRD ELTKNQVSLT CLVKGFYPSD IAVEWESNGQ PENNYKTTPP 400
VLDSDGSFFL YSKLTVDKSR WQQGNVFSCS VVHEALHNHY TQKSLSLSPG 450
K                                                       451
```

Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPVT LSVSPGERVT LSCRASQSVS TNLAWYQQKL GQGPRLLIYG  50
ASTRATDIPA RFSGSGSETE FTLTISSLQS EDFAVYYCQQ YDKWPDTFGQ 100
GTKLEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 148-204 265-325 371-429
22''-96'' 148''-204'' 265''-325'' 371''-429''
Intra-L (C23-C104) 23'-88' 134'-194'
23'''-88''' 134'''-194'''
Inter-H-L (h 5-CL 126) 224-214' 224''-214'''
Inter-H-H (h 11, h 14) 230-230'' 233-233''

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H VH N84
76, 76''
H CH2 N84.4:
301, 301''
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

ianalumabum #

ianalumab	immunoglobulin G1-kappa, anti-[*Homo sapiens* TNFRSF13C (tumor necrosis factor receptor (TNFR) superfamily member 13C, BAFFR, BAFF-R, BR3, B cell activating factor receptor, CD268)], *Homo sapiens* monoclonal antibody; gamma1 heavy chain (1-454) [*Homo sapiens* VH (IGHV6-1*01 (96.00%) -(IGHD) -IGHJ5*01) [10.9.14] (1-124) -*Homo sapiens* IGHG1*03,G1m3, nG1m1 (CH1 R120 (221) (125-222), hinge (223-237), CH2 (238-347), CH3 E12 (363), M14 (365) (348-452), CHS (453-454)) (125-454)], (227-215')-disulfide with kappa light chain (1'-215') [*Homo sapiens* V-KAPPA (IGKV3D-11*01 (86.80%) -IGKJ1*01) [7.3.9] (1'-108') -*Homo sapiens* IGKC*01, Km3 A45.1 (154), V101 (192) (109'-215')]; dimer (233-233'':236-236'')-bisdisulfide
ianalumab	immunoglobuline G1-kappa, anti-[*Homo sapiens* TNFRSF13C (membre 13C de la super famille du récepteur du facteur de nécrose tumorale (TNFR), BAFFR, BAFF-R, BR3, récepteur du facteur d'activation des lymphocytes B], *Homo sapiens* anticorps monoclonal; chaîne lourde gamma1 (1-454) [*Homo sapiens* VH (IGHV6-1*01 (96.00%) -(IGHD) -IGHJ5*01) [10.9.14] (1-124) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (221) (125-222), charnière (223-237), CH2 (238-347), CH3 E12 (363), M14 (365) (348-452), CHS (453-454)) (125-454)], (227-215')-disulfure avec la chaîne légère (1'-215') [*Homo sapiens* V-KAPPA (IGKV3D-11*01 (86.80%) -IGKJ1*01) [7.3.9] (1'-108') -*Homo sapiens* IGKC*01, Km3 A45.1 (154), V101 (192) (109'-215')]; dimère (233-233'':236-236'')-bisdisulfure
ianalumab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* TNFRSF13C (miembro 13C de la super familia del receptor del factor de necrosis tumoral (TNFR), BAFFR, BAFF-R, BR3, receptor del factor de activación de los linfocitos B], *Homo sapiens* anticuerpo monoclonal; cadena pesada gamma1 (1-454) [*Homo sapiens* VH (IGHV6-1*01 (96.00%) -(IGHD) -IGHJ5*01) [10.9.14] (1-124) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (221) (125-222), bisagra (223-237), CH2 (238-347), CH3 E12 (363), M14 (365) (348-452), CHS (453-454)) (125-454)], (227-215')-disulfuro con la cadena ligera (1'-215') [*Homo sapiens* V-KAPPA (IGKV3D-11*01 (86.80%) -IGKJ1*01) [7.3.9] (1'-108') -*Homo sapiens* IGKC*01, Km3 A45.1 (154), V101 (192) (109'-215')]; dímero (233-233'':236-236'')-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLQQSGPG LVKPSQTLSL TCAISGDSVS SNSAAWGWIR QSPGRGLEWL  50
GRIYYRSKWY NSYAVSVKSR ITINPDTSKN QFSLQLNSVT PEDTAVYYCA 100
RYQWVPKIGV FDSWGQGTLV TVSSASTKGP SVFPLAPSSK STSGGTAALG 150
CLVKDYFPEP VTVSWNSGAL TSGVHTFPAV LQSSGLYSLS SVVTVPSSSL 200
GTQTYICNVN HKPSNTKVDK RVEPKSCDKT HTCPPCPAPE LLGGPSVFLF 250
PPKPKDTLMI SRTPEVTCVV VDVSHEDPEV KFNWYVDGVE VHNAKTKPRE 300
EQYNSTYRVV SVLTVLHQDW LNGKEYKCKV SNKALPAPIE KTISKAKGQP 350
REPQVYTLPP SREEMTKNQV SLTCLVKGFY PSDIAVEWES NGQPENNYKT 400
TPPVLDSDGS FFLYSKLTVD KSRWQQGNVF SCSVMHEALH NHYTQKSLSL 450
SPGK                                                    454
```

Light chain / Chaîne légère / Cadena ligera

```
DIVLTQSPAT LSLSPGERAT LSCRASQFIL PEYLSWYQQK PGQAPRLLIY  50
GSSSRATGVP ARFSGSGSGT DFTLTISSLE PEDFAVYYCQ QFYSSPLTFG 100
QGTKVEIKRT VAAPSVFIFP PSDEQLKSGT ASVVCLLNNF YPREAKVQWK 150
VDNALQSGNS QESVTEQDSK DSTYSLSSTL TLSKADYEKH KVYACEVTHQ 200
GLSSPVTKSF NRGEC                                       215
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-99 151-207 268-328 374-432
22"-99" 151"-207" 268"-328" 374"-432"
Intra-L (C23-C104) 23'-89' 135'-195'
23'"-89'" 135'"-195'"
Inter-H-L (h 5-CL 126) 227-215' 227"-215'"
Inter-H-H (h 11, h 14) 233-233" 236-236"

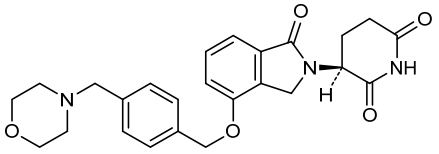
N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
304, 304"
Afucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes afucosylés / glicanos de tipo CHO biantenarios complejos afucosilados
N-terminal glutamine cyclization
H VH Q1: 1, 1"
C-terminal lysine clipping
H CHS K2: 454, 454"

iberdomidum
iberdomide — (3*S*)-3-[4-({4-[(morpholin-4-yl)methyl]phenyl}methoxy)-1-oxo-1,3-dihydro-2*H*-isoindol-2-yl]piperidine-2,6-dione

iberdomide — (3*S*)-3-[4-({4-[(morpholin-4-yl)méthyl]phényl}méthoxy)-1-oxo-1,3-dihydro-2*H*-isoindol-2-yl]pipéridine-2,6-dione

iberdomida — (3*S*)-3-[4-({4-[(morfolin-4-il)metil]fenil}metoxi)-1-oxo-1,3-dihidro-2*H*-isoindol-2-il]piperidina-2,6-diona

$C_{25}H_{27}N_3O_5$



imlifidasum #
imlifidase — human immunoglobulin G-degrading cysteine protease from *Streptococcus pyogenes* (IdeS, residues 30-339), produced in *Escherichia coli*; L-methionyl-immunoglobulin G-degrading protease (*Streptococcus pyogenes*) (IdeS) pro-protein (30-339)-peptide, produced by *Escherichia coli*

imlifidase

cystéine protéase de *Streptococcus pyogenes* dégradant l'immunoglobuline G humaine (IdeS, résidus 30-339), produite par *Escherichia coli*;
L-méthionyl-protéase dégradant l'immunoglobuline G (*Streptococcus pyogenes*) (IdeS) pro-protéine (30-339)-peptide, produite par *Escherichia coli*

imlifidasa

cisteína proteasa de *Streptococcus pyogenes* que degrada a la inmunoglobulina G humana (IdeS, residuos 30-339), producida por *Escherichia coli*;
L-metionil-proteasa que degrada la inmunoglobulina G (*Streptococcus pyogenes*) (IdeS) pro-proteína (30-339)-péptido, producido por *Escherichia coli*

Sequence / Séquence / Secuencia

```
MDSFSANQEI RYSEVTPYHV TSVWTKGVTP PANFTQGEDV FHAPYVANQG 50
WYDITKTFNG KDDLLCGAAT AGNMLHWWFD QNKDQIKRYL EEHPEKQKIN 100
FNGEQMFDVK EAIDTKNHQL DSKLFEYFKE KAFPYLSTKH LGVFPDHVID 150
MFINGYRLSL TNHGPTPVKE GSKDPRGGIF DAVFTRGDQS KLLTSRHDFK 200
EKNLKEISDL IKKELTEGKA LGLSHTYANV RINHVINLWG ADFDSNGNLK 250
AIYVTDSDSN ASIGMKKYFV GVNSAGKVAI SAKEIKEDNI GAQVLGLFTL 300
STGQDSWNQT N                                           311
```

istiratumabum #

istiratumab

immunoglobulin G1-kappa anti-[*Homo sapiens* IGF1R (insulin-like growth factor 1 receptor, IGF1-R, IGF-1R, CD221)], each heavy chain being fused to a scFv anti-[*Homo sapiens* ERBB3 (receptor tyrosine-protein kinase erbB-3, HER3)], *Homo sapiens* monoclonal antibody, bispecific tetravalent;
gamma1 heavy chain anti-IGFR1 fused to a scFv anti-ERBB3 (1-720) [*Homo sapiens* gamma1 heavy chain {(*Homo sapiens* VH (IGHV3-23*01 (90.80%) -(IGHD) -IGHJ4*01 L123>T (117))[8.8.15] (1-122) -*Homo sapiens* IGHG1*03v,G1m3>G1m17, nG1m1 (CH1 R120>K (219) (123-220), hinge (221-235), CH2 (236-345), CH3 E12 (361), M14 (363) (346-450), CHS K2>del (451))(123-451)}(1-451)-15-mer tris(tetraglycyl-seryl) linker (452-466) -scFv {(*Homo sapiens* VH (IGHV3-9*01 (92.90%) -(IGHD) -IGHJ4*01) [8.8.15] (467-588) -23-mer alanyl-seryl-threonyl-tetrakis(tetraglycyl-seryl) linker (589-611) -*Homo sapiens* V-LAMBDA (IGLV3-19*01 (94.80%) -IGLJ3*02 L124>V (716)) [6.3.11] (612-719) -glycyl (720)}(467-720)],(225-214')-disulfide with kappa light chain anti-IGFR1 (1'-214') [*Homo sapiens* V-KAPPA(IGKV1-12*01 (90.50%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (231-231''':234-234'')-bisdisulfide

istiratumab

immunoglobuline G1-kappa anti-[*Homo sapiens* IGF1R (récepteur du facteur de croissance 1 analogue à l'insuline, IGF1-R, IGF-1R, CD221)], chaque chaîne lourde étant fusionnée à un scFv anti-[*Homo sapiens* ERBB3 (récepteur à activité tyrosine kinase erbB-3, HER3)], *Homo sapiens* anticorps monoclonal, bispécifique tétravalent; chaîne lourde gamma1 anti-IGFR1 fusionnée à un

scFv anti-ERBB3 (1-720) [chaîne lourde gamma1 *Homo sapiens* {(*Homo sapiens* VH (IGHV3-23*01 (90.80%) -(IGHD) -IGHJ4*01 L123>T (117))[8.8.15] (1-122) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (219)(123-220), charnière (221-235), CH2 (236-345), CH3 E12 (361), M14 (363) (346-450), CHS K2>del (451))(123-451)}(1-451) -15-mer tris(tétraglycyl-séryl) linker (452-466)-scFv {(*Homo sapiens* VH (IGHV3-9*01 (92.90%) -(IGHD) -IGHJ4-01) [8.8.15](467-588) -23-mer alanyl-séryl-thréonyl-tétrakis(tétraglycyl-séryl) linker (589-611) -*Homo sapiens* V-LAMBDA (IGLV3-19*01 (94.80%) -IGLJ3*02 L124>V (716)) [6.3.11] (612-719) -glycyl (720)}(467-720)], (225-214')-disulfure avec la chaîne légère kappa anti-IGFR1 (1'-214') [*Homo sapiens* V-KAPPA (IGKV1-12*01 (90.50%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (231-231'':234-234'')-bisdisulfure

istiratumab

inmunoglobulina G1-kappa anti-[*Homo sapiens* IGF1R (receptor del factor de crecimiento 1 análogo a la insulina, IGF1-R, IGF-1R, CD221)], cada cadena pesada estando fusionada con un scFv anti-[*Homo sapiens* ERBB3 (receptor tirosina-proteína kinasa erbB-3, HER3)], *Homo sapiens* anticuerpo monoclonal, biespecífico tetravalente;
cadena pesada gamma1 anti-IGFR1 fusionada con un scFv anti-ERBB3 (1-720) [cadena pesada gamma1 *Homo sapiens* {(*Homo sapiens* VH (IGHV3-23*01 (90.80%) -(IGHD) -IGHJ4*01 L123>T (117))[8.8.15] (1-122) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (219)(123-220), bisagra (221-235), CH2 (236-345), CH3 E12 (361), M14 (363) (346-450), CHS K2>del (451))(123-451)}(1-451) -15-mer tris(tetraglicil-seril) espaciador (452-466)-scFv {(*Homo sapiens* VH (IGHV3-9*01 (92.90%) -(IGHD) -IGHJ4-01) [8.8.15](467-588) -23-mer alanil-seril-treonil-tetrakis(tetraglicil-seril) espaciador (589-611) -*Homo sapiens* V-LAMBDA (IGLV3-19*01 (94.80%) -IGLJ3*02 L124>V (716)) [6.3.11] (612-719) -glicil (720)}(467-720)], (225-214')-disulfuro con la cadena ligera kappa anti-IGFR1 (1'-214') [*Homo sapiens* V-KAPPA (IGKV1-12*01 (90.50%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (231-231'':234-234'')-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLLQSGGG LVQPGGSLRL SCAASGFMFS RYPMHWVRQA PGKGLEWVGS  50
ISGSGGATPY ADSVKGRFTI SRDNSKNTLY LQMNSLRAED TAVYYCAKDF 100
YQILTGNAFD YWGQGTTVTV SSASTKGPSV FPLAPSSKST SGGTAALGCL 150
VKDYFPEPVT VSWNSGALTS GVHTFPAVLQ SSGLYSLSSV VTVPSSSLGT 200
QTYICNVNHK PSNTKVDKKV EPKSCDKTHT CPPCPAPELL GGPSVFLFPP 250
KPKDTLMISR TPEVTCVVVD VSHEDPEVKF NWYVDGVEVH NAKTKPREEQ 300
YNSTYRVVSV LTVLHQDWLN GKEYKCKVSN KALPAPIEKT ISKAKGQPRE 350
PQVYTLPPSR EEMTKNQVSL TCLVKGFYPS DIAVEWESNG QPENNYKTTP 400
PVLDSDGSFF LYSKLTVDKS RWQQGNVFSC SVMHEALHNH YTQKSLSLSP 450
GGGGGSGGGG SGGGGSQVQL VQSGGGLVQP GGSLRLSCAA SGFTFDDYAM 500
HWVRQAPGKG LEWVAGISWD SGSTGYADSV KGRFTISRDN AKNSLYLQMN 550
SLRAEDTALY YCARDLGAYQ WVEGFDYWGQ GTLVTVSSAS TGGGGSGGGG 600
SGGGGSGGGG SSYELTQDPA VSVALGQTVR ITCQGDSLRS YYASWYQQKP 650
GQAPVLVIYG KNNRPSGIPD RFSGSTSGNS ASLTITGAQA EDEADYYCNS 700
RDSPGNQWVF GGGTKVTVLG                                  720
```

Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS LSASLGDRVT ITCRASQGIS SYLAWYQQKP GKAPKLLIYA  50
KSTLQSGVPS RFSGSGSGTD FTLTISSLQP EDSATYYCQQ YWTFPLTFGG 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 149-205 266'-326" 372"-430" 488"-562" 633"-698"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (h 5-CL 126) 225-214' 225"-214'"
Inter-H-H (h 11, h 14) 231-231" 234-234"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
302, 302"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

ladiratuzumabum #	
ladiratuzumab	immunoglobulin G1-kappa, anti-[*Homo sapiens* SLC39A6 (solute carrier family 39 member 6, solute carrier family 39 (metal ion transporter) member 6, solute carrier family 39 (zinc transporter) member 6, LIV-1)], humanized monoclonal antibody; gamma1 heavy chain (1-450) [humanized VH (*Homo sapiens* IGHV1-2*02 (87.60%) -(IGHD) -IGHJ4*01) [8.8.13] (1-120) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (217) (121-218), hinge (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-219')-disulfide with kappa light chain (1'-219') [humanized V-KAPPA (*Homo sapiens* IGKV2-30*02 (89.00%) -IGKJ4*01) [11.3.9] (1'-112') -*Homo sapiens* IGKC*01, Km3 A45.1 (158), V101 (196) (113'-219')]; dimer (229-229":232-232")-bisdisulfide
ladiratuzumab	immunoglobuline G1-kappa, anti-[*Homo sapiens* SLC39A6 (membre 6 de la famille 39 des transporteurs de soluté, membre 6 de la famille 39 (transporteur d'ion métal) des transporteurs de soluté, membre 6 de la famille 39 (transporteur du zinc) des transporteurs de soluté, LIV-1)], anticorps monoclonal humanisé; chaîne lourde gamma1 (1-450) [VH humanisé (*Homo sapiens* IGHV1-2*02 (87.60%) -(IGHD) -IGHJ4*01) [8.8.13] (1-120) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (217) (121-218), charnière (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-219')-disulfure avec la chaîne légère kappa (1'-219') [V-KAPPA humanisé (*Homo sapiens* IGKV2-30*02 (89.00%) -IGKJ4*01) [11.3.9] (1'-112') -*Homo sapiens* IGKC*01, Km3 A45.1 (158), V101 (196) (113'-219')]; dimère (229-229":232-232")-bisdisulfure
ladiratuzumab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* SLC39A6 (miembro 6 de la familia 39 de los transportadores de soluto, miembro 6 de la familia 39 (transportador del ión metal) de los transportadores de soluto, miembro 6 de la familia 39 (transportador de zinc) de los transportadores de soluto, LIV-1)], anticuerpo monoclonal humanizado; cadena pesada gamma1 (1-450) [VH humanizado (*Homo sapiens* IGHV1-2*02 (87.60%) -(IGHD) -IGHJ4*01) [8.8.13] (1-120) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (217) (121-218), bisagra (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-219')-disulfuro con la cadena ligera kappa (1'-219') [V-KAPPA humanizado (*Homo sapiens* IGKV2-30*02 (89.00%) -IGKJ4*01) [11.3.9] (1'-112') -*Homo sapiens* IGKC*01, Km3 A45.1 (158), V101 (196) (113'-219')]; dímero (229-229":232-232")-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGASVKV SCKASGLTIE DYYMHWVRQA PGQGLEWMGW  50
IDPENGDTEY GPKFQGRVTM TRDTSINTAY MELSRLRSDD TAVYYCAVHN 100
AHYGTWFAYW GQGTLVTVSS ASTKGPSVFP LAPSSKSTSG GTAALGCLVK 150
DYFPEPVTVS WNSGALTSGV HTFPAVLQSS GLYSLSSVVT VPSSSLGTQT 200
YICNVNHKPS NTKVDKKVEP KSCDKTHTCP PCPAPELLGG PSVFLFPPKP 250
KDTLMISRTP EVTCVVVDVS HEDPEVKFNW YVDGVEVHNA KTKPREEQYN 300
STYRVVSVLT VLHQDWLNGK EYKCKVSNKA LPAPIEKTIS KAKGQPREPQ 350
VYTLPPSRDE LTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPV 400
LDSDGSFFLY SKLTVDKSRW QQGNVFSCSV MHEALHNHYT QKSLSLSPGK 450
```

Light chain / Chaîne légère / Cadena ligera

```
DVVMTQSPLS LPVTLGQPAS ISCRSSQSLL HSSGNTYLEW YQQRPGQSPR  50
PLIYKISTRF SGVPDRFSGS GSGTDFTLKI SRVEAEDVGV YYCFQGSHVP 100
YTFGGGTKVE IKRTVAAPSV FIFPPSDEQL KSGTASVVCL LNNFYPREAK 150
VQWKVDNALQ SGNSQESVTE QDSKDSTYSL SSTLTLSKAD YEKHKVYACE 200
VTHQGLSSPV TKSFNRGEC                                   219
```

Post-translational modifications

Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro

Intra-H (C23-C104) 22-96 147-203 264-324 370-428
22"-96" 147"-203" 264"-324" 370"-428"
Intra-L (C23-C104) 23'-93' 139'-199'
23'"-93'" 139'"-199'"
Inter-H-L (h 5-CL 126) 223-219' 223"-219'"
Inter-H-H (h 11, h 14) 229-229" 232-232"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación

H CH2 N84.4:
300, 300"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados.

ladiratuzumabum vedotinum #

ladiratuzumab vedotin

immunoglobulin G1-kappa, anti-[*Homo sapiens* SLC39A6 (solute carrier family 39 member 6, solute carrier family 39 (metal ion transporter) member 6, solute carrier family 39 (zinc transporter) member 6, LIV-1)], humanized monoclonal antibody conjugated to auristatin E; gamma1 heavy chain (1-450) [humanized VH (*Homo sapiens* IGHV1-2*02 (87.60%) -(IGHD) -IGHJ4*01) [8.8.13] (1-120) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (217) (121-218), hinge (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-219')-disulfide with kappa light chain (1'-219') [humanized V-KAPPA (*Homo sapiens* IGKV2-30*02 (89.00%) -IGKJ4*01) [11.3.9] (1'-112') -*Homo sapiens* IGKC*01, Km3 A45.1 (158), V101 (196) (113'-219')]; dimer (229-229":232-232")-bisdisulfide; conjugated, on an average of 4 cysteinyl, to monomethylauristatin E (MMAE), via a cleavable maleimidocaproyl-valyl-citrullinyl-p-aminobenzyloxycarbonyl (mc-val-cit-PABC) type linker

For the *vedotin* part, please refer to the document *"INN for pharmaceutical substances: Names for radicals, groups and others"*.

ladiratuzumab védotine

immunoglobuline G1-kappa, anti-[*Homo sapiens* SLC39A6 (membre 6 de la famille 39 des transporteurs de soluté, membre 6 de la famille 39 (transporteur d'ion métal) des transporteurs de soluté, membre 6 de la famille 39 (transporteur du zinc) des transporteurs de soluté, LIV-1)], anticorps monoclonal humanisé conjugué à l'auristatine E; chaîne lourde gamma1 (1-450) [VH humanisé (*Homo sapiens* IGHV1-2*02 (87.60%) -(IGHD) -IGHJ4*01) [8.8.13] (1-120) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (217) (121-218), charnière (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-219')-disulfure avec la chaîne légère kappa

(1'-219') [V-KAPPA humanisé (*Homo sapiens* IGKV2-30*02 (89.00%) -IGKJ4*01) [11.3.9] (1'-112') -*Homo sapiens* IGKC*01, Km3 A45.1 (158), V101 (196) (113'-219')]; dimère (229-229":232-232")-bisdisulfure; conjugué, sur 4 cystéinyl en moyenne, au monométhylauristatine E (MMAE), via un linker clivable de type maléimidocaproyl-valyl-citrullinyl-p-aminobenzyloxycarbonyl (mc-val-cit-PABC)

Pour la partie *védotine*, veuillez-vous référer au document *"INN for pharmaceutical substances: Names for radicals, groups and others"*.*

ladiratuzumab vedotina

inmunoglobulina G1-kappa, anti-[*Homo sapiens* SLC39A6 (miembro 6 de la familia 39 de los transportadores de soluto, miembro 6 de la familia 39 (transportador del ión metal) de los transportadores del soluto, miembro 6 de la familia 39 (transportador del zinc) de los transportadores del soluto, LIV-1)], anticuerpo monoclonal humanizado conjugado con la auristatina E;
cadena pesada gamma1 (1-450) [VH humanizado (*Homo sapiens* IGHV1-2*02 (87.60%) -(IGHD) -IGHJ4*01) [8.8.13] (1-120) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (217) (121-218), bisagra (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-219')-disulfuro con la cadena ligera kappa (1'-219') [V-KAPPA humanizado (*Homo sapiens* IGKV2-30*02 (89.00%) -IGKJ4*01) [11.3.9] (1'-112') -*Homo sapiens* IGKC*01, Km3 A45.1 (158), V101 (196) (113'-219')]; dímero (229-229":232-232")-bisdisulfuro; conjugado, con 4 restos cisteinil, por término medio, con monometilauristatina E (MMAE), mediante un enlace de tipo maleimidocaproil-valil-citrulinil-p-aminobenziloxicarbonil (mc-val-cit-PABC)

Para la fracción *vedotina, pueden referirse al documento "INN for pharmaceutical substances: Names for radicals, groups and others"*.*

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGASVKV SCKASGLTIE DYYMHWVRQA PGQGLEWMGW  50
IDPENGDTEY GPKFQGRVTM TRDTSINTAY MELSRLRSDD TAVYYCAVHN 100
AHYGTWFAYW GQGTLVTVSS ASTKGPSVFP LAPSSKSTSG GTAALGCLVK 150
DYFPEPVTVS WNSGALTSGV HTFPAVLQSS GLYSLSSVVT VPSSSLGTQT 200
YICNVNHKPS NTKVDKKVEP KSCDKTHTCP PCPAPELLGG PSVFLFPPKP 250
KDTLMISRTP EVTCVVVDVS HEDPEVKFNW YVDGVEVHNA KTKPREEQYN 300
STYRVVSVLT VLHQDWLNGK EYKCKVSNKA LPAPIEKTIS KAKGQPREPQ 350
VYTLPPSRDE LTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPV 400
LDSDGSFFLY SKLTVDKSRW QQGNVFSCSV MHEALHNHYT QKSLSLSPGK 450
```

Light chain / Chaîne légère / Cadena ligera

```
DVVMTQSPLS LPVTLGQPAS ISCRSSQSLL HSSGNTYLEW YQQRPGQSPR 50
PLIYKISTRF SGVPDRFSGS GSGTDFTLKI SRVEAEDVGV YYCFQGSHVP 100
YTFGGGTKVE IKRTVAAPSV FIFPPSDEQL KSGTASVVCL LNNFYPREAK 150
VQWKVDNALQ SGNSQESVTE QDSKDSTYSL SSTLTLSKAD YEKHKVYACE 200
VTHQGLSSPV TKSFNRGEC                                   219
```

Post-translational modifications

Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro

Intra-H (C23-C104) 22-96 147-203 264-324 370-428
22"-96" 147"-203" 264"-324" 370"-428"

Intra-L (C23-C104) 23'-93' 139'-199'
23'"-93'" 139'"-199'"

Inter-H-L (h 5-CL 126) * 223-219' 223"-219'"

Inter-H-H (h 11, h 14) * 229-229" 232-232"

*Two or three of the inter-chain disulfide bridges are not present, an average of 4 cysteinyl being conjugated each via a thioether bond to a drug linker.

*Deux ou trois des ponts disulfures inter-chaînes ne sont pas présents, 4 cystéinyl en moyenne étant chacun conjugué via une liaison thioéther à un linker-principe actif.

*Faltan dos o tres puentes disulfuro inter-catenarios, una media de 4 cisteinil está conjugada a conectores de principio activo.

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación

H CH2 N84.4:
300, 300"

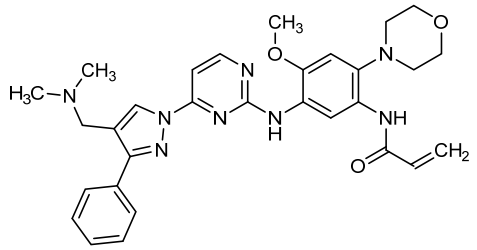
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados.

lanacogenum vosiparvovecum #

lanacogene vosiparvovec	Non-replicating recombinant adeno-associated virus type 5 (AAV5) vector containing a codon-optimised of the wild type human coagulation factor IX (F9, FIX) gene under the control of the liver promoter 1 (LP1).
lanacogène vosiparvovec	vecteur viral adéno-associé recombinant de type 5 (AAV5) non-répliquant contenant une version avec des codons optimisés du gène du facteur IX de coagulacion de type sauvage (F9, FIX) humain sous le contrôle du promoteur LP1 des cellules hépatiques.
lanacogén vosiparvovec	Vector del Virus Adeno-asociado de serotipo 5 (AAV5) recombinante, no replicativo, que contiene una versión con codones optimizados del gen del factor de coagulación IX humano (F9, FIX) bajo el control del promotor hepático 1 (LP1).

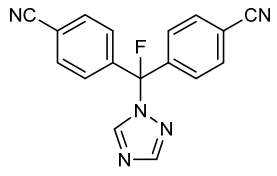
lazertinibum

lazertinib	*N*-{5-[(4-{4-[(dimethylamino)methyl]-3-phenyl-1*H*-pyrazol-1-yl}pyrimidin-2-yl)amino]-4-methoxy-2-(morpholin-4-yl)phenyl}prop-2-enamide
lazertinib	*N*-{5-[(4-{4-[(diméthylamino)méthyl]-3-phényl-1*H*-pyrazol-1-yl}pyrimidin-2-yl)amino]-4-méthoxy-2-(morpholin-4-yl)phényl}prop-2-enamide
lazertinib	*N*-{5-[(4-{4-[(dimetilamino)metil]-3-fenil-1*H*-pirazol-1-il}pirimidin-2-il)amino]-4-metoxi-2-(morfolin-4-il)fenil}prop-2-enamida $C_{30}H_{34}N_8O_3$



leflutrozolum

leflutrozole	4,4'-[fluoro(1*H*-1,2,4-triazol-1-yl)methylene]dibenzonitrile
léflutrozole	4,4'-[fluoro(1*H*-1,2,4-triazol-1-yl)méthylène]dibenzonitrile
leflutrozol	4,4'-[fluoro(1*H*-1,2,4-triazol-1-il)metileno]dibenzonitrilo $C_{17}H_{10}FN_{55}$



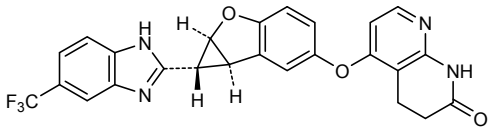
lifirafenibum

lifirafenib — 5-({(1*R*,1a*S*,6b*R*)-1-[5-(trifluoromethyl)-1*H*-benzimidazol-2-yl]-1a,6b-dihydro-1*H*-cyclopropa[*b*][1]benzofuran-5-yl}oxy)-3,4-dihydro-1,8-naphthyridin-2(1*H*)-one

lifirafénib — 5-({(1*R*,1a*S*,6b*R*)-1-[5-(trifluorométhyl)-1*H*-benzimidazol-2-yl]-1a,6b-dihydro-1*H*-cyclopropa[*b*][1]benzofuran-5-yl}oxy)-3,4-dihydro-1,8-naphthyridin-2(1*H*)-one

lifirafenib — 5-({(1*R*,1a*S*,6b*R*)-1-[5-(trifluorometil)-1*H*-benzimidazol-2-il]-1a,6b-dihidro-1*H*-ciclopropa[*b*][1]benzofuran-5-il}oxi)-3,4-dihidro-1,8-naftiridin-2(1*H*)-ona

$C_{25}H_{17}F_3N_4O_3$



lonapegsomatropinum #

lonapegsomatropin — human somatotropin (growth hormone, GH) produced in *Escherichia coli*, conjugated to a multi-arm polyethylene glycol carrier molecule;

somatotropin (human), produced by *Escherichia coli*, $N^{6.Lys}$-substitued with one ({(1*RS*)-5-[bis(6-{[(3*RS*)-1-{3-[(3-{(2*RS*)-2,3-bis[ω-methoxypoly(oxyethylene)$_n$-α-yl]propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl]sulfanyl}hexyl)amino]-1-[4-({[3-(dimethylamino)propyl](methyl)carbamoyl}oxy)phenyl]-5-oxopentyl}oxy)carbonyl group

lonapegsomatropine — somatotropine humaine (hormone de croissance, GH) produite par *Escherichia coli*, conjuguée à une molécule transporteur multi-bras de polyéthylène glycol;

somatotropine (humaine), produite par *Escherichia coli*, substituée en $N^{6.Lys}$ par un groupe ({(1*RS*)-5-[bis(6-{[(3*RS*)-1-{3-[(3-{(2*RS*)-2,3-bis[ω-méthoxypoly(oxyéthylène)$_n$-α-yl]propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl]sulfanyl}hexyl)amino]-1-[4-({[3-(diméthylamino)propyl](méthyl)carbamoyl}oxy)phényl]-5-oxopentyl}oxy)carbonyle

lonapegsomatropina — somatotropina humana (hormona de crecimiento, GH) producida por *Escherichia coli*, conjugada a una molécula transportadora multi-bras de polietileno glicol;

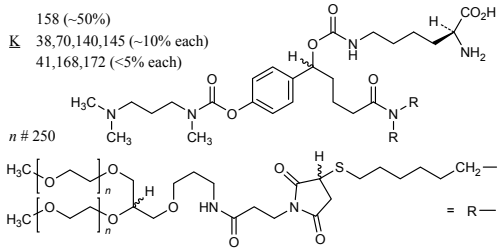
somatotropina (humana), producida por *Escherichia coli*, sustituida en $N^{6.Lys}$ por un grupo ({(1*RS*)-5-[bis(6-{[(3*RS*)-1-{3-[(3-{(2*RS*)-2,3-bis[ω-metoxipoli(oxietileno)$_n$-α-il]propoxi}propil)amino]-3-oxopropil}-2,5-dioxopirrolidin-3-il]sulfanil}hexil)amino]-1-[4-({[3-(dimetilamino)propil](metil)carbamoil}oxi)fenil]-5-oxopentil}oxi)carbonilo

Sequence / Séquence / Secuencia

```
FPTIPLSRLF DNAMLRAHRL HQLAFDTYQE FEEAYIPKEQ KYSFLQNPQT  50
SLCFSESIPT PSNREETQQK SNLELLRISL LLIQSWLEPV QFLRSVFANS 100
LVYGASDSNV YDLLKDLEEG IQTLMGRLED GSPRTGQIFK QTYSKFDTNS 150
HNDDALLKNY GLLYCFRKDM DKVETFLRIV QCRSVEGSCG F          191
```

Disulfide bridges location / Position des ponts disulfure / Posición de los puentes disulfuro
53-165 182-189

Potential modified residues / Résidus modifiés potentiels / Restos modificados potenciales



loncastuximabum #

loncastuximab

immunoglobulin G1-kappa, anti-[*Homo sapiens* CD19 (B lymphocyte surface antigen B4, Leu-12)], chimeric monoclonal antibody;
gamma1 heavy chain (1-449) [*Mus musculus* VH (IGHV1-69*02 (85.70%) -(IGHD) -IGHJ4*01) [8.8.13] (1-120) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (217) (121-218), hinge (219-233), CH2 (234-343), CH3 E12 (359), M14 (361) (344-448), CHS K2>del (449)) (121-449)], (223-211')-disulfide with kappa light chain (1'-211') [*Mus musculus* V-KAPPA (IGKV4-70*01 (91.40%) -IGKJ1*01) [5.3.7] (1'-104') -*Homo sapiens* IGKC*01, Km3 A45.1 (150), V101 (188) (105'-211')]; dimer (229-229'':232-232'')-bisdisulfide

loncastuximab

immunoglobuline G1-kappa, anti-[*Homo sapiens* CD19 (antigène de surface B4 des lymphocytes B, Leu-12)], anticorps monoclonal chimérique;
chaîne lourde gamma1 (1-449) [*Mus musculus* VH (IGHV1-69*02 (85.70%) -(IGHD) -IGHJ4*01) [8.8.13] (1-120) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (217) (121-218), charnière (219-233), CH2 (234-343), CH3 E12 (359), M14 (361) (344-448), CHS K2>del (449)) (121-449)], (223-211')-disulfure avec la chaîne légère kappa (1'-211') [*Mus musculus* V-KAPPA (IGKV4-70*01 (91.40%) -IGKJ1*01) [5.3.7] (1'-104') -*Homo sapiens* IGKC*01, Km3 A45.1 (150), V101 (188) (105'-211')]; dimère (229-229'':232-232'')-bisdisulfure

loncastuximab

inmunoglobulina G1-kappa, anti-[*Homo sapiens* CD19 (antígeno de superficie B4 de los linfocitos B, Leu-12)], anticuerpo monoclonal quimérico;
cadena pesada gamma1 (1-449) [*Mus musculus* VH (IGHV1-69*02 (85.70%) -(IGHD) -IGHJ4*01) [8.8.13] (1-120) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (217) (121-218), bisagra (219-233), CH2 (234-343), CH3 E12 (359), M14 (361) (344-448), CHS K2>del (449)) (121-449)], (223-211')-disulfuro con la cadena ligera kappa (1'-211') [*Mus musculus* V-KAPPA (IGKV4-70*01 (91.40%) -IGKJ1*01) [5.3.7] (1'-104') -*Homo sapiens* IGKC*01, Km3 A45.1 (150), V101 (188) (105'-211')]; dímero (229-229'':232-232'')-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQPGAE VVKPGASVKL SCKTSGYTFT SNWMHWVKQA PGQGLEWIGE  50
IDPSDSYTNY NQNFQGKAKL TVDKSTSTAY MEVSSLRSDD TAVYYCARGS 100
NPYYYAMDYW GQGTSVTVSS ASTKGPSVFP LAPSSKSTSG GTAALGCLVK 150
DYFPEPVTVS WNSGALTSGV HTFPAVLQSS GLYSLSSVVT VPSSSLGTQT 200
YICNVNHKPS NTKVDKKVEP KSCDKTHTCP PCPAPELLGG PSVFLFPPKP 250
KDTLMISRTP EVTCVVVDVS HEDPEVKFNW YVDGVEVHNA KTKPREEQYN 300
STYRVVSVLT VLHQDWLNGK EYKCKVSNKA LPAPIEKTIS KAKGQPREPQ 350
VYTLPPSREE MTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPV 400
LDSDGSFFLY SKLTVDKSRW QQGNVFSCSV MHEALHNHYT QKSLSLSPG  449
```

Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPAI MSASPGERVT MTCSASSGVN YMHWYQQKPG TSPRRWIYDT  50
SKLASGVPAR FSGSGSGTSY SLTISSMEPE DAATYYCHQR GSYTFGGGTK 100
LEIKRTVAAP SVFIFPPSDE QLKSGTASVV CLLNNFYPRE AKVQWKVDNA 150
LQSGNSQESV TEQDSKDSTY SLSSTLTLSK ADYEKHKVYA CEVTHQGLSS 200
PVTKSFNRGE C                                           211
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 147-203 264-324 370-428
22"-96" 147"-203" 264"-324" 370"-428"
Intra-L (C23-C104) 23'-87' 131'-191'
23'"-87'" 131'"-191'"
Inter-H-L (h 5-CL 126) 223-211' 223"-211'"
Inter-H-H (h 11, h 14) 229-229" 232-232"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
300, 300"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

loncastuximabum tesirinum #

loncastuximab tesirine

immunoglobulin G1-kappa, anti-[*Homo sapiens* CD19 (B lymphocyte surface antigen B4, Leu-12)], chimeric monoclonal antibody conjugated to the pyrrolobenzodiazepine (PBD) dimer SCX;
gamma1 heavy chain (1-449) [*Mus musculus* VH (IGHV1-69*02 (85.70%) -(IGHD) -IGHJ4*01) [8.8.13] (1-120) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (217) (121-218), hinge (219-233), CH2 (234-343), CH3 E12 (359), M14 (361) (344-448), CHS K2>del (449)) (121-449)], (223-211')-disulfide with kappa light chain (1'-211') [*Mus musculus* V-KAPPA (IGKV4-70*01 (91.40%) -IGKJ1*01) [5.3.7] (1'-104') -*Homo sapiens* IGKC*01, Km3 A45.1 (150), V101 (188) (105'-211')]; dimer (229-229"':232-232'')-bisdisulfide;conjugated, on an average of 2 cysteines, to the pyrrolobenzodiazepine (PBD) dimer SCX, via a cleavable (valine-alanine dipeptide as cathepsin B cleavage site) maleimide type linker containing a spacer PEG (n=8)
For the *tesirine* part, please refer to the prop.INN List 113, published in *the WHO Drug Information, Vol.29, No.2, 2015.*

loncastuximab tésirine

immunoglobuline G1-kappa, anti-[*Homo sapiens* CD19 (antigène de surface B4 des lymphocytes B, Leu-12)], anticorps monoclonal chimérique conjugué au dimère de pyrrolobenzodiazépine (PDB) SCX;
chaîne lourde gamma1 (1-449) [*Mus musculus* VH (IGHV1-69*02 (85.70%) -(IGHD) -IGHJ4*01) [8.8.13] (1-120) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (217) (121-218), charnière (219-233), CH2 (234-343), CH3 E12 (359), M14 (361) (344-448), CHS K2>del (449)) (121-449)], (223-211')-disulfure avec la

chaîne légère kappa (1'-211') [*Mus musculus* V-KAPPA (IGKV4-70*01 (91.40%) -IGKJ1*01) [5.3.7] (1'-104') -*Homo sapiens* IGKC*01, Km3(105'-211')]; dimère (229-229":232-232")-bisdisulfure; conjugué, sur 2 cystéines en moyenne, au dimère de pyrrolobenzodiazépine (PBD) SCX, via un linker clivable (dipeptide valine-alanine clivable par la cathepsine B) de type maléimide et comprenant un espaceur PEG (n=8)
Pour la partie *tésirine*, veuillez-vous référer à la Liste 113 des DCI prop, publiée dans le *WHO Drug Information, Vol.29, No.2, 2015.*

loncastuximab tesirina

inmunoglobulina G1-kappa, anti-[*Homo sapiens* CD19 (antígeno de superficie B4 de los linfocitos B, Leu-12)], anticuerpo monoclonal quimérico conjugado con el dímero de pirrolobenzodiazepina (PDB) SCX;
cadena pesada gamma1 (1-449) [*Mus musculus* VH (IGHV1-69*02 (85.70%) -(IGHD) -IGHJ4*01) [8.8.13] (1-120) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (217) (121-218), bisagra (219-233), CH2 (234-343), CH3 E12 (359), M14 (361) (344-448), CHS K2>del (449)) (121-449)], (223-211')-disulfuro con la cadena ligera kappa (1'-211') [*Mus musculus* V-KAPPA (IGKV4-70*01 (91.40%) -IGKJ1*01) [5.3.7] (1'-104') -*Homo sapiens* IGKC*01, Km3(105'-211')]; dímero (229-229":232-232")-bisdisulfuro; conjugado, en una media de 2 cisteinil, con el dímero de pirrolobenzodiazepina (PBD) SCX, mediante un conector escindible (dipéptido valina-alanina escindible por la catepsina B) de tipo maleimida y comprende un espaciador PEG (n=8)
Para la fracción *tesirina* se puede referir a la Lista 113 de DCI prop., publicada en el *WHO Drug Information, Vol.29, No.2, 2015*.

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQPGAE VVKPGASVKL SCKTSGYTFT SNWMHWVKQA PGQGLEWIGE  50
IDPSDSYTNY NQNFQGKAKL TVDKSTSTAY MEVSSLRSDD TAVYYCARGS 100
NPYYYAMDYW GQGTSVTVSS ASTKGPSVFP LAPSSKSTSG GTAALGCLVK 150
DYFPEPVTVS WNSGALTSGV HTFPAVLQSS GLYSLSSVVT VPSSSLGTQT 200
YICNVNHKPS NTKVDKKVEP KSCDKTHTCP PCPAPELLGG PSVFLFPPKP 250
KDTLMISRTP EVTCVVVDVS HEDPEVKFNW YVDGVEVHNA KTKPREEQYN 300
STYRVVSVLT VLHQDWLNGK EYKCKVSNKA LPAPIEKTIS KAKGQPREPQ 350
VYTLPPSREE MTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPV 400
LDSDGSFFLY SKLTVDKSRW QQGNVFSCSV MHEALHNHYT QKSLSLSPG  449
```

Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPAI MSASPGERVT MTCSASSGVN YMHWYQQKPG TSPRRWIYDT  50
SKLASGVPAR FSGSGSGTSY SLTISSMEPE DAATYYCHQR GSYTFGGGTK 100
LEIKRTVAAP SVFIFPPSDE QLKSGTASVV CLLNNFYPRE AKVQWKVDNA 150
LQSGNSQESV TEQDSKDSTY SLSSTLTLSK ADYEKHKVYA CEVTHQGLSS 200
PVTKSFNRGE C                                            211
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 147-203 264-324 370-428
22"-96" 147"-203" 264"-324" 370"-428"
Intra-L (C23-C104) 23'-87' 131'-191'
23'"-87'" 131'"-191'"
Inter-H-L (h 5-CL 126) * 223-211' 223"-211"
Inter-H-H (h 11, h 14) 229-229" 232-232"
*One or two of the inter-chain disulfide bridges are not present, an average of 2 cysteinyl being conjugated each via a thioether bond to a drug linker.
*Un ou deux des ponts disulfures inter-chaînes ne sont pas présents, 2 cystéinyl en moyenne étant chacun conjugué via une liaison thioéther à un linker-principe actif.
*Faltan dos o tres puentes disulfuro inter-catenarios, una media de 2 cisteinil conjugados con sendos enlaces tioéter, a conectores de principio activo.

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
300, 300"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

lumasiranum

lumasiran

{(*2S*,4*R*)-1-{1-[(2-acetamido-2-deoxy-β-D-galactopyranosyl)oxy]-16,16-bis-({3-[(3-{5-[(2-acetamido-2-deoxy-β-D-galactopyranosyl)oxy]pentanamido}propyl)amino]-3-oxopropoxy}methyl)-5,11,18-trioxo-14-oxa-6,10,17-triazanonacosan-29-oyl}-4-hydroxypyrrolidin-2-yl}methyl hydrogen *all-P-ambo*-2'-*O*-methyl-*P*-thioguanylyl-(3'→5')-2'-*O*-methyl-*P*-thioadenylyl-(3'→5')-2'-*O*-methylcytidylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-deoxy-2'-fluorocytidylyl-(3'→5')-2'-*O*-methyladenylyl-(3'→5')-2'-deoxy-2'-fluorouridylyl-(3'→5')-2'-deoxy-2'-fluorocytidylyl-(3'→5')-2'-deoxy-2'-fluorocytidylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-*O*-methylguanylyl-(3'→5')-2'-*O*-methylguanylyl-(3'→5')-2'-*O*-methyladenylyl-(3'→5')-2'-*O*-methyladenylyl-(3'→5')-2'-*O*-methyladenylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-*O*-methyl-3'-adenylate duplex with *all-P-ambo*-2'-*O*-methyl-*P*-thioadenylyl-(5'→3')-2'-*O*-methyl-*P*-thiocytidylyl-(5'→3')-2'-*O*-methylcytidylyl-(5'→3')-2'-*O*-methyluridylyl-(5'→3')-2'-*O*-methylguanylyl-(5'→3')-2'-*O*-methyladenylyl-(5'→3')-2'-*O*-methyladenylyl-(5'→3')-2'-deoxy-2'-fluoroadenylyl-(5'→3')-2'-*O*-methylguanylyl-(5'→3')-2'-deoxy-2'-fluorouridylyl-(5'→3')-2'-*O*-methyladenylyl-(5'→3')-2'-*O*-methylguanylyl-(5'→3')-2'-*O*-methylguanylyl-(5'→3')-2'-*O*-methyladenylyl-(5'→3')-2'-deoxy-2'-fluorocytidylyl-(5'→3')-2'-deoxy-2'-fluorocytidylyl-(5'→3')-2'-*O*-methyluridylyl-(5'→3')-2'-deoxy-2'-fluorouridylyl-(5'→3')-2'-*O*-methyluridylyl-(5'→3')-2'-*O*-methyladenylyl-(5'→3')-2'-*O*-methyl-*P*-thiouridylyl-(5'→3')-2'-deoxy-2'-fluoro-*P*-thioadenylyl-(5'→3')-2'-*O*-methyluridine

lumasiran

hydrogéno-*tout-P-ambo*-2'-*O*-méthyl-*P*-thioguanylyl-(3'→5')-2'-*O*-méthyl-*P*-thioadénylyl-(3'→5')-2'-*O*-méthylcytidylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-désoxy-2'-fluorocytidylyl-(3'→5')-2'-*O*-méthyladénylyl-(3'→5')-2'-désoxy-2'-fluorouridylyl-(3'→5')-2'-désoxy-2'-fluorocytidylyl-(3'→5')-2'-désoxy-2'-fluorocytidylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-*O*-méthylguanylyl-(3'→5')-2'-*O*-méthylguanylyl-(3'→5')-2'-*O*-méthyladénylyl-(3'→5')-2'-*O*-méthyladénylyl-(3'→5')-2'-*O*-méthyladénylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-*O*-méthyladénylyl-(3'→5')-2'-*O*-méthyl-3'-adénylate de {(*2S*,4*R*)-1-{1-[(2-acétamido-2-désoxy-β-D-galactopyranosyl)oxy]-16,16-bis-({3-[(3-{5-[(2-acétamido-2-désoxy-β-D-galactopyranosyl)oxy]pentanamido}propyl)amino]-3-oxopropoxy}méthyl)-6,10,18-trioxo-14-oxa-6,10,17-triazanonacosan-29-oyl}-4-hydroxypyrrolidin-2-yl}méthyle duplex avec *tout-P-ambo*-2'-*O*-méthyl-*P*-thioadénylyl-(5'→3')-2'-*O*-méthyl-*P*-thiocytidylyl-(5'→3')-2'-*O*-méthylcytidylyl-(5'→3')-2'-*O*-méthyluridylyl-(5'→3')-2'-*O*-méthylguanylyl-(5'→3')-2'-*O*-méthyladénylyl-(5'→3')-2'-*O*-méthyladénylyl-(5'→3')-2'-désoxy-2'-fluoroadénylyl-(5'→3')-2'-*O*-méthylguanylyl-(5'→3')-2'-désoxy-2'-fluorouridylyl-(5'→3')-2'-*O*-méthyladénylyl-(5'→3')-2'-*O*-méthylguanylyl-(5'→3')-2'-*O*-méthylguanylyl-(5'→3')-2'-*O*-méthyladénylyl-(5'→3')-2'-désoxy-2'-fluorocytidylyl-(5'→3')-2'-désoxy-2'-fluorocytidylyl-(5'→3')-2'-*O*-méthyluridylyl-(5'→3')-2'-désoxy-2'-fluorouridylyl-(5'→3')-2'-*O*-méthyluridylyl-(5'→3')-2'-*O*-méthyladénylyl-(5'→3')-2'-*O*-méthyl-*P*-thiouridylyl-(5'→3')-2'-désoxy-2'-fluoro-*P*-thioadénylyl-(5'→3')-2'-*O*-méthyluridine

lumasirán

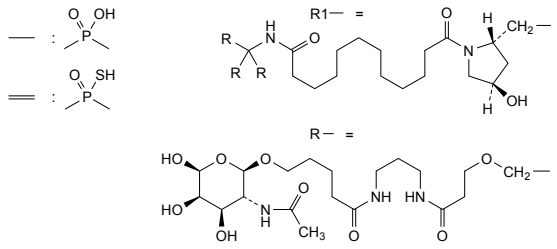
hydrógeno-*todo*-*P*-*ambo*-2'-*O*-metil-*P*-tioguanilil-(3'→5')-2'-*O*-metil-*P*-tioadenylyl-(3'→5')-2'-*O*-metilcitidilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-desoxi-2'-fluorocitidilil-(3'→5')-2'-*O*-metiladenilil-(3'→5')-2'-desoxi-2'-fluorouridilil-(3'→5')-2'-desoxi-2'-fluorocitidilil-(3'→5')-2'-desoxi-2'-fluorocitidilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metilguanilil-(3'→5')-2'-*O*-metilguanilil-(3'→5')-2'-*O*-metiladenilil-(3'→5')-2'-*O*-metiladenilil-(3'→5')-2'-*O*-metiladenilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metiladenilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metil-3'-adenilato de {(*2S*,4*R*)-1-{1-[(2-acetamido-2-desoxi-β-D-galactopiranosil)oxi]-16,16-bis-({3-[(3-{5-[(2-acetamido-2-desoxi-β-D-galactopiranosil)oxi]pentanamido}propil)amino]-3-oxopropoxi}metil)-6,10,18-trioxo-14-oxa-6,10,17-triazanonacosan-29-oil}-4-hidroxipirrolidin-2-il}metilo dúplex con *todo*-*P*-*ambo*-2'-*O*-metil-*P*-tioadenilil-(5'→3')-2'-*O*-metil-*P*-tiocitidilil-(5'→3')-2'-*O*-metilcitidilil-(5'→3')-2'-*O*-metiluridilil-(5'→3')-2'-*O*-metilguanilil-(5'→3')-2'-*O*-metiladenilil-(5'→3')-2'-*O*-metiladenilil-(5'→3')-2'-desoxi-2'-fluoroadenilil-(5'→3')-2'-*O*-metilguanilil-(5'→3')-2'-desoxi-2'-fluorouridilil-(5'→3')-2'-*O*-metiladenilil-(5'→3')-2'-*O*-metilguanilil-(5'→3')-2'-*O*-metilguanilil-(5'→3')-2'-*O*-metiladenilil-(5'→3')-2'-desoxi-2'-fluorocitidilil-(5'→3')-2'-desoxi-2'-fluorocitidilil-(5'→3')-2'-*O*-metiluridilil-(5'→3')-2'-desoxi-2'-fluorouridilil-(5'→3')-2'-*O*-metiluridilil-(5'→3')-2'-*O*-metiladenilil-(5'→3')-2'-*O*-metil-*P*-tiouridilil-(5'→3')-2'-desoxi-2'-fluoro-*P*-tioadenilil-(5'→3')-2'-*O*-metiluridina

$C_{530}H_{712}F_{10}N_{173}O_{320}P_{43}S_6$

(3'-5')G=A=C-U-U-U-**C**-A-**U**-**C**-**C**-U-G-G-A-A-A-U-A-U-A-(R1)

(5'-3')A=C=C-U-G-A-A-**A**-G-**U**-A-G-G-A-**C**-**C**-U-**U**-U-A-U=**A**=U

X : 2'-deoxy-2'-fluoro-X / **X** : 2'-désoxy-2'-fluoro-X
X : 2'-*O*-methyl-X / X : 2'-*O*-méthyl-X



mardepodectum

mardepodect

2-({4-[1-methyl-4-(pyridin-4-yl)-1*H*-pyrazol-3-yl]phenoxy}methyl)quinoline

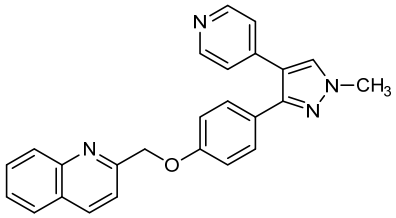
mardépodect

2-({4-[1-méthyl-4-(pyridin-4-yl)-1*H*-pyrazol-3-yl]phénoxy}méthyl)quinoléine

mardepodect

2-({4-[1-metil-4-(piridin-4-il)-1*H*-pirazol-3-il]fenoxi}metil)quinoleína

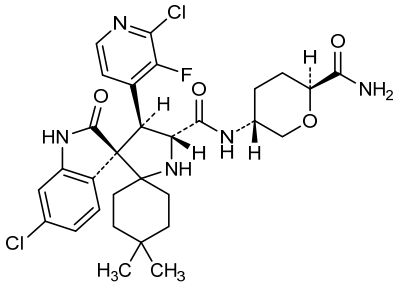
$C_{25}H_{20}N_4O$



milademetanum

milademetan	(3'*R*,4'*S*,5'*R*)-*N*-[(3*R*,6*S*)-6-carbamoyloxan-3-yl]-6''-chloro-4'-(2-chloro-3-fluoropyridin-4-yl)-4,4-dimethyl-2''-oxo-1'',2''-dihydrodispiro[cyclohexane-1,2'-pyrrolidine-3',3''-indole]-5'-carboxamide
miladémétan	(3'*R*,4'*S*,5'*R*)-*N*-[(3*R*,6*S*)-6-carbamoyloxan-3-yl]-6''-chloro-4'-(2-chloro-3-fluoropyridin-4-yl)-4,4-diméthyl-2''-oxo-1'',2''-dihydrodispiro[cyclohexane-1,2'-pyrrolidine-3',3''-indole]-5'-carboxamide
milademetán	(3'*R*,4'*S*,5'*R*)-*N*-[(3*R*,6*S*)-6-carbamoiloxan-3-il]-6''-cloro-4'-(2-cloro-3-fluoropiridin-4-il)-4,4-dimetil-2''-oxo-1'',2''-dihidrodispiro[ciclohexano-1,2'-pirrolidina-3',3''-indol]-5'-carboxamida

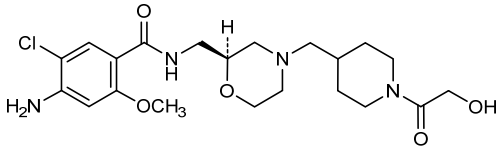
$C_{30}H_{34}Cl_2FN_5O_4$



minesapridum

minesapride	4-amino-5-chloro-*N*-{[(2*S*)-4-{[1-(hydroxyacetyl)piperidin-4-yl]methyl}morpholin-2-yl]methyl}-2-methoxybenzamide
minésapride	4-amino-5-chloro-*N*-{[(2*S*)-4-{[1-(hydroxyacétyl)pipéridin-4-yl]méthyl}morpholin-2-yl]méthyl}-2-méthoxybenzamide
minesaprida	4-amino-5-cloro-*N*-{[(2*S*)-4-{[1-(hidroxiacetil)piperidin-4-il]metil}morfolin-2-il]metil}-2-metoxibenzamida

$C_{21}H_{31}ClN_4O_5$



miralimogenum ensolisbacum #

miralimogene ensolisbac	Recombinant live-attenuated double-deleted (LADD) strain of *Listeria monocytogenes* (*Lm* Δ*actA*/Δ*inlB*) expressing a fusion protein comprising the N-terminal 100 amino acids of the *Lm* ActA protein (ActAN100) and amino acids 35-622 of human mesothelin (MSLN) protein, under the control of the *Lm actA* (actin-assembly inducing protein precursor) promoter, and contained within an expression cassette of 2306 bp inserted at the *Lm inlB* (internalin B) locus
miralimogène ensolisbac	souche vivante atténuée recombinante de *Listeria monocytogenes* (*Lm* Δ*actA*/Δ*inlB*) avec double deletion, exprimant une protéine de fusion qui consiste en les 100 acides aminés à l'extrémité N-terminale de la protéine *Lm* ActA (ActAN100) et les acides aminés 35-622 de la mésothéline humaine (MSLN), sous le contrôle du promoteur de *Lm actA* (précurseur de la protéine induisant l'assemblage de l'actine), et contenu dans une cassette d'expression de 2306 paires de bases insérée sur le locus de *Lm inlB* (internaline B).
miralimogén ensolisbac	Cepa viva atenuada recombinante, con doble deleción, de *Listeria monocytogenes* (*Lm* Δ*actA*/Δ*inlB*) que expresa una proteína de fusión consistente en los 100 amino ácidos N-terminales de la proteína *Lm* ActA (ActAN100) y los amino ácidos 35-622 de la mesotelina humana (MSLN), bajo el control del promotor de *Lm actA* (precursor de la proteína inductora del ensamblaje de la actina), y contenido dentro de un casete de expresión de 2306 pares de bases insertado en el locus de *Lm inlB* (internalina B).

mirikizumabum #

mirikizumab	immunoglobulin G4-kappa, anti-[*Homo sapiens* IL23A (interleukin 23 subunit alpha, IL-23A, IL-23 subunit p19, IL23p19)], humanized monoclonal antibody; gamma4 heavy chain (1-441) [humanized VH (*Homo sapiens* IGHV1-2*02 (82.70%) -(IGHD) -IGHJ6*01) [8.8.8] (1-115) -*Homo sapiens* IGHG4*01 (CH1 (116-213), hinge S10>P (223) (214-225), CH2 F1.3>A (229), L1.2>A (230) (226-335), CH3 (336-440), CHS K>del (441)) (116-441)], (129-214')-disulfide with kappa light chain (1'-214') [humanized V-KAPPA (*Homo sapiens* IGKV1-39*01 (85.30%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (221-221'':224-224'')-bisdisulfide
mirikizumab	immunoglobuline G4-kappa, anti-[*Homo sapiens* IL23A (interleukine 23 sous-unité alpha, IL-23A, IL-23 sous-unité p19, IL23p19)], anticorps monoclonal humanisé;

chaîne lourde gamma4 (1-441) [VH humanisé (*Homo sapiens* IGHV1-2*02 (82.70%) -(IGHD) -IGHJ6*01) [8.8.8] (1-115) -*Homo sapiens* IGHG4*01 (CH1 (116-213), charnière S10>P (223) (214-225), CH2 F1.3>A (229), L1.2>A (230) (226-335), CH3 (336-440), CHS K>del (441)) (116-441)], (129-214')-disulfure avec la chaîne légère kappa (1'-214') [V-KAPPA humanisé (*Homo sapiens* IGKV1-39*01 (85.30%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (221-221":224-224")-bisdisulfure

mirikizumab

inmunoglobulina G4-kappa, anti-[*Homo sapiens* IL23A (interleukina 23 subunidad alfa, IL-23A, IL-23 subunidad p19, IL23p19)], anticuerpo monoclonal humanizado; cadena pesada gamma4 (1-441) [VH humanizado (*Homo sapiens* IGHV1-2*02 (82.70%) -(IGHD) -IGHJ6*01) [8.8.8] (1-115) -*Homo sapiens* IGHG4*01 (CH1 (116-213), bisagra S10>P (223) (214-225), CH2 F1.3>A (229), L1.2>A (230) (226-335), CH3 (336-440), CHS K>del (441)) (116-441)], (129-214')-disulfuro con la cadena ligera kappa (1'-214') [V-KAPPA humanizado (*Homo sapiens* IGKV1-39*01 (85.30%) -IGKJ4*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (221-221":224-224")-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGSSVKV SCKASGYKFT RYVMHWVRQA PGQGLEWMGY  50
INPYNDGTNY NEKFKGRVTI TADKSTSTAY MELSSLRSED TAVYYCARNW 100
DTGLWGQGTT VTVSSASTKG PSVFPLAPCS RSTSESTAAL GCLVKDYFPE 150
PVTVSWNSGA LTSGVHTFPA VLQSSGLYSL SSVVTVPSSS LGTKTYTCNV 200
DHKPSNTKVD KRVESKYGPP CPPCPAPEAA GGPSVFLFPP KPKDTLMISR 250
TPEVTCVVVD VSQEDPEVQF NWYVDGVEVH NAKTKPREEQ FNSTYRVVSV 300
LTVLHQDWLN GKEYKCKVSN KGLPSSIEKT ISKAKGQPRE PQVYTLPPSQ 350
EEMTKNQVSL TCLVKGFYPS DIAVEWESNG QPENNYKTTP PVLDSDGSFF 400
LYSRLTVDKS RWQEGNVFSC SVMHEALHNH YTQKSLSLSL G          441
```

Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS LSASVGDRVT ITCKASDHIL KFLTWYQQKP GKAPKLLIYG  50
ATSLETGVPS RFSGSGSGTD FTLTISSLQP EDFATYYCQM YWSTPFTFGG 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 142-198 256-316 362-420
22"-96" 142"-198" 256"-316" 362"-420"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (h 5-CL 126) 129-214' 129"-214'"
Inter-H-H (h 11, h 14) 221-221" 224-224"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
292, 292"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

mosunetuzumabum #
mosunetuzumab

immunoglobulin G1-kappa, anti-[*Homo sapiens* CD3E (CD3 epsilon) and*Homo sapiens* MS4A1 (membrane-spanning 4-domains subfamily A member 1, CD20)], humanized monoclonal antibody, bispecific;

	gamma1 heavy chain anti-CD3E (1-449) [humanized VH (*Homo sapiens* IGHV1-3*01 (82.70%) -(IGHD) -IGHJ4*01) [8.8.12] (1-119) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (216) (120-217), hinge (218-232), CH2 N84.4>G (299) (233-342), CH3 E12 (358), M14 (360), T22>S (368) / L24>A (370) / Y86>V (409) (hole) (343-447), CHS (448-449)) (120-449)], (222-219')-disulfide with kappa light chain anti-CD3E (1'-219') [humanized V-KAPPA (*Homo sapiens* IGKV4-1*01 (91.80%) -IGKJ1*01) [12.3.8] (1'-112') -*Homo sapiens* IGKC*01, Km3 A45.1 (158), V101 (196) (113'-219')]; gamma1 heavy chain anti-MS4A1 (1-452) [humanized VH (*Homo sapiens* IGHV3-23*04 (81.60%) -(IGHD)-IGHJ4*01) [8.8.15] (1-122) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (219) (123-220), hinge (221-235), CH2 N84.4>G (302) (236-345), CH3 E12 (361), M14 (363), T22>W (371) (knob) (346-450), CHS (451-452)) (123-452)], (225-213')-disulfide with kappa light chain anti-MS4A1 (1'-213') [humanized V-KAPPA (*Homo sapiens* IGKV1-39*01 (86.50%) -IGKJ1*01) [5.3.9] (1'-106') -*Homo sapiens* IGKC*01, Km3 A45.1 (152), V101 (190) (107'-213')]; dimer (228-231":231-234")-bisdisulfide
mosunétuzumab	immunoglobuline G1-kappa, anti-[*Homo sapiens* CD3E (CD3 epsilon) et *Homo sapiens* MS4A1 (membre 1 de la sous-famille A à 4 domaines transmembranaires, CD20)], anticorps monoclonal humanisé, bispécifique; chaîne lourde gamma1 anti-CD3E (1-449) [VH humanisé (*Homo sapiens* IGHV1-3*01 (82.70%) -(IGHD) -IGHJ4*01) [8.8.12] (1-119) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (216) (120-217), charnière (218-232), CH2 N84.4>G (299) (233-342), CH3 E12 (358), M14 (360), T22>S (368) / L24>A (370) / Y86>V (409) (hole) (343-447), CHS (448-449)) (120-449)], (222-219')-disulfure avec la chaîne légère kappa anti-CD3E (1'-219') [V-KAPPA humanisé (*Homo sapiens* IGKV4-1*01 (91.80%) -IGKJ1*01) [12.3.8] (1'-112') -*Homo sapiens* IGKC*01, Km3 A45.1 (158), V101 (196) (113'-219')]; chaîne lourde gamma1 anti-MS4A1 (1-452) [VH humanisé (*Homo sapiens* IGHV3-23*04 (81.60%) -(IGHD) -IGHJ4*01) [8.8.15] (1-122) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (219) (123-220), charnière (221-235), CH2 N84.4>G (302) (236-345), CH3 E12 (361), M14 (363), T22>W (371) (knob) (346-450), CHS (451-452)) (123-452)], (225-213')-disulfure avec la chaîne légère kappa anti-MS4A1 (1'-213') [V-KAPPA humanisé (*Homo sapiens* IGKV1-39*01 (86.50%) -IGKJ1*01) [5.3.9] (1'-106') -*Homo sapiens* IGKC*01, Km3 A45.1 (152), V101 (190) (107'-213')]; dimère (228-231":231-234")-bisdisulfure
mosunetuzumab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* CD3E (CD3 epsilon) y *Homo sapiens* MS4A1 (miembro 1 de la subfamilia A con 4 dominios transmembranarios, CD20)], anticuerpo monoclonal humanizado, biespecífico;

cadena pesada gamma1 anti-CD3E (1-449) [VH humanizado (*Homo sapiens* IGHV1-3*01 (82.70%) -(IGHD) -IGHJ4*01) [8.8.12] (1-119) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (216) (120-217), bisagra (218-232), CH2 N84.4>G (299) (233-342), CH3 E12 (358), M14 (360), T22>S (368) / L24>A (370) / Y86>V (409) (hole) (343-447), CHS (448-449)) (120-449)], (222-219')-disulfuro con la cadena ligera kappa anti-CD3E (1'-219') [V-KAPPA humanizado (*Homo sapiens* IGKV4-1*01 (91.80%) -IGKJ1*01) [12.3.8] (1'-112') -*Homo sapiens* IGKC*01, Km3 A45.1 (158), V101 (196) (113'-219')];
cadena pesada gamma1 anti-MS4A1 (1-452) [VH humanizado (*Homo sapiens* IGHV3-23*04 (81.60%) -(IGHD) -IGHJ4*01) [8.8.15] (1-122) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (219) (123-220), bisagra (221-235), CH2 N84.4>G (302) (236-345), CH3 E12 (361), M14 (363), T22>W (371) (knob) (346-450), CHS (451-452)) (123-452)], (225-213')-disulfuro con la cadena ligera kappa anti-MS4A1 (1'-213') [V-KAPPA humanizado (*Homo sapiens* IGKV1-39*01 (86.50%) -IGKJ1*01) [5.3.9] (1'-106') -*Homo sapiens* IGKC*01, Km3 A45.1 (152), V101 (190) (107'-213')];
dímero (228-231":231-234")-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada (anti-CD3E)

```
EVQLVQSGAE VKKPGASVKV SCKASGYTFT NYYIHWVRQA PGQGLEWIGW  50
IYPGDGNTKY NEKFKGRATL TADTSTSTAY LELSSLRSED TAVYYCARDS 100
YSNYYFDYWG QGTLVTVSSA STKGPSVFPL APSSKSTSGG TAALGCLVKD 150
YFPEPVTVSW NSGALTSGVH TFPAVLQSSG LYSLSSVVTV PSSSLGTQTY 200
ICNVNHKPSN TKVDKKVEPK SCDKTHTCPP CPAPELLGGP SVFLFPPKPK 250
DTLMISRTPE VTCVVVDVSH EDPEVKFNWY VDGVEVHNAK TKPREEQYGS 300
TYRVVSVLTV LHQDWLNGKE YKCKVSNKAL PAPIEKTISK AKGQPREPQV 350
YTLPPSREEM TKNQVSLSCA VKGFYPSDIA VEWESNGQPE NNYKTTPPVL 400
DSDGSFFLVS KLTVDKSRWQ QGNVFSCSVM HEALHNHYTQ KSLSLSPGK  449
```

Light chain / Chaîne légère / Cadena ligera (anti-CD3E)

```
DIVMTQSPDS LAVSLGERAT INCKSSQSLL NSRTRKNYLA WYQQKPGQPP  50
KLLIYWASTR ESGVPDRFSG SGSGTDFTLT ISSLQAEDVA VYYCTQSFIL 100
RTFGQGTKVE IKRTVAAPSV FIFPPSDEQL KSGTASVVCL LNNFYPREAK 150
VQWKVDNALQ SGNSQESVTE QDSKDSTYSL SSTLTLSKAD YEKHKVYACE 200
VTHQGLSSPV TKSFNRGEC                                   219
```

Heavy chain / Chaîne lourde / Cadena pesada (anti-MS4A1)

```
EVQLVESGGG LVQPGGSLRL SCAASGYTFT SYNMHWVRQA PGKGLEWVGA  50
IYPGNGDTSY NQKFKGRFTI SVDKSKNTLY LQMNSLRAED TAVYYCARVV 100
YYSNSYWYFD VWGQGTLVTV SSASTKGPSV FPLAPSSKST SGGTAALGCL 150
VKDYFPEPVT VSWNSGALTS GVHTFPAVLQ SSGLYSLSSV VTVPSSSLGT 200
QTYICNVNHK PSNTKVDKKV EPKSCDKTHT CPPCPAPELL GGPSVFLFPP 250
KPKDTLMISR TPEVTCVVVD VSHEDPEVKF NWYVDGVEVH NAKTKPREEQ 300
YGSTYRVVSV LTVLHQDWLN GKEYKCKVSN KALPAPIEKT ISKAKGQPRE 350
PQVYTLPPSR EEMTKNQVSL WCLVKGFYPS DIAVEWESNG QPENNYKTTP 400
PVLDSDGSFF LYSKLTVDKS RWQQGNVFSC SVMHEALHNH YTQKSLSLSP 450
GK                                                     452
```

Light chain / Chaîne légère / Cadena ligera (anti-MS4A1)

```
DIQMTQSPSS LSASVGDRVT ITCRASSSVS YMHWYQQKPG KAPKPLIYAP  50
SNLASGVPSR FSGSGSGTDF TLTISSLQPE DFATYYCQQW SFNPPTFGQG 100
TKVEIKRTVA APSVFIFPPS DEQLKSGTAS VVCLLNNFYP REAKVQWKVD 150
NALQSGNSQE SVTEQDSKDS TYSLSSTLTL SKADYEKHKV YACEVTHQGL 200
SSPVTKSFNR GEC                                         213
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro

Intra-H (C23-C104)	22-96	146-202	263-323	369-427
	22"-96"	149"-205"	266"-326"	372"-430"
Intra-L (C23-C104)	23'-94'	139'-199'		
	23'"-87"'	133'"-193"'		
Inter-H-L (h 5-CL 126)	222-219'	225"-213'"		
Inter-H-H (h 11, h 14)	228-231"	231-234"		

nadofaragenum firadenovecum #

nadofaragene firadenovec

Replication-deficient adenovirus type 5 (Ad5) vector encoding the human interferon alpha 2 (IFNA2, interferon alpha-2b) gene under the control of the cytomegalovirus (CMV) immediate-early enhancer/promoter.

nadofaragène firadénovec

vecteur adénoviral de type 5 (Ad5) à la réplication déficiente, codant pour le gène de l'interféron alpha 2 (IFNA2, interféron alpha-2b) humain sous le contrôle de l'activateur/promoteur immédiat-précoce du cytomégalovirus (CMV).

nadofaragén firadenovec

Vector de Adenovirus tipo 5 (Ad5) deficiente de replicación, que codifica para el gen del interferón alfa 2 humano (IFNA2, inteferón alfa-2b) bajo el control del promotor/*enhancer* inmediato-temprano del citomegalovirus (CMV).

namodenosonum

namodenoson

1-(2-chloro-6-{[(3-iodophenyl)methyl]amino}-9*H*-purin-9-yl)-1-deoxy-*N*-methyl-β-D-ribofuranuronamide

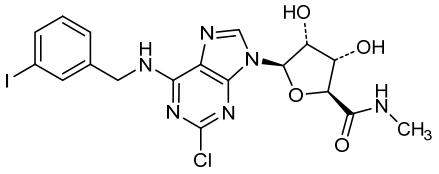
namodénoson

1-(2-chloro-6-{[(3-iodophényl)methyl]amino}-9*H*-purin-9-yl)-1-désoxy-*N*-méthyl-β-D-ribofuranuronamide

namodenosón

1-(2-cloro-6-{[(3-iodofenil)metil]amino}-9*H*-purin-9-il)-1-desoxi-*N*-metil-β-D-ribofuranuronamida

$C_{18}H_{18}ClIN_6O_4$



nangibotidum

nangibotide

human trem-like transcript 1 protein (TLT-1, triggering receptor expressed on myeloid cells-like protein 1) (79-90)-peptide 12-amide:
L-leucyl-L-glutaminyl-L-α-glutamyl-L-α-glutamyl-L-α-aspartyl-L-alanylglycyl-L-α-glutamyl-L-tyrosylglycyl-L-cysteinyl-L-methioninamide

nangibotide

protéine transcrit 1 semblable au trem humaine (TLT-1, protéine 1 semblable au récepteur déclenchant exprimé par les cellules myéloïdes) (79-90)-peptide 12-amide:
L-leucyl-L-glutaminyl-L-α-glutamyl-L-α-glutamyl-L-α-aspartyl-L-alanylglycyl-L-α-glutamyl-L-tyrosylglycyl-L-cystéinyl-L-méthioninamide

nangibotida

proteína transcrito 1 parecido al trem humano (TLT-1, proteína 1 parecida al receptor desencadenante expresado por las células mieloides) (79-90)-péptido 12-amida:

L-leucil-L-glutaminil-L-α-glutamil-L-α-glutamil-L-α-aspartil-L-alanilglicil-L-α-glutamil-L-tirosilglicil-L-cisteinil-L-metioninamida

$C_{54}H_{82}N_{14}O_{22}S_2$

H-Leu-Gln-Glu-Glu-Asp-Ala-Gly-Glu-Tyr-Gly-Cys-Met-NH_2
12

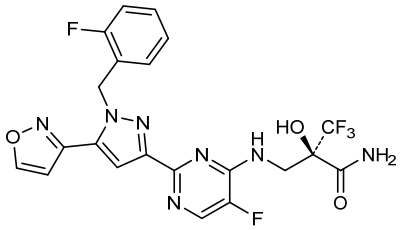
olinciguatum

olinciguat — (2*R*)-3,3,3-trifluoro-2-{[(5-fluoro-2-{1-[(2-fluorophenyl)methyl]-5-(1,2-oxazol-3-yl)-1*H*-pyrazol-3-yl}pyrimidin-4-yl)amino]methyl}-2-hydroxypropanamide

olinciguat — (2*R*)-3,3,3-trifluoro-2-{[(5-fluoro-2-{1-[(2-fluorophényl)méthyl]-5-(1,2-oxazol-3-yl)-1*H*-pyrazol-3-yl}pyrimidin-4-yl)amino]méthyl}-2-hydroxypropanamide

olinciguat — (2*R*)-3,3,3-trifluoro-2-{[(5-fluoro-2-{1-[(2-fluorofenil)metil]-5-(1,2-oxazol-3-il)-1*H*-pirazol-3-il}pirimidin-4-il)amino]metil}-2-hidroxipropanamida

$C_{21}H_{16}F_5N_7O_3$



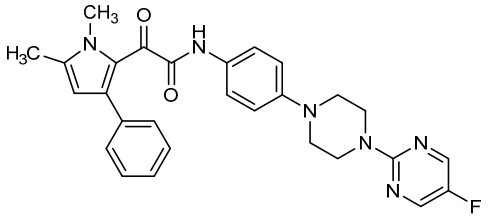
olorofimum

olorofim — 2-(1,5-dimethyl-3-phenyl-1*H*-pyrrol-2-yl)-*N*-{4-[4-(5-fluoropyrimidin-2-yl)piperazin-1-yl]phenyl}-2-oxoacetamide

olorofim — 2-(1,5-diméthyl-3-phényl-1*H*-pyrrol-2-yl)-*N*-{4-[4-(5-fluoropyrimidin-2-yl)pipérazin-1-yl]phényl}-2-oxoacétamide

olorofim — 2-(1,5-dimetil-3-fenil-1*H*-pirrol-2-il)-*N*-{4-[4-(5-fluoropirimidin-2-il)piperazin-1-il]fenil}-2-oxoacetamida

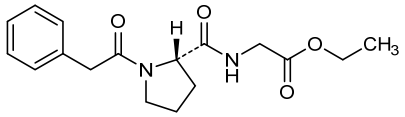
$C_{28}H_{27}FN_6O_2$



omberacetamum

omberacetam	ethyl 1-phenylacetyl-L-prolylglycinate
ombéracétam	1-phénylacétyl-L-prolylglycinate d'éthyle
omberacetam	1-fenilacetil-L-prolilglicinato de etilo

$C_{17}H_{22}N_2O_4$



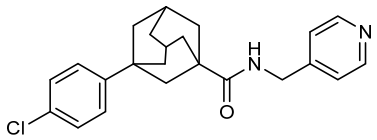
onasemnogenum abeparvovecum #

onasemnogene abeparvovec	Non-replicating recombinant self-complementary (sc) adeno-associated viral serotype 9 (AAV9) vector containing the cDNA of the survival of motor neuron 2 (SMN2) gene under the control of the hybrid cytomegalovirus (CMV) enhancer/chicken beta-actin promoter (CBA).
onasemnogène abéparvovec	vecteur viral adéno-associé recombinant de sérotype 9 (**r**AAV9) non-répliquant et auto-complémentaire, contenant l'ADNc du gène de survie des motoneurones 2 (SMN2) sous le contrôle de l'hybride de l'activateur du cytomégalovirus (CMV) et du promoteur de l'actine bêta du poulet (ABP, CBA).
onasemnogén abeparvovec	vector del virus adeno-asociado de serotipo 9 (AAV9) recombinante, no replicativo y auto complementario, que contiene el cDNA del gen de la supervivencia de neuronas motoras 2 (SMN2) bajo el control del híbrido del *enhancer* de citomegalovirus (CMV) y el promotor de la beta-actina de pollo (CBA).

opaganibum

opaganib	3-(4-chlorophenyl)-*N*-[(pyridin-4-yl)methyl]adamantane-1-carboxamide
opaganib	3-(4-chlorophényl)-*N*-[(pyridin-4-yl)méthyl]adamantane-1-carboxamide
opaganib	3-(4-clorofenil)-*N*-[(piridin-4-il)metil]adamantano-1-carboxamida

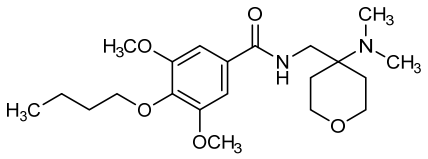
$C_{23}H_{25}ClN_2O$



opiranserinum

opiranserin	4-butoxy-*N*-{[4-(dimethylamino)oxan-4-yl]methyl}-3,5-dimethoxybenzamide
opiransérine	4-butoxy-*N*-{[4-(diméthylamino)oxan-4-yl]méthyl}-3,5-diméthoxybenzamide
opiranserina	4-butoxi-*N*-{[4-(dimetilamino)oxan-4-il]metil}-3,5-dietoxibenzamida

$C_{21}H_{34}N_2O_5$



opolimogenum capmilisbacum #

opolimogene capmilisbac	Recombinant live-attenuated double-deleted (LADD) strain of *Listeria monocytogenes* (*Lm* Δ*actA*/Δ*inlB*) expressing three recombinant fusion proteins as follows: (i) the N-terminal 100 amino acids of the *Lm* ActA (actin-assembly inducing protein precursor) protein (ActAN100), 5 tandem copies of a 21 amino acid fragment of human epidermal growth factor receptor variant III (EGFRvIII) and human protein SSX2 (synovial sarcoma, X breakpoint 2, also known as cancer/testis antigen 5.2 (CT5.2), tumor antigen HOM-MEL-40), under the control of the *Lm actA* promoter, and contained within an expression cassette of 1434 bp inserted at the *actA* locus; (ii) the N-terminal 100 amino acids of the *Lm* ActA protein (ActAN100), 5 tandem copies of a 21 amino acid fragment of human epidermal growth factor receptor variant III (EGFRvIII) and amino acids 33-386 of human prostatic acid phosphatase (PAP), under the control the *Lm actA* promoter, and contained within an expression cassette of 2057 bp inserted at the *inlB* (internalin B) locus; (iii) the N-terminal 100 amino acids of the *Lm* ActA protein (ActAN100), 5 tandem copies of a 21 amino acid fragment of human epidermal growth factor receptor variant III (EGFRvIII) and amino acids 11-234 of human homeobox protein Nkx-3.1 (NKX3-1) plus amino acids 1-20, 44-138 and 169-750 of human glutamate carboxypeptidase 2 (also known as folate hydrolase 1 (FOLH1), prostate-specific membrane antigen (PSMA)), under the control the *Lm actA* promoter, and contained within an expression cassette of 4984 bp at the *tRNA*^{Arg} locus.
opolimogène capmilisbac	Souche vivante atténuée recombinante de *Listeria monocytogenes (Lm ΔactA/ΔinlB)* avec double délétion, exprimant les trois protéines de fusion suivantes: (i) les 100 acides aminés à l'extrémité N-terminale de la protéine *Lm actA* (précurseur de la protéine induisant l'assemblage de l'actine) (ActAN100), 5 copies en tandem d'un fragment de 21 acides aminés de la variante III du récepteur du facteur de croissance épidermique humain (EGFRvIII) et la protéine humaine SSX2 (sarcome synovial, point de cassure X2, aussi connu comme antigène cancer/testicule 5.2 (CT5.2), antigène tumoral HOM-MEL-40), sous le contrôle du promoteur *Lm actA*, et contenu dans une cassette d'expression de 1434 paires de bases insérée sur le locus de *actA*;

	(ii) les 100 acides aminés à l'extrémité N-terminale de la protéine *Lm actA (*ActAN100), 5 copies en tandem d'un fragment de 21 acides aminés de la variante III du récepteur du facteur de croissance épidermique humain (EGFRvIII) et les acides aminés 33-386 de la phosphatase acide prostatique (PAP) humaine, sous le contrôle du promoteur *Lm actA*, contenu dans une cassette d'expression de 2057 paires de bases insérée sur le locus de *inlB* (internaline B); (iii) les 100 acides aminés à l'extrémité N-terminale de la protéine *Lm actA (*ActAN100), 5 copies en tandem d'un fragment de 21 acides aminés de la variante III du récepteur du facteur de croissance épidermique humain (EGFRvIII) et les acides aminés 11-234 de la protéine homéoboîte humaine Nkx-3.1 (NKX3-1) plus les acides aminés 1-20, 44-138, 169-750 de la glutamate caroxypeptidase 2 humaine (folate hydrolase 1, FOLH1, antigène membranaire spécifique de la prostate, PSMA) sous le contrôle du promoteur *Lm actA*, contenu dans une cassette d'expression de 4984 paires de bases insérée sur le locus de *Lm tRNA*^{Arg}.
opolimogén capmilisbac	Cepa viva atenuada recombinante, con doble deleción, de *Listeria monocytogenes* (*Lm* Δ*actA*/Δ*inlB*) que expresa las siguientes tres proteínas recombinantes de fusión: (i) los 100 amino ácidos N-terminales de la proteína *Lm* ActA (precursor de la proteína inductora del ensamblaje de la actina) (ActAN100), 5 copias en tándem de un fragmento de 21 amino ácidos de la variante III del receptor para el factor de crecimiento epidérmico humano (EGFRvIII) y la proteína humana SSX2 (synovial sarcoma, X breakpoint 2, also known as cancer/testis antigen 5.2 (CT5.2), tumor antigen HOM-MEL-40), bajo el control del promotor de *Lm actA*, y contenido dentro de un casete de expresión de 1434 pares de bases insertado en el locus de *actA*; (ii) los 100 amino ácidos N-terminales de la proteína *Lm* ActA (ActAN100), 5 copias en tándem de un fragmento de 21 amino ácidos de la variante III del receptor para el factor de crecimiento epidérmico humano (EGFRvIII) y los amino ácidos 33-386 de la fosfatasa ácida prostática (PAP) humana, bajo el control del promotor de *Lm actA*, y contenido dentro de un casete de expresión de 2057 pares de bases insertado en el locus de*inlB* (internalina B); (iii) los 100 amino ácidos N-terminales de la proteína *Lm* ActA (ActAN100), 5 copias en tándem de un fragmento de 21 amino ácidos de la variante III del receptor para el factor de crecimiento epidérmico humano (EGFRvIII) y los amino ácidos 11-234 de la proteína *homeobox* humana Nkx-3.1 (NKX3-1) más los amino ácidos 1-20, 44-138 y 169-750 de la glutamato carboxipeptidasa 2 humana (también conocida como folato hidrolasa 1 (FOLH1), antígeno de membrana específico de próstata (PSMA)), bajo el control del promotor de *Lm actA* y contenido dentro de un casete de expresión de 4984 pares de bases insertado en el locus de *Lm tRNA*^{Arg}.
pamiparibum pamiparib	(10a*R*)-2-fluoro-10a-methyl-5,8,9,10,10a,11-hexahydro-5,6,7a,11-tetraazacyclohepta[*def*]cyclopenta[*a*]fluoren-4(7*H*)-one

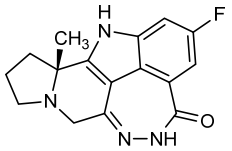
pamiparib

(10a*R*)-2-fluoro-10a-méthyl-5,8,9,10,10a,11-hexahydro-5,6,7*a*,11-tétraazacyclohepta[*def*]cyclopenta[*a*]fluorén-4(7*H*)-one

pamiparib

10a*R*)-2-fluoro-10a-metil-5,8,9,10,10a,11-hexahidro-5,6,7*a*,11-tetraazaciclohepta[*def*]ciclopenta[*a*]fluoren-4(7*H*)-ona

$C_{16}H_{15}FN_4O$



parsaclisibum

parsaclisib

(4*R*)-4-{3-[(1*S*)-1-(4-amino-3-methyl-1*H*-pyrazolo[3,4-*d*]pyrimidin-1-yl)ethyl]-5-chloro-2-ethoxy-6-fluorophenyl}pyrrolidin-2-one

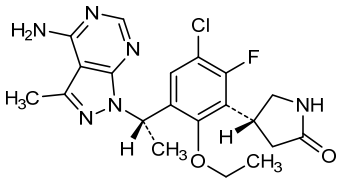
parsaclisib

(4*R*)-4-{3-[(1*S*)-1-(4-amino-3-méthyl-1*H*-pyrazolo[3,4-*d*]pyrimidin-1-yl)éthyl]-5-chloro-2-éthoxy-6-fluorophényl}pyrrolidin-2-one

parsaclisib

(4*R*)-4-{3-[(1*S*)-1-(4-amino-3-metil-1*H*-pirazolo[3,4-*d*]pirimidin-1-il)etil]-5-cloro-2-etoxi-6-fluorofenil}pirrolidin-2-ona

$C_{20}H_{22}ClFN_6O_2$



pegdarbepoetinum beta #

pegdarbepoetin beta

N-terminal pegylated human erythropoietin fragment, mutated, produced in Chinese hamster ovary (CHO) cells, glycoform beta;

[Ala^{30}>Asn,His^{32}>Thr,Pro^{87}>Val,Trp^{88}>Asn,Pro^{90}>Thr]erythropoietin (human)-(1-165)-peptide, produced in Chinese hamster ovary (CHO) cells, glycoform beta, chemically modified on Ala^{1}-*N* with a 4-[ω-methoxypoly(oxyethylene)$_n$-α-yl]butyl group (n ~ 682).

pegdarbépoétine bêta

fragment d'érythropoïétine humaine pégylé à l'extrémité N-terminale, modifié, produit par des cellules ovariennes de hamster chinois (CHO), glycoforme bêta;

[Ala^{30}>Asn,His^{32}>Thr,Pro^{87}>Val,Trp^{88}>Asn,Pro^{90}>Thr]érythropoïétine (humaine)-(1-165)-peptide, produit par des cellules ovariennes de hamster chinois (CHO), glycoforme bêta, chimiquement modifié sur l'Ala^{1}-*N* avec un groupe 4-[ω-méthoxypoly(oxyéthylène)$_n$-α-yl]butyle (n ~ 682).

pegdarbepoetina beta

fragmente de eritropoyetina humana pegilado en la extremidad N-terminale, modificado, producido por las células ováricas de hamster chino (CHO), glicoforma beta;

[Ala^{30}>Asn,His^{32}>Thr,Pro^{87}>Val,Trp^{88}>Asn,Pro^{90}>Thr]eritropoyetina (humana)-(1-165)-péptido, producido por las células ováricas de hamster chino (CHO), glicoforma beta, químicamente modificado sobre la Ala^{1}-*N* con un grupo 4-[ω-metoxipoli(oxietileno)$_n$-α-il]butilo (n ~ 682).

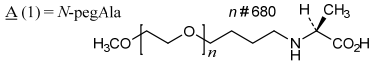
$C_{805}H_{1310}N_{228}O_{245}S_5(C_2H_4O)_n$

Sequence / Séquence / Secuencia

APPRLICDSR VLERYLLEAK EAENITTGCN ETCSLNENIT VPDTKVNFYA 50
WKRMEVGQQA VEVWQGLALL SEAVLRGQAL LVNSSQVNET LQLHVDKAVS 100
GLRSLTTLLR ALGAQKEAIS PPDAASAAPL RTITADTFRK LFRVYSNFLR 150
GKLKLYTGEA CRTGD 165

Disulfide bridge location / Position du pont disulfure / Posición del puente disulfuro
7-161 29-33

Modified residue / Résidu modifié / Resto modificado



Glycosylation site (N , S) / Site de glycosylation (N , S) / Posición de glicosilatión (N , S)
Asn-24 Asn-30 Asn-38 Asn-88 Asn-80 Ser-126

pegilodecakinum #

pegilodecakin

N-terminal pegylated human interleukin 10 (IL10) analogue, with an added methionine at the N-terminus, dimer, produced in recombinant *Escherichia coli*; *N*-{3-[ω-methoxypoly(oxyethylene)-α-yl]propyl}-L-methionyl-interleukin 10 (human), homodimer (non-covalent), produced in recombinant *Escherichia coli*

pégilodécakine

analogue de l'interleukine 10 humaine, pégylé en position N-terminale, avec l'ajout d'une méthionine en position N-terminale, dimère, produit par *Escherichia coli;* *N*-{3-[ω-méthoxypoly(oxyéthylène)-α-yl]propyl}-L-méthionyl-interleukine 10 (humaine), homodimère (non covalent), produit par *Escherichia coli*

pegilodecakina

análogo de la interleukina 10 humano , pegilado en posición N-terminal, con la ayuda de una metionina en posición N-terminal, dímero, producido por *Escherichia coli;* *N*-{3-[ω-metoxipoli(oxietileno)-α-il]propil}-L-metionil-interleukina 10 (humano), homodímero (no covalente), producido por *Escherichia coli*

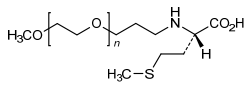
Monomer sequence / Séquence du monomère / Secuencia del monómero

```
                                                          M  0
SPGQGTQSEN SCTHFPGNLP NMLRDLRDAF SRVKTFFQMK DQLDNLLLKE  50
SLLEDFKGYL GCQALSEMIQ FYLEEVMPQA ENQDPDIKAH VNSLGENLKT 100
LRLRLRRCHR FLPCENKSKA VEQVKNAFNK LQEKGIYKAM SEFDIFINYI 150
EAYMTMKIRN                                              160
```

Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
12-108 62-114

Modified residues / Résidus modifiés / Restos modificados

M
0, 0'
pegylated-L-methionine



pegzilarginasum #
pegzilarginase

pegylated human arginine amidinase (arginase I, EC=3.5.3.1), mutated, cobalt ions replacing native manganese ions, trimer, produced in *Escherichia coli*;

des-Met[1]-arginase-1 (human) dicobalt(II) complex, trimer, produced by *Escherichia coli*, substituted on an average of 8 to 16 primary amino groups of each protein monomer with [ω-methoxypoly(oxyethylene)$_n$-α-yl]acetyl groups (n ~ 120)

pegzilarginase

arginine amidinase humaine pégylée (arginase I, EC=3.5.3.1), modifiée, dans laquelle le manganèse est remplacé par du cobalt, trimère, produit par *Escherichia coli*;

dès-Mét[1]-arginase-1 (humaine) dicobalt(II) complexe, trimère, produit par *Escherichia coli*, substituée sur une moyenne de 8 sur 16 groupes amines primaires de chaque monomère de la protéine avec des groupes [ω-méthoxypoly(oxyéthylène)$_n$-α-yl]acétyles (n ~ 120)

pegzilarginasa

arginina amidinasa humana pegilada (arginasa I, EC=3.5.3.1), modificada, iones de cobalto que reemplazan iones de manganeso nativos, trímero, producido por *Escherichia coli*;

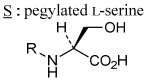
des-Met[1]-arginasa-1 (humana) dicobalto(II) complejo, trímero, producido por *Escherichia coli*, sustituida por una media de 8 a 16 grupos aminas primarias de cada monómero de la proteína con los grupos [ω-metoxipoli(oxietileno)$_n$-α-il]acetilos (n ~ 120)

Monomer sequence / Séquence du monomère / Secuencia del monómero

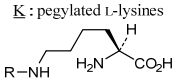
```
SAKSRTIGII GAPFSKGQPR GGVEEGPTVL RKAGLLEKLK EQECDVKDYG  50
DLPFADIPND SPFQIVKNPR SVGKASEQLA GKVAEVKKNG RISLVLGGDH 100
SLAIGSISGH ARVHPDLGVI WVDAHTDINT PLTTTSGNLH GQPVSFLLKE 150
LKGKIPDVPG FSWVTPCISA KDIVYIGLRD VDPGEHYILK TLGIKYFSMT 200
EVDRLGIGKV MEETLSYLLG RKKRPIHLSF DVDGLDPSFT PATGTPVVGG 250
LTYREGLYIT EEIYKTGLLS GLDIMEVNPS LGKTPEEVTR TVNTAVAITL 300
ACFGLAREGN HKPIDYLNPP K                                 321
```

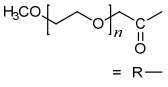
Potential modified residues / Résidus modifiés potentiels / Restos modificados potenciales

S : pegylated L-serine



K : pegylated L-lysines





= R—

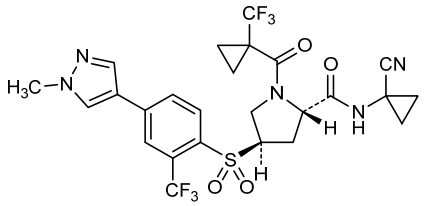
pemlimogenum merolisbacum #

pemlimogene merolisbac	Recombinant live-attenuated double-deleted (LADD) strain of *Listeria monocytogenes* (*Lm* Δ*actA*/Δ*inlB*) expressing a fusion protein comprising the N-terminal 100 amino acids of the Lm ActA protein (ActAN100), 5 tandem copies of a 21 amino acid fragment of human epidermal growth factor receptor variant III (EGFRvIII) and amino acids 35-622 of human mesothelin (MSLN), under the control the *Lm actA* (actin-assembly inducing protein precursor) promoter, and contained within an expression cassette of 3874 bp inserted at the *Lm tRNA*^{Arg} locus.
pemlimogène mérolisbac	Souche vivante atténuée recombinante de *Listeria monocytogenes* (*Lm* Δ*actA*/Δ*inlB*) avec double délétion, exprimant une protéine de fusion qui consiste en les 100 acides aminés à l'extrémité N-terminale de la protéine *Lm* ActA (ActAN100), 5 copies en tandem d'un fragment de 21 acides aminés de la variante III du récepteur du facteur de croissance épidermique humain (EGFRvIII) et les acides aminés 35-622 de la mésothéline humaine (MSLN), sous le contrôle du promoteur de *Lm actA* (précurseur de la protéine induisant l'assemblage de l'actine), et contenu dans une cassette d'expression de 3874 paires de bases insérée sur le locus de *Lm tRNA*^{Arg}.
pemlimogén merolisbac	Cepa viva atenuada recombinante, con doble deleción, de *Listeria monocytogenes* (*Lm* Δ*actA*/Δ*inlB*) que expresa una proteína de fusión consistente en los 100 amino ácidos N-terminales de la proteína *Lm* ActA (ActAN100), 5 copias en tándem de un fragmento de 21 amino ácidos de la variante III del receptor para el factor de crecimiento epidérmico humano (EGFRvIII) y los amino ácidos 35-622 de la mesotelina humana (MSLN), bajo el control del promotor de *Lm actA* (precursor de la proteína inductora del ensamblaje de la actina), y contenido dentro de un casete de expresión de 3874 pares de bases insertado en el locus de *Lm tRNA*^{Arg}

petesicatibum

petesicatib	(2*S*,4*R*)-*N*-(1-cyanocyclopropyl)-4-[4-(1-methyl-1*H*-pyrazol-4-yl)-2-(trifluromethyl)benzenesulfonyl]-1-[1-(trifluoromethyl)cyclopropane-1-carbonyl]pyrrolidine-2-carboxamide
pétésicatib	(2*S*,4*R*)-*N*-(1-cyanocyclopropyl)-4-[4-(1-méthyl-1*H*-pyrazol-4-yl)-2-(trifluorométhyl)benzènesulfonyl]-1-[1-(trifluorométhyl)cyclopropane-1-carbonyl]pyrrolidine-2-carboxamide
petesicatib	2*S*,4*R*)-*N*-(1-cianociclopropil)-4-[4-(1-metil-1*H*-pirazol-4-il)-2-(triflurometil)bencenosulfonil]-1-[1-(trifluorometil)ciclopropano-1-carbonil]pirrolidina-2-carboxamida

$C_{25}H_{23}F_6N_5O_4S$



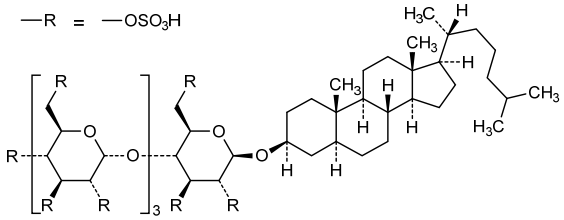
pixatimodum

pixatimod — 5α-cholestan-3β-yl 2,3,4,6-tetra-*O*-sulfo-α-D-glucopyranosyl-(1→4)-2,3,6-tri-*O*-sulfo-α-D-glucopyranosyl-(1→4)-2,3,6-tri-*O*-sulfo-α-D-glucopyranosyl-(1→4)-2,3,6-tri-*O*-sulfo-β-D-glucopyranoside

pixatimod — 2,3,4,6-tétra-*O*-sulfo-α-D-glucopyranosyl-(1→4)-2,3,6-tri-*O*-sulfo-α-D-glucopyranosyl-(1→4)-2,3,6-tri-*O*-sulfo-α-D-glucopyranosyl-(1→4)-2,3,6-tri-*O*-sulfo-β-D-glucopyranoside de 5α-cholestan-3β-yle

pixatimod — 2,3,4,6-tetra-*O*-sulfo-α-D-glucopiranosil-(1→4)-2,3,6-tri-*O*-sulfo-α-D-glucopi-ranosil-(1→4)-2,3,6-tri-*O*-sulfo-α-D-glucopiranosil-(1→4)-2,3,6-tri-*O*-sulfo-β-D-glucopiranósida de 5α-colestan-3β-ilo

$C_{51}H_{88}O_{60}S_{13}$



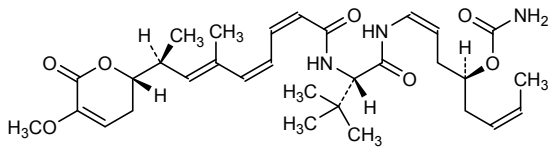
plocabulinum

plocabulin — (1*Z*,4*S*,6*Z*)-1-[(2*S*)-2-{(2*Z*,4*Z*,6*E*,8*S*)-8-[(2*S*)-5-methoxy-6-oxo-3,6-dihydro-2*H*-pyran-2-yl]-6-methylnona-2,4,6-trienamido}-3,3-dimethylbutanamido]octa-1,6-dien-4-yl carbamate

plocabuline — carbamate de (1*Z*,4*S*,6*Z*)-1-[(2*S*)-2-{(2*Z*,4*Z*,6*E*,8*S*)-8-[(2*S*)-5-méthoxy-6-oxo-3,6-dihydro-2*H*-pyran-2-yl]-6-méthylnona-2,4,6-triénamido}-3,3-diméthylbutanamido]octa-1,6-dien-4-yle

plocabulina — carbamato de (1*Z*,4*S*,6*Z*)-1-[(2*S*)-2-{(2*Z*,4*Z*,6*E*,8*S*)-8-[(2*S*)-5-metoxi-6-oxo-3,6-dihidro-2*H*-piran-2-il]-6-metilnona-2,4,6-trienamido}-3,3-dimetilbutanamido]octa-1,6-dien-4-ilo

$C_{31}H_{45}N_3O_7$



prasinezumabum #

prasinezumab	immunoglobulin G1-kappa, anti-[*Homo sapiens* SNCA (synuclein alpha, PARK1, PARK4, Parkinson disease (autosomal dominant, Lewy body) 4, alpha-synuclein, aSyn, non A4 component of amyloid precursor, NACP)], humanized monoclonal antibody; gamma1 heavy chain (1-446) [humanized VH (*Homo sapiens* IGHV3-7*01 (87.80%) -(IGHD) -IGHJ4*01) [8.8.9] (1-116) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120(213) (117-214), hinge (215-229), CH2 (230-339), CH3 E12 (355), M14(357) (340-444), CHS (445-446)) (117-446)], (219-220')-disulfide with kappa light chain (1'-220') [humanized V-KAPPA (*Homo sapiens* IGKV1-16*01 (81.20%) -IGKJ4*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC*01, Km3 A45.1 (159), V101 (197) (114'-220')]; dimer (225-225'':228-228'')-bisdisulfide
prasinezumab	immunoglobuline G1-kappa, anti-[*Homo sapiens* SNCA (synucléine alpha, PARK1, PARK4, maladie de Parkinson (autosomique dominante, corps de Lewy) 4, synucléine-alpha, aSyn, composant non A4 du précurseur amyloïde, NACP)], anticorps monoclonal humanisé; chaîne lourde gamma1 (1-446) [VH humanisé (*Homo sapiens* IGHV3-7*01 (87.80%) -(IGHD) -IGHJ4*01) [8.8.9] (1-116) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120(213) (117-214), charnière (215-229), CH2 (230-339), CH3 E12 (355), M14(357) (340-444), CHS (445-446)) (117-446)], (219-220')-disulfure avec la chaîne légère (1'-220') [V-KAPPA humanisé (*Homo sapiens* IGKV1-16*01 (81.20%) -IGKJ4*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC*01, Km3 A45.1 (159), V101 (197) (114'-220')]; dimère (225-225'':228-228'')-bisdisulfure
prasinezumab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* SNCA (sinucleína alfa, PARK1, PARK4, enfermedad de Parkinson (autosómica dominante, cuerpos de Lewy) 4, sinucleína-alfa, aSyn, componente no A4 del precursor amieloide, NACP)], anticuerpo monoclonal humanizado; cadena pesada gamma1 (1-446) [VH humanizado (*Homo sapiens* IGHV3-7*01 (87.80%) -(IGHD) -IGHJ4*01) [8.8.9] (1-116) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120(213) (117-214), bisagra (215-229), CH2 (230-339), CH3 E12 (355), M14(357) (340-444), CHS (445-446)) (117-446)], (219-220')-disulfuro con la cadena ligera (1'-220') [V-KAPPA humanizado (*Homo sapiens* IGKV1-16*01 (81.20%) -IGKJ4*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC*01, Km3 A45.1 (159), V101 (197) (114'-220')]; dímero (225-225'':228-228'')-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVESGGG LVQPGGSLRL SCAASGFTFS NYGMSWVRQA PGKGLEWVAS  50
ISSGGGSTYY PDNVKGRFTI SRDDAKNSLY LQMNSLRAED TAVYYCARGG 100
AGIDYWGQGT LVTVSSASTK GPSVFPLAPS SKSTSGGTAA LGCLVKDYFP 150
EPVTVSWNSG ALTSGVHTFP AVLQSSGLYS LSSVVTVPSS SLGTQTYICN 200
VNHKPSNTKV DKRVEPKSCD KTHTCPPCPA PELLGGPSVF LFPPKPKDTL 250
MISRTPEVTC VVVDVSHEDP EVKFNWYVDG VEVHNAKTKP REEQYNSTYR 300
VVSVLTVLHQ DWLNGKEYKC KVSNKALPAP IEKTISKAKG QPREPQVYTL 350
PPSREEMTKN QVSLTCLVKG FYPSDIAVEW ESNGQPENNY KTTPPVLDSD 400
GSFFLYSKLT VDKSRWQQGN VFSCSVMHEA LHNHYTQKSL SLSPGK     446
```

Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS LSASVGDRVT ITCKSIQTLL YSSNQKNYLA WFQQKPGKAP  50
KLLIYWASIR KSGVPSRFSG SGSGTDFTLT ISSLQPEDLA TYYCQQYYSY 100
PLTFGGGTKL EIKRTVAAPS VFIFPPSDEQ LKSGTASVVC LLNNFYPREA 150
KVQWKVDNAL QSGNSQESVT EQDSKDSTYS LSSTLTLSKA DYEKHKVYAC 200
EVTHQGLSSP VTKSFNRGEC                                   220
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 143-199 260-320 366-424
22"-96" 143"-199" 260"-320" 366"-424"
Intra-L (C23-C104) 23'-94' 140'-200'
23'"-94'" 140'"-200'"
Inter-H-L (h 5-CL 126) 219-220' 219"-220'"
Inter-H-H (h 11, h 14) 225-225" 228-228"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
296, 296"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

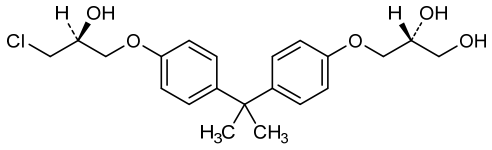
ralanitenum

ralaniten — (2*R*)-3-[4-(2-{4-[(2*S*)-3-chloro-2-hydroxypropoxy]phenyl}propan-2-yl)phenoxy]propane-1,2-diol

ralaniten — (2*R*)-3-[4-(2-{4-[(2*S*)-3-chloro-2-hydroxypropoxy]phényl}propan-2-yl)phénoxy]propane-1,2-diol

ralanitén — (2*R*)-3-[4-(2-{4-[(2*S*)-3-cloro-2-hidroxipropoxi]fenil}propan-2-il)fenoxi]propano-1,2-diol

$C_{21}H_{27}ClO_5$



ravulizumabum #

ravulizumab — immunoglobulin G2-4-kappa, anti-[*Homo sapiens* C5 (complement 5)], humanized monoclonal antibody; gamma2-4 heavy chain (1-448) [humanized VH (*Homo sapiens* IGHV1-46*01 (81.60%) -(IGHD) -IGHJ4*01) [8.8.15] (1-122) -*Homo sapiens* IGHG2*01 (CH1 (123-220), hinge (221-232), CH2 1.6-1.1 (233-237)) (123-237) -*Homo sapiens* IGHG4*01 (CH2 1-125 (238-341), CH3 M107>L (429), N114>S (435) (342-446), CHS (447-448)) (238-448)], (146-214')-disulfide with kappa light chain (1'-214') [humanized V-KAPPA (*Homo sapiens* IGKV1-39*01 (84.20%) -IGKJ1*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (224-224":225-225":228-228":231-231")-tetrakisdisulfide

ravulizumab

immunoglobuline G2-4-kappa, anti-[*Homo sapiens* C5 (complément 5)], anticorps monoclonal humanisé; chaîne lourde gamma2-4 (1-448) [VH humanisé (*Homo sapiens* IGHV1-46*01 (81.60%) -(IGHD) -IGHJ4*01) [8.8.15] (1-122) -*Homo sapiens* IGHG2*01 (CH1 (123-220), charnière (221-232), CH2 1.6-1.1 (233-237)) (123-237) -*Homo sapiens* IGHG4*01 (CH2 1-125 (240-341), CH3 M107>L (429), N114>S (435) (342-446), CHS (447-448)) (240-448)], (146-214')-disulfure avec la chaîne légère kappa (1'-214') [V-KAPPA humanisé (*Homo sapiens* IGKV1-39*01 (84.20%) -IGKJ1*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*0, Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (224-224":225-225":228-228":231-231")-tétrakisdisulfure

ravulizumab

inmunoglobulina G2-4-kappa, anti-[*Homo sapiens* C5 (complemento 5)], anticuerpo monoclonal humanizado; cadena pesada gamma2-4 (1-448) [VH humanizado (*Homo sapiens* IGHV1-46*01 (81.60%) -(IGHD) -IGHJ4*01) [8.8.15] (1-122) -*Homo sapiens* IGHG2*01 (CH1 (123-220), bis (221-232), CH2 1.6-1.1 (233-237)) (123-237) -*Homo sapiens* IGHG4*01 (CH2 1-125 (240-341), CH3 M107>L (429), N114>S (435) (342-446), CHS (447-448)) (240-448)], (146-214')-disulfuro con la cadena ligera kappa (1'-214') [V-KAPPA humanizado (*Homo sapiens* IGKV1-39*01 (84.20%) -IGKJ1*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*0, Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (224-224":225-225":228-228":231-231")-tetrakisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGASVKV SCKASGHIFS NYWIQWVRQA PGQGLEWMGE  50
ILPGSGHTEY TENFKDRVTM TRDTSTSTVY MELSSLRSED TAVYYCARYF 100
FGSSPNWYFD VWGQGTLVTV SSASTKGPSV FPLAPCSRST SESTAALGCL 150
VKDYFPEPVT VSWNSGALTS GVHTFPAVLQ SSGLYSLSSV VTVPSSNFGT 200
QTYTCNVDHK PSNTKVDKTV ERKCCVECPP CPAPPVAGPS VFLFPPKPKD 250
TLMISRTPEV TCVVVDVSQE DPEVQFNWYV DGVEVHNAKT KPREEQFNST 300
YRVVSVLTVL HQDWLNGKEY KCKVSNKGLP SSIEKTISKA KGQPREPQVY 350
TLPPSQEEMT KNQVSLTCLV KGFYPSDIAV EWESNGQPEN NYKTTPPVLD 400
SDGSFFLYSR LTVDKSRWQE GNVFSCSVLH EALHSHYTQK SLSLSLGK   448
```

Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS LSASVGDRVT ITCGASENIY GALNWYQQKP GKAPKLLIYG  50
ATNLADGVPS RFSGSGSGTD FTLTISSLQP EDFATYYCQN VLNTPLTFGQ 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

Post-translational modifications

Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro

Intra-H (C23-C104) 22-96 149-205 262-322 368-426
22"-96" 149"-205" 262"-322" 368"-426"

Intra-L (C23-C104) 23'-88' 134'-194'
23"'-88"' 134"'-194"'

Inter-H-L (CH1 10-CL 126) 136-214' 136"-214"'

Inter-H-H (h 4, h 5, h 8, h 11) 224-224" 225-225" 228-228" 231-231"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación

H CH2 N84.4:
298, 298"

Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

redasemtidum
redasemtide — human high mobility group protein B1 (HMG-1)-(1-44)-peptide (including Met[1]), chemically synthesized (without any modified residues)

rédasemtide — protéine B1 du groupe à haute mobilité humaine (HMGB1)-(1-44)- peptide (incluant Met[1]), synthétisé chimiquement (sans aucun résidu modifié)

redasemtida — proteína B1 del grupo de alta movilidad humana (HMGB1)-(1-44)-péptido (incluyendo Met[1]), sintetizado químicamente (sin restos modificados)

$C_{224}H_{351}N_{65}O_{64}S_3$

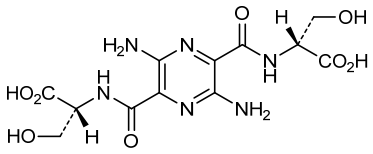
Sequence / Séquence / Secuencia
MGKGDPKKPR GKMSSYAFFV QTCREEHKKK HPDASVNFSE FSKK 44

relmapirazinum
relmapirazin — *N*,*N*'-(3,6-diaminopyrazine-2,5-dicarbonyl)di-D-serine

relmapirazine — *N*,*N*'-(3,6-diaminopyrazine-2,5-dicarbonyl)di-D-sérine

relmapirazina — *N*,*N*'-(3,6-diaminopirazina-2,5-dicarbonil)di-D-serina

$C_{12}H_{16}N_6O_8$



reloxaliasum #
reloxaliase — oxalate decarboxylase (OxdC, EC=4.1.1.2, *Bacillus subtilis* gene yvrK), hexamer, produced in *Escherichia coli*

réloxaliase — oxalate décarboxylase (OxdC, EC=4.1.1.2, gène yvrK de *Bacillus subtilis*), hexamère, produit par *Escherichia coli*

reloxaliasa — oxalate decarboxilasa (OxdC, EC=4.1.1.2, gén yvrK de *Bacillus subtilis*), hexámero, producido por *Escherichia coli*

$C_{1961}H_{2991}N_{519}O_{588}S_{10}$ (monomer)

Monomer sequence / Séquence du monomère / Secuencia del monómero
MKKQNDIPQP IRGDKGATVK IPRNIERDRQ NPDMLVPPET DHGTVSNMKF 50
SFSDTHNRLE KGGYAREVTV RELPISENLA SVNMRLKPGA IRELHWHKEA 100
EWAYMIYGSA RVTIVDEKGR SFIDDVGEGD LWYFPSGLPH SIQALEEGAE 150
FLLVFDDGSF SENSTFQLTD WLAHTPKEVI AANFGVTKEE ISNLPGKEKY 200
IFENQLPGSL KDDIVEGPNG EVPYPFTYRL LEQEPIESEG GKVYIADSTN 250
FKVSKTIASA LVTVEPGAMR ELHWHPNTHE WQYYISGKAR MTVFASDGHA 300
RTFNYQAGDV GYVPFAMGHY VENIGDEPLV FLEIFKDDHY ADVSLNQWLA 350
MLPETFVQAH LDLGKDFTDV LSKEKHPVVK KKCSK 385

remlarsenum

remlarsen

(2*RS*)-3-{[6-(cholest-5-en-3β-yloxy)hexyl]oxy}-2-hydroxypropyl hydrogen 2'-*O*-methyladenylyl-(3'→5')-2'-*O*-methyladenylyl-(3'→5')-2'-*O*-methylcytidylyl-(3'→5')-adenylyl-(3'→5')-2'-*O*-methylcytidylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-guanylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-adenylyl-(3'→5')-2'-*O*-methylcytidylyl-(3'→5')-adenylyl-(3'→5')-adenylyl-(3'→5')-adenylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-guanylyl-(3'→5')-guanylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-*O*-methylcytidylyl-(3'→5')-2'-*O*-methylcytidylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-3'-adenylate duplex with *all-P-ambo-P*-thiouridylyl-(5'→3')-*P*-thiouridylyl-(5'→3')-2'-deoxy-2'-fluorouridylyl-(5'→3')-2'-deoxy-2'-fluorouridylyl-(5'→3')-guanylyl-(5'→3')-2'-deoxy-2'-fluorouridylyl-(5'→3')-guanylyl-(5'→3')-adenylyl-(5'→3')-2'-deoxy-2'-fluorocytidylyl-(5'→3')-2'-deoxy-2'-fluorouridylyl-(5'→3')-adenylyl-(5'→3')-adenylyl-(5'→3')-adenylyl-(5'→3')-guanylyl-(5'→3')-2'-deoxy-2'-fluorouridylyl-(5'→3')-2'-deoxy-2'-fluorouridylyl-(5'→3')-2'-deoxy-2'-fluorouridylyl-(5'→3')-adenylyl-(5'→3')-2'-deoxy-2'-fluorocytidylyl-(5'→3')-2'-deoxy-2'-fluorocytidylyl-(5'→3')-adenylyl-(5'→3')-2'-deoxy-2'-fluorocytidylyl-(5'→3')-guanylyl-(5'→3')-adenylyl-(5'→3')-2'-deoxy-2'-fluorouridine

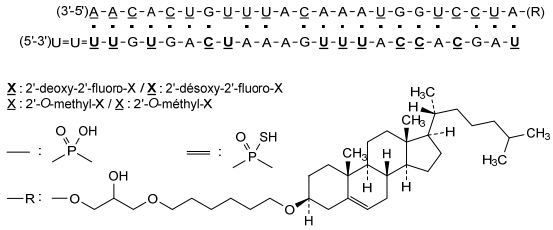
remlarsen

hydrogéno-2'-*O*-méthyladénylyl-(3'→5')-2'-*O*-méthyladénylyl-(3'→5')-2'-*O*-méthylcytidylyl-(3'→5')-adénylyl-(3'→5')-2'-*O*-méthylcytidylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-guanylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-adénylyl-(3'→5')-2'-*O*-méthylcytidylyl-(3'→5')-adénylyl-(3'→5')-adénylyl-(3'→5')-adénylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-guanylyl-(3'→5')-guanylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-*O*-méthylcytidylyl-(3'→5')-2'-*O*-méthylcytidylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-3'-adénylate de (2*RS*)-3-{[6-(cholest-5-én-3β-yloxy)hexyl]oxy}-2-hydroxypropyle duplex avec *tout-P-ambo-P*-thiouridylyl-(5'→3')-*P*-thiouridylyl-(5'→3')-2'-désoxy-2'-fluorouridylyl-(5'→3')-2'-désoxy-2'-fluorouridylyl-(5'→3')-guanylyl-(5'→3')-2'-désoxy-2'-fluorouridylyl-(5'→3')-guanylyl-(5'→3')-adénylyl-(5'→3')-2'-désoxy-2'-fluorocytidylyl-(5'→3')-2'-désoxy-2'-fluorouridylyl-(5'→3')-adénylyl-(5'→3')-adénylyl-(5'→3')-adénylyl-(5'→3')-guanylyl-(5'→3')-2'-désoxy-2'-fluorouridylyl-(5'→3')-2'-désoxy-2'-fluorouridylyl-(5'→3')-2'-désoxy-2'-fluorouridylyl-(5'→3')-adénylyl-(5'→3')-2'-désoxy-2'-fluorocytidylyl-(5'→3')-2'-désoxy-2'-fluorocytidylyl-(5'→3')-adénylyl-(5'→3')-2'-désoxy-2'-fluorocytidylyl-(5'→3')-guanylyl-(5'→3')-adénylyl-(5'→3')-2'-désoxy-2'-fluorouridine

remlarsén

hidrógeno-2'-*O*-metiladenilil-(3'→5')-2'-*O*-metiladenilil-(3'→5')-2'-*O*-metilcitidilil-(3'→5')-adenilil-(3'→5')-2'-*O*-metilcitidilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-guanylyl-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-adenilil-(3'→5')-2'-*O*-metilcitidilil-(3'→5')-adenilil-(3'→5')-adenilil-(3'→5')-adenilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-guanilil-(3'→5')-guanilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metilcitidilil-(3'→5')-2'-*O*-metilcitidilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-3'-adenilato de (2*RS*)-3-{[6-(colest-5-en-3β-iloxi)hexil]oxi}-2-hidroxipropilo dúplex con *todo-P-ambo-P*-tiouridilil-(5'→3')-*P*-tiouridilil-(5'→3')-2'-desoxi-2'-fluorouridilil-(5'→3')-2'-desoxi-2'-fluorouridilil-(5'→3')-guanilil-(5'→3')-2'-desoxi-2'-fluorouridilil-(5'→3')-guanilil-(5'→3')-adenilil-(5'→3')-2'-desoxi-2'-fluorocitidilil-(5'→3')-2'-desoxi-2'-fluorouridilil-(5'→3')-adenilil-(5'→3')-adenilil-(5'→3')-adenilil-(5'→3')-guanilil-(5'→3')-2'-desoxi-2'-fluorouridilil-(5'→3')-2'-desoxi-2'-fluorouridilil-(5'→3')-2'-desoxi-2'-fluorouridilil-(5'→3')-adenilil-(5'→3')-2'-desoxi-2'-fluorocitidilil-(5'→3')-2'-desoxi-2'-fluorocitidilil-(5'→3')-adenilil-(5'→3')-2'-desoxi-2'-fluorocitidilil-(5'→3')-guanilil-(5'→3')-adenilil-(5'→3')-2'-desoxi-2'-fluorouridina

$C_{504}H_{640}F_{12}N_{171}O_{326}P_{47}S_2$



rezafungini acetas
rezafungin acetate

$N^{5.1}$,6-anhydro[(4*R*,5*R*)-4-hydroxy-2-[3^4-(pentyloxy)[1^1,2^1:2^4,3^1-terphenyl]-1^4-carboxamido]-5-[2-(trimethylazaniumyl)ethyl]-L-ornithyl-L-threonyl-*trans*-4-hydroxy-L-prolyl-(4*S*)-4-hydroxy-4-(4-hydroxyphenyl)-L-threonyl-L-threonyl-(3*S*,4S)-3-hydroxy-4-methyl-L-proline] acetate

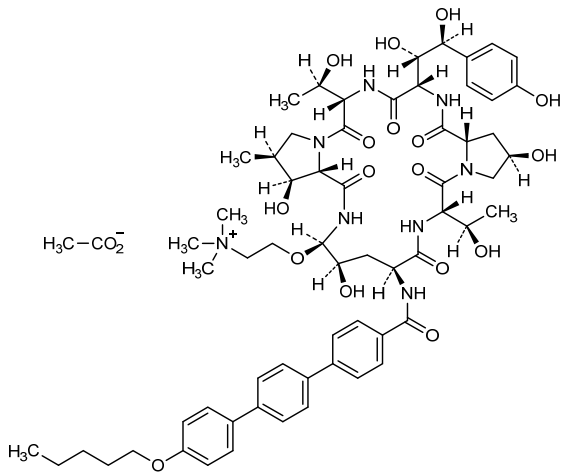
acétate de rézafungine

acétate de $N^{5.1}$,6-anhydro[(4*R*,5*R*)-4-hydroxy-2-[3^4-(pentyloxy)[1^1,2^1:2^4,3^1-terphényl]-1^4-carboxamido]-5-[2-(triméthylazaniumyl)éthyl]-L-ornithyl-L-thréonyl-*trans*-4-hydroxy-L-prolyl-(4*S*)-4-hydroxy-4-(4-hydroxyphényl)-L-thréonyl-L-thréonyl-(3*S*,4S)-3-hydroxy-4-méthyl-L-proline]

acetato de rezafungina

acetato de $N^{5.1}$,6-anhidro[(4*R*,5*R*)-4-hidroxi-2-[3^4-(pentiloxi)[1^1,2^1:2^4,3^1-terfenil]-1^4-carboxamido]-5-[2-(trimetilazaniumil)etil]-L-ornitil-L-treonil-*trans*-4-hidroxi-L-prolil-(4*S*)-4-hidroxi-4-(4-hidroxifenil)-L-treonil-L-treonil-(3*S*,4S)-3-hidroxi-4-metil-L-prolina]

$C_{63}H_{85}N_8O_{17} \cdot C_2H_3O_2$



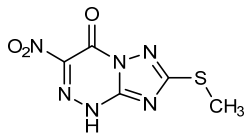
riamilovirum
riamilovir

7-(methylsulfanyl)-3-nitro[1,2,4]triazolo[5,1-*c*][1,2,4]triazin-4(1*H*)-one

riamilovir — 7-(méthylsulfanyl)-3-nitro[1,2,4]triazolo[5,1-*c*][1,2,4]triazin-4(1*H*)-one

riamilovir — 7-(metilsulfanil)-3-nitro[1,2,4]triazolo[5,1-*c*][1,2,4]triazin-4(1*H*)-ona

$C_5H_4N_6O_3S$



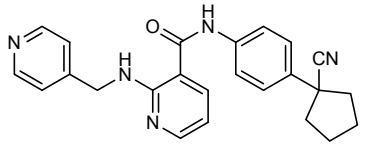
rivoceranibum

rivoceranib — *N*-[4-(1-cyanocyclopentyl)phenyl]-2-{[(pyridin-4-yl)methyl]amino}pyridine-3-carboxamide

rivocéranib — *N*-[4-(1-cyanocyclopentyl)phényl]-2-{[(pyridin-4-yl)méthyl]amino}pyridine-3-carboxamide

rivoceranib — *N*-[4-(1-cianociclopentil)fenil]-2-{[(piridin-4-il)metil]amino}piridina-3-carboxamida

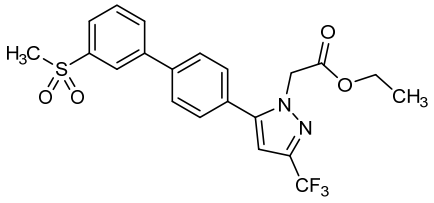
$C_{24}H_{23}N_5O$



rivogenlecleucelum #

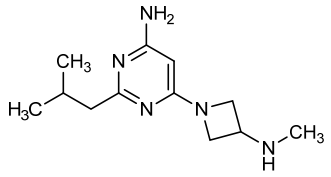
rivogenlecleucel — Human culture expanded genetically modified allogenic T cells for cell-based therapy. Cells are derived from isolated blood of a healthy human donor chosen by available HLA match (haploidentical up to fully matched) and are transduced with a Gibbon ape leukemia virus (GalV) pseudotyped gammaretroviral vector carrying an inducible caspase 9 suicide transgene and a truncated CD19 marker gene allowing selection, and a drug binding domain consisting of human FK506 (tacrolimus)-binding protein (FKBP12) with an F36V mutation. Cells exhibit anti-infective activity as adjunctive T-cell therapy in combination with allogenic hematopoietic stem cell transplantation, in combination with an inducible suicide mechanism in the event of donor T-cell induced graft versus host disease (GvHD).

rivogenlecleucel — Lymphocytes T humains allogéniques, en culture d'expansion et modifiés génétiquement en vue d'une thérapie cellulaire. Les cellules sont dérivées du sang prélevé chez un donneur sain choisi pour sa compatibilité HLA (de haploidentique à correspondant totalement) et sont transduites avec un vecteur rétroviral gamma

	pseudotypé virus de la leucémie du singe Gibbon (GalV) transportant un transgène suicide inductible de la caspase 9 et un gène CD19 tronqué comme marqueur permettant la sélection, ainsi qu'un domaine de liaison médicamenteuse consistant en la protéine humaine (FKBP12) se liant au tacrolimus (FK506) avec une mutation F36V. Les cellules montrent une activité anti-infectieuse comme thérapie adjuvante de lymphocytes T en association avec la transplantation de cellules souches hématopoïétiques allogéniques, en association aussi avec un mécanisme suicide inductible en cas de réaction du greffon contre l'hôte (GVH) induit par les lymphocytes T du donneur.
rivogenlecleucel	Linfocitos T alogénicos, humanos, expandidos en cultivo y modificados genéticamente para terapia celular. Las células se derivan a partir de sangre aislada de un donante humano sano elegido por su compatibilidad HLA (desde haploidéntico hasta totalmente coincidente) y están transducidas con un vector gamma-retroviral seudotipado del virus de la leucemia de monos Gibbon (GalV) que porta un transgen inducible suicida de caspasa 9 y un gen CD19 truncado como marcador que permite la selección, y un dominio de unión a drogas consistente en la proteína de unión al tacrólimus (FK506) humana (FKBP12) con una mutación F36V. Las células muestran actividad anti-infecciosa en terapia adyuvante de linfocitos T en combinación con trasplante alogénico de células madre hematopoyéticas, en combinación con un mecanismo suicida inducible en caso de enfermedad injerto contra huésped (EICH) inducida por los linfocitos T del donante.
rovazolacum	
rovazolac	ethyl {5-[3'-(methanesulfonyl)[1,1'-biphenyl]-4-yl]-3-(trifluoromethyl)-1*H*-pyrazol-1-yl}acetate
rovazolac	{5-[3'-(méthanesulfonyl)[1,1'-biphényl]-4-yl]-3-(trifluorométhyl)-1*H*-pyrazol-1-yl}acétate d'éthyle
rovazolac	{5-[3'-(metanosulfonil)[1,1'-bifenil]-4-il]-3-(trifluorometil)-1*H*-pirazol-1-il}acetato de etilo
	$C_{21}H_{19}F_3N_2O_4S$ 
seliforantum	
seliforant	6-[3-(methylamino)azetidin-1-yl]-2-(2-methylpropyl)pyrimidin-4-amine

séliforant	6-[3-(méthylamino)azétidin-1-yl]-2-(2-méthylpropyl)pyrimidin-4-amine
seliforant	6-[3-(metilamino)azetidin-1-il]-2-(2-metilpropil)pirimidin-4-amina

$C_{12}H_{21}N_5$



setrusumabum #

setrusumab	immunoglobulin G2-lambda, anti-[*Homo sapiens* SOST (sclerostin)], *Homo sapiens* monoclonal antibody; gamma2 heavy chain (1-443) [*Homo sapiens* VH (IGHV3-66*01 (89.80%) -(IGHD) -IGHJ4*01) [8.8.10] (1-117) -IGHG2*01, G2m.. (CH1 (118-215), hinge (216-227), CH2 V45.1 (278) (228-336), CH3 (337-441), CHS (442-443)) (118-443)], (131-216')-disulfide with lambda light chain (1'-217') [*Homo sapiens* V-LAMBDA (IGLV2-23*02 (92.60%) -IGLJ2*01) [9.3.11] (1'-111') -IGLC2*01 (112'-217')]; dimer (219-219'':220-220'':223-223'':226-226'')-tetrakisdisulfide
sétrusumab	immunoglobuline G2-lambda, anti-[*Homo sapiens* SOST (sclérostine)], *Homo sapiens* anticorps monoclonal; chaîne lourde gamma2 (1-443) [*Homo sapiens* VH (IGHV3-66*01 (89.80%) -(IGHD) -IGHJ4*01) [8.8.10] (1-117) -IGHG2*01, G2m.. (CH1 (118-215), charnière (216-227), CH2 V45.1 (278) (228-336), CH3 (337-441), CHS (442-443)) (118-443)], (131-216')-disulfure avec la chaîne légère lambda (1'-217') [*Homo sapiens* V-LAMBDA (IGLV2-23*02 (92.60%) -IGLJ2*01) [9.3.11] (1'-111') -IGLC2*01 (112'-217')]; dimère (219-219'':220-220'':223-223'':226-226'')-tétrakisdisulfure
setrusumab	inmunoglobulina G2-lambda, anti-[*Homo sapiens* SOST (esclerostina)], *Homo sapiens* anticuerpo monoclonal; cadena pesada gamma2 (1-443) [*Homo sapiens* VH (IGHV3-66*01 (89.80%) -(IGHD) -IGHJ4*01) [8.8.10] (1-117) -IGHG2*01, G2m.. (CH1 (118-215), bisagra (216-227), CH2 V45.1 (278) (228-336), CH3 (337-441), CHS (442-443)) (118-443)], (131-216')-disulfuro con la cadena ligera lambda (1'-217') [*Homo sapiens* V-LAMBDA (IGLV2-23*02 (92.60%) -IGLJ2*01) [9.3.11] (1'-111') -IGLC2*01 (112'-217')]; dímero (219-219'':220-220'':223-223'':226-226'')-tetrakisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVESGGG LVQPGGSLRL SCAASGFTFR SHWLSWVRQA PGKGLEWVSN  50
INYDGSSTYY ADSVKGRFTI SRDNSKNTLY LQMNSLRAED TAVYYCARDT 100
YLHFDYWGQG TLVTVSSAST KGPSVFPLAP CSRSTSESTA ALGCLVKDYF 150
PEPVTVSWNS GALTSGVHTF PAVLQSSGLY SLSSVVTVPS SNFGTQTYTC 200
NVDHKPSNTK VDKTVERKCC VECPPCPAPP VAGPSVFLFP PKPKDTLMIS 250
RTPEVTCVVV DVSHEDPEVQ FNWYVDGVEV HNAKTKPREE QFNSTFRVVS 300
VLTVVHQDWL NGKEYKCKVS NKGLPAPIEK TISKTKGQPR EPQVYTLPPS 350
REEMTKNQVS LTCLVKGFYP SDIAVEWESN GQPENNYKTT PPMLDSDGSF 400
FLYSKLTVDK SRWQQGNVFS CSVMHEALHN HYTQKSLSLS PGK        443
```

Light chain / Chaîne légère / Cadena ligera

```
DIALTQPASV SGSPGQSITI SCTGTSSDVG DINDVSWYQQ HPGKAPKLMI  50
YDVNNRPSGV SNRFSGSKSG NTASLTISGL QAEDEADYYC QSYAGSYLSE 100
VFGGGTKLTV LGQPKAAPSV TLFPPSSEEL QANKATLVCL ISDFYPGAVT 150
VAWKADSSPV KAGVETTTPS KQSNNKYAAS SYLSLTPEQW KSHRSYSCQV 200
THEGSTVEKT VAPTECS                                     217
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 144-200 257-317 363-421
22"-96" 144"-200" 257"-317" 363"-421"
Intra-L (C23-C104) 22'-90' 139'-198'
22'"-90'" 139'"-198'"
Inter-H-L (CH1 10-CL 126) 131-216' 131"-216'"
Inter-H-H (h 4, h 5, h 8, h 11) 219-219" 220-220" 223-223" 226-226"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
293, 293"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

spartalizumabum #

spartalizumab — immunoglobulin G4-kappa, anti-[*Homo sapiens* PDCD1 (programmed cell death 1, PD-1, PD1, CD279)], humanized monoclonal antibody;
gamma4 heavy chain (1-443) [humanized VH (*Homo sapiens* IGHV1-69-2*01 (75.00%) -(IGHD) -IGHJ6*01) [8.8.10] (1-117) -*Homo sapiens* IGHG4*01 (CH1 (118-215), hinge S10>P (225) (216-227), CH2 (228-337), CH3 (338-442), CHS K2>del (443)) (118-443)], (131-220')-disulfide with kappa light chain (1'-220') [humanized V-KAPPA (*Homo sapiens* IGKV3D-11*03 (75.80%) -IGKJ1*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (114'-220')]; dimer (223-223":226-226")-bisdisulfide

spartalizumab — immunoglobuline G4-kappa, anti-[*Homo sapiens* PDCD1 (protéine 1 de mort cellulaire programmée, PD-1, PD1, CD279)], anticorps monoclonal humanisé;
chaîne lourde gamma4 (1-443) [VH humanisé (*Homo sapiens* IGHV1-69-2*01 (75.00%) -(IGHD) -IGHJ6*01) [8.8.10] (1-117) -*Homo sapiens* IGHG4*01 (CH1 (118-215), charnière S10>P (225) (216-227), CH2 (228-337), CH3 (338-442), CHS K2>del (443)) (118-443)], (131-220')-disulfure avec la chaîne légère kappa (1'-220') [V-KAPPA humanisé (*Homo sapiens* IGKV3D-11*03 (75.80%) -IGKJ1*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (114'-220')]; dimère (223-223":226-226")-bisdisulfure

espartalizumab — inmunoglobulina G4-kappa, anti-[*Homo sapiens* PDCD1 (proteína 1 de muerte celular programada, PD-1, PD1, CD279)], anticuerpo monoclonal humanizado;

cadena pesada gamma4 (1-443) [VH humanizado (*Homo sapiens* IGHV1-69-2*01 (75.00%) -(IGHD) -IGHJ6*01) [8.8.10] (1-117) -*Homo sapiens* IGHG4*01 (CH1 (118-215), bisagra S10>P (225) (216-227), CH2 (228-337), CH3 (338-442), CHS K2>del (443)) (118-443)], (131-220')-disulfuro con la cadena ligera kappa (1'-220') [V-KAPPA humanizado (*Homo sapiens* IGKV3D-11*03 (75.80%) -IGKJ1*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (114'-220')]; dímero (223-223":226-226")-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVQSGAE VKKPGESLRI SCKGSGYTFT TYWMHWVRQA TGQGLEWMGN  50
IYPGTGGSNF DEKFKNRVTI TADKSTSTAY MELSSLRSED TAVYYCTRWT 100
TGTGAYWGQG TTVTVSSAST KGPSVFPLAP CSRSTSESTA ALGCLVKDYF 150
PEPVTVSWNS GALTSGVHTF PAVLQSSGLY SLSSVVTVPS SSLGTKTYTC 200
NVDHKPSNTK VDKRVESKYG PPCPPCPAPE FLGGPSVFLF PPKPKDTLMI 250
SRTPEVTCVV VDVSQEDPEV QFNWYVDGVE VHNAKTKPRE EQFNSTYRVV 300
SVLTVLHQDW LNGKEYKCKV SNKGLPSSIE KTISKAKGQP REPQVYTLPP 350
SQEEMTKNQV SLTCLVKGFY PSDIAVEWES NGQPENNYKT TPPVLDSDGS 400
FFLYSRLTVD KSRWQEGNVF SCSVMHEALH NHYTQKSLSL SLG        443
```

Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPAT LSLSPGERAT LSCKSSQSLL DSGNQKNFLT WYQQKPGQAP  50
RLLIYWASTR ESGVPSRFSG SGSGTDFTFT ISSLEAEDAA TYYCQNDYSY 100
PYTFGQGTKV EIKRTVAAPS VFIFPPSDEQ LKSGTASVVC LLNNFYPREA 150
KVQWKVDNAL QSGNSQESVT EQDSKDSTYS LSSTLTLSKA DYEKHKVYAC 200
EVTHQGLSSP VTKSFNRGEC                                  220
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 144-200 258-318 364-422
22"-96" 144"-200" 258"-318" 364"-422"
Intra-L (C23-C104) 23'-94' 140'-200'
23'"-94'" 140'"-200'"
Inter-H-L (h 5-CL 126) 131-220' 131"-220'"
Inter-H-H (h 11, h 14) 223-223" 226-226"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
294, 294"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados.

sultimotidum alfa #
sultimotide alfa

a fusion protein consisting of fragments of hepatitis B virus transcription factor X, large S-protein antigen (envelope antigen), B antigen (core antigen) and of a C-terminal six-histidine tag, expressed by engineered whole heat-killed *Saccharomyces cerevisiae*, glycoform alfa;

Met-Ala-Asp-Glu-Ala-Pro-Thr-Ser-{des-(69-83)-[P^{59}>F]pro-tein X (hepatitis B virus)-(52-127)-peptide (9-69)}-{[M^{1}>E,G^{3}>Q,Q^{10}>K,P^{19}S,G^{35}>R,N^{39}>A,H^{51}>T,P^{65}>L,T^{86}>Q,A^{91}>N]large S protein (hepatitis B virus) (70-243)}-{[T^{4}>I,V^{25}>I,N^{207}>S,L^{209}>V,L^{213}>I]small S protein (hepatitis B virus) (244-469)}-{des-Met^{1}-[S^{12}>T]capsid protein (hepatitis B virus) (470-651)}-His_{6} (652-657) fusion protein, produced in *Saccharomyces cerevisiae,* glycoform alfa

sultimotide alfa

protéine de fusion consistant en des fragments du facteur X de transcription du virus de l'hépatite B, de l'antigène de la grande protéine S (antigène de l'enveloppe), antigène B (antigène core) et d'un fragment de 6 histidines, produite par une souche de *Saccharomyces cerevisiae* inactivée par la chaleur, glycoforme alfa:

Met-Ala-Asp-Glu-Ala-Pro-Thr-Ser-{dès-(69-83)-[P^{59}>F]pro-téine X (virus de l'hépatite B)-(52-127)-peptide (9-69)}-{[M^{1}>E,G^{3}>Q,Q^{10}>K,P^{19}S,G^{35}>R,N^{39}>A,H^{51}>T,P^{65}>L,T^{86}>Q,A^{91}>N]grande protéine S (virus de l'hépatite B) (70-243)}-{[T^{4}>I,V^{25}>I,N^{207}>S,L^{209}>V,L^{213}>I]petite protéine S (virus de l'hépatite B) (244-469)}-{dès-$Mét^{1}$-[S^{12}>T]protéine de la capside (virus de l'hépatite B) (470-651)}-His_6 (652-657) protéine de fusion, produite par *Saccharomyces cerevisiae,* glycoforme alfa

sultimotida alfa

proteína de fusión consistente en los fragmentos del factor X de transcripción del virus de la hepatitis B, del antígeno de la proteína S grande (antígeno de la envoltura), antígeno B (antígeno nuclear) y de un fragmento de 6 histidinas, producida por una cepa de *Saccharomyces cerevisiae* inactivada por el calor, glicoforma alfa:

Met-Ala-Asp-Glu-Ala-Pro-Thr-Ser-{des-(69-83)-[P^{59}>F]proteína X (virus de la hepatitis B)-(52-127)-péptido}-{[M^{1}>E,G^{3}>Q,Q^{10}>K,P^{19}S,G^{35}>R,N^{39}>A,H^{51}>T,P^{65}>L,T^{86}>Q,A^{91}>N]proteína S grande (virus de la hepatitis B)}-{[T^{4}>I,V^{25}>I,N^{207}>S,L^{209}>V,L^{213}>I]proteína S pequeña (virus de la hepatitis B)}-{des-Met^{1}-[S^{12}>T]proteína de la cápside (virus de la hepatitis B)}-His_6 proteína de fusión, producida por *Saccharomyces cerevisiae,* glicoforma alfa

Sequence / Séquence / Secuencia

```
MADEAPTSHL SLRGLFVCAF SSAGPNAHQF LPKVLHKRTL GLSAMSTTDL 50
EAYFKDCLFK DWEELGEELE GQWSSKPRKG MGTNLSVSNP LGFFPDHQLD 100
PAFRANSANP DWDFNPNKDT WPEANQVGVG AFGLGFTPPH GGLLGWSPQA 150
QGILQTVPAN PPPASTNRQS GRQPTPISPP LRDSHPQAMQ WNSTTFHQAL 200
LDPRVRGLYF PAGGSSSGTV NPVPTTASPI SSIFSRTGDP ALNMENITSG 250
FLGPLLVLQA GFFLLTRILT IPQSLDSWWT SLNFLGGTTT CPGQNSQSPT 300
SNHSPTSCPP ICPGYRWMCL RRFIIFLFIL LLCLIFLLVL LDYQGMLPVC 350
PLLPGTSTTS TGPCKTCTIP AQGTSMFPSC CCTKPSDGNC TCIPIPSSWA 400
FARFLWEWAS VRFSWLSLLV PFVQWFVGLS PTVWLSVIWM MWYWGPSLYS 450
IVSPFIPLLP IFFCLWVYID IDPYKEFGAT VELLSFLPSD FFPSVRDLLD 500
TASALYREAL ESPEHCSPHH TALRQAILCW GELMNLATWV GSNLEDPASR 550
ELVVSYVNVN MGLKIRQLLW FHISCLTFGR ETVLEYLVSF GVWIRTPPAY 600
RPPNAPILST LPETTVVRRR GRSPRRRTPS PRRRRSQSPR RRRSQSRESQ 650
CHHHHHH                                               657
```

Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
18-350 57-308 291-319 312-529 333-380
364-367 381-390 382-392 464-651 516-575

Glycosylation sites (N) / Sites de glycosylation (N) / Posiciones de glicosilación (N)
Asn-84 Asn-192 Asn-246 Asn-302 Asn-389

tabelecleucelum
tabelecleucel

Human culture enriched allogenic Epstein-Barr virus-specific cytotoxic T cells (EBV-CTL) for cell-based therapy. Cells are isolated from blood of EBV seropositive healthy human donors. EBV-CTLs exhibit human leukocyte antigen (HLA)-restricted cytotoxic activity against EBV+ cells in allogeneic hematopoietic cell transplant patients with EBV associated post-transplant lymphoproliferative disease.

tabélecleucel	Lymphocytes T cytotoxiques spécifiques du virus d'Epstein-Barr (EBV-CTL), allogéniques, humains, enrichis en culture pour thérapie cellulaire. Les cellules sont isolées à partir du sang de donneurs humains sains séropositifs à l'EBV. Les EBV-CTL montrent une activité cytotoxique restreinte à l'antigène leucocytaire humain (HLA) contre les cellules EBV+ chez des patients transplantés avec des cellules hématopoïétiques allogéniques souffrants d'un syndrome lymphoprolifératif associé à l'EBV post-transplantation.
tabelecleucel	Linfocitos T citotóxicos específicos del virus de Epstein-Barr (EBV-CTL), alogénicos, humanos, enriquecidos en cultivo para terapia celular. Las células están asiladas a partir de sangre de donantes humanos sanos seropositivo para EBV. Los EBV-CTLs muestran actividad citotóxica restringida por HLA contra células EBV+ in pacientes trasplantados con células hematopoyéticas alogénicas con enfermedad linfoproliferativa post-trasplante asociada a EBV.
talacotuzumabum #	
talacotuzumab	immunoglobulin G1-2-kappa, anti-[*Homo sapiens* IL3RA (interleukin 3 receptor subunit alpha, interleukin 3 receptor alpha (low affinity), CD123)], humanized monoclonal antibody; gamma1-2 heavy chain (1-450) [humanized VH (*Homo sapiens* IGHV5-51*01 (82.70%) -(IGHD) -IGHJ3*01) [8.8.13] (1-120) -*Homo sapiens* IGHG1*01 (CH1 G1m17, K120 (217) (121-218) -hinge (219-233) -CH2 1.6-1.1 (234-239)) (121-239) -*Homo sapiens* IGHG2*01 (CH2 1-125, S3>D (242), G2m.. V45.1 (285), G110>A (330), I117>E (335) (240-343) -CH3 nG1m1 E12 (359), M14 (361) (344-448), CHS (449-450)) (240-450)], (223-220')-disulfide with kappa light chain (1'-220') [humanized V-KAPPA (*Homo sapiens* IGKV4-1*01 (90.10%) -IGKJ2*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC*01, Km3 A45.1 (159), V101 (197) (114'-220')]; dimer (229-229":232-232")-bisdisulfide
talacotuzumab	immunoglobuline G1-2-kappa, anti-[*Homo sapiens* IL3RA (sous-unité alpha du récepteur de l'interleukine 3, récepteur alpha (faible affinité) de l'interleukine 3, CD123)], anticorps monoclonal humanisé; chaîne lourde gamma1-2 (1-450) [VH humanisé (*Homo sapiens* IGHV5-51*01 (82.70%) -(IGHD) -IGHJ3*01) [8.8.13] (1-120) -*Homo sapiens* IGHG1*01 (CH1 G1m17, K120 (217) (121-218) -charnière (219-233) -CH2 1.6-1.1 (234-239))(121-239) -*Homo sapiens* IGHG2*01 (CH2 1-125, S3>D (242), G2m.. V45.1 (285), G110>A (330), I117>E (335) (240-343) -CH3 nG1m1 E12 (359), M14 (361) (344-448), CHS (449-450)) (240-450)], (223-220')-disulfure avec la chaîne légère kappa (1'-220') [V-KAPPA humanisé (*Homo sapiens* IGKV4-1*01 (90.10%) -IGKJ2*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC*01, Km3 A45.1, V101 (114'-220')]; dimère (229-229":232-232")-bisdisulfure

talacotuzumab

inmunoglobulina G1-2-kappa, anti-[*Homo sapiens* IL3RA (subunidad alfa del receptor de la interleukina 3, receptor alfa (baja afinidad) de la interleukina 3, CD123)], anticuerpo monoclonal humanizado;
cadena pesada gamma1-2 (1-450) [VH humanizado (*Homo sapiens* IGHV5-51*01 (82.70%) -(IGHD) -IGHJ3*01) [8.8.13] (1-120) -*Homo sapiens* IGHG1*01 (CH1 G1m17, K120 (217) (121-218) -bisagra (219-233) -CH2 1.6-1.1 (234-239)) (121-239) -*Homo sapiens* IGHG2*01 (CH2 1-125, S3>D (242), G2m.. V45.1 (285), G110>A (330), I117>E (335) (240-343) -CH3 nG1m1 E12 (359), M14 (361) (344-448), CHS (449-450)) (240-450)], (223-220')-disulfuro con la cadena ligera kappa (1'-220') [V-KAPPA humanizado (*Homo sapiens* IGKV4-1*01 (90.10%) -IGKJ2*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC*01, Km3 A45.1, V101 (114'-220')]; dímero (229-229":232-232")-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVQSGAE VKKPGESLKI SCKGSGYSFT DYYMKWARQM PGKGLEWMGD  50
IIPSNGATFY NQKFKGQVTI SADKSISTTY LQWSSLKASD TAMYYCARSH 100
LLRASWFAYW GQGTMVTVSS ASTKGPSVFP LAPSSKSTSG GTAALGCLVK 150
DYFPEPVTVS WNSGALTSGV HTFPAVLQSS GLYSLSSVVT VPSSSLGTQT 200
YICNVNHKPS NTKVDKKVEP KSCDKTHTCP PCPAPELLGG PDVFLFPPKP 250
KDTLMISRTP EVTCVVVDVS HEDPEVQFNW YVDGVEVHNA KTKPREEQFN 300
STFRVVSVLT VVHQDWLNGK EYKCKVSNKA LPAPEEKTIS KTKGQPREPQ 350
VYTLPPSREE MTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPM 400
LDSDGSFFLY SKLTVDKSRW QQGNVFSCSV MHEALHNHYT QKSLSLSPGK 450
```

Light chain / Chaîne légère / Cadena ligera

```
DIVMTQSPDS LAVSLGERAT INCESSQSLL NSGNQKNYLT WYQQKPGQPP  50
KPLIYWASTR ESGVPDRFSG SGSGTDFTLT ISSLQAEDVA VYYCQNDYSY 100
PYTFGQGTKL EIKRTVAAPS VFIFPPSDEQ LKSGTASVVC LLNNFYPREA 150
KVQWKVDNAL QSGNSQESVT EQDSKDSTYS LSSTLTLSKA DYEKHKVYAC 200
EVTHQGLSSP VTKSFNRGEC                                   220
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 147-203 264-324 370-428
22"-96" 147"-203" 264"-324" 370"-428"
Intra-L (C23-C104) 23'-94' 140'-200'
23'"-94'" 140'"-200'"
Inter-H-L (h 5-CL 126) 223-220' 223"-220'"
Inter-H-H (h 11, h 14) 229-229" 232-232"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
300, 300"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados.

tasadenoturevum #
tasadenoturev

Conditionally replicating adenovirus (CRAd) serotype 5 carrying a 24-bp deletion in early E1A gene and insertion of an integrin-binding motif (Arg-Gly-Asp) (RGD) motif into the H1 loop of the fiber knob.

tasadénoturev

adénovirus de sérotype 5 dont la réplication est conditionnelle et portant une délétion de 24 paires de bases sur le gène précoce E1A et l'insertion d'un motif d'union à l'intégrine dans la boucle H1 du *knob* de la fibre

tasadenoturev

Adenovirus de serotipo 5, con replicación condicionada, portando una deleción de 24 pares de bases en el gen temprano E1A y la inserción de un motivo de unión a integrina (Arg-Gly-Asp) (RGD) en el bucle H1 del *knob* de fibra

tasipimidinum

tasipimidine

rac-2-[(1*R*)-5-methoxy-3,4-dihydro-1*H*-2-benzopyran-1-yl]-4,5-dihydro-1*H*-imidazole

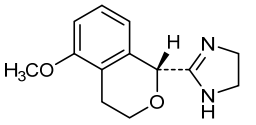
tasipimidine

rac-2-[(1*R*)-5-méthoxy-3,4-dihydro-1*H*-2-benzopyran-1-yl]-4,5-dihydro-1*H*-imidazole

tasipimidina

rac-2-[(1*R*)-5-metoxi-3,4-dihidro-1*H*-2-benzopiran-1-il]-4,5-dihidro-1*H*-imidazol

$C_{13}H_{16}N_2O_2$



and enantiomer
et énantiomère
y enantiómero

telacebecum

telacebec

6-chloro-2-ethyl-*N*-[(4-{4-[4-(trifluoromethoxy)phenyl]piperidin-1-yl}phenyl)methyl]imidazo[1,2-*a*]pyridine-3-carboxamide

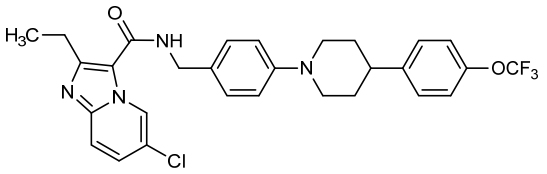
télacébec

6-chloro-2-éthyl-*N*-[(4-{4-[4-(trifluorométhoxy)phényl]pipéridin-1-yl}phényl)méthyl]imidazo[1,2-*a*]pyridine-3-carboxamide

telacebec

6-cloro-2-etil-*N*-[(4-{4-[4-(trifluorometoxi)fenil]piperidin-1-il}fenil)metil]imidazo[1,2-*a*]piridina-3-carboxamida

$C_{29}H_{28}ClF_3N_4O_2$

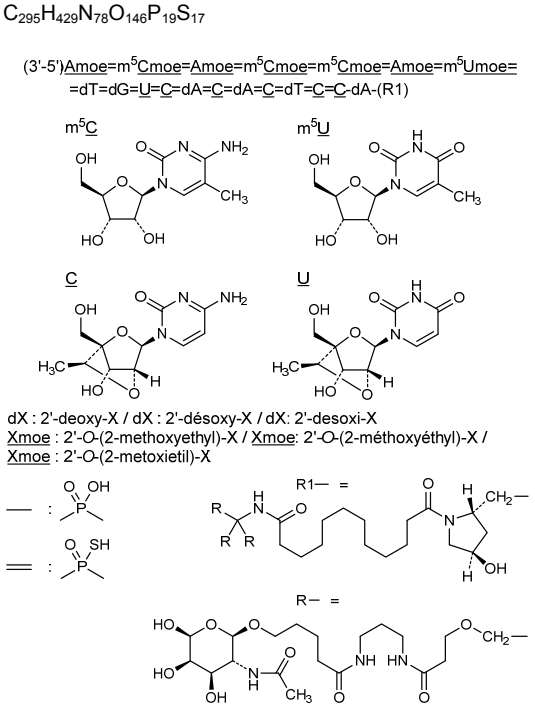


temavirsenum

temavirsen

[(2*S*,4*R*)-1-{1-[(2-acetamido-2-deoxy-β-D-galactopyranosyl)oxy]-16,16-bis({3-[(3-{5-[(2-acetamido-2-deoxy-β-D-galactopyranosyl)oxy]pentanamido}propyl)amino]-3-oxopropoxy}methyl)-5,11,18-trioxo-14-oxa-6,10,17-triazanonacosan-29-oyl}-4-hydroxypyrrolidin-2-yl]methyl hydrogen *all*-*P*-*ambo*-2'-*O*-(2-methoxyethyl)-*P*-thioadenylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-5-methyl-*P*-thiocytidylyl

	-(3'→5')-2'-*O*-(2-methoxyethyl)-*P*-thioadenylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-5-methyl-*P*-thiocytidylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-5-methyl-*P*-thiocytidylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-*P*-thioadenylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-5-methyl-*P*-thiouridylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-ethane-1,1-diyl]-*P*-thiouridylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-ethane-1,1-diyl]-*P*-thiocytidylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-ethane-1,1-diyl]-*P*-thiocytidylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-ethane-1,1-diyl]-*P*-thiocytidylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-ethane-1,1-diyl]-*P*-thiocytidylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-ethane-1,1-diyl]cytidylyl-(3'→5')-2'-deoxy-3'-adenylate
témavirsen	hydrogéno-*tout-P-ambo*-2'-*O*-(2-méthoxyéthyl)-*P*-thioadénylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-5-méthyl-*P*-thiocytidylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-*P*-thioadénylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-5-méthyl-*P*-thiocytidylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-5-méthyl-*P*-thiocytidylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-*P*-thioadénylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-5-méthyl-*P*-thiouridylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-éthane-1,1-diyl]-*P*-thiouridylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-éthane-1,1-diyl]-*P*-thiocytidylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-éthane-1,1-diyl]-*P*-thiocytidylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-éthane-1,1-diyl]-*P*-thiocytidylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-éthane-1,1-diyl]-*P*-thiocytidylyl-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-éthane-1,1-diyl]cytidylyl-(3'→5')-2'-désoxy-3'-adénylate de [(2*S*,4*R*)-1-{1-[(2-acétamido-2-désoxy-β-D-galactopyranosyl)oxy]-16,16-bis({3-[(3-{5-[(2-acétamido-2-désoxy-β-D-galactopyranosyl)oxy]pentanamido}propyl)amino]-3-oxopropoxy}méthyl)-5,11,18-trioxo-14-oxa-6,10,17-triazanonacosan-29-oyl}-4-hydroxypyrrolidin-2-yl]méthyle
temavirsén	hydrógeno-*todo-P-ambo*-2'-*O*-(2-metoxietil)-*P*-tioadenilil-(3'→5')-2'-*O*-(2-metoxietil)-5-metil-*P*-tiocitidilil-(3'→5')-2'-*O*-(2-metoxietil)-*P*-tioadenilil-(3'→5')-2'-*O*-(2-metoxietil)-5-metil-*P*-tiocitidilil-(3'→5')-2'-*O*-(2-metoxietil)-5-metil-*P*-tiocitidilil-(3'→5')-2'-*O*-(2-metoxietil)-*P*-tioadenilil-(3'→5')-2'-*O*-(2-metoxietil)-5-metil-*P*-tiouridilil-(3'→5')-*P*-tiotimidilil-(3'→5')-2'-desoxi-*P*-tioguanilil-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-etano-1,1-diil]-*P*-tiouridill-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-etano-1,1-diil]-*P*-tiocitidilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-etano-1,1-diyl]-*P*-thiocytidylyl-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-etano-1,1-diil]-*P*-tiocitidilil-(3'→5')-*P*-tiotimidilil-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-etano-1,1-diil]-*P*-tiocitidilil-(3'→5')-2'-*O*,4'-*C*-[(1*S*)-etano-1,1-diil]citidilil-(3'→5')-2'-desoxi-3'-adenilato de [(2*S*,4*R*)-1-{1-[(2-acetamido-2-desoxi-β-D-galactopiranosil)oxi]-16,16-bis({3-[(3-{5-[(2-acetamido-2-desoxi-β-D-galactopiranosil)oxi]pentanamido}propil)amino]-3-oxopropoxi}metil)-5,11,18-trioxo-14-oxa-6,10,17-triazanonacosan-29-oil}-4-hidroxipirrolidin-2-il]metilo



tibulizumabum #

tibulizumab

immunoglobulin G4-kappa anti-[*Homo sapiens* TNFSF13B (tumor necrosis factor (TNF) superfamily member 13B, BAFF, THANK, TALL1, TALL-1, BLYS, BLyS, B cell activating factor, B lymphocyte activator, CD257)] , each heavy chain being fused to a scFv anti-[*Homo sapiens* IL17A (interleukin 17A, IL-17A)], humanized monoclonal antibody, bispecific tetravalent;
gamma4 heavy chain anti-TNFSF13B fused to a scFv anti-IL17A (1-714) [gamma4 heavy chain {(*Homo sapiens* VH (IGHV4-34*01 (100.00%) -(IGHD) -IGHJ4*01) [8.7.17] (1-123) -*Homo sapiens* IGHG4*01 (CH1 (124-221), hinge S10>P (231) (222-233), CH2 (234-343), CH3L125>del (344-447), CHS G1>del, K2>del) (124-447)} (1-447) -16-mer linker (448-463) -scFv {(humanized VH (*Homo sapiens* IGHV1-69*01 (83.70%) -(IGHD) -IGHJ4*01) [8.8.12] (464-582) -20-mer tetra(tetraglycyl-seryl) linker (583-602) -humanized V-KAPPA (*Homo sapiens* IGKV2D-29*02 (89.00%) -IGKJ2*02) [11.3.9] (603-714)} (464-714)], (137-214')-disulfide with kappa light chain anti-TNFSF13B (1'-214') [*Homo sapiens* V-KAPPA (IGKV3-11*01 (97.90%) -IGKJ1*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*05, Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (229-229'':232-232'')-bisdisulfide

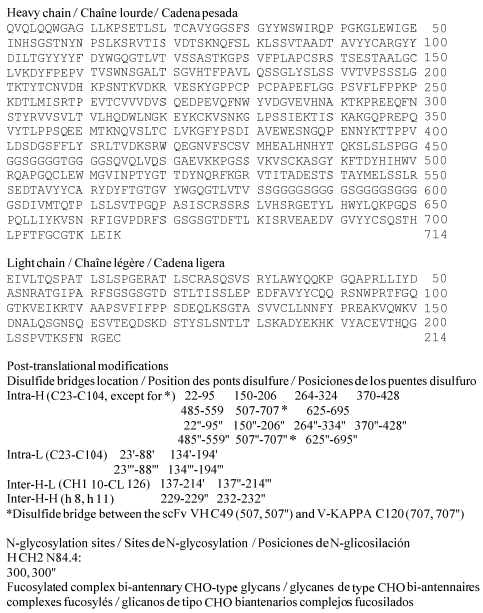
tibulizumab

immunoglobuline G4-kappa anti-[*Homo sapiens* TNFSF13B (membre 13B de la superfamille des facteurs de nécrose tumorale (TNF), BAFF, THANK, TALL1, TALL-1, BLYS, BLyS, facteur d'activation des lymphocytes B, activateur des lymphocytes B, CD257)], chaque chaîne lourde étant fusionnée à un scFv anti-[*Homo sapiens* IL17A (interleukine 17A, IL-17A)], anticorps monoclonal humanisé, bispécifique tétravalent;

chaîne lourde gamma4 anti-TNFSF13B fusionnée à un scFv anti-IL17A (1-714) [chaîne lourde gamma4 {(*Homo sapiens* VH (IGHV4-34*01 (100.00%) -(IGHD) -IGHJ4*01) [8.7.17] (1-123) -*Homo sapiens* IGHG4*01 (CH1 (124-221), charnière S10>P (231) (222-233), CH2 (234-343), CH3 L125>del (344-447), CHS G1>del, K2>del) (124-447)} (1-447) -16-mer linker (448-463) -scFv {(VH humanisé (*Homo sapiens* IGHV1-69*01 (83.70%) -(IGHD) -IGHJ4*01) [8.8.12] (464-582) -20-mer tétra(tétraglycyl-séryl) linker (583-602) -V-KAPPA humanisé (*Homo sapiens* IGKV2D-29*02 (89.00%) -IGKJ2*02) [11.3.9] (603-714)} (464-714)], (137-214')-disulfure avec la chaîne légère anti-TNFSF13B (1'-214') [*Homo sapiens* V-KAPPA (IGKV3-11*01 (97.90%) -IGKJ1*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*05, Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (229-229":232-232")-bisdisulfure

tibulizumab

inmunoglobulina G4-kappa anti-[*Homo sapiens* TNFSF13B (miembro 13B de la superfamilia de los factores de necrosis tumoral (TNF), BAFF, THANK, TALL1, TALL-1, BLYS, BLyS, factor de activación de linfocitos B, activador de linfocitos B, CD257)], cada cadena pesada estando fusionada con un scFv anti-[*Homo sapiens* IL17A (interleukina 17A, IL-17A)], anticuerpo monoclonal humanizado, biespecífico tetravalente;
cadena pesada gamma4 anti-TNFSF13B fusionada con un scFv anti-IL17A (1-714) [cadena pesada gamma4 {(*Homo sapiens* VH (IGHV4-34*01 (100.00%) -(IGHD) -IGHJ4*01) [8.7.17] (1-123) -*Homo sapiens* IGHG4*01 (CH1 (124-221), bisagra S10>P (231) (222-233), CH2 (234-343), CH3 L125>del (344-447), CHS G1>del, K2>del) (124-447)} (1-447) -16-mer de conexión (448-463) -scFv {(VH humanizado (*Homo sapiens* IGHV1-69*01 (83.70%) -(IGHD) -IGHJ4*01) [8.8.12] (464-582) -20-mer tetra(tetraglicil-seril) linker (583-602) -V-KAPPA humanizado (*Homo sapiens* IGKV2D-29*02 (89.00%) -IGKJ2*02) [11.3.9] (603-714)} (464-714)], (137-214')-disulfuro con la cadena ligera anti-TNFSF13B (1'-214') [*Homo sapiens* V-KAPPA (IGKV3-11*01 (97.90%) -IGKJ1*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*05, Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (229-229":232-232")-bisdisulfuro



Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLQQWGAG LLKPSETLSL TCAVYGGSFS GYYWSWIRQP PGKGLEWIGE  50
INHSGSTNYN PSLKSRVTIS VDTSKNQFSL KLSSVTAADT AVYYCARGYY 100
DILTGYYYYF DYWGQGTLVT VSSASTKGPS VFPLAPCSRS TSESTAALGC 150
LVKDYFPEPV TVSWNSGALT SGVHTFPAVL QSSGLYSLSS VVTVPSSSLG 200
TKTYTCNVDH KPSNTKVDKR VESKYGPPCP PCPAPEFLGG PSVFLFPPKP 250
KDTLMISRTP EVTCVVVDVS QEDPEVQFNW YVDGVEVHNA KTKPREEQFN 300
STYRVVSVLT VLHQDWLNGK EYKCKVSNKG LPSSIEKTIS KAKGQPREPQ 350
VYTLPPSQEE MTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPV 400
LDSDGSFFLY SRLTVDKSRW QEGNVFSCSV MHEALHNHYT QKSLSLSPGG 450
GGSGGGGTGG GGSQVQLVQS GAEVKKPGSS VKVSCKASGY KFTDYHIHWV 500
RQAPGQCLEW MGVINPTYGT TDYNQRFKGR VTITADESTS TAYMELSSLR 550
SEDTAVYYCA RYDYFTGTGV YWGQGTLVTV SSGGGGSGGG GSGGGGSGGG 600
GSDIVMTQTP LSLSVTPGQP ASISCRSSRS LVHSRGETYL HWYLQKPGQS 650
PQLLIYKVSN RFIGVPDRFS GSGSGTDFTL KISRVEAEDV GVYYCSQSTH 700
LPFTFGCGTK LEIK                                        714
```

Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPAT LSLSPGERAT LSCRASQSVS RYLAWYQQKP GQAPRLLIYD  50
ASNRATGIPA RFSGSGSGTD STLTISSLEP EDFAVYYCQQ RSNWPRTFGQ 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSNTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104, except for *) 22-95 150-206 264-324 370-428
485-559 507-707 * 625-695
22"-95" 150"-206" 264"-334" 370"-428"
485"-559" 507"-707" * 625"-695"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (CH1 10-CL 126) 137-214' 137"-214'"
Inter-H-H (h 8, h 11) 229-229" 232-232"
*Disulfide bridge between the scFv VH C49 (507, 507") and V-KAPPA C120 (707, 707")

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
300, 300"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

tigilanoli tiglas

tigilanol tiglate

(1a*R*,1b*R*,1c*S*,2a*R*,3*S*,3a*S*,6a*S*,6b*R*,7*R*,8*R*,8a*S*)-3,3a,6b-trihydroxy-2a-(hydroxymethyl)-1,1,5,7-tetramethyl-4-oxo-1,1a,1b,1c,2a,3,3a,4,6a,6b,7,8-dodecahydro-8a*H*-cyclopropa[5',6']benzo[1',2':-7,8]azuleno[5,6-*b*]oxirene-8,8a-diyl 8a-[(2*S*)-2-methylbutanoate] 8-[(2*E*)-2-methylbut-2-enoate]

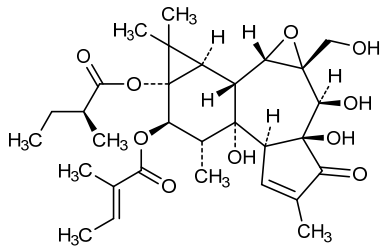
tiglate de tigilanol

8a-[(2*S*)-2-méthylbutanoate] et 8-[(2*E*)-2-méthylbut-2-énoate] de (1a*R*,1b*R*,1c*S*,2a*R*,3*S*,3a*S*,6a*S*,6b*R*,7*R*,8*R*,8a*S*)-3,3a,6b-trihydroxy-2a-(hydroxyméthyl)-1,1,5,7-tétraméthyl-4-oxo-1,1a,1b,1c,2a,3,3a,4,6a,6b,7,8-dodécahydro-8a*H*-cyclopropa[5',6']benzo[1',2':7,8]azuléno[5,6-*b*]oxirène-8,8a-diyle

toglato de tigilanol

8a-[(2*S*)-2-metilbutanoato] y 8-[(2*E*)-2-metilbut-2-enoato] de (1a*R*,1b*R*,1c*S*,2a*R*,3*S*,3a*S*,6a*S*,6b*R*,7*R*,8*R*,8a*S*)-3,3a,6b-trihidroxi-2a-(hidroximetil)-1,1,5,7-tetrametil-4-oxo-1,1a,1b,1c,2a,3,3a,4,6a,6b,7,8-dodecahidro-8a*H*-ciclopropa[5',6']benzo[1',2':7,8]azuleno[5,6-*b*]oxireno-8,8a-diilo

$C_{30}H_{42}O_{10}$



tigolanerum

tigolaner

2-chloro-*N*-(1-cyanocyclopropyl)-5-[2'-methyl-5'-(pentafluoroethyl)-4'-(trifluoromethyl)-2'*H*-[1,3'-bipyrazol]-4-yl]benzamide

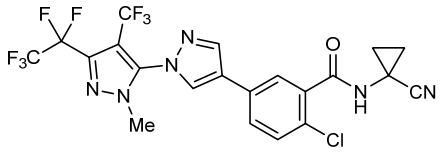
tigolaner

2-chloro-*N*-(1-cyanocyclopropyl)-5-[2'-méthyl-5'-(pentafluoroéthyl)-4'-(trifluorométhyl)-2'*H*-[1,3'-bipyrazol]-4-yl]benzamide

tigolaner

2-cloro-*N*-(1-cianociclopropil)-5-[2'-metil-5'-(pentafluoroetil)-4'-(trifluorometil)-2'*H*-[1,3'-bipirazol]-4-il]benzamida

$C_{21}H_{13}ClF_8N_6O$



tilsotolimodum

tilsotolimod

O,*O*'-(2-hydroxypropane-1,3-diyl) bis(hydrogen *all-P-ambo-P*-thiothymidylyl-(3'→5')-2'-deoxy-*P*-thiocytidylyl-(3'→5')-2'-deoxy-7-carba-*P*-thioguanylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-2'-deoxy-*P*-thiocytidylyl-(3'→5')-2'-deoxy-7-carba-*P*-thioguanylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-deoxy-*P*-thiocytidylyl-(3'→5')-2'-deoxy-7-carba-*P*-thio-3'-guanylate)

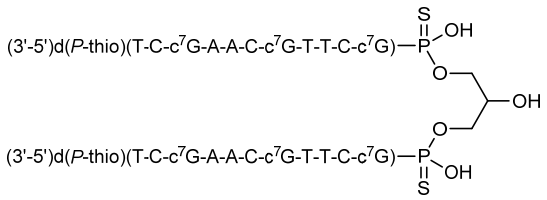
tilsotolimod

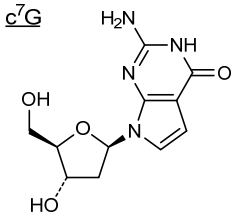
bis(hydrogéno-*tout-P-ambo-P*-thiothymidylyl-(3'→5')-2'-désoxy-*P*-thiocytidylyl-(3'→5')-2'-désoxy-7-carba-*P*-thioguanylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-2'-désoxy-*P*-thiocytidylyl-(3'→5')-2'-désoxy-7-carba-*P*-thioguanylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-désoxy-*P*-thiocytidylyl-(3'→5')-2'-désoxy-7-carba-*P*-thio-3'-guanylate) de *O*,*O*'-(2-hydroxypropane-1,3-diyle)

tilsotolimod

bis(hidrógeno-*todo-P-ambo-P*-tiotimidilil-(3'→5')-2'-desoxi-*P*-tiocitidilil-(3'→5')-2'-desoxi-7-carba-*P*-tioguanilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-2'-desoxi-*P*-tiocitidilil-(3'→5')-2'-desoxi-7-carba-*P*-tioguanilil-(3'→5')-*P*-tiotimidilil-(3'→5')-*P*-tiotimidilil-(3'→5')-2'-desoxi-*P*-tiocitidilil-(3'→5')-2'-desoxi-7-carba-*P*-tio-3'-guanilato) de *O*,*O*'-(2-hidroxipropano-1,3-diilo)

$C_{223}H_{284}N_{74}O_{115}P_{22}S_{22}$





timrepigenum emparvovecum #

timrepigene emparvovec

Non-replicating recombinant adeno-associated virus serotype 2 (rAAV2) vector encoding the cDNA of human Rab escort protein 1 (CHM, REP-1), driven by the hybrid cytomegalovirus (CMV) enhancer/chicken beta-actin promoter (CBA).

timrépigène emparvovec

Vecteur viral adéno-associé recombinant de sérotype 2 (rAAV2) non-répliquant codant pour l'ADN cyclique (ADNc) de la protéine escorte Rab 1 (CHM, REP-1) humaine sous

	le contrôle de l'hybride de l'activateur du cytomégalovirus (CMV) et du promoteur de l'actine bêta du poulet (ABP, CBA).
timrepigén emparvovec	Vector no replicativo del Virus Adeno-asociado de serotipo 2 (rAAV2) que codifica el cDNA de la proteína escolta Rab 1 (CHM, REP-1) humana, impulsado por el híbrido del *enhancer* de citomegalovirus (CMV) y el promotor de la beta-actina de pollo (CBA).
tiragolumabum #	
tiragolumab	immunoglobulin G1-kappa, anti-[*Homo sapiens* TIGIT (T-cell immunoreceptor with Ig domain and ITIM, V-set Ig member 9, VSIG9, V-set and transmembrane member 3, VSTM3)], *Homo sapiens* monoclonal antibody; gamma1 heavy chain (1-456) [*Homo sapiens* VH (IGHV6-1*01 (93.10%) -(IGHD) -IGHJ4*01) [10.9.16] (1-126) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (223) (127-224), hinge (225-239), CH2 (240-349), CH3 E12 (365), M14 (367) (350-454), CHS (455-456)) (127-456)], (229-220')-disulfide with kappa light chain (1'-220') [*Homo sapiens* V-KAPPA (IGKV4-1*01 (97.00%) -IGKJ3*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC*01, Km3 A45.1 (159), V101 (197) (114'-220')]; dimer (235-235'':238-238'')-bisdisulfide
tiragolumab	immunoglobuline G1-kappa, anti-[*Homo sapiens* TIGIT (immunorécepteur des lymphocytes T avec domaine Ig et ITIM, membre 9 de l'Ig V-set, VSIG9, membre 3 de l'Ig V-set et région transmembrane, VSTM3)], *Homo sapiens* anticorps monoclonal; chaîne lourde gamma1 (1-456) [*Homo sapiens* VH (IGHV6-1*01 (93.10%) -(IGHD) -IGHJ4*01) [10.9.16] (1-126) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (223) (127-224), charnière (225-239), CH2 (240-349), CH3 E12 (365), M14 (367) (350-454), CHS (455-456)) (127-456)], (229-220')-disulfure avec la chaîne légère (1'-220') [*Homo sapiens* V-KAPPA (IGKV4-1*01 (97.00%) -IGKJ3*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC*01, Km3 A45.1 (159), V101 (197) (114'-220')]; dimère (235-235'':238-238'')-bisdisulfure
tiragolumab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* TIGIT (inmunoreceptor de linfocitos T con dominio Ig e ITIM, miembro 9 de la Ig V-set, VSIG9, miembro 3 de la Ig V-set y región transmembrana, VSTM3)], *Homo sapiens* anticuerpo monoclonal; cadena pesada gamma1 (1-456) [*Homo sapiens* VH (IGHV6-1*01 (93.10%) -(IGHD) -IGHJ4*01) [10.9.16] (1-126) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (223) (127-224), bisagra (225-239), CH2 (240-349), CH3 E12 (365), M14 (367) (350-454), CHS (455-456)) (127-456)], (229-220')-disulfuro con la cadena ligera (1'-220') [*Homo sapiens* V-KAPPA (IGKV4-1*01 (97.00%) -IGKJ3*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC*01, Km3 A45.1 (159), V101 (197) (114'-220')]; dímero (235-235'':238-238'')-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLQQSGPG LVKPSQTLSL TCAISGDSVS SNSAAWNWIR QSPSRGLEWL  50
GKTYYRFKWY SDYAVSVKGR ITINPDTSKN QFSLQLNSVT PEDTAVFYCT 100
RESTTYDLLA GPFDYWGQGT LVTVSSASTK GPSVFPLAPS SKSTSGGTAA 150
LGCLVKDYFP EPVTVSWNSG ALTSGVHTFP AVLQSSGLYS LSSVVTVPSS 200
SLGTQTYICN VNHKPSNTKV DKKVEPKSCD KTHTCPPCPA PELLGGPSVF 250
LFPPKPKDTL MISRTPEVTC VVVDVSHEDP EVKFNWYVDG VEVHNAKTKP 300
REEQYNSTYR VVSVLTVLHQ DWLNGKEYKC KVSNKALPAP IEKTISKAKG 350
QPREPQVYTL PPSREEMTKN QVSLTCLVKG FYPSDIAVEW ESNGQPENNY 400
KTTPPVLDSD GSFFLYSKLT VDKSRWQQGN VFSCSVMHEA LHNHYTQKSL 450
SLSPGK                                                  456
```

Light chain / Chaîne légère / Cadena ligera

```
DIVMTQSPDS LAVSLGERAT INCKSSQTVL YSSNNKKYLA WYQQKPGQPP 50
NLLIYWASTR ESGVPDRFSG SGSGTDFTLT ISSLQAEDVA VYYCQQYYST 100
PFTFGPGTKV EIKRTVAAPS VFIFPPSDEQ LKSGTASVVC LLNNFYPREA 150
KVQWKVDNAL QSGNSQESVT EQDSKDSTYS LSSTLTLSKA DYEKHKVYAC 200
EVTHQGLSSP VTKSFNRGEC                                   220
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-99 153-209 270-330 376-434
22"-99" 153"-209" 270"-330" 376"-434"
Intra-L (C23-C104) 23'-94' 140'-200'
23'"-94'" 140'"-200'"
Inter-H-L (h 5-CL 126) 229-220' 229"-220'"
Inter-H-H (h 11, h 14) 235-235" 238-238"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
306, 306"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

tirvalimogenum teraplasmidum #
tirvalimogene teraplasmid

plasmid DNA vector encoding E6 and E7 antigens of human papillomavirus types 16 and 18 (HPV 16/18), the extracellular domain of fms-like tyrosine kinase-3 ligand (FLT3L) and signal sequences of tissue plasminogen activator (tpa) driven by a cytomegalovirus promoter.

tirvalimogène téraplasmide

vecteur constitué d'ADN plasmidique codant pour les antigènes E6 et E7 des papillomavirus humains de types 16 et 18 (VPH 16/18), le domaine extracellulaire du ligand de la tyrosine kinase 3 semblable au *fms* (FLT3L) et les séquences signal de l'activateur tissulaire du plasmogène (tpa) sous le contrôle d'un promoteur de cytomégalovirus.

tirvalimogén teraplásmido

Vector de DNA plasmídico que codifica los antígenos E6 y E7 de los tipos 16 y 18 del virus del papiloma humano (VPH 16/18), el dominio extracelular del ligando de la tirosina quinasa-3 similar a *fms* (FLT3L) y secuencias señal del activador de plasminógeno tisular (tpa) impulsado por un promotor de citomegalovirus.

tisagenlecleucelum #
tisagenlecleucel

human culture expanded genetically modified autologous T cells for cell-based gene therapy. Cells are derived from isolated blood of the patient and are transduced with non-replicative lentiviral vector encoding an FMC63 anti-CD19 single chain variable fragment (scFv) 4-1BB/CD3zeta chimeric antigen receptor (CAR) under the control of the EF-1 alpha promoter. Cells exhibit anti-tumoral activity in patients with CD19-expressing B cell malignancies.

tisagenlecleucel	Lymphocytes T autologues humains en culture d'expansion, modifiés génétiquement en vue d'une thérapie génique avec cellules. Les cellules sont isolées à partir du sang prélevé chez le patient et sont transduites avec un veceur lentiviral non-répliquant codant pour le récepteur de l'antigène chimérique (CAR) FMC63 anti-CD-19 fragment de la chaîne simple de la région variable de l'anticorps (scFv) 4-1BB/CD3zêta (SFG-1928z CAR) sous le contrôle du promoteur EF-1 alpha. Les cellules montrent une activité anti-tumorale chez les patients présentant des lymphocytes B malins exprimant le CD19.
tisagenlecleucel	Linfocitos T autólogos, humanos, expandidos en cultivo y modificados genéticamente, para terapia génica con células. Las células se derivan a partir de sangre aislada del paciente y están transducidas con un vector lentiviral no replicativo que codifica para el receptor de antígenos quimérico (CAR) FMC63 anti-CD19 fragmento de cadena simple de la región variable del anticuerpo (scFv) 4-1BB/CD3zeta bajo el control del promotor EF-1 alfa. Las células muestran actividad anti-tumoral en pacientes con malignidades de linfocitos B que expresan CD19.
tislelizumabum #	
tislelizumab	immunoglobulin G4-kappa, anti-[*Homo sapiens* PDCD1 (programmed cell death 1, PD-1, PD1, CD279)], humanized monoclonal antibody; gamma4 heavy chain (1-445) [humanized VH (*Homo sapiens* IGHV4-59*01 (88.70%) -(IGHD) -IGHJ3*01 M123>T (113)) [8.7.12] (1-118) -*Homo sapiens* IGHG4*01 (CH1 (119-216), hinge S10>P (226) (217-228), CH2 E1.4>P (231), F1.3>V (232), L1.2>A (233), D27>A (263) (229-338), CH3 R88>K (407) (339-443), CHS (444-445)) (119-445)], (132-214')-disulfide with kappa light chain (1'-214') [humanized V-KAPPA (*Homo sapiens* IGKV4-1*01 (81.20%) -IGKJ2*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (224-224":227-227")-bisdisulfide
tislélizumab	immunoglobuline G4-kappa, anti-[*Homo sapiens* PDCD1 (protéine 1 de mort cellulaire programmée, PD-1, PD1, CD279)], anticorps monoclonal humanisé; chaîne lourde gamma4 (1-445) [VH humanisé (*Homo sapiens* IGHV4-59*01 (88.70%) -(IGHD) -IGHJ3*01 M123>T (113)) [8.7.12] (1-118) -*Homo sapiens* IGHG4*01 (CH1 (119-216), charnière S10>P (226) (217-228), CH2 E1.4>P (231), F1.3>V (232), L1.2>A (233), D27>A (263) (229-338), CH3 R88>K (407) (339-443), CHS (444-445)) (119-445)], (132-214')-disulfure avec la chaîne légère kappa (1'-214') [V-KAPPA humanisé (*Homo sapiens* IGKV4-1*01 (81.20%) -IGKJ2*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (224-224":227-227")-bisdisulfure

tislelizumab

inmunoglobulina G4-kappa, anti-[*Homo sapiens* PDCD1 (proteína 1 de muerte celular programada, PD-1, PD1, CD279)], anticuerpo monoclonal humanizado;
cadena pesada gamma4 (1-445) [VH humanizado (*Homo sapiens* IGHV4-59*01 (88.70%) -(IGHD) -IGHJ3*01 M123>T (113)) [8.7.12] (1-118) -*Homo sapiens* IGHG4*01 (CH1 (119-216), bisagra S10>P (226) (217-228), CH2 E1.4>P (231), F1.3>V (232), L1.2>A (233), D27>A (263) (229-338), CH3 R88>K (407) (339-443), CHS (444-445)) (119-445)], (132-214')-disulfuro con la cadena ligera kappa (1'-214') [V-KAPPA humanizado (*Homo sapiens* IGKV4-1*01 (81.20%) -IGKJ2*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')];
dímero (224-224":227-227")-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLQESGPG LVKPSETLSL TCTVSGFSLT SYGVHWIRQP PGKGLEWIGV  50
IYADGSTNYN PSLKSRVTIS KDTSKNQVSL KLSSVTAADT AVYYCARAYG 100
NYWYIDVWGQ GTTVTVSSAS TKGPSVFPLA PCSRSTSEST AALGCLVKDY 150
FPEPVTVSWN SGALTSGVHT FPAVLQSSGL YSLSSVVTVP SSSLGTKTYT 200
CNVDHKPSNT KVDKRVESKY GPPCPPCPAP PVAGGPSVFL FPPKPKDTLM 250
ISRTPEVTCV VVAVSQEDPE VQFNWYVDGV EVHNAKTKPR EEQFNSTYRV 300
VSVLTVVHQD WLNGKEYKCK VSNKGLPSSI EKTISKAKGQ PREPQVYTLP 350
PSQEEMTKNQ VSLTCLVKGF YPSDIAVEWE SNGQPENNYK TTPPVLDSDG 400
SFFLYSKLTV DKSRWQEGNV FSCSVMHEAL HNHYTQKSLS LSLGK      445
```

Light chain / Chaîne légère / Cadena ligera

```
DIVMTQSPDS LAVSLGERAT INCKSSESVS NDVAWYQQKP GQPPKLLINY  50
AFHRFTGVPD RFSGSGYGTD FTLTISSLQA EDVAVYYCHQ AYSSPYTFGQ 100
GTKLEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro

Intra-H (C23-C104)	22-95	145-201	259-319	365-423
	22"-95"	145"-201"	259"-319"	365"-423"
Intra-L (C23-C104)	23'-88'	134'-194'		
	23'"-88'"	134'"-194'"		
Inter-H-L (CH1 10-CL 126)	132-214'	132"-214'"		
Inter-H-H (h 8, h 11)	224-224"	227-227"		

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
295, 295"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados.

tralesinidasum alfa #
tralesinidase alfa

human α-*N*-acetylglucosaminidase fused to truncated human insulin-like growth factor II (IGF2) via a peptide linker, produced in Chinese hamster ovary (CHO) cells, glycoform alfa;

human α-*N*-acetylglucosaminidase (NAG, EC=3.2.1.50) (1-720) fusion protein with glycyl-L-alanyl-L-prolyltriglycyl-L-seryl-bis(L-prolyl-L-alanyl-L-prolyl-L-alanyl-L-prolyl-L-threonyl)-bis(L-prolyl-L-alanyl)-triglycyl-L-prolyl-L-serylglycyl-L-alanyl-L-prolyl-[37-L-alanine(R^{37}>$A_{(781)}$)]human insulin-like growth factor II (somatomedin-A, T3M-11-derived growth factor, IGF-II) (8-67)-peptide (752-811), produced in Chinese hamster ovary (CHO) cells, glycoform alfa

tralésinidase alfa

alpha-*N*-acétylglucosaminidase humaine fusionnée au facteur II de croissance humain analogue à l'insuline (IGF2) tronqué, via un peptide de liaison, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa;

alpha-*N*-acétylglucosaminidase humaine (NAG, EC=3.2.1.50) (1-720) protéine de fusion avec glycyl-L-alanyl-L-prolyltriglycyl-L-séryl-bis(L-prolyl-L-alanyl-L-prolyl-L-alanyl-L-prolyl-L-thréonyl)-bis(L-prolyl-L-alanyl)-triglycyl-L-prolyl-L-sérylglycyl-L-alanyl-L-prolyl-[37-L-alanine(R^{37}>$A_{(781)}$)]facteur II de croissance analogue à l'insuline humain (somatomédine-A, T3M-11-facteur de croissance dérivé, IGF-II) (8-67)-peptide (752-811), produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

tralesinidasa alfa

alfa-*N*-acetilglucosaminidasa humana fusionada con el factor II de crecimiento humano análogo a la insulina (IGF2) truncada, vía un péptido de unión, producida en las células ováricas de hamster chino (CHO), glicoforma alfa;

alfa-*N*-acetilglucosaminidasa humana (NAG, EC=3.2.1.50) (1-720) proteína de fusión con glicil-L-alanil-L-proliltriglicil-L-seril-bis(L-prolil-L-alanil-L-prolil-L-alanil-L-prolil-L-treonil-bis(L-prolil-L-alanil)-triglicil-L-prolil-L-serilglicil-L-alanil-L-prolil-[37-L-alanina(R^{37}>$A_{(781)}$)]factor II de crecimiento análogo a la insulina humano (somatomedina-A, T3M-11-factor de crecimiento derivado, IGF-II) (8-67)-péptido (752-811), producido en las células ováricas de hamster chino (CHO), glicoforma alfa

Sequence / Séquence / Secuencia

```
DEAREAAAVR ALVARLLGPG PAADFSVSVE RALAAKPGLD TYSLGGGGAA 50
RVRVRGSTGV AAAAGLHRYL RDFCGCHVAW SGSQLRLPRP LPAVPGELTE 100
ATPNRYRYYQ NVCTQSYSFV WWDWARWERE IDWMALNGIN LALAWSGQEA 150
IWQRVYLALG LTQAEINEFF TGPAFLAWGR MGNLHTWDGP LPPSWHIKQL 200
YLQHRVLDQM RSFGMTPVLP AFAGHVPEAV TRVFPQVNVT KMGSWGHFNC 250
SYSCSFLLAP EDPIFPIIGS LFLRELIKEF GTDHIYGADT FNEMQPPSSE 300
PSYLAAATTA VYEAMTAVDT EAVWLLQGWL FQHQPQFWGP AQIRAVLGAV 350
PRGRLLVLDL FAESQPVYTR TASFQGQPFI WCMLHNFGGN HGLFGALEAV 400
NGGPEAARLF PNSTMVGTGM APEGISQNEV VYSLMAELGW RKDPVPDLAA 450
WVTSFAARRY GVSHPDAGAA WRLLLRSVYN CSGEACRGHN RSPLVRRPSL 500
QMNTSIWYNR SDVFEAWRLL LTSAPSLATS PAFRYDLLDL TRQAVQELVS 550
LYYEEARSAY LSKELASLLR AGGVLAYELL PALDEVLASD SRFLLGSWLE 600
QARAAAVSEA EADFYEQNSR YQLTLWGPEG NILDYANKQL AGLVANYYTP 650
RWRLFLEALV DSVAQGIPFQ QHQFDKNVFQ LEQAFVLSKQ RYPSQPRGDT 700
VDLAKKIFLK YYPRWVAGSW GAPGGGSPAP APTPAPAPTP APAGGGPSGA 750
PLCGGELVDT LQFVCGDRGF YFSRPASRVS ARSRGIVEEC CFRSCDLALL 800
ETYCATPAKS E                                          811
```

Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
74-76 250-254 481-486 753-791 765-804 790-795

Glycosylation sites (N) / Sites de glycosylation (N) / Posiciones de glicosilación (N)
Asn-238 Asn-249 Asn-412 Asn-480 Asn-490 Asn-503 Asn-509

Glycosylation sites (O) / Sites de glycosylation (O) / Posiciones de glicosilación (O)
Ser-727 Thr-733 Thr-739 Ser-748

trilaciclibum

trilaciclib

2'-{[5-(4-methylpiperazin-1-yl)pyridin-2-yl]amino}-7',8'-dihydro-6'*H*-spiro[cyclohexane-1,9'-pyrazino[1',2':1,5]pyrrolo[2,3-*d*]pyrimidin]-6'-one

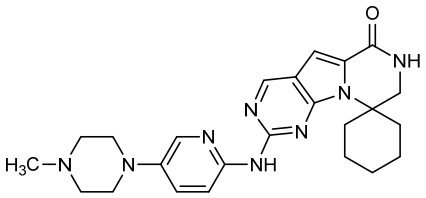
trilaciclib

2'-{[5-(4-méthylpipérazin-1-yl)pyridin-2-yl]amino}-7',8'-dihydro-6'*H*-spiro[cyclohexane-1,9'-pyrazino[1',2':1,5]pyrrolo[2,3-*d*]pyrimidin]-6'-one

trilaciclib

2'-{[5-(4-metilpiperazin-1-il)piridin-2-il]amino}-7',8'-dihidro-6'*H*-spiro[ciclohexano-1,9'-pirazino[1',2':1,5]pirrolo[2,3-*d*]pirimidin]-6'-ona

$C_{24}H_{30}N_8O$



vactosertibum

vactosertib

2-fluoro-*N*-{[4-(6-methylpyridin-2-yl)-5-([1,2,4]triazolo[1,5-*a*]pyridin-6-yl)-1*H*-imidazol-2-yl]methyl}aniline

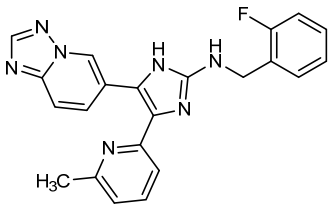
vactosertib

2-fluoro-*N*-{[4-(6-méthylpyridin-2-yl)-5-([1,2,4]triazolo[1,5-*a*]pyridin-6-yl)-1*H*-imidazol-2-yl]méthyl}aniline

vactosertib

2-fluoro-*N*-{[4-(6-metilpiridin-2-il)-5-([1,2,4]triazolo[1,5-*a*]piridin-6-il)-1*H*-imidazol-2-il]metil}anilina

$C_{22}H_{18}FN_7$



vadacabtagenum leraleucelum #

vadacabtagene leraleucel

human culture expanded genetically modified autologous T cells for cell-based gene therapy. Cells are derived from isolated blood of the patient and are transduced with non-replicative retroviral vector encoding the SJ25C1 anti-CD19 single chain variable fragment (scFv) CD28/CD3zeta chimeric antigen receptor (SFG-1928z CAR). Cells exhibit anti-tumoral activity in patients with CD19-expressing B cell malignancies.

vadacabtagène léraleucel

Lymphocytes T humains autologues en culture d'expansion et modifiés génétiquement pour thérapie génique avec cellules. Les cellules sont dérivées du sang prélévé chez le patient et sont transduites avec un vecteur rétroviral non-répliquant codant pour le récepteur de

	l'antigène chimérique SJ25C1 anti-CD-19 fragment de la chaîne simple de la région variable de l'anticorps (scFv) CD28/CD3zêta (SFG-1928z CAR). Les cellules montrent une activité anti-tumorale chez les patients présentant des lymphocytes B malins exprimant le CD19.
vadacabtagén leraleucel	Linfocitos T autólogos, humanos, expandidos en cultivo y modificados genéticamente, para terapia génica con células. Las células se derivan a partir de sangre aislada del paciente y están transducidas con un vector retroviral no replicativo que codifica para el receptor de antígenos quimérico SJ25C1 anti-CD19 fragmento de cadena simple de la región variable del anticuerpo (scFv) CD28/CD3zeta (SFG-1928z CAR). Las células muestran actividad anti-tumoral en pacientes con malignidades de linfocitos B que expresan CD19.
valzifloceptum #	
valziflocept	human immunoglobulin gamma Fc region receptor II-b (FcγRII-b), extracellular N-terminal fragment, produced in *Escherichia coli*; human low affinity immunoglobulin gamma Fc region receptor II-b (IgG Fc receptor II-b, CDw32, Fc-gamma RII-b, FcRII-b, antigen CD32)-(4-179) peptide (N-terminal extracellular portion), produced in *Escherichia coli*
valziflocept	récepteur II-b de la région Fc de l'immunoglobuline gamma humaine (FcγRII-b), fragment extracellulaire N-terminal, produit par *Escherichia coli;* récepteur II-b de faible affinité pour la région Fc de l'immunoglobuline gamma humaine (IgG Fc récepteur II-b, CDw32, Fc-gamma RII-b, FcRII-b, antigène CD32)-(4-179) peptide (partie extracellulaire
valziflocept	receptor II-b de la región Fc de la inmunoglobulina gamma humana (FcγRII-b), fragmento extracelular N-terminal, producido por *Escherichia coli;* receptor II-b de baja afinidad para la región Fc de la inmunoglobulina gamma humana (IgG Fc receptor II-b, CDw32, Fc-gamma RII-b, FcRII-b, antígeno CD32)-(4-179) péptido (parte extracelular N-terminal), producido por *Escherichia coli*

Sequence / Séquence / Secuencia

```
APPKAVLKLE PQWINVLQED SVTLTCRGTH SPESDSIQWF HNGNLIPTHT 50
QPSYRFKANN NDSGEYTCQT GQTSLSDPVH LTVLSEWLVL QTPHLEFQEG 100
ETIVLRCHSW KDKPLVKVTF FQNGKSKKFS RSDPNFSIPQ ANHSHSGDYH 150
CTGNIGYTLY SSKPVTITVQ APSSSP                          176
```

Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
26-68 107-151

vatinoxanum	
vatinoxan	*N*-{2-[(2*R*,12b*S*)-2'-oxo-1,3,4,6,7,12b-hexahydrospiro[[1]benzofuro[2,3-*a*]quinolizine-2,4'-imidazolidin]-3'-yl]ethyl}methanesulfonamide

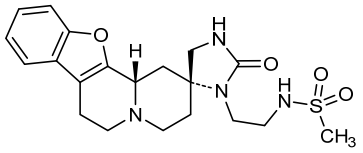
vatinoxan

N-{2-[(2*R*,12b*S*)-2'-oxo-1,3,4,6,7,12b-hexahydrospiro[[1]benzofuro[2,3-*a*]quinolizine-2,4'-imidazolidin]-3'-yl]ethyl}méthanesulfonamide

vatinoxán

N-{2-[(2*R*,12b*S*)-2'-oxo-1,3,4,6,7,12b-hexahidrospiro[[1]benzofuro[2,3-*a*]quinolizina-2,4'-imidazolidin]-3'-il]etil}metanosulfonamida

$C_{20}H_{26}N_4O_4S$



vecabrutinibum

vecabrutinib

(3*R*,3'*R*,4'*S*)-1'-(6-amino-5-fluoropyrimidin-4-yl)-3-[3-chloro-5-(trifluoromethyl)anilino]-2-oxo[1,3'-bipiperidine]-4'-carboxamide

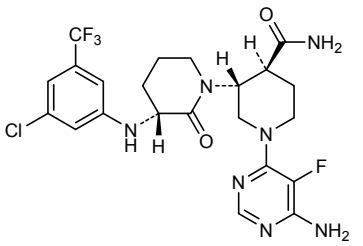
vécabrutinib

(3*R*,3'*R*,4'*S*)-1'-(6-amino-5-fluoropyrimidin-4-yl)-3-{[3-chloro-5-(trifluorométhyl)phényl]amino}-2-oxo-[1,3'-bipipéridine]-4'-carboxamide

vecabrutinib

(3*R*,3'*R*,4'*S*)-1'-(6-amino-5-fluoropirimidin-4-il)-3-{[3-cloro-5-(trifluorometil)fenil]amino}-2-oxo-[1,3'-bipiperidina]-4'-carboxamida

$C_{22}H_{24}ClF_3N_7O_2$



veldoreotidum

veldoreotide

$N^{4.1}$,$C^{\alpha.8}$-anhydro[*N*-(2-amino-2-oxoethyl)-4-aminobutanoyl-4-aminobutanoyl-L-phenylalanyl-L-tryptophyl-D-tryptophyl-L-lysyl-L-threonyl-L-phenylalanine]

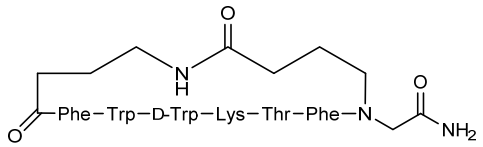
veldoréotide

$N^{4.1}$,$C^{\alpha.8}$-anhydro[*N*-(2-amino-2-oxoéthyl)-4-aminobutanoyl-4-aminobutanoyl-L-phénylalanyl-L-tryptophyl-D-tryptophyl-L-lysyl-L-thréonyl-L-phénylalanine]

veldoreotida

$N^{4.1}$,$C^{\alpha.8}$-anhidro[*N*-(2-amino-2-oxoetil)-4-aminobutanoil-4-aminobutanoil-L-fenilalanil-L-triptofil-D-triptofil-L-lisil-L-treonil-L-fenilalanina]

$C_{60}H_{74}N_{12}O_{10}$



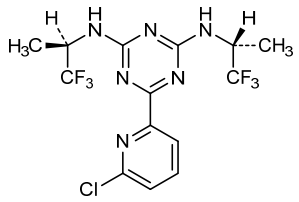
vorasidenibum

vorasidenib — 6-(6-chloropyridin-2-yl)-N^2,N^4-bis[(2*R*)-1,1,1-trifluoropropan-2-yl]-1,3,5-triazine-2,4-diamine

vorasidénib — 6-(6-chloropyridin-2-yl)-N^2,N^4-bis[(2*R*)-1,1,1-trifluoropropan-2-yl]-1,3,5-triazine-2,4-diamine

vorasidenib — 6-(6-cloropiridin-2-il)-N^2,N^4-bis[(2*R*)-1,1,1-trifluoropropan-2-il]-1,3,5-triazina-2,4-diamina

$C_{14}H_{13}ClF_6N_6$



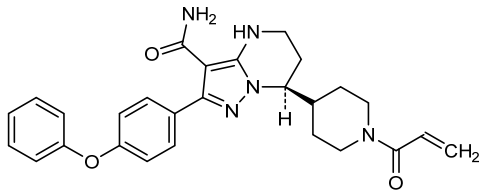
zanubrutinibum

zanubrutinib — (7*S*)-2-(4-phenoxyphenyl)-7-[1-(prop-2-enoyl)piperidin-4-yl]-4,5,6,7-tetrahydropyrazolo[1,5-*a*]pyrimidine-3-carboxamide

zanubrutinib — (7*S*)-2-(4-phénoxyphényl)-7-[1-(prop-2-enoyl)pipéridin-4-yl]-4,5,6,7-tétrahydropyrazolo[1,5-*a*]pyrimidine-3-carboxamide

zanubrutinib — (7*S*)-2-(4-fenoxifenil)-7-[1-(prop-2-enoil)piperidin-4-il]-4,5,6,7-tetrahidropirazolo[1,5-*a*]pirimidina-3-carboxamida

$C_{27}H_{29}N_5O_3$



zenocutuzumabum #

zenocutuzumab — immunoglobulin G1-kappa, anti-[*Homo sapiens* ERBB3 (receptor tyrosine-protein kinase erbB-3, HER3) and *Homo sapiens* ERBB2 (epidermal growth factor receptor 2, receptor tyrosine-protein kinase erbB-2, EGFR2, HER2, HER-2, p185c-erbB2, NEU, CD340)], humanized monoclonal antibody, bispecific;

	gamma1 heavy chain anti-ERBB3 (1-453) [*Homo sapiens* VH (IGHV1-2*02 (100.00%) -(IGHD) -IGHJ4*01) [8.8.17] (1-124) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (221) (125-222), hinge (223-237), CH2 (238-347), CH3 L7>K (358), E12 (363), M14 (365), T22>K (373) (348-452), CHS K>del (453)) (125-453)], (227-214')-disulfide with kappa light chain (1'-214') [*Homo sapiens* V-KAPPA (IGKV1-39*01 (100.00%) -IGKJ1*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; gamma1 heavy chain anti-ERBB2 (1-450) [humanized VH (*Homo sapiens* IGHV1-46*01 (83.70%) -(IGHD) -IGHJ4*01) [8.8.14] (1-121) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (218) (122-219), hinge (220-234), CH2 (235-344), CH3 L7>D (355), E12 (360), M14 (362), L24>E (372) (345-449), CHS K>del (450)) (122-450)] (224-214')-disulfide with kappa light chain (1'-214') [*Homo sapiens* V-KAPPA (IGKV1-39*01 (100.00%) -IGKJ1*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (233-230":236-233")-bisdisulfide
zénocutuzumab	immunoglobuline G1-kappa, anti-[*Homo sapiens* ERBB3 (récepteur à activité tyrosine kinase erbB-3, HER3) et *Homo sapiens* ERBB2 (récepteur 2 du facteur de croissance épidermique, récepteur tyrosine-protéine kinase erbB-2, EGFR2, HER2, HER-2, p185c-erbB2, NEU, CD340)], anticorps monoclonal humanisé, bispécifique; chaîne lourde gamma1 anti-ERBB3 (1-453) [*Homo sapiens* VH (IGHV1-2*02 (100.00%) -(IGHD) -IGHJ4*01) [8.8.17] (1-124) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (221) (125-222), charnière (223-237), CH2 (238-347), CH3 L7>K (358), E12 (363), M14 (365), T22>K (373) (348-452), CHS K>del (453)) (125-453)], (227-214')-disulfure avec la chaîne légère kappa (1'-214') [*Homo sapiens* V-KAPPA (IGKV1-39*01 (100.00%) -IGKJ1*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; chaîne lourde gamma1 anti-ERBB2 (1-450) [VH humanisé (*Homo sapiens* IGHV1-46*01 (83.70%) -(IGHD) -IGHJ4*01) [8.8.14] (1-121) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (218) (122-219), charnière (220-234), CH2 (235-344), CH3 L7>D (355), E12 (360), M14 (362), L24>E (372) (345-449), CHS K>del (450)) (122-450)] (224-214')-disulfure avec la chaîne légère kappa (1'-214') [*Homo sapiens* V-KAPPA (IGKV1-39*01 (100.00%) -IGKJ1*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (233-230":236-233")-bisdisulfure
zenocutuzumab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* ERBB3 (receptor de la actividad tirosina kinasa erbB-3, HER3) y *Homo sapiens* ERBB2 (receptor 2 del factor de crecimiento epidérmico, receptor tirosina-proteína kinasa erbB-2, EGFR2, HER2, HER-2, p185c-erbB2, NEU, CD340)], anticuerpo monoclonal humanizado, biespecífico; cadena pesada gamma1 anti-ERBB3 (1-453) [*Homo sapiens* VH (IGHV1-2*02 (100.00%) -(IGHD) -IGHJ4*01) [8.8.17] (1-124) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (221) (125-222), bisagra (223-237), CH2 (238-347), CH3 L7>K (358), E12 (363), M14 (365), T22>K (373) (348-452), CHS K>del (453)) (125-453)], (227-214')-disulfuro con la cadena ligera kappa (1'-214') [*Homo sapiens* V-KAPPA (IGKV1-39*01 (100.00%) -IGKJ1*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; cadena pesada gamma1 anti-ERBB2 (1-450) [VH humanizado (*Homo sapiens* IGHV1-46*01 (83.70%) -(IGHD) -IGHJ4*01) [8.8.14] (1-121) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (218) (122-219), bisagra (220-234), CH2 (235-344), CH3 L7>D (355), E12 (360), M14 (362), L24>E (372) (345-449), CHS K>del (450)) (122-450)] (224-214')-disulfuro con la cadena ligera kappa (1'-214') [*Homo sapiens* V-KAPPA (IGKV1-39*01 (100.00%) -IGKJ1*01) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01, Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (233-230":236-233")-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada (anti-ERBB3)

```
QVQLVQSGAE VKKPGASVKV SCKASGYTFT GYYMHWVRQA PGQGLEWMGW  50
INPNSGGTNY AQKFQGRVTM TRDTSISTAY MELSRLRSDD TAVYYCARDH 100
GSRHFWSYWG FDYWGQGTLV TVSSASTKGP SVFPLAPSSK STSGGTAALG 150
CLVKDYFPEP VTVSWNSGAL TSGVHTFPAV LQSSGLYSLS SVVTVPSSSL 200
GTQTYICNVN HKPSNTKVDK RVEPKSCDKT HTCPPCPAPE LLGGPSVFLF 250
PPKPKDTLMI SRTPEVTCVV VDVSHEDPEV KFNWYVDGVE VHNAKTKPRE 300
EQYNSTYRVV SVLTVLHQDW LNGKEYKCKV SNKALPAPIE KTISKAKGQP 350
REPQVYTKPP SREEMTKNQV SLKCLVKGFY PSDIAVEWES NGQPENNYKT 400
TPPVLDSDGS FFLYSKLTVD KSRWQQGNVF SCSVMHEALH NHYTQKSLSL 450
SPG                                                     453
```

Heavy chain / Chaîne lourde / Cadena pesada (anti-ERBB2)

```
QVQLVQSGAE VKKPGASVKL SCKASGYTFT AYYINWVRQA PGQGLEWIGR  50
IYPGSGYTSY AQKFQGRATL TADESTSTAY MELSSLRSED TAVYFCARPP 100
VYYDSAWFAY WGQGTLVTVS SASTKGPSVF PLAPSSKSTS GGTAALGCLV 150
KDYFPEPVTV SWNSGALTSG VHTFPAVLQS SGLYSLSSVV TVPSSSLGTQ 200
TYICNVNHKP SNTKVDKRVE PKSCDKTHTC PPCPAPELLG GPSVFLFPPK 250
PKDTLMISRT PEVTCVVVDV SHEDPEVKFN WYVDGVEVHN AKTKPREEQY 300
NSTYRVVSVL TVLHQDWLNG KEYKCKVSNK ALPAPIEKTI SKAKGQPREP 350
QVYTDPPSRE EMTKNQVSLT CEVKGFYPSD IAVEWESNGQ PENNYKTTPP 400
VLDSDGSFFL YSKLTVDKSR WQQGNVFSCS VMHEALHNHY TQKSLSLSPG 450
```

Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS LSASVGDRVT ITCRASQSIS SYLNWYQQKP GKAPKLLIYA  50
ASSLQSGVPS RFSGSGSGTD FTLTISSLQP EDFATYYCQQ SYSTPPTFGQ 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                         214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 151-207 268-328 374-432
22"-96" 148"-204" 265"-325" 371"-429"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (h 5-CL 126) 227-214' 224"-214'"
Inter-H-H (h 11, h 14) 233-230" 236-233"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
304, 301"
Defucosylated (≥ 90%) complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes défucosylés (≥ 90%) / glicanos de tipo CHO biantenarios complejos defucosilados (≥ 90%)

zolbetuximabum #

zolbetuximab

immunoglobulin G1-kappa, anti-[*Homo sapiens* CLDN18 (claudin 18, claudin-18, SFTPJ, surfactant associated protein J) isoform 2, extracellular domain 1 (EC1)], chimeric monoclonal antibody;
gamma1 heavy chain (1-448) [*Mus musculus* VH (IGHV1-61*01 (92.90%) -(IGHD) -IGHJ2*01) [8.8.11] (1-118) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (215) (119-216), hinge (217-231), CH2 (232-341), CH3 E12 (357), M14 (359) (342-446), CHS (447-448)) (119-448)], (221-220')-disulfide with kappa light chain (1'-220') [*Mus musculus* V-KAPPA (IGKV8-19*01 (100.00%) -IGKJ4*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC*01, Km3 A45.1 (159), V101 (197) (114'-220')]; dimer (227-227'":230-230'")-bisdisulfide

zolbétuximab

immunoglobuline G1-kappa, anti-[*Homo sapiens* CLDN18 (claudine 18, claudine-18, SFTPJ, surfactant associé à la protéine J) isoforme 2, domaine extracellulaire 1 (EC1)], anticorps monoclonal chimérique;
chaîne lourde gamma1 (1-448) [*Mus musculus* VH (IGHV1-61*01 (92.90%) -(IGHD) -IGHJ2*01) [8.8.11] (1-118) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (215) (119-216), charnière (217-231), CH2 (232-341), CH3 E12 (357), M14 (359) (342-446), CHS (447-448)) (119-448)], (221-220')-disulfure avec la chaîne légère kappa (1'-220') [*Mus musculus* V-KAPPA (IGKV8-19*01 (100.00%) -IGKJ4*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC*01, Km3 A45.1 (159), V101 (197) (114'-220')]; dimère (227-227'":230-230'")-bisdisulfure

zolbetuximab

inmunoglobulina G1-kappa, anti-[*Homo sapiens* CLDN18 (claudina 18, claudina-18, SFTPJ, surfactante asociado a la proteína J) isoforma 2, dominio extracelular 1 (EC1)], anticuerpo monoclonal quimérico;
cadena pesada gamma1 (1-448) [*Mus musculus* VH (IGHV1-61*01 (92.90%) -(IGHD) -IGHJ2*01) [8.8.11] (1-118) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (215) (119-216), bisagra (217-231), CH2 (232-341), CH3 E12 (357), M14 (359) (342-446), CHS (447-448)) (119-448)], (221-220')-disulfuro con la cadena ligera kappa (1'-220') [*Mus musculus* V-KAPPA (IGKV8-19*01 (100.00%) -IGKJ4*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC*01, Km3 A45.1 (159), V101 (197) (114'-220')];
dímero (227-227":230-230")-bisdisulfuro

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLQQPGAE LVRPGASVKL SCKASGYTFT SYWINWVKQR PGQGLEWIGN  50
IYPSDSYTNY NQKFKDKATL TVDKSSSTAY MQLSSPTSED SAVYYCTRSW 100
RGNSFDYWGQ GTTLTVSSAS TKGPSVFPLA PSSKSTSGGT AALGCLVKDY 150
FPEPVTVSWN SGALTSGVHT FPAVLQSSGL YSLSSVVTVP SSSLGTQTYI 200
CNVNHKPSNT KVDKRVEPKS CDKTHTCPPC PAPELLGGPS VFLFPPKPKD 250
TLMISRTPEV TCVVVDVSHE DPEVKFNWYV DGVEVHNAKT KPREEQYNST 300
YRVVSVLTVL HQDWLNGKEY KCKVSNKALP APIEKTISKA KGQPREPQVY 350
TLPPSREEMT KNQVSLTCLV KGFYPSDIAV EWESNGQPEN NYKTTPPVLD 400
SDGSFFLYSK LTVDKSRWQQ GNVFSCSVMH EALHNHYTQK SLSLSPGK   448
```

Light chain / Chaîne légère / Cadena ligera

```
DIVMTQSPSS LTVTAGEKVT MSCKSSQSLL NSGNQKNYLT WYQQKPGQPP  50
KLLIYWASTR ESGVPDRFTG SGSGTDFTLT ISSVQAEDLA VYYCQNDYSY 100
PFTFGSGTKL EIKRTVAAPS VFIFPPSDEQ LKSGTASVVC LLNNFYPREA 150
KVQWKVDNAL QSGNSQESVT EQDSKDSTYS LSSTLTLSKA DYEKHKVYAC 200
EVTHQGLSSP VTKSFNRGEC                                   220
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 145-201 262-322 368-426
22"-96" 145"-201" 262"-322" 368"-426"
Intra-L (C23-C104) 23'-94' 140'-200'
23'"-94'" 140'"-200'"
Inter-H-L (h 5-CL 126) 221-220' 221"-220'"
Inter-H-H (h 11, h 14) 227-227" 230-230"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
298, 298"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaire complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

Electronic structure available on Mednet: http://mednet.who.int/
Structure électronique disponible sur Mednet: http://mednet.who.int/
Estructura electrónica disponible en Mednet: http://mednet.who.int/
* http://www.who.int/medicines/services/inn/publication/en/

AMENDMENTS TO PREVIOUS LISTS
MODIFICATIONS APPORTÉES AUX LISTES ANTÉRIEURES
MODIFICACIONES A LAS LISTAS ANTERIORES

Recommended International Nonproprietary Names (Rec. INN): List 47
Dénominations communes internationales recommandées (DCI Rec.): Liste 47
Denominaciones Comunes Internacionales Recomendadas (DCI Rec.): Lista 47
(WHO Drug Information, Vol. 16, No 1, 2002)

p. 84 **alicaforsenum**

alicaforsen — *replace the chemical name and the molecular formula by the following ones*

alicaforsen — *remplacer le nom chimique et la formule moléculaire brute par les suivants*

alicaforsén — *sustitúyase el nombre químico y la fórmula molecular por los siguientes*

all-P-(R)-2'-deoxy-*P*-thioguanylyl-(3'→5')-2'-deoxy-*P*-thiocytidylyl-(3'→5')-2'-deoxy-*P*-thiocytidylyl-(3'→5')-2'-deoxy-*P*-thiocytidylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-2'-deoxy-*P*-thiocytidylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-2'-deoxy-*P*-thiocytidylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-deoxy-*P*-thiocytidylyl-(3'→5')-2'-deoxy-*P*-thiocytidylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-deoxy-*P*-thiocytidylyl-(3'→5')-2'-deoxyadenosine

tout-P-(R)-2'-désoxy-*P*-thioguanylyl-(3'→5')-2'-désoxy-*P*-thiocytidylyl-(3'→5')-2'-désoxy-*P*-thiocytidylyl-(3'→5')-2'-désoxy-*P*-thiocytidylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'_5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-2'-désoxy-*P*-thiocytidylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-2'-désoxy-*P*-thiocytidylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-désoxy-*P*-thiocytidylyl-(3'→5')-2'-désoxy-*P*-thiocytidylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-désoxy-*P*-thiocytidylyl-(3'→5')-2'-désoxyadénosine

todo-P-(R)-2'-desoxi-*P*-tioguanilil-(3'→5')-2'-desoxi-*P*-tiocitidilil-(3'→5')-2'-desoxi-*P*-tiocitidilil-(3'→5')-2'-desoxi-*P*-tiocitidilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-2'-desoxi-*P*-tioguanilil-(3'→5')-2'-desoxi-*P*-tiocitidilil-(3'→5')-*P*-tiotimidilil-(3'→5')-2'-desoxi-*P*-tioguanilil-(3'→5')-2'-desoxi-*P*-tioguanilil-(3'→5')-2'-desoxi-*P*-tiocitidilil-(3'_5')-2'-desoxi-*P*-tioadenilil-(3'→5')-*P*-tiotimidilil-(3'→5')-2'-desoxi-*P*-tiocitidilil-(3'→5')-2'-desoxi-*P*-tiocitidilil-(3'→5')-2'-desoxi-*P*-tioguanilil-(3'→5')-*P*-tiotimidilil-(3'→5')-2'-desoxi-*P*-tiocitidilil-(3'→5')-2'-desoxiadenosina

$C_{192}H_{244}N_{75}O_{98}P_{19}S_{19}$

Recommended International Nonproprietary Names (Rec. INN): List 71
Dénominations communes internationales recommandées (DCI Rec.): Liste 71
Denominaciones Comunes Internacionales Recomendadas (DCI Rec.): Lista 71
(WHO Drug Information, Vol. 28, No 1, 2014)

p. 101 **patisiranum**

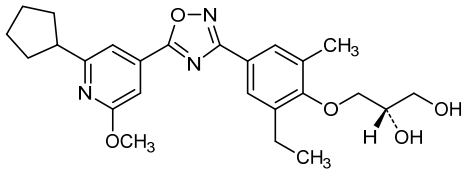
patisiran	*replace the molecular formula by the following one*
patisiran	*remplacer la formule moléculaire brute par la suivante*
patisirán	*sustitúyase la fórmula molecular por la siguiente*

$C_{412}H_{520}N_{148}O_{290}P_{40}$

Recommended International Nonproprietary Names (Rec. INN): List 75
Dénominations communes internationales recommandées (DCI Rec.): Liste 75
Denominaciones Comunes Internacionales Recomendadas (DCI Rec.): Lista 75
(WHO Drug Information, Vol. 30, No 1, 2016)

p. 105 **cenerimodum #**

cenerimod	*replace the structure by the following one*
cénérimod	*remplacer la structure par la suivante*
cenerimod	*sustitúyase la estructura por la siguiente*



Procedure and Guiding Principles / Procédure et Directives / Procedimientos y principios generales

The text of the *Procedures for the Selection of Recommended International Nonproprietary Names for Pharmaceutical Substances* and *General Principles for Guidance in Devising International Nonproprietary Names for Pharmaceutical Substances* will be reproduced in proposed INN lists only.

Les textes de la *Procédure à suivre en vue du choix de dénominations communes internationales recommandées pour les substances pharmaceutiques* et des *Directives générales pour la formation de dénominations communes internationales applicables aux substances pharmaceutiques* seront publiés seulement dans les listes des DCI proposées.

El texto de los *Procedimientos de selección de denominaciones comunes internacionales recomendadas para las sustancias farmacéuticas* y de los *Principios generales de orientación para formar denominaciones comunes internacionales para sustancias farmacéuticas* aparece solamente en las listas de DCI propuestas.

ボラシデニブ　クエン酸水和物

医薬品製造販売承認申請書添付資料

第 1 部（モジュール 1）

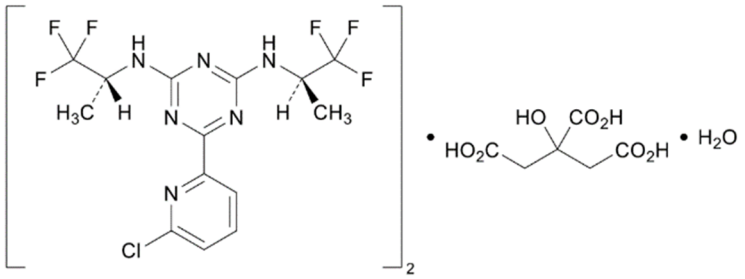
1.10　毒薬・劇薬等の指定審査資料のまとめ

日本セルヴィエ株式会社

目次

1.　毒薬・劇薬等の指定審査資料のまとめ 3

1. 毒薬・劇薬等の指定審査資料のまとめ

<table>
<tr><td>化学名・別名</td><td>6-(6-クロロピリジン-2-イル)-N²,N⁴-ビス[(2R)-1,1,1-トリフルオロプロパン-2-イル]-1,3,5-トリアジン-2,4-ジアミン　ヘミクエン酸　ヘミ水和物</td></tr>
<tr><td>構造式</td><td></td></tr>
<tr><td>効能・効果</td><td>IDH1 又は IDH2 遺伝子変異陽性の神経膠腫</td></tr>
<tr><td>用法・用量</td><td>通常、成人及び 12 歳以上の小児には、ボラシデニブとして以下の用量を 1 日 1 回、空腹時に経口投与する。
体重 40kg 以上の場合：40mg
体重 40kg 未満の場合：20mg</td></tr>
<tr><td>劇薬等の指定</td><td></td></tr>
<tr><td>市販名及び有効成分・分量</td><td>原体：ボラシデニブ　クエン酸水和物
製剤：ボラニゴ錠 10mg（1 錠中ボラシデニブ　クエン酸水和物 12.5mg 含有）、ボラニゴ錠 40mg（1 錠中ボラシデニブ　クエン酸水和物 50.1mg 含有）</td></tr>
<tr><td>毒性</td><td>単回投与
<table>
<tr><th>動物種</th><th>性別</th><th>投与方法</th><th>概略の致死量等</th></tr>
<tr><td>サル</td><td>雌雄</td><td>経口</td><td>算出できず（最大投与量 80 mg/kg で死亡なし）</td></tr>
</table>
反復投与
<table>
<tr><th>動物種</th><th>投与期間</th><th>投与方法</th><th>投与量</th><th>無影響量</th><th>主な所見</th></tr>
<tr><td>ラット</td><td>7 日間</td><td>経口</td><td>0.2、2、10 mg/kg/日</td><td>10 mg/kg/日</td><td>特になし</td></tr>
<tr><td>ラット</td><td>7 日間</td><td>経口</td><td>30、100、300、1000 mg/kg/日</td><td>30 mg/kg/日（最大耐用量）</td><td>死亡、重度の一般状態の所見、臨床検査値に関連した変化、並びに体重と臓器重量及び摂餌量に対する影響</td></tr>
</table></td></tr>
</table>

	ラット	7日間	経口	50、100、200、400 mg/kg/日	100 mg/kg/日（最大耐用量）	体重減少、摂餌量減少 活動性低下、前肢捻転、削痩、衰弱、振戦、冷たい身体、種々の表面に黄色、赤及び／又は茶色の物質の付着、及び便の減少 副腎の暗赤色変色、腺胃部分の膨張（暗赤色領域がある場合もない場合もある）、脾臓及び／又は甲状腺の萎縮、盲腸の暗赤色領域、肝臓肥大、削痩、及び／又は膀胱中の赤い液状内容物、胃の暗赤色変色、脾臓萎縮及び腎臓萎縮 皮膚緊張低下、四肢のほてり
	ラット	28日間	経口	3、10、30、100 mg/kg/日	30 mg/kg/日（最大耐用量）	動物の死亡／瀕死状態／ボラシデニブ投与に伴う体重減少／飢餓衰弱 腺胃／十二指腸の潰瘍と腹膜炎 肝細胞肥大、発情周期消失／雌生殖器の萎縮、中耳の好中球浸潤、皮膚表皮過形成、及び、消耗を示す顕微鏡所見（臓器及び皮下脂肪組織の萎縮）、並びに終末期ストレス（リンパ球枯渇／リンパ系臓器の壊死、及び胸腺と脾臓の肉眼的萎縮に関連する脾臓の赤色脾萎縮、並びに骨髄低細胞性）
	ラット	13週間	経口	5、15、50 mg/kg/日	15 mg/kg/日（最大耐用量）	死亡、体重減少、骨格筋萎縮及び／又は尿細管変性
	サル	7日間	経口	1、10、50、100 mg/kg/日	50 mg/kg/日（最大耐用量）	軽度から重度の振戦、運動失調、眼球振盪、瞳孔の異常な拡大、顔領域の赤み、食欲不振及び体重減少
	サル	28日間	経口	3、10、40 mg/kg/日	3 mg/kg/日（最大耐用量）	一般状態の変化（振戦、運動失調、平衡感覚障害、頭部傾斜） 軽度の肝細胞肥大（肝臓重量増加と血清生化学検査パラメータ値増加と相関）及び副腎皮質空胞化の軽度の減少
	サル	13週間	経口	2、6、20 mg/kg/日	2 mg/kg/日	拡張型心筋症、二次性うっ血性心不全 肝臓重量増加とこれに相関した顕微鏡所見（肝細胞肥大、混合細胞浸潤及びクッパー細胞過形成） 肝細胞肥大に関連する肝酵素値の変化

<table>
<tr><td>副　　作　　用</td><td>国際共同第 III 相試験（AG881-C-004 試験）：本剤群（中間解析時点）
副作用の発現率：109/167 例＝65.3%
<table><tr><th>副作用の種類</th><th>例数（%）</th></tr><tr><td>ALT 増加</td><td>61（36.5）</td></tr><tr><td>AST 増加</td><td>41（24.6）</td></tr><tr><td>疲労</td><td>35（21.0）</td></tr><tr><td>悪心</td><td>25（15.0）</td></tr><tr><td>GGT 増加</td><td>22（13.2）</td></tr><tr><td>下痢</td><td>20（12.0）</td></tr></table></td></tr>
<tr><td>会　　社</td><td>日本セルヴィエ株式会社　　製剤：輸入</td></tr>
</table>

第3部（モジュール3）：品質に関する文書　添付資料一覧
3.2 データ又は報告書
3.2.S 原薬
3.2.S.1　一般情報

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.S.1.1	-	Nomenclature	-	-	-	海外	社内資料	評価
3.2.S.1.2	-	Structure	-	-	-	海外	社内資料	評価
3.2.S.1.3	-	General Properties	-	-	-	海外	社内資料	評価

3.2.S.2　製造

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.S.2.1	-	Manufacturer of The Drug Substance	-	-	-	海外	社内資料	評価
3.2.S.2.2	-	Description of Manufacturing Process and Process Controls	-	-	-	海外	社内資料	評価
3.2.S.2.3.1	-	Control of Materials – Summary	-	-	-	海外	社内資料	評価
3.2.S.2.3.2	-	Control of Materials – Starting Material [redacted]	-	-	-	海外	社内資料	評価
3.2.S.2.3.3	-	Control of Materials – Starting Material [redacted]	-	-	-	海外	社内資料	評価
3.2.S.2.3.4	-	Control of Materials – Starting Material [redacted]	-	-	-	海外	社内資料	評価
3.2.S.2.3.5	-	Control of Materials	-	-	-	海外	社内資料	評価
3.2.S.2.4.1	-	Controls of Critical Steps and Intermediates – Critical Steps	-	-	-	海外	社内資料	評価
3.2.S.2.4.2	-	Controls of Critical Steps and Intermediates – Intermediate [redacted]	-	-	-	海外	社内資料	評価
3.2.S.2.4.3	-	Controls of Critical Steps and Intermediates – Intermediate [redacted]	-	-	-	海外	社内資料	評価

第3部（モジュール3）：品質に関する文書　添付資料一覧
3.2 データ又は報告書
3.2.S 原薬

3.2.S.2.5	-	Process Validation and/or Evaluation	-	-	-	海外	社内資料	評価
3.2.S.2.6	-	Manufacturing Process Development	-	-	-	海外	社内資料	評価

3.2.S.3　特性

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.S.3.1.1	-	Elucidation of Structure and Other Characteristics	-	-	-	海外	社内資料	評価
3.2.S.3.1.2	-	Solid State Study	-	-	-	海外	社内資料	評価
3.2.S.3.2	-	Impurities	-	-	-	海外	社内資料	評価

3.2.S.4　原薬の管理

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.S.4.1	-	Specifications	-	-	-	海外	社内資料	評価
3.2.S.4.2.1	-	Analytical Procedures – Summary	-	-	-	海外	社内資料	評価
3.2.S.4.2.2	-	Analytical Procedures – Characters	-	-	-	海外	社内資料	評価
3.2.S.4.2.3	-	Analytical Procedures – Identification by IR	-	-	-	海外	社内資料	評価
3.2.S.4.2.4	-	Analytical Procedures – Identification by HPLC	-	-	-	海外	社内資料	評価
3.2.S.4.2.5	-	Analytical Procedures – Identification by [redacted]	-	-	-	海外	社内資料	評価
3.2.S.4.2.6	-	Analytical Procedures – Citric Acid by Titration	-	-	-	海外	社内資料	評価
3.2.S.4.2.7	-	Analytical Procedures – Assay and Related Substances by HPLC	-	-	-	海外	社内資料	評価

第3部（モジュール3）：品質に関する文書　添付資料一覧
3.2 データ又は報告書
3.2.S 原薬

3.2.S.4.2.8	-	Analytical Procedures – Residual Solvents by GC	-	-	-	海外	社内資料	評価
3.2.S.4.2.9	-	Analytical Procedures – Residual [redacted] by GC	-	-	-	海外	社内資料	評価
3.2.S.4.2.10	-	Analytical Procedures – Water Content by KF	-	-	-	海外	社内資料	評価
3.2.S.4.2.11	-	Analytical Procedures – Sulphated Ash/Residue on Ignition	-	-	-	海外	社内資料	評価
3.2.S.4.2.12	-	Analytical Procedures – Particle Size Distribution by Laser Light Diffraction	-	-	-	海外	社内資料	評価
3.2.S.4.2.13	-	Analytical Procedures – Microbiology	-	-	-	海外	社内資料	評価
3.2.S.4.3.1	-	Validation of Analytical Procedures – Identification by IR	-	-	-	海外	社内資料	評価
3.2.S.4.3.2	-	Validation of Analytical Procedures – Identification by [redacted]	-	-	-	海外	社内資料	評価
3.2.S.4.3.3	-	Validation of Analytical Procedures – Citric Acid by Potentiometry	-	-	-	海外	社内資料	評価
3.2.S.4.3.4	-	Validation of Analytical Procedures – Assay and Related Substances by HPLC	-	-	-	海外	社内資料	評価
3.2.S.4.3.5	-	Validation of Analytical Procedures – Residual Solvents by GC	-	-	-	海外	社内資料	評価
3.2.S.4.3.6	-	Validation of Analytical Procedures – Residual [redacted] by GC	-	-	-	海外	社内資料	評価
3.2.S.4.3.7	-	Validation of Analytical Procedures – Water Content by KF	-	-	-	海外	社内資料	評価
3.2.S.4.3.8	-	Validation of Analytical Procedures – Particle Size Distribution by Laser Light Diffraction	-	-	-	海外	社内資料	評価
3.2.S.4.3.9	-	Validation of Analytical Procedures – Microbiology	-	-	-	海外	社内資料	評価
3.2.S.4.4	-	Batch Analyses	-	-	-	海外	社内資料	評価
3.2.S.4.5	-	Justification of Specification	-	-	-	海外	社内資料	評価

第3部（モジュール3）：品質に関する文書　添付資料一覧
3.2 データ又は報告書
3.2.S 原薬
3.2.S.5　標準品又は標準物質

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.S.5	-	Reference Standards or Materials	-	-	-	海外	社内資料	評価

3.2.S.6　容器及び施栓系

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.S.6.1	-	Container Closure System	-	-	-	海外	社内資料	評価
3.2.S.6.2	-	Statement	-	-	-	海外	社内資料	評価

3.2.S.7　安定性

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.S.7.1	-	Stability Summary and Conclusions	-	-	-	海外	社内資料	評価
3.2.S.7.2	-	Post-Approval Stability Protocol and Stability Commitment	-	-	-	海外	社内資料	評価
3.2.S.7.3.1	-	Primary Stability Study Results	-	-	-	海外	社内資料	評価
3.2.S.7.3.2	-	Photostability Study Results	-	-	-	海外	社内資料	評価
3.2.S.7.3.3	-	Forced Degradation Studies Results	-	-	-	海外	社内資料	評価

第3部（モジュール3）：品質に関する文書　添付資料一覧

3.2 データ又は報告書

3.2.P 製剤

3.2.P.1　製剤及び処方

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.P.1	-	Description and Composition of the Drug Product	-	-	-	海外	社内資料	評価

3.2.P.2　製剤開発の経緯

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.P.2.1	-	Components of the Drug Product	-	-	-	海外	社内資料	評価
3.2.P.2.2	-	Drug Product	-	-	-	海外	社内資料	評価
3.2.P.2.3	-	Manufacturing Process Development	-	-	-	海外	社内資料	評価
3.2.P.2.4	-	Container Closure System	-	-	-	海外	社内資料	評価
3.2.P.2.5	-	Microbiological Attributes	-	-	-	海外	社内資料	評価
3.2.P.2.6	-	Compatibility	-	-	-	海外	社内資料	評価

3.2.P.3　製造

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.P.3.1	-	Manufacturer	-	-	-	海外	社内資料	評価
3.2.P.3.2	-	Batch Formula	-	-	-	海外	社内資料	評価
3.2.P.3.3	-	Description of Manufacturing Process and Process Controls	-	-	-	海外	社内資料	評価
3.2.P.3.4	-	Controls of Critical Steps and Intermediates	-	-	-	海外	社内資料	評価

第3部（モジュール3）：品質に関する文書　添付資料一覧
3.2 データ又は報告書
3.2.P 製剤

3.2.P.3.5	-	Process Validation and/or Evaluation	-	-	-	海外	社内資料	評価

第3部（モジュール3）：品質に関する文書　添付資料一覧
3.2 データ又は報告書
3.2.P 製剤
3.2.P.4　添加剤の管理

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.P.4.1.1	-	Specifications	-	-	-	海外	社内資料	評価
3.2.P.4.1.2	-	Specifications	-	-	-	海外	社内資料	評価
3.2.P.4.2.1	-	Analytical Procedure of [redacted]	-	-	-	海外	社内資料	評価
3.2.P.4.2.2	-	Analytical Procedure	-	-	-	海外	社内資料	評価
3.2.P.4.3	-	Validation of Analytical Procedures	-	-	-	海外	社内資料	評価
3.2.P.4.4.1	-	Justification of Excipient Specifications	-	-	-	海外	社内資料	評価
3.2.P.4.4.2	-	Batch Analyses for Excipients	-	-	-	海外	社内資料	参考
3.2.P.4.5	-	Excipients of Human or Animal Origin	-	-	-	海外	社内資料	評価
3.2.P.4.6	-	Novel Excipients	-	-	-	海外	社内資料	評価

3.2.P.5　製剤の管理

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.P.5.1	-	Specification(s)	-	-	-	海外	社内資料	評価
3.2.P.5.2	-	Analytical Procedures	-	-	-	海外	社内資料	評価
3.2.P.5.3.1	-	Validation of Analytical Procedures – Summary	-	-	-	海外	社内資料	評価
3.2.P.5.3.2	-	Validation of Analytical Procedures – Identificaiton, Assay, and Degradation Products	-	-	-	海外	社内資料	評価

第3部（モジュール3）：品質に関する文書　添付資料一覧
3.2 データ又は報告書
3.2.P 製剤

3.2.P.5.3.3	-	Validation of Analytical Procedures – Uniformity of Dosage Units	-	-	-	海外	社内資料	評価
3.2.P.5.3.4	-	Validation of Analytical Procedures – Dissolution	-	-	-	海外	社内資料	評価
3.2.P.5.4.1	-	Batch Analyses	-	-	-	海外	社内資料	評価
3.2.P.5.4.2	-	Batch Analyses - Validation of Dissolution Method 1	-	-	-	海外	社内資料	評価
3.2.P.5.4.3	-	Batch Analyses - Validation Summary of Dissolution Method 2 by HPLC	-	-	-	海外	社内資料	評価
3.2.P.5.5	-	Characterisation of Impurities	-	-	-	海外	社内資料	評価
3.2.P.5.6.1	-	Justification of Specification(s)	-	-	-	海外	社内資料	評価
3.2.P.5.6.2	-	Summary of The Elemental Impurities Product Risk Assessment （ICH Q3D）	-	-	-	海外	社内資料	評価

第3部（モジュール3）：品質に関する文書　添付資料一覧
3.2 データ又は報告書
3.2.P 製剤

3.2.P.6　標準品又は標準物質

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.P.6	-	Reference Standards or Materials	-	-	-	海外	社内資料	評価

3.2.P.7　容器及び施栓系

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.P.7	-	Container Closure System	-	-	-	海外	社内資料	評価

3.2.P.8　安定性

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.P.8.1	-	Stability Summary and Conclusion	-	-	-	海外	社内資料	評価
3.2.P.8.2	-	Post-Approval Stability Protocol and Stability Commitment	-	-	-	海外	社内資料	評価
3.2.P.8.3.1	-	Stability Study Results – Primary Registration Batches	-	-	-	海外	社内資料	評価
3.2.P.8.3.2	-	Stability Study Results – Supportive Stability - [redacted] Batch	-	-	-	海外	社内資料	参考
3.2.P.8.3.3	-	Stability Study Results – Supportive Stability - [redacted] Batch	-	-	-	海外	社内資料	参考
3.2.P.8.3.4	-	Stability Study Results – Supportive Stability - [redacted] Batch	-	-	-	海外	社内資料	参考
3.2.P.8.3.5	-	Stability Study Results – Supportive Stability - [redacted] Batch	-	-	-	海外	社内資料	参考
3.2.P.8.3.6	-	Stability Study Results – Supportive Stability - [redacted] Batch	-	-	-	海外	社内資料	参考
3.2.P.8.3.7	-	Stability Study Results – Photostability	-	-	-	海外	社内資料	評価

第3部（モジュール3）：品質に関する文書　添付資料一覧
3.2 データ又は報告書
3.2.P 製剤

3.2.P.8.3.8	-	Stability Study Results – Forced Degredation Studies Results	-	-	-	海外	社内資料	評価
3.2.P.8.3.9	-	Stability Study Results – In-Use Stability	-	-	-	海外	社内資料	評価
3.2.P.8.3.10	-	Stability Study Results – Bulk Packaging	-	-	-	海外	社内資料	参考
3.2.P.8.3.11	-	Stability Study Results – Transportation Stability	-	-	-	海外	社内資料	参考
3.2.P.8.3.12	-	Stability Study Results – Freeze/Thaw Stability Study	-	-	-	海外	社内資料	参考

第3部（モジュール3）：品質に関する文書　添付資料一覧

3.2 データ又は報告書

3.2.A その他

3.2.A.1　製造施設及び設備

該当資料なし

3.2.A.2　外来性感染性物質の安全性評価

添付資料番号	報告書番号	タイトル	著者	試験実施期間	試験実施場所	報種類（国内／海外）	掲載誌	評価資料・参考資料の別
3.2.A.2	-	Medical Products containing or using in the Manufacturing Process Materials of Animal and/or Human Origin	-	-	-	海外	社内資料	評価

3.2.A.3　添加剤

該当資料なし

3.2.R 各極の要求資料

該当資料なし

第3部（モジュール3）：品質に関する文書　添付資料一覧
3.3 参考文献

添付資料番号	報告書番号	著者・タイトル・掲載誌
3.3.1	-	[redacted]
3.3.2	-	
3.3.3	-	
3.3.4	-	
3.3.5	-	
3.3.6	-	
3.3.7	-	
3.3.8	-	

第4部（モジュール4）：非臨床試験報告書　添付資料一覧
4.2 試験報告書
4.2.1 薬理試験
4.2.1.1 効力を裏付ける試験

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考
4.2.1.1-1	np41940	AG881-N-042	AG-881: Inhibition and characterization in IDH1 and IDH2 biochemical systems	海外	社内資料	評価
4.2.1.1-2	np41860	AG881-N-043-R1	AG-881: Inhibition of 2-HG in IDH1 and IDH2 Mutant Expressing Cells	海外	社内資料	評価
4.2.1.1-3	np41865	AG881-N-068	Inhibition of 2-HG production by AG-881 and its metabolite AGI-69460 in two cell lines containing IDH1 mutations	海外	社内資料	参考
4.2.1.1-4	np41866	AG881-N-069	Inhibition of wild-type IDH1/2 and IDH1R132H by AG-881 and its metabolite AGI-69460	海外	社内資料	参考
4.2.1.1-5	np42942	R-00004806	Inhibition of 2-HG production by AG-881 and its metabolite AGI-69460 in one cell line containing IDH2R172K mutation	海外	社内資料	評価
4.2.1.1-6	np41288	AG120-881-N-001	Study of inhibition of IDH1 and IDH2 wild type activity in cell-based and in vivo mouse xenograft systems	海外	社内資料	参考
4.2.1.1-7	np41862	AG881-N-044-R1	AG-881: Reversal of Mutant IDH-induced Differentiation Block in TF-1 IDH1R132H and TF-1 IDH2R140Q Cells: Hemoglobin and KLF-1 Expression	海外	社内資料	評価
4.2.1.1-8	np41864	AG881-N-045-R1	AG-881: Induction of Myeloid Differentiation in Primary IDH1 and IDH2 Mutant AML Patient Samples	海外	社内資料	評価
4.2.1.1-9	np41858	AG881-N-033-R1	AG-881: PKPD Study Following Three Oral Doses of AG-881 at 0.3 mg/kg, 1 mg/kg, 3 mg/kg or 30 mg/kg to HT1080 IDHIR132C Xenograft Bearing Female Nude BALB/c Mice	海外	社内資料	評価
4.2.1.1-10	np41859	AG881-N-034-R1	AG-881: PKPD Study Following Three Oral Doses of AG-881 to U87IDH2R140Q Xenograft Bearing Female BALB/c Mice	海外	社内資料	評価

第4部（モジュール4）：非臨床試験報告書　添付資料一覧

4.2 試験報告書

4.2.1 薬理試験

4.2.1.1-11	np41861	AG881-N-035-R1	AG-881: PKPD Study Following Three Oral Doses of AG-881 at 5 mg/kg, 30 mg/kg or 150 mg/kg to U87IDH2R140Q Zenograft Bearing Female Nude BABL/c Mice	海外	社内資料	評価
4.2.1.1-12	np41863	AG881-N-046-R1	PKPD Study of AG-881 Following Oral Administrations of AG-881 to Male ICR SCID Mice Bearing Orthotopic TS603 IDH1R132H Glioma Tumor Xenograft	海外	社内資料	評価

4.2.1.2　副次的薬理試験

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考
4.2.1.2-1	np41856	AG881-N-020-R1	Secondary Pharmacology Assessment of AGI-23088	海外	社内資料	参考
4.2.1.2-2	np41857	AG881-N-021-R1	Secondary Pharmacology Assessment (Adnosine A3 Agonism / Antagonisum) of AGI-23088	海外	社内資料	評価
4.2.1.2-3	np42842	TW04-0016507	AGI-69460 Off-target Screening Panel: Genera	海外	社内資料	参考

4.2.1.3　安全性薬理試験

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考
4.2.1.3-1	np41869	AG881-N-018-R1	Report of hERG Activity for Compound AGI-23088	海外	社内資料	参考
4.2.1.3-2	np41868	AG881-N-019-R1	Effect of AG-881 on Cloned hERG Potassium Channels Expressed in Human Embryonic Kidney Cells	海外	社内資料	評価
4.2.1.3-3	np41972	AG881-N-066	Effect of AGI-69460 on Cloned hERG Potassium Channels Expressed in Human Embryonic Kidney Cells	海外	社内資料	評価
4.2.1.3-4	np41973	AG881-N-012-R1	A 28-Day Oral (Gavage) Toxicity and Toxicokinetic Study of AGI-23088 in Aprague Dawley Rats with a 14-Day Recovery Peiod	海外	社内資料	評価

第4部（モジュール4）：非臨床試験報告書　添付資料一覧

4.2 試験報告書

4.2.1 薬理試験

4.2.1.3-5	np41976	AG881-N-013-R1	A 28-Day Oral (Nasogastric) Toxicity and Toxicokinetic Study of AGI-23088 in Cynomologus Mondeys with a 14-Day Recovery Period	海外	社内資料	評価

4.2.1.4　薬力学的薬物相互作用試験

該当資料なし

第4部（モジュール4）：非臨床試験報告書　添付資料一覧
4.2 試験報告書
4.2.2 薬物動態試験
4.2.2.1 分析法及びバリデーション報告書

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考
4.2.2.1-1	np41938	AG881-Q-004-R1	Quantitative Determination of AGI-23088 in Sprague-Dawley Rat Plasma (K2EDTA) by LC-MS/MS	海外	社内資料	評価
4.2.2.1-2	np41936	AG881-Q-003-R1	Quantitative Determination of AGI-23088 in Cynomolgus Monkey Plasma (K2EDTA) by LC-MS/MS	海外	社内資料	評価
4.2.2.1-3	np42338	PB-22-95032-002-DRVA	Validation of an LC-MS/MS method for the determination of S095032 and its metabolite concentration in rat and its metabolite concentration in rat plasma including stability in blood and plasma	海外	社内資料	評価
4.2.2.1-4	np42315	PB-22-95032-003-DLVA	Validation of an LC-MS/MS method for the determination of S095032 and its metabolite concentration in rabbit and its metabolite concentration in rabbit plasma including stability in blood and plasma	海外	社内資料	評価
4.2.2.1-5	np42563	AG881-Q-011 (Method Transfer from AG881-Q-003)	Transfer of a Method for the Quantitative Determination of AG-881 in Cynomolgus Monkey Plasma (K2EDTA) by LC-MS/MS	海外	社内資料	評価
4.2.2.1-6	np42564	AG881-Q-012 (Method Transfer from AG881-Q-004)	Transfer of a Method for the Quantitative Determination of AG-881 in Rat Plasma (K2EDTA) by LC-MS/MS	海外	社内資料	評価

4.2.2.2 吸収

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考
4.2.2.2-1	np41880	AG881-N-023-R1	Pharmacokinetics and Oral Bioavailability of AG-881 in Female BALB/c Nude Mice Following Single Intravenous (0.3 mg/kg or 1 mg/kg) Administration of AG-881 Free Base or Oral (0.3 mg/kg or 1 mg/kg) Administration of [redacted]/[redacted]([redacted]).	海外	社内資料	評価

第4部（モジュール4）：非臨床試験報告書　添付資料一覧
4.2 試験報告書
4.2.2 薬物動態試験

4.2.2.2-2	np41882	AG881-N-026-R1	Pharmacokinetics and Oral Bioavailability of AG-881 Following Single Intravenous (1 mg/kg) or Oral (10 mg/kg) Administration to Male Sprague-Dawley Rats	海外	社内資料	評価
4.2.2.2-3	np41883	AG881-N-029-R1	Pharmacokinetics of AG-881 Following Single Intravenous Infusion or Oral Administration of AG-881 to Male Beagle Dogs	海外	社内資料	評価
4.2.2.2-4	np41884	AG881-N-030-R1	Pharmacokinetics of AG-881 Following Single Intravenous Dose of AG-881Free Base or Oral Administration of [redacted]/[redacted] ([redacted]) to Male Cynomolgus Monkeys	海外	社内資料	評価
4.2.2.2-5	np41885	AG881-N-049-R1	Pharmacokinetics of AG-881 Following Single Oral Administration of AG-881 Tablets or Suspension to Male Cynomolgus Monkeys	海外	社内資料	評価

4.2.2.3　分布

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考
4.2.2.3-1	np41886	AG881-N-022-R1	AG881 Brain Distribution Study Following Oral (50 mg/kg or 150 mg/kg) Administration to Female BLBAc/ Nude Mice	海外	社内資料	評価
4.2.2.3-2	np41889	AG881-N-025-R1	Brain and CSF Distribution of AG-881 Following Single or Multiple QD Oral Doses of AG-881 in Male Sprague-Dawley Rats	海外	社内資料	評価
4.2.2.3-3	np41895	AG881-N-053	Tissue Distribution of Radioactivity Following a Single Oral Dose of [14C]AG-881 in Male Long-Evans Rats Using Quantitative Whole Body Autoradiography (QWBA)	海外	社内資料	評価
4.2.2.3-4	np41890	AG881-N-037-R1	AG-881: Plasma Protein Binding in Human, Monkey, Dog, Rat, and Mouse Plasma using Equilibrium Method	海外	社内資料	評価
4.2.2.3-5	np41894	AG881-N-067	In Vitro Protein Binding Determination of AG-881 and AGI-69460 in Human Plasma	海外	社内資料	評価

第4部（モジュール4）：非臨床試験報告書　添付資料一覧
4.2 試験報告書
4.2.2 薬物動態試験

4.2.2.3-6	np42869	240001_6916	Advanced Plasma Protein Binding in Human using 3 Concentrations of AG-881 and AGI-69460	海外	社内資料	評価
4.2.2.3-7	np42890	240001_6907	Fu Determination of AG-881 in Rat, Rabbit and Monkey Plasma with RED Device. Fu Determination of AGI-69460 in Mouse, Rat, Rabbit, Dog, Monkey and Human Plasma with RED Device	海外	社内資料	評価
4.2.2.3-8	np42870	240001_6913	Fu Determination of AG-881 and AGI-69460 in Rat Brain with RED device	海外	社内資料	評価
4.2.2.3-9	np42856	S095032_A-R-00006829-DHPB	In Vitro Protein Binding of S095032 and its Metabolite AGI-69460 in Tumor Cell Lysate and in Culture Medium	海外	社内資料	参考
4.2.2.3-10	np42891	240001_6877	Determination of AG-881 Response in Blood/Plasma Tests Performed in Human, Mouse, Rat, Rabbit, Dog and Monkey Plasma Samples	海外	社内資料	評価
4.2.2.3-11	np42843	240001_6878	Red Blood Cell Partition Coefficient in Human Blood and Qualification of AGI-69460 in Human Plasma	海外	社内資料	評価
4.2.2.3-12	np41893	AG881-N-036-R1	AG-881: Red Blood Cell Partition in Human, Monkey, Dog, Rat, and Mouse Blood	海外	社内資料	評価
4.2.2.3-13	np42556	AG881-N-055	Projection of Human Exposure to Carbon-14 Radioactivity Following Oral Administration of 100 µCi [14C]AG-881 in Human Research Subjects	海外	社内資料	評価

4.2.2.4　代謝

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考
4.2.2.4-1	np41954	AG881-N-041	Identification of Metabolites of AG-881 in Plasma Samples of Mouse, Rat, and Monkey	海外	社内資料	参考
4.2.2.4-2	np41910	AG881-N-070	Pharmacokinetic Profile Of AG-881 And Its Metabolite AGI-69460 After Seven Days Of QD PO Dosing Of Ag-881 In Male Sprague-Dawley Rats	海外	社内資料	参考

第4部（モジュール4）：非臨床試験報告書　添付資料一覧

4.2 試験報告書

4.2.2 薬物動態試験

4.2.2.4-3	np41911	AG881-N-071	AG881-N-071: Pharmacokinetic Profile Of AG-881 And Its Metabolite AGI-69460 After Seven Days Of QD PO Dosing Of AG-881 In Male Cyno Monkeys	海外	社内資料	参考
4.2.2.4-4	np41941	AG881-N-038	Metabolic Stability of AG-881 in Mouse, Rat, Dog, Monkey and Human Hepatocytes and Liver Microsomes	海外	社内資料	評価
4.2.2.4-5	np41986	AG881-N-001	CYTOCHROME P450 REACTION PHENOTYPING FOR ^{14}C AGI-0023088	海外	社内資料	評価
4.2.2.4-6	np41987	AG881-N-001-R2	CYTOCHROME P450 REACTION PHENOTYPING FOR ^{14}C AGI-0023088: NON-CYP PATHWAYS	海外	社内資料	評価
4.2.2.4-7	np41900	AG881-N-064	Identification of the Human Cytochrome P450 Enzyme(s) Responsible for the In Vitro Metabolism of AG-881	海外	社内資料	参考
4.2.2.4-8	np42349	RB-23-095032-001-DHIZ	IDENTIFICATION OF THE ENZYMES INVOLVED IN THE HEPATIC METABOLISM S 095032	海外	社内資料	参考
4.2.2.4-9	np42839	S095032_A-R-00006524-DHIZ	In Vitro Evaluation of AGI-69460 as a Substrate of the Human CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6 and CYP3A4/5 Metabolic Enzymes in Liver Microsomes and in Recombinant Enzyme System	海外	社内資料	評価
4.2.2.4-10	np41944	AG881-N-007	Identification of Metabolites of AG-881 in Mouse, Rat, Dog, Monkey and Human Hepatocytes	海外	社内資料	参考
4.2.2.4-11	np41898	AG881-N-052	In Vitro Metabolism of [^{14}C]AG-881 in Rats and Human Liver Microsomes and Hepatocytes	海外	社内資料	評価

4.2.2.5　排泄

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考
4.2.2.5-1	np41899	AG881-N-050	In Vivo Metabolism and Excretion of [14C]AG-881 in Rats	海外	社内資料	評価

第4部（モジュール4）：非臨床試験報告書　添付資料一覧
4.2 試験報告書
4.2.2 薬物動態試験

4.2.2.5-2	np41901	AG881-N-027-R1	AG-881 Biliary Excretion Study Following Single Intravenous Administration (1 mg/kg) in Male Sprague-Dawley Rats	海外	社内資料	評価

4.2.2.6　薬物動態学的薬物相互作用

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考
4.2.2.6-1	np41964	AG881-N-002	In Vitro Evaluation of AG-881 as an Inducer of Cytochrome P450 Expression in Cultured Human Hepatocytes	海外	社内資料	評価
4.2.2.6-2	np41965	AG881-N-003	In Vitro Evaluation of AG-881 as an Autoinducer in Cultured Human Hepatocytes	海外	社内資料	評価
4.2.2.6-3	np41902	AG881-N-059	In Vitro Evaluation of AG-881 as an Inducer of Cytochrome P450 and Uridine Diphosphate-Glucuronosyltransferase Enzymes in Cultured Human Hepatocytes	海外	社内資料	評価
4.2.2.6-4	np42841	S095032_A-R-00006521-DHIN	In Vitro Evaluation of AGI-69460 as an Inducer of the Human CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19 and CYP3A4 Metabolic Enzymes in Hepatocytes	海外	社内資料	評価
4.2.2.6-5	np41966	AG881-N-005	In Vitro Evaluation of AG-881 as an Inhibitor of Cytochrome P450 (CYP) Enzymes in Human Liver Microsomes	海外	社内資料	評価
4.2.2.6-6	np42813	S095032_A-R-00006525-DHIP	In Vitro Evaluation of AGI-69460 as an Inhibitor of the Human CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6 and CYP3A4/5 Metabolic Enzymes	海外	社内資料	評価
4.2.2.6-7	np42279	PB-22-095032-007-DHAB	PERMEABILITY AND GASTROINTESTINAL FLUID STABILITY OF VORASIDENIB (AG-881) ACCORDING TO THE BIOPHARMACEUTICS CLASSIFICATION SYSTEM (BCS)	海外	社内資料	評価
4.2.2.6-8	np41903	AG881-N-048-R1	AG-881: In Vitro Evaluation of Bidirectional Permeability across Caco-2 Cells	海外	社内資料	評価

第4部（モジュール4）：非臨床試験報告書　添付資料一覧
4.2 試験報告書
4.2.2 薬物動態試験

4.2.2.6-9	np41967 (np41047)	AG881-N-004-R1	In Vitro Evaluation of AG-881 as an Inhibitor and Substrate of Human P-gp and BCRP Transporters	海外	社内資料	評価
4.2.2.6-10	np42853	S095032_A-R-00006898-DHTI	In Vitro Inhibition Studies of Vorasidenib with Human MDR1 Efflux (ABC) Transporter in Caco-2 Cells	海外	社内資料	評価
4.2.2.6-11	np41906	AG881-N-058	In Vitro Evaluation of AG-881 as an Inhibitor of MATE-1 and MATE2-K and a Substrate of OATP1B1 and OATP1B3	海外	社内資料	評価
4.2.2.6-12	np41905	AG881-N-051	In Vitro Evaluation of AG-881 as an Inhibitor of Human ABC (BSEP, MRP2 and MRP3) and SLC (OATP1B1, OATP1B3, OAT1, OAT3 and OCT2) Transporters	海外	社内資料	評価
4.2.2.6-13	np41913	AG881-N-073	Evaluation of AGI-69460 as a Potential P-glycoprotein Substrate, Using Verapamil and LY335979 as Inhibitor in Caco-2 Cell Monolayers	海外	社内資料	評価
4.2.2.6-14	np41912	AG881-N-072	Evaluation of AGI-69460 as a Potential BCRP Substrate, Using Novobiocin and Ko143 as Inhibitor in Caco-2 Cell Line	海外	社内資料	評価
4.2.2.6-15	np41914	AG881-N-074	Evaluation of AGI-69460 as Substrate of OATP1B1 and OATP1B3	海外	社内資料	評価
4.2.2.6-16	np41915	AG881-N-075	Evaluation of AGI-69460 as Inhibitor of OATP1B1 and OATP1B3	海外	社内資料	評価
4.2.2.6-17	np42812	S095032_A-R-00006522-DHTI	In vitro Interaction Studies of AGI-69460 with of with Human BCRP and MDR1 Efflux (ABC) Transporters, and with Human MATE1, MATE2-K, OAT1, OAT3 and OCT2 Uptake Transporters	海外	社内資料	評価
4.2.2.6-18	np41904	AG881-N-006	In Vitro Evaluation of AG-881 as an Inhibitor of UGT1A1 in Human Liver Microsomes	海外	社内資料	評価

4.2.2.7　その他の薬物動態試験
該当資料なし

第4部（モジュール4）：非臨床試験報告書　添付資料一覧
4.2 試験報告書
4.2.3 毒性試験
4.2.3.1 単回投与毒性試験

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考
4.2.3.1-1	np41946	AG881-N-008-R1	A Single-Dose Oral (Nasogastric) Toxicokinetic Study of AGI-23088 in Cynomolgus Monkeys	海外	社内資料	探索

4.2.3.2 反復投与毒性試験

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考
4.2.3.2-1	np41947	AG881-N-009-R1	A 7-Day (Twice Daily Dosing) Oral Gavage Tolerability and Toxicokinetic Study of AGI-23088 in Sprague Dawley Rats	海外	社内資料	評価
4.2.3.2-2	np41948	AG881-N-011-R1	A 7-Day (Twice Daily Dosing) Oral Gavage Tolerability and Toxicokinetic Study of AGI-23088 in Male Sprague Dawley Rats	海外	社内資料	評価
4.2.3.2-3	np41971	AG881-N-014-R1	A 7-Day Oral (Gavage) Toxicity Study of AGI-23088 in Sprague Dawley Rats	海外	社内資料	評価
4.2.3.2-4	np41973	AG881-N-012-R	A 28-Day Oral (Gavage) Toxicity and Toxicokinetic Study of AGI-23088 in Sprague Dawley Rats with a 14-Day Recovery Period	海外	社内資料	評価
4.2.3.2-5	np41974	AG881-N-056	A 13-Week Toxicity Study of AG-881 Given by Oral Gavage to Sprague Dawley Rats with a 4-Week Recovery Period	海外	社内資料	評価
4.2.3.2-6	np41977	AG881-N-010-R1	A 7-Day (Once Daily) Oral (Nasogastric) Dose Range-Finding Study of AGI-23088 in Male Cynomolgus Monkeys	海外	社内資料	評価
4.2.3.2-7	mp41976	AG881-N-013-R1	A 28-Day Oral (Nasogastric) Toxicity and Toxicokinetic Study of AGI-23088 in Cynomolgus Monkeys with a 14-Day Recovery Period	海外	社内資料	評価
4.2.3.2-8	np41981	AG881-N-057	A 13-Week GLP Toxicity Study of AG-881 Given by Oral Gavage to Cynomolgus Monkeys with a 4-Week Recovery Period	海外	社内資料	評価

第4部（モジュール4）：非臨床試験報告書　添付資料一覧
4.2 試験報告書
4.2.3 毒性試験
4.2.3.3 遺伝毒性試験

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考
4.2.3.3.1-1	np41979	AG881-N-017-R1	Bacterial Reverse Mutation Assay of AGI-23088	海外	社内資料	評価
4.2.3.3.1-2	np41980	AG881-N-054	AG-881 In Vitro Mammalian Cell Micronucleus Test in Human Peripheral Blood Lymphocytes	海外	社内資料	評価
4.2.3.3.2-1	np42502	8500632	S95032-1:Rat Bone Marrow Micronucleus Assay	海外	社内資料	評価

4.2.3.4 がん原性試験
該当資料なし

4.2.3.5 生殖発生毒性試験

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考
4.2.3.5.2-1	np42346	20360623	Dose Range Finding Embryo-Fetal Developmental Toxicity Study of S95032-1 by the Oral (Gavage) Route in the Female CD® (Sprague Dawley) IGS Rat	海外	社内資料	評価
4.2.3.5.2-2	np42429	20360627	Embryo-Fetal Developmental Toxicity Study of S95032-1 by the Oral (Gavage) Route in the Female CD® (Sprague Dawley) IGS Rat	海外	社内資料	評価
4.2.3.5.2-3	np42410	20360618	Dose Range Finding Embryo-Fetal Developmental Toxicity Study of S95032-1 by the Oral (Gavage) Route in the New Zealand White Rabbit	海外	社内資料	評価
4.2.3.5.2-4	np42503	20360619	Embryo-Fetal Developmental Toxicity Study of S95032-1 by the Oral (Gavage) Route in the New Zealand White Rabbit	海外	社内資料	評価

4.2.3.6 局所刺激性試験

第4部（モジュール4）：非臨床試験報告書　添付資料一覧

4.2 試験報告書

4.2.3 毒性試験

該当資料なし

第4部（モジュール4）：非臨床試験報告書　添付資料一覧
4.2 試験報告書
4.2.3 毒性試験
4.2.3.7 その他の毒性試験

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考
4.2.3.7.5-1	np42134	AG-881-N-065	AGI-69460: Bacterial Reverse Mutation Test in Salmonella typhimurium and Escherichia coli	海外	社内資料	評価
4.2.3.7.6-1	np42257	AG881-N-061	[redacted]: Bacterial Reverse Mutation Test in Salmonella typhimurium and Escherichia coli	海外	社内資料	評価
4.2.3.7.6-2	np42258	AG881-N-062	[redacted]: Bacterial Reverse Mutation Test in Salmonella Typhimurium and Escherichia Coli	海外	社内資料	評価
4.2.3.7.7-1	np41984	AG881-N-015-R1	28-Day Ototoxicity Evaluation of AGI-23088 in Male Sprague Dawley Rats with a 2-Week Recovery	海外	社内資料	評価
4.2.3.7.7-2	np41251	AG881-N-060	Neutral Red Uptake Phototoxicity Assay of AG-881 in BALB/c 3T3 Mouse Fibroblasts	海外	社内資料	評価

第4部（モジュール4）：非臨床試験報告書　添付資料一覧
4.3 参考文献

添付資料番号	報告書番号	著者・タイトル・掲載誌
4.3.1	—	Al-Saab F, Manoukian JJ, Al-Sabah B, Almot S, Nguyen LH, et al. Linking larygopharyngeal reflux to otitis media with effusion: pepsinogen study of adenoid tissue and middle ear fluid. Journal of Otolaryngology - Head and Neck Surgery 2008, 37(4), 565-571.
4.3.2	—	Bjornsson TD, Callaghan JT, Einolf HJ, Fischer V, Gan L, Grimm S, et al. The conduct of in vitro and in vivo drug-drug interaction studies: a Pharmaceutical Research and Manufacturers of America (PhRMA) perspective. Drug Metab Dispos. 2003;31(7):815-32.
4.3.3	—	Chuntova P, Yamamichi A, Chen T, et al. Inhibition of D-2HG leads to upregulation of a proinflammatory gene signature in a novel HLA-A2/ HLA-DR1 transgenic mouse model of IDH1R132H-expressing glioma. J Immunother Cancer. 2022;10(5):e004644. [PE0167746]
4.3.4	—	Dang L, White DW, Gross S, Bennett BD, Bittinger MA, Driggers EM, et al. Cancer-associated IDH1 mutations produce 2-hydroxyglutarate. Nature. 2009;462(7274):739-44.
4.3.5	—	FDA. Clinical Drug Interaction Studies — Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions Guidance for Industry, 2020.
4.3.6	—	FDA. Guidance for Industry: Bioanalytical Method Validation. DHHS, 2018.
4.3.7	—	FDA. Guidance for Industry: S9 Nonclinical Evaluation for Anticancer Pharmaceuticals. DHHS, ed. 2010; Pp. 1-12: U.S. Department of Health and Human Services.
4.3.8	—	Hamilton RA, Garnett WR, and Kline BJ. Determination of mean valproic acid serum level by assay of a single pooled sample. Clin Pharmacol Ther. 1981;29(3):408-13.
4.3.9	—	Huang SM, Strong JM, Zhang L, Reynolds KS, Nallani S, Temple R, et al. New era in drug interaction evaluation: US Food and Drug Administration update on CYP enzymes, transporters, and the guidance process. J Clin Pharmacol. 2008;48(6):662-70.
4.3.10	—	Inserm Prevalence and incidence of rare diseases: Bibliographic data, 2022
4.3.11	—	EMA ICH S9: Nonclinical Evaluation for Anticancer Pharmaceuticals, 2009.
4.3.12	—	Koury MJ, Sawyer ST, and Brandt SJ. New insights into erythropoiesis. Curr Opin Hematol. 2002;9(2):93-100. [PE0172164]
4.3.13	—	Mitelman F. International System for Cytogenetic Nomenclature. Guidelines for Cancer Cytogenetics. Supplement to: An International System for Human Cytogenetic Nomenclature. New York: Basel. 1995.
4.3.14	—	Norol F, Vitrat N, Cramer E, Guichard J, Burstein SA, Vainchenker W, et al. Effects of cytokines on platelet production from blood and marrow CD34+ cells. Blood. 1998;91(3):830-43. [PE0162783]
4.3.15	—	Parisi R, Cowen EA, Stoll JR, Zhu H, Dusza S, Pulitzer MP, et al. Dermatologic adverse events associated with IDH inhibitors ivosidenib and enasidenib for the treatment of acute myeloid leukemia. Leuk Res. 2022 Dec;123:106970. doi: 10.1016/j.leukres.2022.106970. Epub 2022 Oct 22.
4.3.16	—	Popovici-Muller J, Saunders JO, Salituro FG, Travins JM, Yan S, et al. Discovery of the first potent inhibitors of mutant IDH1 that lower tumor 2-HG in vivo. ACS Med Chem Lett. 2012;3(10):850-5. [PE0173147]

第4部（モジュール4）：非臨床試験報告書　添付資料一覧
4.3 参考文献

添付資料番号	報告書番号	著者・タイトル・掲載誌
4.3.17	—	Ogilvie BW, Usuki E, Yerino P, and Parkinson A. In vitro approaches for studying the inhibition of drug-metabolizing enzymes responsible for the metabolism of drugs (reaction phenotyping) with emphasis on cytochrome P450. In Drug-Drug Interactions. A.D. Rodrigues, ed. Pp. 231-358. New York, NY: Informa Healthcare, USA. 2008.
4.3.18	—	Rohle D, Popovici-Muller J, Palaskas N, Turcan S, Grommes C, et al. An inhibitor of mutant IDH1 delays growth and promotes differentiation of glioma cells. Science. 2013; 340(6132):626-630. [PE0163596]
4.3.19	—	Rose Parisi, Emily A Cowen, Joseph R Stoll, Haoling Zhu, Stephen Dusza, Melissa P Pulitzer, Eytan M Stein, Alina Markova. Dermatologic adverse events associated with IDH inhibitors ivosidenib and enasidenib for the treatment of acute myeloid leukemia. Leuk Res. 2022 Dec; 123: 106970. doi: 10.1016/j.leukres.2022.106970. Epub 2022 Oct 22.
4.3.20	—	Sasaki M, Knobbe CB, Munger JC, Lind EF, Brenner D, Brustle A, et al. IDH1(R132H) mutation increases murine haematopoietic progenitors and alters epigenetics. Nature. 2012;488(7413):656-659. [PE0162784]
4.3.21	—	医薬品開発における生体試料中薬物濃度分析法のバリデーションに関するガイドライン（薬食審査発0711第1号）、平成25年7月11日
4.3.22	—	医薬品開発と適正な情報提供のための薬物相互作用ガイドライン（薬生薬審発0723 第6号）、平成30 年7 月23 日

第5部（モジュール5）：臨床試験報告書　添付資料一覧

5.2　臨床試験一覧表

添付資料番号	報告書番号	タイトル	評価資料・ 参考資料の別	申請電子データの提出有無
5.2	—	5.2. Tabular Listing of All Clinical Studies	—	—

第5部（モジュール5）：臨床試験報告書　添付資料一覧

5.3　試験報告書及び関連情報

5.3.1　生物薬剤学試験報告書

5.3.1.1　バイオアベイラビリティ（BA）試験報告書

添付資料番号	報告書番号	報告書番号、治験実施計画書番号	タイトル	国内／海外	社内資料／公表論文	評価/参考	申請電子データ提出有無
5.3.1.1-1	np41876	AG881-C-007	A Phase 1, Open-Label Study to Compare the Relative Bioavailability of Two AG-881 Formulations and to Evaluate the Effect of Food and Multiple-Dose Omeprazole on the Pharmacokinetics of a Single Dose of AG-881 in Healthy Adult Subjects (AG881-C-007)	海外	社内資料	参考	有
5.3.1.1-2	np41876	AG881-C-007-BA	Quantitation of AG-881 in Human Plasma via HPLC with MS/MS Detection	海外	社内資料	参考	有

5.3.1.2　比較 BA 試験及び生物学的同等性（BE）試験報告書

該当資料なし

5.3.1.3　*In Vitro-In Vivo* の関連を検討した試験報告書

該当資料なし

5.3.1.4　生物学的及び理化学的分析法検討報告書

添付資料番号	報告書番号	報告書番号、治験実施計画書番号	タイトル	国内／海外	社内資料／公表論文	評価/参考	申請電子データ提出有無
5.3.1.4-1	np42357	AGI0001196-Q-002	Quantitation of 2-HG in Human Brain Tumor Homogenate via LC-MS/MS Detection	海外	社内資料	参考	無
5.3.1.4-2	np42473	AG881-Q-013	Quantitation of AG-881 in Human Urine with Tween 20 via LC-MS/MS Detection	海外	社内資料	参考	無
5.3.1.4-3	np42474	AG881-Q-014	Quantitation of AG-881 and [$^{13}C_3$ $^{15}N_3$] AG-881 in Human Plasma via LC-MS/MS Detection	海外	社内資料	参考	無
5.3.1.4-4	np42475	AG881-Q-015	Quantitation of AG-881 and AGI-69460 in Human Plasma via LC-MS/MS Detection	海外	社内資料	参考	無
5.3.1.4-5	np42479	AIKO2 - EPD P028	Quantitation of 2-Hydroxyglutarate (2-HG) in Human Urine with 10% Tween 20 via HPLC with MS/MS Detection	海外	社内資料	参考	無

第5部（モジュール5）：臨床試験報告書　添付資料一覧
5.3　試験報告書及び関連情報

5.3.1.4-6	np42580	AGX-R3136	Determination of 4β-Hydroxycholesterol and Cholesterol in K_2EDTA Human Plasma by LC/MS/MS	海外	社内資料	参考	無
5.3.1.4-7	np42581	AIOB2 - EPD P031	Quantitation of 2-Hydroxyglutarate (2-HG) in Human Bone Marrow via HPLC with MS/MS Detection	海外	社内資料	参考	無
5.3.1.4-8	np42589	ALBU2 - P1719	Quantitation of Lamotrigine in Human Plasma via HPLC with MS/MS Detection	海外	社内資料	参考	無
5.3.1.4-9	np42590	AG881-Q-008	Quantitation of AG-881 in Human Cerebrospinal Fluid via HPLC with MS/MS Detection	海外	社内資料	参考	無
5.3.1.4-10	np42591	AG881-Q-007	Quantitation of AG-881 in Human Brain Tumor Homogenate via HPLC with MS/MS Detection	海外	社内資料	参考	無
5.3.1.4-11	np42592	AGI0001196-Q-001	Quantitation of 2-HG in Human Plasma via LC-MS/MS Detection	海外	社内資料	参考	無
5.3.1.4-12	np42593	AIKC2 - EPD P024	Quantitation of 2-Hydroxyglutarate (2-HG) in Human Plasma via HPLC with MS/MS Detection	海外	社内資料	参考	無
5.3.1.4-13	np42594	AIOB4 - EPD P029	Quantitation of 2-Hydroxyglutarate (2-HG) in Human Cerebral Spinal Fluid with 10% Tween 20 via HPLC with MS/MS Detection	海外	社内資料	参考	無
5.3.1.4-14	np42595	AIOB3 - EPD P030	Quantitation of 2-Hydroxyglutarate (2-HG) in Human Brain Tumor via HPLC with MS/MS Detection	海外	社内資料	参考	無
5.3.1.4-15	np42596	AG881-Q-006	Quantitation of AG-881 in Human Plasma via HPLC with MS/MS Detection	海外	社内資料	参考	無
5.3.1.4-16	np42619	S-A-BIO-22-344	Validation of an LC-MS/MS method for the determination of Ciprofloxacin in human K_2-EDTA plasma samples	海外	社内資料	参考	無
5.3.1.4-17	np42476	AG881-Q-016	Qualification of a 2-in-1 Method for the Determination of AG-881 and AGI-69460 in Human plasma:phosphate buffer (1:1, v/v) mixed matrix by LC-MS/MS	海外	社内資料	参考	無
5.3.1.4-18	np42943	[redacted]project AOZC	Quantitation of AG-881 in Human Plasma via LC/MS/MS Detection	海外	社内資料	参考	無

第5部（モジュール5）：臨床試験報告書　添付資料一覧
5.3　試験報告書及び関連情報

5.3.1.4-19	np42999	AG881-C-004-PPK-PED-ADDENDUM-01	Quantitation of AG-881 in Human Plasma via LC/MS/MS Detection	海外	社内資料	参考	無

第5部（モジュール5）：臨床試験報告書　添付資料一覧
5.3　試験報告書及び関連情報

5.3.2 ヒト生体試料を用いた薬物動態関連の試験報告書
5.3.2.1　血漿蛋白結合/血球移行試験報告書

添付資料番号	報告書番号	報告書番号、治験実施計画書番号	タイトル	国内／海外	社内資料／公表論文	評価/参考	申請電子データ提出有無
5.3.2.1-1	np41890	AG881-N-037-R1	Plasma protein binding of vorasidenib	海外	社内資料	参考	無
5.3.2.1-2	np41894	AG881-N-067	Plasma protein binding of vorasidenib and metabolite AGI-69460	海外	社内資料	参考	無
5.3.2.1-3	np41893	AG881-N-036-R1	Red blood cell partitioning of vorasidenib	海外	社内資料	参考	無
5.3.2.1-4	np42843	240001_6878	Red blood cell partitioning coefficient determination in human blood and qualification of AGI-69460 in human plasma	海外	社内資料	参考	無
5.3.2.1-5	np42891	240001_6877	Determination of AG-881 response in blood/plasma tests performed in human, mouse, rat, rabbit, dog, and monkey plasma samples	海外	社内資料	参考	無
5.3.2.1-6	np42869	240001_6916	Advanced plasma protein binding in human using 3 concentrations of AG-881 and AGI-69460	海外	社内資料	参考	無
5.3.2.1-7	np42890	240001_6907	Fu determination of AGI-69460 in mouse, rat, rabbit, dog, monkey and human plasma with RED device	海外	社内資料	参考	無
5.3.2.1-8	np42856	S095032_A-R-00006829-DHPB	In vitro protein binding of S095032 and its metabolite AGI-69460 in tumor cell lysate and in culture medium	海外	社内資料	参考	無

第5部（モジュール5）：臨床試験報告書　添付資料一覧
5.3　試験報告書及び関連情報
5.3.2.2　肝代謝及び薬物相互作用試験報告書

添付資料番号	報告書番号	報告書番号、治験実施計画書番号	タイトル	国内／海外	社内資料／公表論文	評価/参考	申請電子データ提出有無
5.3.2.2-1	np41941	AG881-N-038	Metabolic stability of vorasidenib in rat, dog, monkey, and human liver microsomes	海外	社内資料	参考	無
5.3.2.2-2	np41986	AG881-N-001	Vorasidenib metabolism was examined using human liver microsomes and recombinant CYP enzymes	海外	社内資料	参考	無
5.3.2.2-3	np41987	AG881-N-001-R2	Vorasidenib metabolism was examined using human liver microsomes	海外	社内資料	参考	無
5.3.2.2-4	np41944	AG881-N-007	In vitro metabolism of vorasidenib using rat, mouse, dog, monkey, and human hepatocytes	海外	社内資料	参考	無
5.3.2.2-5	np41898	AG881-N-052	In vitro metabolism of [^{14}C]vorasidenib in liver microsomes and hepatocytes derived from rats and humans	海外	社内資料	参考	無
5.3.2.2-6	np41900	AG881-N-064	Identification of the human cytochrome P450 enzyme(s) responsible for the in vitro metabolism of vorasidenib	海外	社内資料	参考	無
5.3.2.2-7	np42349	RB-23-095032-001-DHIZ	Identification of enzymes involved in hepatic metabolism of vorasidenib using human hepatocytes	海外	社内資料	参考	無
5.3.2.2-8	np41964	AG881-N-002	In vitro evaluation of vorasidenib as an inducer of cytochrome P450 expression in cultured human hepatocytes	海外	社内資料	参考	無
5.3.2.2-9	np41965	AG881-N-003	In vitro evaluation of vorasidenib as an autoinducer in cultured human hepatocytes	海外	社内資料	参考	無

第5部（モジュール5）：臨床試験報告書　添付資料一覧
5.3　試験報告書及び関連情報

5.3.2.2-10	np41966	AG881-N-005	In vitro evaluation of vorasidenib as an inhibitor of cytochrome P450 (CYP) enzymes in human liver microsomes	海外	社内資料	参考	無

第5部（モジュール5）：臨床試験報告書　添付資料一覧
5.3　試験報告書及び関連情報

5.3.2.2-11	np41902	AG881-N-059	In vitro evaluation of vorasidenib as an inducer of cytochrome P450 and uridine diphosphate-glucuronosyltransferase enzymes in cultured human hepatocytes	海外	社内資料	参考	無
5.3.2.2-12	np41047	AG881-N-004	In vitro evaluation of vorasidenib as an inhibitor and substrate of human P-gp and BCRP transporters	海外	社内資料	参考	無
5.3.2.2-13	np41904	AG881-N-006	In vitro evaluation of vorasidenib as an inhibitor of UGT1A1 in human liver microsomes	海外	社内資料	参考	無
5.3.2.2-14	np41905	AG881-N-051	In vitro evaluation of vorasidenib as an inhibitor of human ABC (BSEP, MRP2 and MRP3) and SLC (OATP1B1, OATP1B3, OAT1, OAT3 and OCT2) transporters	海外	社内資料	参考	無
5.3.2.2-15	np41906	AG881-N-058	In vitro evaluation of vorasidenib as an inhibitor of MATE-1 and MATE2-K and a substrate of OATP1B1 and OATP1B3	海外	社内資料	参考	無
5.3.2.2-16	np41912	AG881-N-072	Evaluation of AGI-69460 as a potential BCRP substrate, using novobiocin and Ko143 as inhibitor in Caco-2 cell line	海外	社内資料	参考	無
5.3.2.2-17	np41913	AG881-N-073	Evaluation of AGI-69460 as a potential P-glycoprotein in substrate, using verapamil and LY335979 as inhibitor in Caco-2 cell monolayers	海外	社内資料	参考	無
5.3.2.2-18	np41914	AG881-N-074	Evaluation of AGI-69460 as substrate of OATP1B1 and OATP1B3	海外	社内資料	参考	無
5.3.2.2-19	np41915	AG881-N-075	Evaluation of AGI-69460 as inhibitor of OATP1B1 and OATP1B3	海外	社内資料	参考	無
5.3.2.2-20	np42841	S095032_A-R-00006521-DHIN	In vitro evaluation of AGI-69460 as an inducer of the human CYP2A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19 and CYP3A4 metabolic enzymes in hepatocytes	海外	社内資料	参考	無

第5部（モジュール5）：臨床試験報告書　添付資料一覧
5.3　試験報告書及び関連情報

5.3.2.2-21	np42839	S095032_A-R-00006524-DHIZ	In vitro evaluation of AGI-69460 as a substrate of the human CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6 and CYP3A4/5	海外	社内資料	参考	無
5.3.2.2-22	np42813	S095032_A-R-00006525-DHIP	In vitro evaluation of AGI-69460 as an inhibitor of the human CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6 and CYP3A4/5 metabolic enzymes	海外	社内資料	参考	無
5.3.2.2-23	np42812	S095032_A-R-00006522-DHTI	In vitro interaction studies of AGI-69460 with human BCRP and MDR1 efflux (ABC) transporters and with human MATE1, MATE2-K, OAT1, OAT3 and OCT2 uptake transporters	海外	社内資料	参考	無
5.3.2.2-24	np42853	S095032_A-R-00006898-DHTI	In vitro inhibition studies of vorasidenib with human MDR1 efflux (ABC) transporter in Caco-2 cells	海外	社内資料	参考	無

第5部（モジュール5）：臨床試験報告書　添付資料一覧
5.3　試験報告書及び関連情報

5.3.2.3　他のヒト生体試料を用いた試験報告書

添付資料番号	報告書番号	報告書番号、治験実施計画書番号	タイトル	国内／海外	社内資料／公表論文	評価/参考	申請電子データ提出有無
5.3.2.3-1	np41903	AG881-N-048-R1	In vitro evaluation of bidirectional permeability of vorasidenib across Caco-2 cells	海外	社内資料	参考	無
5.3.2.3-2	np42279	PB-22-095032-007-DHAB / 22SERVP2	Assessment of uni- and bi-directional permeability in Caco-2 cells and stability in simulated gastrointestinal fluids	海外	社内資料	参考	無
5.3.2.3-3	np41865	AG881-N-068	Inhibition of 2-HG production by AG-881 and its metabolite AGI-69460 in two cell lines containing IDH1 mutations	海外	社内資料	参考	無

第5部（モジュール5）：臨床試験報告書　添付資料一覧

5.3　試験報告書及び関連情報

5.3.3　臨床薬物動態(PK)試験報告書

5.3.3.1　健康被験者における PK 及び初期忍容性試験報告書

添付資料番号	報告書番号	報告書番号、治験実施計画書番号	タイトル	国内／海外	社内資料／公表論文	評価/参考	申請電子データ提出有無
5.3.3.1-1	np41892	AG881-C-005	A Phase I, Open-label Study to Evaluate the Absorption, Distribution, Metabolism, and Excretion, and to Assess the Absolute Bioavailability of AG-881 in Healthy Male Subjects Following Administration of a Single Oral Dose of [^{14}C]AG-881 and Concomitant Intravenous Microdose of [$^{13}C_3$ $^{15}N_3$] AG-881	海外	社内資料	参考	無
5.3.3.1-2	np41892	AG881-C-005-BA-Plasma	Quantitation of AG-881 and [$^{13}C_3$ $^{15}N_3$] AG-881 in Human Plasma via LC-MS/MS Detection	海外	社内資料	参考	無
5.3.3.1-3	np41892	AG881-C-005-BA-Urine	Quantitation of AG-881 in Human Urine via LC-MS/MS Detection	海外	社内資料	参考	無
5.3.3.1-4	np41892	AG881-C-005-MB	Radioanalysis in Support of Clinical Protocol AG881-C-005	海外	社内資料	参考	無
5.3.3.1-5	np41892	AG881-C-005-METID	Metabolite Profiling and Identification in Support of AG881-C-005	海外	社内資料	参考	無
5.3.3.1-6	np41892	AG881-C-005-RA	Determination of concentrations of radioactivity in plasma and whole blood samples derived from humans administered an oral dose of ^{14}C-AG-881(~100μCi / 50 mg)	海外	社内資料	参考	無

5.3.3.2　患者における PK 及び初期忍容性試験報告書

添付資料番号	報告書番号	報告書番号、治験実施計画書番号	タイトル	国内／海外	社内資料／公表論文	評価/参考	申請電子データ提出有無
5.3.3.2-1	np42428	AG120-881-C-001	A Phase 1, Multicenter, Randomized, Controlled, Open-label, Perioperative Study of AG-120 and AG-881 in Subjects with Recurrent, Non-enhancing, IDH1 Mutant, Low-grade Glioma	海外	社内資料	評価	有

第5部（モジュール5）：臨床試験報告書　添付資料一覧
5.3　試験報告書及び関連情報

5.3.3.2-2	np42428	2-HG-AG120-881-C-001-BA-CSF 2-HG-AG120-881-C-001-BA-Plasma AG120-881-C-001-BA-CSF-AG-120 AG120-881-C-001-BA-CSF-AG-881 AG120-881-C-001-BA-Brain Tumor-AG-120 AG120-881-C-001-BA-Brain Tumor-AG-881 AG120-881-C-001-BA-Plasma-AG-120 AG120-881-C-001-BA-Plasma-AG-881 2-HG-AG120-881-C-001-BA-Tumor AG120-881-C-001 – Translational Biomarker	Quantitation of 2-Hydroxyglutarate (2-HG) in Human Cerebrospinal Fluid with 10% Tween 20 via HPLC with MS/MS Detection Quantitation of 2-Hydroxyglutarate (2-HG) in Human Plasma via HPLC with MS/MS Detection Quantitation of AG-120 in Human Cerebrospinal Fluid with 10% Tween 20 via HPLC with MS/MS Detection Quantitation of AG-881 in Human Cerebrospinal Fluid with 10% Tween 20 via HPLC with MS/MS Detection Quantitation of AG-120 in Human Brain Tumor via HPLC with MS/MS Detection Quantitation of AG-881 in Human Brain Tumor via HPLC with MS/MS Detection Quantitation of AG-120 in Human Plasma via HPLC with MS/MS Detection Quantitation of AG-881 in Human Plasma via HPLC with MS/MS Detection Quantitation of 2-Hydroxyglutarate (2-HG) in Human Brain Tumor via HPLC with MS/MS Detection Exploratory Translational Biomarker Report PK and PK/PD Analysis Plan PK and PK/PD Report	海外	社内資料	参考	無
5.3.3.2-3	np42430	AG881-C-002	A Phase 1, Multicenter, Open-Label, Dose Escalation and Expansion, Safety, Pharmacokinetic, Pharmacodynamic, and Clinical Activity Study of Orally Administered AG-881 in Patients with Advanced Solid Tumors, Including Gliomas, with an IDH1 and/or IDH2 Mutation	海外	社内資料	参考	無
5.3.3.2-4	np42430	2-HG-AG881-C-002-BA-CSF 2-HG-AG881-C-002-BA-Brain tumor AG881-C-002-BA-Plasma 2-HG-AG881-C-002-BA-Plasma 2-HG-AG881-C-002-BA-Urine	Quantitation of 2-Hydroxyglutarate (2-HG) in Human CSF via HPLC with MS/MS Detection Quantitation of 2-Hydroxyglutarate (2-HG) in Human Brain Tumor via HPLC with MS/MS Detection Quantitation of AG-881 in Human Plasma via HPLC with MS/MS Detection Quantitation of 2-Hydroxyglutarate (2-HG) in Human Plasma via HPLC with MS/MS Detection Quantitation of 2-Hydroxyglutarate (2-HG) in Human Urine via HPLC with MS/MS Detection	海外	社内資料	参考	無

第5部（モジュール5）：臨床試験報告書　添付資料一覧

5.3　試験報告書及び関連情報

5.3.3.2-5	np42600	AG881-C-002-PKPD	Pharmacokinetic, Pharmacodynamic and PK/PD Analysis of AG-881 Administered Orally in Patients with Non-Glioma Tumors, and/or in Patients with Glioma, that Harbor an IDH1 and/or IDH2 Mutation	海外	社内資料	参考	有
5.3.3.2-6	np42834	AG881-C-002-PK-Addendum	Pharmacokinetic Analysis of Metabolite AGI-69460 when AG-881 was Administered Orally in Patients with Non-Glioma Tumors, and/or in Patients with Glioma, that Harbor an IDH1 and/or IDH2 Mutatio	海外	社内資料	参考	無

5.3.3.3　内因性要因を検討した PK 試験報告書

添付資料番号	報告書番号	報告書番号、治験実施計画書番号	タイトル	国内／海外	社内資料／公表論文	評価/参考	申請電子データ提出有無
5.3.3.3-1	np412878	AG881-C-008	A Phase 1, Open-label, Single Ascending Dose Study to Evaluate AG-881 in Healthy Japanese and Non-Asian Subjects	海外	社内資料	評価	無
5.3.3.3-2	np41878	AG881-C-008-BA	Quantitation of AG-881 in Human Plasma via HPLC with MS/MS Detection	海外	社内資料	参考	無
5.3.3.3-3	np42432	PKH-95032-008	A Phase 1, Open-Label, Single-Dose Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of a 20-mg Dose of Vorasidenib in Subjects with Moderate or Mild Hepatic Impairment and Matched Subjects with Normal Hepatic Function	海外	社内資料	参考	有
5.3.3.3-4	np42476	AG881-Q-016	Qualification of a 2-in-1 Method for the Determination of AG-881 and AGI-69460 in Human plasma:phosphate buffer (1:1, v/v) mixed matrix by LC-MS/MS	海外	社内資料	参考	無
5.3.3.3-5	np42432	PKH-095032-008-BA-Plasma	Quantitation of AG-881 and AGI-69460 in Human Plasma via LC-MS/MS Detection	海外	社内資料	参考	無
5.3.3.3-6	np42432	PKH-095032-008-PB-Plasma	Ex Vivo Protein Binding Determination of AG-881 and AGI-69460 in Human Plasma Samples from Clinical Protocol No. PKH-95032-008	海外	社内資料	参考	無
5.3.3.3-7	np42432	SEVR0012 - [redacted]620-22 MCL:	CYP1A2 genotype of patients from PKH PKH-95032-008	海外	社内資料	参考	無

第5部（モジュール5）：臨床試験報告書　添付資料一覧

5.3　試験報告書及び関連情報

5.3.3.4　外因性要因を検討した PK 試験報告書

添付資料番号	報告書番号	報告書番号、治験実施計画書番号	タイトル	国内／海外	社内資料／公表論文	評価/参考	申請電子データ提出有無
5.3.3.4-1	np41875	AG881-C-006	A Phase 1, Open-label Study to Evaluate the Effect of AG-881 on the Pharmacokinetics of a Single Dose of Lamotrigine in Healthy Adult Subjects	海外	社内資料	参考	有
5.3.3.4-2	np41875	AG881-C-006-BA	Quantitation of AG-881 in Human Plasma via HPLC with MS/MS Detection	海外	社内資料	参考	無
5.3.3.4-3	np41875	Cholesterol and 4β-Hydroxycholesterol-AG88 l-C-006-BA-Plasma	LC-MS/MS Determination of Cholesterol and 4P-Hydroxycholesterol in Human Plasma Samples Originating from Agios Pharmaceuticals Clinical Trial AG881-C-006: "A Phase 1, Open-label Study to Evaluate the Effect of AG-881 on the Pharmacokinetics of a Single Dose of Lamotrigine in Healthy Adult Subjects"	海外	社内資料	参考	無
5.3.3.4-4	np41875	Lamotrigine-AG881-C-006-BA	Quantitation of Lamotrigine in Human Plasma via HPLC with MS/MS Detection	海外	社内資料	参考	無
5.3.3.4-5	np42433	PKH-95032-009	A Phase 1, Open-Label Study to Evaluate the Effect of a Low-Fat Meal and Multiple Doses of Ciprofloxacin on the Pharmacokinetics of Vorasidenib in Healthy Subjects	海外	社内資料	参考	無
5.3.3.4-6	np42433	Ciprofloxacin-PKH-095032-009-BA-Plasma	Determination of Ciprofloxacin in human K2-EDTA plasma samples from the clinical study PKH-95032-009 by LC-MS/MS	海外	社内資料	参考	無
5.3.3.4-7	np42433	PKH-095032-009-BA-Plasma	Quantitation of AG-881 and AGI-69460 in Human Plasma via LC/MS/MS Detection	海外	社内資料	参考	無

5.3.3.5　ポピュレーション PK 試験報告書

添付資料番号	報告書番号	報告書番号、治験実施計画書番号	タイトル	国内／海外	社内資料／公表論文	評価/参考	申請電子データ提出有無
5.3.3.5-1	np42597	AG881-C-004-ER	Exposure-Response Analysis of Vorasidenib (AG-881)in Subjects with Residual or Reccurent Grade 2 Glioma with an IDH1 or IDH2 Mutation	海外	社内資料	評価	有
5.3.3.5-2	np42598	AG881-C-004-PPK	Population PK Analysis of Vorasidenib (AG-881) in Subjects with Residual or Recurrent Grade 2 Glioma with an IDH1 or IDH2 Mutation	海外	社内資料	参考	有

第5部（モジュール5）：臨床試験報告書　添付資料一覧
5.3　試験報告書及び関連情報

5.3.3.5-3	np42946	AG881-C-004-PPK-ADO	Vorasidenib PK Predictions Supporting the Dose Selection in the Adolescent (12 to <18 years) Patient Population	海外	社内資料	参考	有
5.3.3.5-4	np43001	AG881-C-004-PPK-JAPAN	Population PK Analysis of Vorasidenib (AG-881) in Subjects with Residual or Recurrent Grade 2 Glioma with an IDH1 or IDH2 Mutation in Support of PMDA Filing	海外	社内資料	参考	有
5.3.3.5-5	np42601	AG881-C-004-PK	Pharmacokinetic Analysis of AG-881 Administered Orally in Patients With Residual or Recurrent Grade 2 Glioma With an IDH1 or IDH2 Mutation	海外	社内資料	参考	有

第5部（モジュール5）：臨床試験報告書　添付資料一覧

5.3　試験報告書及び関連情報

5.3.4　臨床薬力学(PD)試験報告書

5.3.4.1　健康被験者における PD 試験及び PK/PD 試験報告書

該当資料なし

5.3.4.2　患者における PD 試験及び PK/PD 試験報告書

添付資料番号	報告書番号	報告書番号、治験実施計画書番号	タイトル	国内／海外	社内資料／公表論文	評価/参考	申請電子データ提出有無
5.3.4.2-1	np43067	AG881-C-001-ER	Exposure-Response Analysis of Vorasidenib (AG-881) in Subjects with Residual or Recurrent Grade 2 Glioma with an IDH1 or IDH2 Mutation	海外	社内資料	参考	無

5.3.5　有効性及び安全性試験報告書

5.3.5.1　申請する適応症に関する比較対照試験報告書

添付資料番号	報告書番号	報告書番号、治験実施計画書番号	タイトル	国内／海外	社内資料／公表論文	評価/参考	申請電子データ提出有無
5.3.5.1-1	np42431	AG881-C-004	A Phase 3, Multicenter, Randomized, Double-blind, Placebo-Controlled Study of AG-881 in Subjects with Residual or Recurrent Grade 2 Glioma With an IDH1 or IDH2 Mutation	海外（日本を含む国際共同）	社内資料	評価	有
5.3.5.1-2	np42431	AG-881-C-004-BA-Plasma	Quantitation of AG-881 and AGI-69460 in Human Plasma via LC/MS/MS Detection	海外（日本を含む国際共同）	社内資料	参考	無
5.3.5.1-3	np42431	AG881-C-004	A Phase 3, Multicenter, Randomized, Double-blind, Placebo-Controlled Study of AG-881 in Subjects with Residual or Recurrent Grade 2 Glioma With an IDH1 or IDH2 Mutation Japan addenudum	海外（日本を含む国際共同）	社内資料	評価	有

5.3.5.2　非対照試験報告書

添付資料番号	報告書番号	報告書番号、治験実施計画書番号	タイトル	国内／海外	社内資料／公表論文	評価/参考	申請電子データ提出有無
5.3.5.2-1	np41873	AG881-C-001	A Phase 1, Multicenter, Open-Label, Dose-Escalation Safety, Pharmacokinetic, Pharmacodynamic, and Clinical Activity Study of Orally Administered AG-881 in Patients with Advanced Hematologic Malignancies with an IDH1 and/or IDH2 Mutation	海外	社内資料	参考	有
5.3.5.2-2	np41873	2-HG-AG881-C-001-BA-Plasma	Quantitation of 2-Hydroxyglutarate (2-HG) in Human Plasma via HPLC with MS/MS Detection in Support of AG881-C-001	海外	社内資料	参考	

第5部（モジュール5）：臨床試験報告書　添付資料一覧
5.3　試験報告書及び関連情報

5.3.5.2-3	np41873	2-HG-AG881-C-001-BA-Urine	Quantitation of 2-Hydroxyglutarate (2-HG) in Human Urine with 10% Tween 20 via HPLC with MS/MS Detection in Support of AG881-C-001	海外	社内資料	参考	
5.3.5.2-4	np41873	2-HG-AG881-C-001-Bone Marrow	Quantitation of 2-Hydroxyglutarate (2-HG) in Human Bone Marrow via HPLC with MS/MS Detection in Support of AG881-C-001	海外	社内資料	参考	
5.3.5.2-5	np41873	AG881-C-001-BA	Quantitation of AG-881 in Human Plasma via HPLC with MS/MS Detection in Support of Protocol No. AG881-C-001	海外	社内資料	参考	
5.3.5.2-6	np41873	Cholesterol and 4β-Hydroxycholesterol-AG881-C-001-BA-Plasma	LC-MS/MS Determination of Cholesterol and 4β-Hydroxycholesterol in Human Plasma Samples Originating from Agios Pharmaceuticals Clinical Trial AG881-C-001: "A Phase 1, Multicenter, Open-Label, Dose-Escalation, Safety, Pharmacokinetic, Pharmacodynamic, and Clinical Activity Study of Orally Administered AG-881 in Patients with Advanced Hematologic Malignancies with an IDHl and/or IDH2 Mutation"	海外	社内資料	参考	
5.3.5.2-7	np41873	AG881-C-001-PKPD	A Phase 1, Multicenter, Open-Label, Dose-Escalation, Safety, Pharmacokinetic, Pharmacodynamic, and Clinical Activity Study of Orally Administered AG-881 in Patients with Advanced Hematologic Malignancies with an IDH1 and/or IDH2 Mutation	海外	社内資料	参考	

第5部（モジュール5）：臨床試験報告書　添付資料一覧

5.3　試験報告書及び関連情報

5.3.5.3　複数の試験成績を併せて解析した報告書

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考	申請電子データ提出有無
5.3.5.3-1	np42170	AG881-C-META-CQT	Modeling the Relationship Between Vorasidinib (AG-881) Plasma Concentration and Electrocardiogram QTc in Cancer Patients	海外	社内資料	参考	有
5.3.5.3-2	np42602-1	—	STATISTICAL ANALYSIS PLAN (SAP) Summary of Clinical Safety/Integrated Summary of Safety for Subjects with Residual or Recurrent Grade 2 Glioma with an IDH1 or IDH2 Mutation	海外	社内資料	参考	無
5.3.5.3-3	np42602-2	—	INTEGRATED SUMMARY OF SAFETY	海外	社内資料	参考	無
5.3.5.3-4	np42602-3	—	INTEGRATED SUMMARY OF SAFETY Listings, narratives	海外	社内資料	参考	無
5.3.5.3-5	np42603	—	INTEGRATED SUMMARY OF EFFICACY	海外	社内資料	参考	無

5.3.5.4　その他の臨床試験報告書

添付資料番号	報告書番号		タイトル	国内／海外	社内資料／公表論文	評価/参考	申請電子データ提出有無
5.3.5.4-1	np42585	RB-23-095032-014-DHM	Assessment of AGI-69460 Contribution to Target Engagement in Glioma Patient Population with IDH1 Mutation	海外	社内資料	参考	無
5.3.5.4-2	np42612	[redacted]	[redacted]	海外	社内資料	参考	無
5.3.5.4-3	np42612			海外	社内資料	参考	無
5.3.5.4-4	np42613	—		海外	社内資料	参考	無
5.3.5.4-5	np42615	AG881-C-META-PBPK	Development of A PBPK Modeling for Vorasidenib with the Simcyp Population-Based Simulator and Subsequesnt Evaluation of DDI Liability	海外	社内資料	参考	有

5.3.6　市販後の使用経験に関する報告書

該当資料なし

第5部（モジュール5）：臨床試験報告書　添付資料一覧
5.3　試験報告書及び関連情報
5.3.7　患者データー覧表及び症例記録
該当資料なし

第5部（モジュール5）：臨床試験報告書　添付資料一覧

5.4 参考文献

5.4.1 「2.5　臨床に関する概括評価」で引用した参考文献

添付資料番号	報告書番号	著者・タイトル・掲載誌
5.4.1-1	—	Bell EH, Zhang P, Shaw EG, et al. Comprehensive Genomic Analysis in NRG Oncology/RTOG 9802: A Phase III Trial of Radiation Versus Radiation Plus Procarbazine, Lomustine (CCNU), and Vincristine in High-Risk Low-Grade Glioma. J Clin Oncol. 2020;38(29):3407-3417 [PE0173506] doi:10.1200/JCO.19.02983
5.4.1-2	—	Buckner JC, Shaw EG, Pugh SL, et al. Radiation plus Procarbazine, CCNU, and Vincristine in Low-Grade Glioma. N Engl J Med. 2016;374(14):1344-1355 [PE0168779] doi:10.1056/NEJMoa1500925
5.4.1-3	—	Bunse L, Pusch S, Bunse T, et al. Suppression of antitumor T cell immunity by the oncometabolite (R)-2-hydroxyglutarate. Nature Medicine. 2018;24(8):1192-1203 [PE0174734]. doi:10.1038/s41591-018-0095-6
5.4.1-4	—	Cairncross G, Wang M, Shaw E, et al. Phase III trial of chemoradiotherapy for anaplastic oligodendroglioma: long-term results of RTOG 9402. J Clin Oncol. 2013;31(3):337-343 [PE0168444]. doi:10.1200/JCO.2012.43.2674
5.4.1-5	—	Cancer Genome Atlas Research Network. Comprehensive, Integrative Genomic Analysis of Diffuse Lower-Grade Gliomas. N Engl J Med. 2015;372(26):2481-2498 [PE0119525]. doi:10.1056/NEJMoa1402121
5.4.1-6	—	Claus EB, Walsh KM, Wiencke JK, et al. Survival and low-grade glioma: the emergence of genetic information. Neurosurg Focus. 2015;38(1):E6 [PE0166318] doi:10.3171/2014.10.FOCUS12367
5.4.1-7	—	Cohen AL, Holmen SL, Colman H. IDH1 and IDH2 mutations in gliomas. Curr Neurol Neurosci Rep. 2013;13(5):345 [PE0162912]. doi:10.1007/s11910-013-0345-4
5.4.1-8	—	Crocetti E, Trama A, Stiller C, et al. Epidemiology of glial and non-glial brain tumours in Europe. Eur J Cancer. 2012;48(10):1532-1542 [PE0167382]. doi:10.1016/j.ejca.2011.12.013
5.4.1-9	—	Dang L, White DW, Gross S, et al. Cancer-associated IDH1 mutations produce 2-hydroxyglutarate. Nature. 2009;462(7274):739-744 [PE0162691]. doi:10.1038/nature08617
5.4.1-10	—	Dietrich J, Wen PY. Clinical presentation, diagnosis, and initial surgical management of high-grade gliomas. UpToDate; Uptodate: Waltham, MA, USA. 2022 [PE0169833].
5.4.1-11	—	EMA Points to consider on application with 1. meta-analyses; 2. one pivotal study. CPMP/EWP/2330/99 2001 [PE0043787]
5.4.1-12	—	EMA Guideline on the investigation of drug interactions. CPMP/EWP/560/95/Rev. 1 Corr. 2European Medicines Agency 2012 [PE0078267]
5.4.1-13	—	FDA. Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products - Content and Format. 2018:[PE0148396]
5.4.1-14	—	FDA Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials. 2019 [PE0152830]
5.4.1-15	—	FDA Drug-Drug Interaction Assessment for Therapeutic Proteins Guidance for Industry. 2020 [PE0158972]
5.4.1-16	—	Hartmann C, Meyer J, Balss J, et al. Type and frequency of IDH1 and IDH2 mutations are related to astrocytic and oligodendroglial differentiation and age: a study of 1,010 diffuse gliomas. Acta Neuropathol. 2009;118(4):469-474 [PE0171415]. doi:10.1007/s00401-009-0561-9
5.4.1-17	—	Huang FL, Liao EC, Li CL, Yen CY, Yu SJ. Pathogenesis of pediatric B-cell acute lymphoblastic leukemia: Molecular pathways and disease treatments. Oncol Lett. 2020;20(1):448-454 [PE0174735]. doi:10.3892/ol.2020.11583

第5部（モジュール5）：臨床試験報告書　添付資料一覧

5.4 参考文献

5.4.1-18	—	Instituto Tumori. RARECARENet Fact Sheets: Tumours of central nervous system: Tumours of central nervous system (CNS), Embryonal tumors of central nervous system (CNS). In.
5.4.1-19	—	Iwadate Y, Matsutani T, Shinozaki N, Saeki N. Anaplastic oligodendroglial tumors harboring 1p/19q deletion can be successfully treated without radiotherapy. Anticancer Res. 2011;31(12):4475-4479.

第5部（モジュール5）：臨床試験報告書　添付資料一覧
5.4 参考文献

5.4.1-20	—	Iwamoto F, Polley M-Y, Shaw E, et al. CTNI-16. NRG-RTOG 9802 OBSERVATION ARM - LONG TERM RESULT. Neuro-Oncology. 2022;24:vii73-vii73 [PE0174646]. doi:10.1093/neuonc/noac209.282
5.4.1-21	—	Janda M, Steginga S, Langbecker D, Dunn J, Walker D, Eakin E. Quality of life among patients with a brain tumor and their carers. J Psychosom Res. 2007;63(6):617-623. doi:10.1016/j.jpsychores.2007.06.018
5.4.1-22	—	The Japan Neurological Society and The Japanese Society of Pathology. General Rules for Clinical and Pathological Studies on Brain Tumors. (The 5th Edition) 2023.
5.4.1-23	—	Points to Consider for the Instructions for Package Inserts of Prescription Drugs PSEHB/SD Notification No.0608-1. In:2023.
5.4.1-24	—	Johnson DR, Giannini C, Vaubel RA, et al. A Radiologist's Guide to the 2021 WHO Central Nervous System Tumor Classification: Part I—Key Concepts and the Spectrum of Diffuse Gliomas. Radiology. 2022;304(3):494-508 [PE0173398] doi:10.1148/radiol.213063
5.4.1-25	—	Klein M. Health-related quality of life aspects in patients with low-grade glioma. Adv Tech Stand Neurosurg. 2010;35:213-235 [PE0173253]. doi:10.1007/978-3-211-99481-8_8
5.4.1-26	—	Komori T. The 2016 WHO Classification of Tumours of the Central Nervous System: The Major Points of Revision. Neurol Med Chir (Tokyo). 2017;57(7):301-311 [PE0174736]. doi:10.2176/nmc.ra.2017-0010
5.4.1-27	—	Lassman AB, Hoang-Xuan K, Polley MC, et al. Joint Final Report of EORTC 26951 and RTOG 9402: Phase III Trials With Procarbazine, Lomustine, and Vincristine Chemotherapy for Anaplastic Oligodendroglial Tumors. J Clin Oncol. 2022;40(23):2539-2545 [PE0169508] doi:10.1200/JCO.21.02543
5.4.1-28	—	Leu K, Ott GA, Lai A, et al. Perfusion and diffusion MRI signatures in histologic and genetic subtypes of WHO grade II-III diffuse gliomas. J Neurooncol. 2017;134(1):177-188 [PE0173505] doi:10.1007/s11060-017-2506-9
5.4.1-29	—	Liu V, Wetzel EA, Eldred BSC, et al. A single-institution retrospective analysis of pathologically determined malignant transformation in IDH mutant glioma patients. Neurooncol Adv. 2023;5(1):vdad036. doi:10.1093/noajnl/vdad036
5.4.1-30	—	Liu Y, Chen H, Li G, et al. Radiotherapy delays malignant transformation and prolongs survival in patients with IDH-mutant gliomas. Cancer Biol Med. 2022;19(10):1477-1486. doi:10.20892/j.issn.2095-3941.2022.0472
5.4.1-31	—	Louis DN, Perry A, Wesseling P, et al. The 2021 WHO Classification of Tumors of the Central Nervous System: a summary. Neuro Oncol. 2021;23(8):1231-1251 [PE0168762]. doi:10.1093/neuonc/noab106
5.4.1-32	—	Louis DN, Wesseling P, Aldape K, et al. cIMPACT-NOW update 6: new entity and diagnostic principle recommendations of the cIMPACT-Utrecht meeting on future CNS tumor classification and grading. Brain Pathol. 2020;30(4):844-856 [PE0173301] doi:10.1111/bpa.12832
5.4.1-33	—	Malta TM, Sabedot TS, Morosini NS, et al. The Epigenetic Evolution of Glioma Is Determined by the IDH1 Mutation Status and Treatment Regimen. Cancer Res. 2024;84(5):741-756. doi:10.1158/0008-5472.Can-23-2093
5.4.1-34	—	McAleer MF, Brown PD. Neurocognitive Function Following Therapy for Low-Grade Gliomas. Semin Radiat Oncol. 2015;25(3):210-218 [PE0168218]. doi:10.1016/j.semradonc.2015.02.005
5.4.1-35	—	Mellinghoff IK, Ellingson BM, Touat M, et al. Ivosidenib in Isocitrate Dehydrogenase 1-Mutated Advanced Glioma. J Clin Oncol. 2020;38(29):3398-3406 [PE0167777] doi:10.1200/JCO.19.03327
5.4.1-36	—	Mellinghoff IK, Lu M, Wen PY, et al. Vorasidenib and ivosidenib in IDH1-mutant low-grade glioma: a randomized, perioperative phase 1 trial. Nat Med. 2023;29(3):615-622 [PE0171526] doi:10.1038/s41591-022-02141-2
5.4.1-37	—	Mellinghoff IK, Penas-Prado M, Peters KB, et al. Vorasidenib, a Dual Inhibitor of Mutant IDH1/2, in Recurrent or Progressive Glioma; Results of a First-in-Human Phase I Trial. Clin Cancer Res. 2021;27(16):4491-4499 [PE0163216]. doi:10.1158/1078-0432.CCR-21-0611
5.4.1-38	—	Momper JD, Mulugeta Y, Green DJ, et al. Adolescent dosing and labeling since the Food and Drug Administration Amendments Act of 2007. JAMA Pediatr. 2013;167(10):926-932 [PE0092503]. doi:10.1001/jamapediatrics.2013.465
5.4.1-39	—	Murphy ES, Leyrer CM, Parsons M, et al. Risk Factors for Malignant Transformation of Low-Grade Glioma. Int J Radiat Oncol Biol Phys. 2018;100(4):965-971. doi:10.1016/j.ijrobp.2017.12.258

第5部（モジュール5）：臨床試験報告書　添付資料一覧

5.4 参考文献

5.4.1-40	—	National Brain Tumor Society. Brain Tumor Facts. 2022 Accessed 06 September 2023
5.4.1-41	—	NCCN. National Comprehensive Cancer Network. Acute Myelogenous Leukemia. 2021
5.4.1-42	—	NCCN. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) on Central Nervous System Cancers (Version 1.2022). 2022 [PE0168780].
5.4.1-43	—	NCCN. Clinical Practice Guidelines in Oncology (NCCN Guidelines®):Myelodysplastic Syndromes. 2023 [PE0172710].
5.4.1-44	—	Olar A, Wani KM, Alfaro-Munoz KD, et al. IDH mutation status and role of WHO grade and mitotic index in overall survival in grade II-III diffuse gliomas. Acta Neuropathol. 2015;129(4):585-596 [PE0173303] doi:10.1007/s00401-015-1398-z
5.4.1-45	—	Orphanet. Prevalence and incidence of rare diseases: Bibliographic data Prevalence, incidence or number of published cases listed by diseases (in alphabetical order). In:2022:[PE0167958].

第5部（モジュール5）：臨床試験報告書　添付資料一覧
5.4 参考文献

5.4.1-46	—	Ostrom QT, Price M, Neff C, et al. CBTRUS Statistical Report: Primary Brain and Other Central Nervous System Tumors Diagnosed in the United States in 2015-2019. Neuro Oncol. 2022;24(Suppl 5):v1-v95 [PE0171842]. doi:10.1093/neuonc/noac202
5.4.1-47	—	Packer RJ, Pfister S, Bouffet E, et al. Pediatric low-grade gliomas: implications of the biologic era. Neuro Oncol. 2017;19(6):750-761 [PE0173313]. doi:10.1093/neuonc/now209
5.4.1-48	—	Pearman T, Yanez B, Peipert J, Wortman K, Beaumont J, Cella D. Ambulatory cancer and US general population reference values and cutoff scores for the functional assessment of cancer therapy. Cancer. 2014;120(18):2902-2909. doi:10.1002/cncr.28758
5.4.1-49	—	Raman F, Mullen A, Byrd M, et al. Evaluation of RANO Criteria for the Assessment of Tumor Progression for Lower-Grade Gliomas. Cancers. 2023;15:3274 [PE0174737]. doi:10.3390/cancers15133274
5.4.1-50	—	Ryall S, Tabori U, Hawkins C. A comprehensive review of paediatric low-grade diffuse glioma: pathology, molecular genetics and treatment. Brain Tumor Pathol. 2017;34(2):51-61 [PE0173314]. doi:10.1007/s10014-017-0282-z
5.4.1-51	—	Sasaki H, Hirose Y, Yazaki T, et al. Upfront chemotherapy and subsequent resection for molecularly defined gliomas. J Neurooncol. 2015;124(1):127-135. doi:10.1007/s11060-015-1817-y
5.4.1-52	—	Sturm D, Pfister SM, Jones DTW. Pediatric gliomas: current concepts on diagnosis, biology, and clinical management. J Clin Oncol. 2017;35(21):2370-2377 [PE0167884]. doi:10.1200/jco.2017.73.0242
5.4.1-53	—	Suchorska B, Schüller U, Biczok A, et al. Contrast enhancement is a prognostic factor in IDH1/2 mutant, but not in wild-type WHO grade II/III glioma as confirmed by machine learning. Eur J Cancer. 2019;107:15-27 [PE0173310] doi:10.1016/j.ejca.2018.10.019
5.4.1-54	—	Suzuki H, Aoki K, Chiba K, et al. Mutational landscape and clonal architecture in grade II and III gliomas. Nat Genet. 2015;47(5):458-468 [PE0173302] doi:10.1038/ng.3273
5.4.1-55	—	Tom MC, Park DYJ, Yang K, et al. Malignant Transformation of Molecularly Classified Adult Low-Grade Glioma. Int J Radiat Oncol Biol Phys. 2019;105(5):1106-1112. doi:10.1016/j.ijrobp.2019.08.025
5.4.1-56	—	Touat M, Li YY, Boynton AN, et al. Mechanisms and therapeutic implications of hypermutation in gliomas. Nature. 2020;580(7804):517-523 [PE0173504] doi:10.1038/s41586-020-2209-9
5.4.1-57	—	Turcan S, Rohle D, Goenka A, et al. IDH1 mutation is sufficient to establish the glioma hypermethylator phenotype. Nature. 2012;483(7390):479-483 [PE0163021]. doi:10.1038/nature10866
5.4.1-58	—	van den Bent M, Brandes AA, Taphoorn MJ, et al. Adjuvant procarbazine, lomustine, and vincristine chemotherapy in newly diagnosed anaplastic oligodendroglioma: long-term follow-up of EORTC brain tumor group study 26951. J Clin Oncol. 2013;31(3):344-350 [PE0167943]. doi:10.1200/JCO.2012.43.2229
5.4.1-59	—	van den Bent MJ, Afra D, de Witte O, et al. Long-term efficacy of early versus delayed radiotherapy for low-grade astrocytoma and oligodendroglioma in adults: the EORTC 22845 randomised trial. Lancet. 2005;366(9490):985-990 [PE0168777]. doi:10.1016/S0140-6736(05)67070-5
5.4.1-60	—	van den Bent MJ, Loeffler JS. Treatment and prognosis of IDH-mutant, 1p/19q-codeleted oligodendrogliomas in adults. UpToDate; Uptodate: Waltham, MA, USA. 2022 [PE0169837].
5.4.1-61	—	van den Bent MJ, Tesileanu CMS, Wick W, et al. Adjuvant and concurrent temozolomide for 1p/19q non-co-deleted anaplastic glioma (CATNON; EORTC study 26053-22054): second interim analysis of a randomised, open-label, phase 3 study. Lancet Oncol. 2021;22(6):813-823 [PE0168763]. doi:10.1016/S1470-2045(21)00090-5
5.4.1-62	—	van den Bent MJ, Wefel JS, Schiff D, et al. Response assessment in neuro-oncology (a report of the RANO group): assessment of outcome in trials of diffuse low-grade gliomas. Lancet Oncol. 2011;12(6):583-593 [PE0163017]. doi:10.1016/S1470-2045(11)70057-2
5.4.1-63	—	van Lent DI, van Baarsen KM, Snijders TJ, Robe P. Radiological differences between subtypes of WHO 2016 grade II-III gliomas: a systematic review and meta-analysis. Neurooncol Adv. 2020;2(1):vdaa044 [PE0173415] doi:10.1093/noajnl/vdaa044

第5部（モジュール5）：臨床試験報告書　添付資料一覧

5.4 参考文献

5.4.1-64	—	Varn FS, Johnson KC, Martinek J, et al. Glioma progression is shaped by genetic evolution and microenvironment interactions. Cell. 2022;185(12):2184-2199.e2116 [PE0168384]. doi:10.1016/j.cell.2022.04.038
5.4.1-65	—	Wefel JS, Noll KR, Rao G, Cahill DP. Neurocognitive function varies by IDH1 genetic mutation status in patients with malignant glioma prior to surgical resection. Neuro Oncol. 2016;18(12):1656-1663 [PE0174643]. doi:10.1093/neuonc/now165
5.4.1-66	—	Weller M, van den Bent M, Preusser M, et al. EANO guidelines on the diagnosis and treatment of diffuse gliomas of adulthood. Nat Rev Clin Oncol. 2021;18(3):170-186 [PE0161665]. doi:10.1038/s41571-020-00447-z
5.4.1-67	—	Wen PY, Cloughesy TF, Ellingson BM, et al. Report of the Jumpstarting Brain Tumor Drug Development Coalition and FDA clinical trials neuroimaging endpoint workshop (January 30, 2014, Bethesda MD). Neuro Oncol. 2014;16 Suppl 7(Suppl 7):vii36-47 [PE0174644]. doi:10.1093/neuonc/nou226
5.4.1-68	—	Wen PY, Macdonald DR, Reardon DA, et al. Updated response assessment criteria for high-grade gliomas: response assessment in neuro-oncology working group. J Clin Oncol. 2010;28(11):1963-1972 [PE0162985]. doi:10.1200/JCO.2009.26.3541
5.4.1-69	—	World Health Organization (WHO). Central Nervous System Tumours, WHO Classification of Tumours, 5th Edition, Volume 6. Edition 5, Volume 6 ed: IARC Publications; 2021.
5.4.1-70	—	Yeo KK, Alexandrescu S, Cotter JA, et al. Multi-institutional study of the frequency, genomic landscape, and outcome of IDH-mutant glioma in pediatrics. Neuro Oncol. 2023;25(1):199-210 [PE0174645]. doi:10.1093/neuonc/noac132
5.4.1-71	—	Yu Y, Villanueva-Meyer J, Grimmer MR, et al. Temozolomide-induced hypermutation is associated with distant recurrence and reduced survival after high-grade transformation of low-grade IDH-mutant gliomas. Neuro Oncol. 2021;23(11):1872-1884 [PE0168385]. doi:10.1093/neuonc/noab081
5.4.1-72	—	NCCN Guidelines for Central Nervous System Cancers, 2024

第5部（モジュール5）：臨床試験報告書　添付資料一覧

5.4 参考文献

5.4.2 「2.7.1　生物薬剤学及び関連する分析法の概要」で引用した参考文献

添付資料番号	報告書番号	著者・タイトル・掲載誌
5.4.2-1	—	EMA ICH M9 on biopharmaceutics classification system-based biowaivers. 2020 [PE0156787]
5.4.2-2	—	FDA M9 Biopharmaceutics Classification System - Based Biowaivers. 2021 [PE0162444]
5.4.2-3	—	MHLW ICH M9 Biopharmaceutics Classification System (BCS) - Based Biowaivers. 2020 [PSEHB/PED Notification 1225-13, dated December 25. 2020

5.4.3 「2.7.2　臨床薬理の概要」で引用した参考文献

添付資料番号	報告書番号	著者・タイトル・掲載誌
5.4.3-1	—	MHLW ICH S9 Nonclinical Evaluation for Anticancer Pharmaceuticals. PFSB/ELD Notification No. 0928010, dated June 4, 2010
5.4.3-2	—	EMA Guideline on the investigation of drug interactions. CPMP/EWP/560/95/Rev. 1 Corr. 2European Medicines Agency2012 [PE0078267]
5.4.3-3	—	FDA S9 Nonclinical Evaluation for Anticancer Pharmaceuticals. US Department of Health and Human Services, Food and Drug Administration. 2010 [PE0165129]
5.4.3-4	—	FDA Safety Testing of Drug Metabolites Guidance for Industry 2020 [PE0174702]
5.4.3-5	—	MHLW Drug Interaction Guidelines for Drug Development and Appropriate Information Provision. PSEHB/PED Notification No. 0723-6, dated July 23, 2018
5.4.3-6	—	FDA Clinical Drug Interaction Studies — Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions — Guidance for Industry. 2020 [PE0156514]
5.4.3-7	—	FDA Assessing the Effects of Food on Drugs in INDs and NDAs — Clinical Pharmacology Considerations Guidance for Industry. 2022 [PE0168221]
5.4.3-8	—	MHLW ICH E14 The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs. PFSB/ELD Notification No.1023-1, dated October 23, 2009
5.4.3-9	—	EMA ICH E14 (R3) Clinical evaluation of QT/QTc interval prolongation and proarrhythmic potential for non-antiarrhythmic drugs - questions and answers - Scientific guideline. 2016 [PE0126868]
5.4.3-10	—	FDA E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs. 2005 [PE0152505]
5.4.3-11	—	Zanger UM, Schwab M. Cytochrome P450 enzymes in drug metabolism: regulation of gene expression, enzyme activities, and impact of genetic variation. Pharmacol Ther. 2013;138(1):103-141 [PE0117767]. doi:10.1016/j.pharmthera.2012.12.007
5.4.3-12	—	CDC. Percentile Data Files with LMS Values. 2009 Accessed 04 September 2023

第5部（モジュール5）：臨床試験報告書　添付資料一覧

5.4 参考文献

5.4.4 「2.7.3 臨床的有効性の概要」で引用した参考文献

添付資料番号	報告書番号	著者・タイトル・掲載誌
5.4.4-1	—	Babb J, Rogatko A, Zacks S. Cancer phase I clinical trials: efficient dose escalation with overdose control. Stat Med. 1998;17(10):1103-1120 [PE0143069].
5.4.4-2	—	Brookmeyer R, Crowley JJ. A Confidence Interval for the Median Survival Time. Biometrics. 1982;38:29 [PE0125226]
5.4.4-3	—	Cairncross G, Wang M, Shaw E, et al. Phase III trial of chemoradiotherapy for anaplastic oligodendroglioma: long-term results of RTOG 9402. J Clin Oncol. 2013;31(3):337-343 [PE0168444]. doi:10.1200/JCO.2012.43.2674
5.4.4-4	—	Cancer Genome Atlas Research Network. Comprehensive, Integrative Genomic Analysis of Diffuse Lower-Grade Gliomas. N Engl J Med. 2015;372(26):2481-2498 [PE0119525]. doi:10.1056/NEJMoa1402121
5.4.4-5	—	Cohen AL, Holmen SL, Colman H. IDH1 and IDH2 mutations in gliomas. Curr Neurol Neurosci Rep. 2013;13(5):345 [PE0162912]. doi:10.1007/s11910-013-0345-4
5.4.4-6	—	Dang L, White DW, Gross S, et al. Cancer-associated IDH1 mutations produce 2-hydroxyglutarate. Nature. 2009;462(7274):739-744 [PE0162691]. doi:10.1038/nature08617
5.4.4-7	—	Dietrich J, Wen PY. Clinical presentation, diagnosis, and initial surgical management of high-grade gliomas. UpToDate; Uptodate: Waltham, MA, USA. 2022 [PE0169833].
5.4.4-8	—	Eisenhauer EA, Therasse P, Bogaerts J, et al. New response evaluation criteria in solid tumours: revised RECIST guideline (version 1.1). Eur J Cancer. 2009;45(2):228-247 [PE0068306]. doi:10.1016/j.ejca.2008.10.026
5.4.4-9	—	Huang RY, Young RJ, Ellingson BM, et al. Volumetric analysis of IDH-mutant lower-grade glioma: a natural history study of tumor growth rates before and after treatment. Neuro Oncol. 2020;22(12):1822-1830 [PE0170267]. doi:10.1093/neuonc/noaa105
5.4.4-10	—	Iwamoto F, Polley M-Y, Shaw E, et al. CTNI-16. NRG-RTOG 9802 OBSERVATION ARM - LONG TERM RESULT. Neuro-Oncology. 2022;24:vii73-vii73 doi:10.1093/neuonc/noac209.282
5.4.4-11	—	Janda M, Steginga S, Langbecker D, Dunn J, Walker D, Eakin E. Quality of life among patients with a brain tumor and their carers. In: J Psychosom Res. Vol 63.2007:617-623 [PE0174349].
5.4.4-12	—	The Japan Neurological Society and The Japanese Society of Pathology. General Rules for Clinical and Pathological Studies on Brain Tumors (The 5th Edition). 2023.
5.4.4-13	—	Kalbfleisch J, Prentice R. The Statistical Analysis of Failure Time Data. 2nd ed: Wiley-Interscience; 2002.
5.4.4-14	—	Klein M. Health-related quality of life aspects in patients with low-grade glioma. Adv Tech Stand Neurosurg. 2010;35:213-235 [PE0173253]. doi:10.1007/978-3-211-99481-8_8
5.4.4-15	—	McAleer MF, Brown PD. Neurocognitive Function Following Therapy for Low-Grade Gliomas. Semin Radiat Oncol. 2015;25(3):210-218 [PE0168218]. doi:10.1016/j.semradonc.2015.02.005
5.4.4-16	—	NBTS. Brain Tumor Facts. National Brain Tumor Society. https://braintumor.org/brain-tumors/about-brain-tumors/brain-tumor-facts/
5.4.4-17	—	NCCN. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) on Central Nervous System Cancers (Version 1.2022). 2022(2022):[PE0168780].
5.4.4-18	—	Neuenschwander B, Branson M, Gsponer T. Critical aspects of the Bayesian approach to phase I cancer trials. Stat Med. 2008;27(13):2420-2439 [PE0143093]. doi:10.1002/sim.3230
5.4.4-19	—	Ostrom QT, Price M, Neff C, et al. CBTRUS Statistical Report: Primary Brain and Other Central Nervous System Tumors Diagnosed in the United States in 2015-2019. Neuro Oncol. 2022;24(Suppl 5):v1-v95 [PE0171842]. doi:10.1093/neuonc/noac202
5.4.4-20	—	Pearman T, Yanez B, Peipert J, Wortman K, Beaumont J, Cella D. Ambulatory cancer and US general population reference values and cutoff scores for the functional assessment of cancer therapy. Cancer. 2014;120(18):2902-2909 [PE0174347]. doi:10.1002/cncr.28758

第5部（モジュール5）：臨床試験報告書　添付資料一覧

5.4 参考文献

5.4.4-21	—	van den Bent MJ, Afra D, de Witte O, et al. Long-term efficacy of early versus delayed radiotherapy for low-grade astrocytoma and oligodendroglioma in adults: the EORTC 22845 randomised trial. Lancet. 2005;366(9490):985-990 doi:10.1016/S0140-6736(05)67070-5
5.4.4-22	—	van den Bent MJ, Brandes AA, Taphoorn MJ, et al. Adjuvant procarbazine, lomustine, and vincristine chemotherapy in newly diagnosed anaplastic oligodendroglioma: long-term follow-up of EORTC brain tumor group study 26951. J Clin Oncol. 2013;31(3):344-350 doi:10.1200/JCO.2012.43.2229
5.4.4-23	—	van den Bent MJ, Loeffler JS. Treatment and prognosis of IDH-mutant, 1p/19q-codeleted oligodendrogliomas in adults. UpToDate; Uptodate: Waltham, MA, USA. 2022 [PE0169837].
5.4.4-24	—	van den Bent MJ, Tesileanu CMS, Wick W, et al. Adjuvant and concurrent temozolomide for 1p/19q non-co-deleted anaplastic glioma (CATNON; EORTC study 26053-22054): second interim analysis of a randomised, open-label, phase 3 study. Lancet Oncol. 2021;22(6):813-823 [PE0168763]. doi:10.1016/S1470-2045(21)00090-5
5.4.4-25	—	van den Bent MJ, Wefel JS, Schiff D, et al. Response assessment in neuro-oncology (a report of the RANO group): assessment of outcome in trials of diffuse low-grade gliomas. Lancet Oncol. 2011;12(6):583-593 [PE0163017]. doi:10.1016/S1470-2045(11)70057-2
5.4.4-26	—	Varn FS, Johnson KC, Martinek J, et al. Glioma progression is shaped by genetic evolution and microenvironment interactions. Cell. 2022;185(12):2184-2199.e2116 [PE0168384]. doi:10.1016/j.cell.2022.04.038
5.4.4-27	—	Weller M, van den Bent M, Preusser M, et al. EANO guidelines on the diagnosis and treatment of diffuse gliomas of adulthood. Nat Rev Clin Oncol. 2021;18(3):170-186 [PE0161665]. doi:10.1038/s41571-020-00447-z
5.4.4-28	—	Wen PY, Macdonald DR, Reardon DA, et al. Updated response assessment criteria for high-grade gliomas: response assessment in neuro-oncology working group. J Clin Oncol. 2010;28(11):1963-1972 [PE0162985]. doi:10.1200/JCO.2009.26.3541
5.4.4-29	—	Westfall PH, Krishen A. Optimally weighted, fixed sequence and gatekeeper multiple testing procedures. Journal of Statistical Planning and Inference. 2001;99(1):25-40 [PE0163002]. doi:https://doi.org/10.1016/S0378-3758(01)00077-5
5.4.4-30	—	WHO. Central Nervous System Tumours, WHO Classification of Tumours, 5th Edition, Volume 6. Vol 6. 5 ed: IARC Publications; 2021.
5.4.4-31	—	Yu Y, Villanueva-Meyer J, Grimmer MR, et al. Temozolomide-induced hypermutation is associated with distant recurrence and reduced survival after high-grade transformation of low-grade IDH-mutant gliomas. Neuro Oncol. 2021;23(11):1872-1884 [PE0168385]. doi:10.1093/neuonc/noab081

第5部（モジュール5）：臨床試験報告書　添付資料一覧
5.4 参考文献

5.4.5 「2.7.4　臨床的安全性の概要」で引用した参考文献

添付資料番号	報告書番号	著者・タイトル・掲載誌
5.4.5-1	—	Points to Consider for the Instructions for Package Inserts of Prescription Drugs PSEHB/SD Notification No.0608-1. In:2023.
5.4.5-2	—	Chen H, Judkins J, Thomas C, et al. Mutant IDH1 and seizures in patients with glioma. Neurology. 2017;88(19):1805-1813 [PE0167622]. doi:10.1212/WNL.0000000000003911
5.4.5-3	—	EMA Guideline on the evaluation of anticancer medicinal products in man. 2017 [PE0144523]
5.4.5-4	—	EMA Designated medical event (DME) list. European Medicines Agency2020 [PE0174752]
5.4.5-5	—	European Commission A guideline on summary of product characteristics. 2009 [PE0067002]
5.4.5-6	—	FDA Guidance for industry: adverse reactions section of labeling for human prescription drug and biological products — content and format. 2006 [PE0174746]

5.4.6 「2.7.6　個々の試験のまとめ」で引用した参考文献

添付資料番号	報告書番号	著者・タイトル・掲載誌
5.4.6-1	—	Mellinghoff IK, Lu M, Wen PY, et al. Vorasidenib and ivosidenib in IDH1-mutant low-grade glioma: a randomized, perioperative phase 1 trial. Nat Med. 2023;29(3):615-622. doi:10.1038/s41591-022-02141-2
5.4.6-2	—	Mellinghoff IK, Penas-Prado M, Peters KB, et al. Vorasidenib, a dual inhibitor of mutant IDH1/2, in recurrent or progressive glioma; results of a first-in-human Phase I trial. Clinical Cancer Res. 2021;27(16):4491-4499. doi:10.1158/1078-0432.CCR-21-0611
5.4.6-3	—	Mellinghoff IK, van den Bent MJ, Blumenthal DT et al. Vorasidenib in IDH1- or IDH2-mutant low-grade glioma. N Engl J Med 2023; 389:589-601. DOI: 10.1056/NEJMoa2304194