ragifilimab

inmunoglobulina G1-kappa, anti-[*Homo sapiens* TNFRSF18 (miembro 18 de la superfamilia de los receptores del TNF, receptor de la familia TNFR inducido por activación, AITR, receptor relacionado con el TNFR e inducido por los glucocorticoides, GITR, CD375), anticuerpo monoclonal humanizado; cadena pesada gamma1 humanizada (1-447) [VH (*Homo sapiens* IGHV1-2*02 (80.6%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (1-118) -*Homo sapiens* IGHG1*03 (100%) G1m3, nG1m1 (CH1 R120 (215) (119-216), bisagra 1-15 (217-231), CH2 (232-341), CH3 E12 (357), M14 (359) (342-446), CHS K>del (447)) (119-447)], (221-220')-disulfuro con la cadena ligera kappa humanizada (1'-220') [V-KAPPA (*Homo sapiens* IGKV4-1*01 (91.1%) -IGKJ2*01 (100%)) CDR-IMGT [12.3.9] (27-38.56-58.95-103) (1'-113') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (159), V101 (197) (114'-220')]; dímero (227-227''':230-230'')-bisdisulfuro, producido por células ováricas de hamster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGASVKV SCKGSGYTFT DYAMYWVRQA PGQGLEWIGV  50
IRTYSGDVTY NQKFKDRATM TVDKSISTAY MELSRLRSDD TAVYYCAKSG 100
TVRGFAYWGQ GTLVTVSSAS 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 SLSLSPG    447
```

Light chain / Chaîne légère / Cadena ligera

```
DIVMTQSPDS LAVSLGERAT INCKSSQSLL NSGNQKNYLI WYQQKPGQPP  50
KLLIYWASTR ESGVPDRFSG SGSGTDFTLT ISSLQAEDVA VYHCQNDYSY 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	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-terminal glutaminyl cyclization to pyroglutamyl (pE, 5-oxoprolyl)
H VH Q1:
1, 1''

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

reciferceptum #
recifercept

human fibroblast growth factor receptor 3 (FGFR-3, CD333) (1-336)-(401-413) fragment (1-349) [soluble isoform (337-400>del, 414-784>del)-sFGFR3], produced in Chinese hamster ovary (CHO) cells, glycoform alfa

récifercept

fragment (1-336)-(401-413) du récepteur 3 du facteur de croissance des fibroblastes humain (FGFR-3, CD333) (1-349) [isoforme soluble (337-400>del, 414-784>del)-sFGFR3], produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

recifercept

fragmento (1-336)-(401-413) del receptor 3 del factor de crecimiento de los fibroblastos humanos (FGFR-3, CD333) (1-349) [isoforma soluble (337-400>del, 414-784>del)-sFGFR3], producido en las células ováricas de hamster chino (CHO), glicoforma alfa

Sequence / Séquence / Secuencia

```
ESLGTEQRVV GRAAEVPGPE PGQQEQLVFG SGDAVELSCP PPGGGPMGPT   50
VWVKDGTGLV PSERVLVGPQ RLQVLNASHE DSGAYSCRQR LTQRVLCHFS  100
VRVTDAPSSG DDEDGEDEAE DTGVDTGAPY WTRPERMDKK LLAVPAANTV  150
RFRCPAAGNP TPSISWLKNG REFRGEHRIG GIKLRHQQWS LVMESVVPSD  200
RGNYTCVVEN KFGSIRQTYT LDVLERSPHR PILQAGLPAN QTAVLGSDVE  250
FHCKVYSDAQ PHIQWLKHVE VNGSKVGPDG TPYVTVLKTA GANTTDKELE  300
VLSLHNVTFE DAGEYTCLAG NSIGFSHHSA WLVVLPVSLE SNASMSSNT   349
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
intra-chain 39-97 154-206 253-317
(Cys-SH: 87)

Glycosylation sites / Sites de glycosylation / Posiciones de glicosilación
N76, N203, N240, N272, N293, N306, N342
Fucosylated complex bi-antennary CHO-type glycans / Glycanes de type CHO bi-antennaires complexes fucosylés / Glicanos de tipo CHO biantenarios complejos fucosilados

relzomostatum

relzomostat

(3*R*,4*S*,5*S*,6*R*)-5-methoxy-4-[(2*R*,3*R*)-2-methyl-3-(3-methylbut-2-en-1-yl)oxiran-2-yl]-1-oxaspiro[2.5]octan-6-yl 6-(2,2-difluoroethyl)-2,6-diazaspiro[3.3]heptane-2-carboxylate

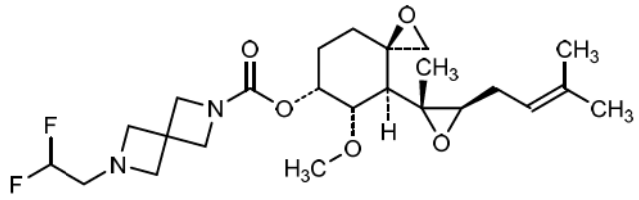
relzomostat

6-(2,2-difluoroéthyl)-2,6-diazaspiro[3.3]heptane-2-carboxylate de (3*R*,4*S*,5*S*,6*R*)-5-méthoxy-4-[(2*R*,3*R*)-2-méthyl-3-(3-méthylbut-2-én-1-yl)oxiran-2-yl]-1-oxaspiro[2.5]octan-6-yle

relzomostat

6-(2,2-difluoroetil)-2,6-diazaspiro[3.3]heptano-2-carboxilato de (3*R*,4*S*,5*S*,6*R*)-5-metoxi-4-[(2*R*,3*R*)-2-metil-3-(3-metilbut-2-en-1-il)oxiran-2-il]-1-oxaspiro[2.5]octan-6-ilo

$C_{24}H_{36}F_2N_2O_5$



resiquimodum pegolum

resiquimod pegol

2,2',2'',2'''-{methanetetrayltetrakis[methylenepoly(oxyethylene)oxy]}tetrakis[*N*-(2-{[2-(ethoxymethyl)-1-(2-hydroxy-2-methylpropyl)-1*H*-imidazo[4,5-*c*]quinolin-4-yl]amino}-2-oxoethyl)acetamide]

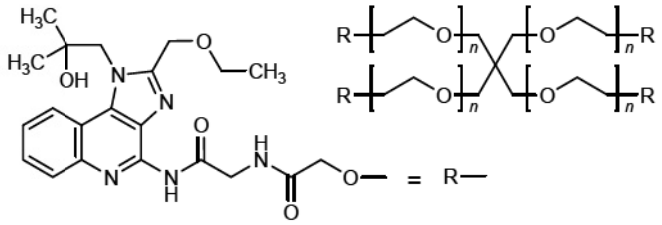
résiquimod pégol

2,2',2'',2'''-{méthanetétrayltétrakis[méthylènepoly(oxyéthylène)oxy]}tétrakis[*N*-(2-{[2-(éthoxyméthyl)-1-(2-hydroxy-2-méthylpropyl)-1*H*-imidazo[4,5-*c*]quinoléin-4-yl]amino}-2-oxoéthyl)acétamide]

resiquimod pegol

2,2',2'',2'''-{metanotetrailtetrakis[metilenepoli(oxietileno)oxi]}tetrakis[*N*-(2-{[2-(etoximetil)-1-(2-hidroxi-2-metilpropil)-1*H*-imidazo[4,5-*c*]quinolin-4-il]amino}-2-oxoetil)acetamida]

$C_{89}H_{112}N_{20}O_{20} . (C_2H_4O)_{4n}$



revdofilimabum #

revdofilimab	immunoglobulin G1-kappa, anti-[*Homo sapiens* TNFRSF4 (tumor necrosis factor receptor (TNFR) superfamily member 4, ACT35, OX40, CD134)], monoclonal antibody; gamma1 heavy chain (1-450) [VH (*Mus musculus* IGHV5-6-3*01 (88.8%) -IGHJ4*01 (93.8%)/*Homo sapiens* IGHV3-7*01 (88.8%) -(IGHD) -IGHJ4*01 (92.3%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (217) (121-218), hinge 1-15 (219-233), CH2 (234-343), CH3 E12 (359), M14 (361) (344-448), CHS (449-450)) (121-450)], (223-218')-disulfide with kappa light chain (1'-218') [V-KAPPA (*Mus musculus* IGKV3-4*01 (83.8%) -IGKJ1*01 (90.9%)/*Homo sapiens* IGKV4-1*01 (83.2%) -IGKJ4*01 (100%)) CDR-IMGT [10.3.9] (27-36.54-56.93-101) (1'-111') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (157), V101 (195) (112'-218')]; dimer (229-229":232-232")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa
revdofilimab	immunoglobuline G1-kappa, anti-[*Homo sapiens* TNFRSF4 (membre 4 de la superfamille des récepteurs du facteur de nécrose tumorale, ACT35, OX40, CD134)], anticorps monoclonal; chaîne lourde gamma1 (1-450) [VH (*Mus musculus* IGHV5-6-3*01 (88.8%) -IGHJ4*01 (93.8%)/*Homo sapiens* IGHV3-7*01 (88.8%) -(IGHD) -IGHJ4*01 (92.3%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (217) (121-218), charnière 1-15 (219-233), CH2 (234-343), CH3 E12 (359), M14 (361) (344-448), CHS (449-450)) (121-450)], (223-218')-disulfure avec la chaîne légère kappa (1'-218') [V-KAPPA (*Mus musculus* IGKV3-4*01 (83.8%) -IGKJ1*01 (90.9%)/*Homo sapiens* IGKV4-1*01 (83.2%) -IGKJ4*01 (100%)) CDR-IMGT [10.3.9] (27-36.54-56.93-101) (1'-111') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (157), V101 (195) (112'-218')]; dimère (229-229":232-232")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa
revdofilimab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* TNFRSF4 (miembro 4 de la superfamilia de los receptores del factor de necrosis tumoral, ACT35, OX40, CD134)], anticuerpo monoclonal;

cadena pesada gamma1 (1-450) [VH (*Mus musculus* IGHV5-6-3*01 (88.8%) -IGHJ4*01 (93.8%)/*Homo sapiens* IGHV3-7*01 (88.8%) -(IGHD) -IGHJ4*01 (92.3%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (217) (121-218), bisagra 1-15 (219-233), CH2 (234-343), CH3 E12 (359), M14 (361) (344-448), CHS (449-450)) (121-450)], (223-218')-disulfuro con la cadena ligera kappa (1'-218') [V-KAPPA (*Mus musculus* IGKV3-4*01 (83.8%) -IGKJ1*01 (90.9%)/*Homo sapiens* IGKV4-1*01 (83.2%) -IGKJ4*01 (100%)) CDR-IMGT [10.3.9] (27-36.54-56.93-101) (1'-111') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (157), V101 (195) (112'-218')]; dímero (229-229":232-232")-bisdisulfuro, producido por células ováricas de hamster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVESGGG LVQPGGSLRL SCAASGFTFS RYGMSWVRQA PGKGLELVAT  50
INSNGGRTYY PDSVKGRFTI SRDNAKNSLY LQMNSLRAED TAVYYCAREG 100
ITTAYAMDYW GQGTTVTVSS 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 QKSLSLSPGK 450
```

Light chain / Chaîne légère / Cadena ligera

```
DIVMTQSPDS LAVSLGERAT INCKASQSVD YDGDSYMHWY QQKPGQPPKL  50
LIYAASILES GVPDRFSGSG SGTDFTLTIS SLQAEDVAVY YCQQSNEDPR 100
TFGGGTKVEI 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	147-203	264-324	370-428
	22"-96"	147"-203"	264"-324"	370"-428"
Intra-L (C23-C104)	23'-92'	138'-198'		
	23'"-92'"	138'"-198'"		
Inter-H-L (h 5-CL 126)	223-218'	223"-218'"		
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

C-terminal lysine clipping:

H CHS K2:
450, 450"

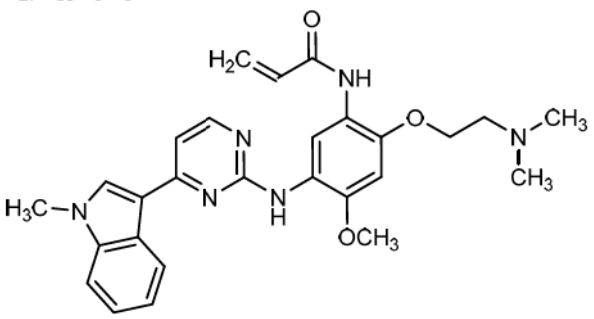
rezivertinibum

rezivertinib — *N*-(2-[2-(dimethylamino)ethoxy]-4-methoxy-5-{[4-(1-methyl-1*H*-indol-3-yl)pyrimidin-2-yl]amino}phenyl)prop-2-enamide

rézivertinib — *N*-(2-[2-(diméthylamino)éthoxy]-4-méthoxy-5-{[4-(1-méthyl-1*H*-indol-3-yl)pyrimidin-2-yl]amino}phényl)prop-2-énamide

rezivertinib — *N*-(2-[2-(dimetilamino)etoxi]-5-{[4-(1-metil-1*H*-indol-3-il)pirimidin-2-il]amino}fenil)-4-metoxiprop-2-enamida

$C_{27}H_{30}N_6O_3$

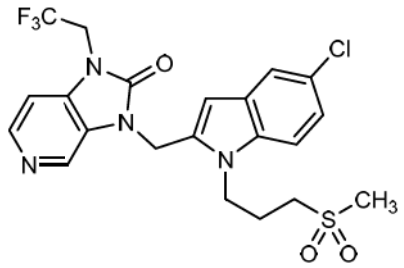


WHO Drug Information, Vol. 34, No. 3, 2020 Recommended INN: List 84

rilematovirum

rilematovir	3-({5-chloro-1-[3-(methanesulfonyl)propyl]-1*H*-indol-2-yl}methyl)-1-(2,2,2-trifluoroethyl)-1,3-dihydro-2*H*-imidazo[4,5-*c*]pyridin-2-one
rilématovir	3-({5-chloro-1-[3-(méthanesulfonyl)propyl]-1*H*-indol-2-yl}méthyl)-1-(2,2,2-trifluoroéthyl)-1,3-dihydro-2*H*-imidazo[4,5-*c*]pyridin-2-one
rilematovir	3-({5-cloro-1-[3-(metanosulfonil)propil]-1*H*-indol-2-il}metil)-1-(2,2,2-trifluoroetil)-1,3-dihidro-2*H*-imidazo[4,5-*c*]piridin-2-ona

$C_{21}H_{20}ClF_3N_4O_3S$



ripafollitropinum alfa (bovinum) #

ripafollitropin alfa (bovine)	bovine follicle-stimulating hormone (synthetic analog): [follitropin (*Bos taurus*) subunit β (1-109)]-[human chorionic gonadotropin (hCG) C-terminal 28-peptide linker (110-137)]-[glycoprotein hormones α chain (follitropin subunit α) (*Bos taurus*) (138-233)] fusion protein, produced in Chinese hamster ovary (CHO) cells, glycoform alfa
ripafollitropine alfa (bovine)	hormone folliculostimulante bovine (analogue synthétique): protéine de fusion [follitropine (*Bos taurus*) sous-unité β (1-109)]-[peptide liant: 28-peptide C-terminal de la gonadotrophine chorionique humaine (hCG) (110-137)]-[chaîne α des hormones glycoprotéiques (follitropine sous-unité α) (*Bos taurus*) (138-233)], produit par des cellules ovariennes de hamster chinois (CHO), forme glycosylée alfa
ripafolitropina alfa (bovina)	hormona estimulante del folículo bovina (análogo sintético): proteína de fusión [folitropina (*Bos taurus*) subunidad β (1-109)]-[conector: 28-péptido C-terminal de la gonadotropina coriónica humana (hCG) (110-137)]-[cadena α de las hormonas glicoproteicas (folitropina subunidad α) (*Bos taurus*) (138-233)], producida por células ováricas de hamster chino (CHO), forma glicosilada alfa

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Sequence / Séquence / Secuencia:
CELTNITITV EKEECGFCIS INTTWCAGYC YTRDLVYRDP ARPNIQKTCT 5(
FKELVYETVK VPGCAHHADS LYTYPVATEC HCSKCDSDST DCTVRGLGPS 1(
YCSFREIKES SSSKAPPPSL PSPSRLPGPS DTPILPQFPD GEFTMQGCPE 1!
CKLKENKYFS KPDAPIYQCM GCCFSRAYPT PARSKKTMLV PKNITSEATC 2(
CVAKAFTKAT VMGNVRVENH TECHCSTCYY HKS 2:

Disulfide bridge location / Position de la pont disulfure / Posición del puente disulfu
(predicted): 1-49, 15-64, 18-102, 26-80, 30-82, 85-92, 148-172,
151-201, 169-223, 173-225, 200-228

Glycosylation sites / Sites de glycosylation / Posiciones de glicosilación
potential N-glycosylation: N5, N22, N193, N219
potential O-glycosylation: S113, S119, S124, S130

Other post-translational modifications:
potential deamidation: N5, N22, N44, Q46, Q137, Q146,
N156, Q168, N193, N214, N219
potential S-oxidation: M145, M170, M188, M212

ripertamabum #

ripertamab	immunoglobulin G1-kappa, anti-[*Homo sapiens* MS4A1 (membrane-spanning 4-domains subfamily A member 1, CD20)], chimeric monoclonal antibody; gamma1 heavy chain chimeric (1-451) [VH (*Mus musculus* IGHV1-12*01 (91.8%) -(IGHD) -IGHJ1*01 (87.5%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (218) (122-219), hinge 1-15 (220-234), CH2 (235-344), CH3 D12 (360), L14 (362) (345-449), CHS (450-451)) (122-451)], (224-213')-disulfide with kappa light chain chimeric (1'-213') [V-KAPPA (*Mus musculus* IGKV4-72*01 (95.8%) -IGKJ1*01 (100%)) CDR-IMGT [5.3.9] (27-31.49-51.88-96) (1'-106') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (152), V101 (190) (107'-213')]; dimer (230-230":233-233")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa
ripertamab	immunoglobuline G1-kappa, anti-[*Homo sapiens* MS4A1 (membre 1 de la sous-famille A à 4 domaines transmembranaires, CD20)], anticorps monoclonal chimérique; chaîne lourde gamma1 chimérique (1-451) [VH (*Mus musculus* IGHV1-12*01 (91.8%) -(IGHD) -IGHJ1*01 (87.5%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (218) (122-219), charnière 1-15 (220-234), CH2 (235-344), CH3 D12 (360), L14 (362) (345-449), CHS (450-451)) (122-451)], (224-213')-disulfure avec la chaîne légère kappa chimérique (1'-213') [V-KAPPA (*Mus musculus* IGKV4-72*01 (95.8%) -IGKJ1*01 (100%)) CDR-IMGT [5.3.9] (27-31.49-51.88-96) (1'-106') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (152), V101 (190) (107'-213')]; dimère (230-230":233-233")-bisdisulfure, produite dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa
ripertamab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* MS4A1 (miembro 1 de la subfamilia A con 4 dominios transmembranarios, CD20)], anticuerpo monoclonal quimérico;

cadena pesada gamma1 quimérica (1-451) [VH (*Mus musculus* IGHV1-12*01 (91.8%) -(IGHD) -IGHJ1*01 (87.5%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (218) (122-219), bisagra 1-15 (220-234), CH2 (235-344), CH3 D12 (360), L14 (362) (345-449), CHS (450-451)) (122-451)], (224-213')-disulfuro con la cadena ligera kappa quimérica (1'-213') [V-KAPPA (*Mus musculus* IGKV4-72*01 (95.8%) -IGKJ1*01 (100%)) CDR-IMGT [5.3.9] (27-31.49-51.88-96) (1'-106') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (152), V101 (190) (107'-213')];
dímero (230-230":233-233")-bisdisulfuro, producida por células ováricas de hamster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLQQPGAE LVKPGASVKM SCKASGYTFT SYNMHWVKQT PGRGLEWIGA  50
IYPGNGDTSY NQKFKGKATL TADKSSSTAY MQLSSLTSED SAVYYCARST 100
YYGGDWYFNV WGAGTTVTVS AASTKGPSVF 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 VMHEALHNHY TQKSLSLSPG 450
K                                                       451
```

Light chain / Chaîne légère / Cadena ligera

```
QIVLSQSPAI LSASPGEKVT MTCRASSSVS YIHWFQQKPG SSPKPWIYAT  50
SNLASGVPVR FSGSGSGTSY SLTISRVEAE DAATYYCQQW TSNPPTFGGG 100
TKLEIKRTVA 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	148-204	265-325	371-429
	22"-96"	148"-204"	265"-325"	371"-429"
Intra-L (C23-C104)	23'-87'	133'-193'		
	23'"-87'"	133'"-193'"		
Inter-H-L (h 5-CL 126)	224-213'	224"-213'"		
Inter-H-H (h 11, h14)	230-230"	233-233"		

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

rocakinogenum sifuplasmidum #

rocakinogene sifuplasmid	A DNA plasmid encoding both subunits of human interleukin-12 (IL12), subunit alpha (IL12A, IL-12 subunit p35) and subunit beta (IL12B; IL-12 subunit p40), under the control of a human cytomegalovirus (CMV) immediate-early 1 (IE1) promoter and a simian cytomegalovirus (sCMV) promoter, respectively.
rocakinogène sifuplasmide	plasmide dont l'ADN code pour les deux sous-unités de l'interleukine 12 humaine (IL-12), sous-unité alpha (IL12A, sous-unité p35 de l'IL-12) et sous-unité bêta (IL12B; sous-unité p40 de l'IL-12), sous le contrôle d'un activateur/promoteur immédiat-précoce 1 (IE1) du cytomégalovirus (CMV) et d'un promoteur du cytomégalovirus simiesque (sCMV), respectivement
rocakinogén sifuplasmida	Un plásmido de DNA que codifica para ambas subunidades de la interleucina 12 (IL12) humana, la subunidad alfa (IL12A, IL-12 subunidad p35) y la subunidad beta (IL12B; IL-12 subunidad p40), bajo el control de un promotor inmediato-temprano 1 (IE1) del citomegalovirus (CMV) humano y un promotor del citomegalovirus de simio (sCMV), respectivamente.

rosopatamabum #	
rosopatamab	immunoglobulin G1-kappa, anti-[*Homo sapiens* FOLH1 (folate hydrolase, prostate specific membrane antigen, PSMA)], monoclonal antibody; gamma1 heavy chain (1-445) [VH (*Mus musculus* IGHV1-26*01 (78.4%) -(IGHD) -IGHJ2*01 (92.9%)/*Homo sapiens* IGHV1-69-2*01 (76.3%) -(IGHD) -IGHJ4*01 (92.9%)) [8.8.8] (1-115) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (212) (116-213), hinge 1-15 (214-228), CH2 (229-338), CH3 D12 (354), L14 (356) (339-443), CHS (444-445)) (116-445)], (218-214')-disulfide with kappa light chain (1'-214') [V-KAPPA (*Mus musculus* IGKV6-23*01 (80.9%) -IGKJ2*03 (72.7%)*Homo sapiens* IGKV1-13*02 (78.7%) -IGKJ3*01 (91.7%)) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (224-224":227-227")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa
rosopatamab	immunoglobuline G1-kappa, anti-[*Homo sapiens* FOLH1 (folate hydrolase, antigène membranaire spécifique de la prostate, PSMA)], anticorps monoclonal; chaîne lourde gamma1 (1-445) [VH (*Mus musculus* IGHV1-26*01 (78.4%) -(IGHD) -IGHJ2*01 (92.9%)/*Homo sapiens* IGHV1-69-2*01 (76.3%) -(IGHD) -IGHJ4*01 (92.9%)) [8.8.8] (1-115) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (212) (116-213), charnière 1-15 (214-228), CH2 (229-338), CH3 D12 (354), L14 (356) (339-443), CHS (444-445)) (116-445)], (218-214')-disulfure avec la chaîne légère kappa (1'-214') [V-KAPPA *Mus musculus* IGKV6-23*01 (80.9%) -IGKJ2*03 (72.7%)/(*Homo sapiens* IGKV1-13*02 (78.7%) -IGKJ3*01 (91.7%)) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (224-224":227-227")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa
rosopatamab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* FOLH1 (folato hidrolasa, antígeno membranario específico de la próstata, PSMA)], anticuerpo monoclonal; cadena pesada gamma1 (1-445) [VH (*Mus musculus* IGHV1-26*01 (78.4%) -(IGHD) -IGHJ2*01 (92.9%)/*Homo sapiens* IGHV1-69-2*01 (76.3%) -(IGHD) -IGHJ4*01 (92.9%)) [8.8.8] (1-115) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (212) (116-213), bisagra 1-15 (214-228), CH2 (229-338), CH3 D12 (354), L14 (356) (339-443), CHS (444-445)) (116-445)], (218-214')-disulfuro con la cadena ligera kappa (1'-214') [V-KAPPA *Mus musculus* IGKV6-23*01 (80.9%) -IGKJ2*03 (72.7%)/(*Homo sapiens* IGKV1-13*02 (78.7%) -IGKJ3*01 (91.7%)) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (224-224":227-227")-bisdisulfuro, producido por células ováricas de hamster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVQSGPE VKKPGATVKI SCKTSGYTFT EYTIHWVKQA PGKGLEWIGN  50
INPNNGGTTY NQKFEDKATL TVDKSTDTAY MELSSLRSED TAVYYCAAGW 100
NFDYWGQGTL LTVSSASTKG PSVFPLAPSS KSTSGGTAAL GCLVKDYFPE 150
PVTVSWNSGA LTSGVHTFPA VLQSSGLYSL SSVVTVPSSS LGTQTYICNV 200
NHKPSNTKVD KKVEPKSCDK THTCPPCPAP ELLGGPSVFL FPPKPKDTLM 250
ISRTPEVTCV VVDVSHEDPE VKFNWYVDGV EVHNAKTKPR EEQYNSTYRV 300
VSVLTVLHQD WLNGKEYKCK VSNKALPAPI EKTISKAKGQ PREPQVYTLP 350
PSRDELTKNQ VSLTCLVKGF YPSDIAVEWE SNGQPENNYK TTPPVLDSDG 400
SFFLYSKLTV DKSRWQQGNV FSCSVMHEAL HNHYTQKSLS LSPGK      445
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Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS LSTSVGDRVT LTCKASQDVG TAVDWYQQKP GPSPKLLIYW  50
ASTRHTGIPS RFSGSGSGTD FTLTISSLQP EDFADYYCQQ YNSYPLTFGP 100
GTKVDIKRTV 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

rosopatamabum tetraxetanum #

rosopatamab tetraxetan

immunoglobulin G1-kappa, anti-[*Homo sapiens* FOLH1 (folate hydrolase, prostate specific membrane antigen, PSMA)], monoclonal antibody, *tetraxetan* conjugate; gamma1 heavy chain (1-445) [VH (*Mus musculus* IGHV1-26*01 (78.4%) -(IGHD) -IGHJ2*01 (92.9%)/*Homo sapiens* IGHV1-69-2*01 (76.3%) -(IGHD) -IGHJ4*01 (92.9%)) [8.8.8] (1-115) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (212) (116-213), hinge 1-15 (214-228), CH2 (229-338), CH3 D12 (354), L14 (356) (339-443), CHS (444-445)) (116-445)], (218-214')-disulfide with kappa light chain (1'-214') [V-KAPPA (*Mus musculus* IGKV6-23*01 (80.9%) -IGKJ2*03 (72.7%)*Homo sapiens* IGKV1-13*02 (78.7%) -IGKJ3*01 (91.7%)) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')];
dimer (224-224":227-227")-bisdisulfide; produced in Chinese hamster ovary (CHO) cells, glycoform alfa, *tetraxetan* (DOTA) conjugate (on an average of 3 to 5 lysyl, linked to the chelator by their N6)

rosopatamab tétraxétan

immunoglobuline G1-kappa, anti-[*Homo sapiens* FOLH1 (folate hydrolase, antigène membranaire spécifique de la prostate, PSMA)], anticorps monoclonal, conjugué au *tétraxétan*;
chaîne lourde gamma1 (1-445) [VH (*Mus musculus* IGHV1-26*01 (78.4%) -(IGHD) -IGHJ2*01 (92.9%)/*Homo sapiens* IGHV1-69-2*01 (76.3%) -(IGHD) -IGHJ4*01 (92.9%)) [8.8.8] (1-115) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (212) (116-213), charnière 1-15 (214-228), CH2 (229-338), CH3 D12 (354), L14 (356) (339-443), CHS (444-445)) (116-445)], (218-214')-disulfure avec la chaîne légère kappa (1'-214') [V-KAPPA *Mus musculus* IGKV6-23*01 (80.9%) -IGKJ2*03 (72.7%)/(*Homo sapiens* IGKV1-13*02 (78.7%) -IGKJ3*01 (91.7%)) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')];

	dimère (224-224":227-227")-bisdisulfure; produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa, conjugué au *tétraxétan* (DOTA) (avec une moyenne de 3 à 5 lysyl liés au chélateur par leur N6)
rosopatamab tetraxetán	inmunoglobulina G1-kappa, anti-[*Homo sapiens* FOLH1 (folato hidrolasa, antígeno membranario específico de la próstata, PSMA)], anticuerpo monoclonal, conjugado con *tetraxetán* ; cadena pesada gamma1 (1-445) [VH (*Mus musculus* IGHV1-26*01 (78.4%) -(IGHD) -IGHJ2*01 (92.9%)/*Homo sapiens* IGHV1-69-2*01 (76.3%) -(IGHD) -IGHJ4*01 (92.9%)) [8.8.8] (1-115) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (212) (116-213), bisagra 1-15 (214-228), CH2 (229-338), CH3 D12 (354), L14 (356) (339-443), CHS (444-445)) (116-445)], (218-214')-disulfuro con la cadena ligera kappa (1'-214') [V-KAPPA *Mus musculus* IGKV6-23*01 (80.9%) -IGKJ2*03 (72.7%)/(*Homo sapiens* IGKV1-13*02 (78.7%) -IGKJ3*01 (91.7%)) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (224-224":227-227")-bisdisulfuro; producido por células ováricas de hamster chino (CHO), forma glicosilada alfa, conjugado con *tetraxetán* (DOTA) (con una media de 3 a 5 restos lisil unidos al quelante por sus respectivos N6)

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVQSGPE VKKPGATVKI SCKTSGYTFT EYTIHWVKQA PGKGLEWIGN  50
INPNNGGTTY NQKFEDKATL TVDKSTDTAY MELSSLRSED TAVYYCAAGW 100
NFDYWGQGTL LTVSSASTKG PSVFPLAPSS KSTSGGTAAL GCLVKDYFPE 150
PVTVSWNSGA LTSGVHTFPA VLQSSGLYSL SSVVTVPSSS LGTQTYICNV 200
NHKPSNTKVD KKVEPKSCDK THTCPPCPAP ELLGGPSVFL FPPKPKDTLM 250
ISRTPEVTCV VVDVSHEDPE VKFNWYVDGV EVHNAKTKPR EEQYNSTYRV 300
VSVLTVLHQD WLNGKEYKCK VSNKALPAPI EKTISKAKGQ PREPQVYTLP 350
PSRDELTKNQ VSLTCLVKGF YPSDIAVEWE SNGQPENNYK TTPPVLDSDG 400
SFFLYSKLTV DKSRWQQGNV FSCSVMHEAL HNHYTQKSLS LSPGK      445
```

Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS LSTSVGDRVT LTCKASQDVG TAVDWYQQKP GPSPKLLIYW  50
ASTRHTGIPS RFSGSGSGTD FTLTISSLQP EDFADYYCQQ YNSYPLTFGP 100
GTKVDIKRTV 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

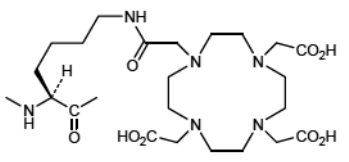
H CH2 N84.4:
295, 295"

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

Potential modified residues / résidus modifiés potentiels / restos modificados potenciales

3 to 5 lysyl (K)
3 à 5 lysyl (K)
3 a 5 lisil (K)

N^6-(tetraxetan)-L-lysyl



sabatolimabum #

sabatolimab	immunoglobulin G4-kappa, anti-[*Homo sapiens* HAVCR2 (hepatitis A virus cellular receptor 2, T-cell immunoglobulin mucin family member 3, Tim-3, TIM3, TIMD3, CD366)], humanized monoclonal antibody; gamma4 heavy chain humanized (1-444) [VH (*Homo sapiens* IGHV1-46*01 (87.8%) -(IGHD) -IGHJ4*01 (92.3%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (1-118)-*Homo sapiens* IGHG4*01, G4v5 h P10 (CH1 (119-216), hinge 1-12 S10>P (226) (217-228), CH2 (229-338), CH3 (339-443), CHS K>del (444)) (119-444)], (132-218')-disulfide with kappa light chain humanized (1'-218') [V-KAPPA (*Homo sapiens* IGKV1-39*01 (81.6%) -IGKJ4*01 (100%)) CDR-IMGT [10.3.9] (27-36.54-56.93-101) (1'-111') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (157), V101 (195) (112'-218')]; dimer (224-224":227-227")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa
sabatolimab	immunoglobuline G4-kappa, anti-[*Homo sapiens* HAVCR2 (récepteur cellulaire 2 du virus de l'hépatite A, CD366, membre 3 de la famille mucine immunoglobuline des cellules T, Tim-3, TIM3, TIMD3, CD366)], anticorps monoclonal humanisé; chaîne lourde gamma4 humanisée (1-444) [VH (*Homo sapiens* IGHV1-46*01 (87.8%) -(IGHD) -IGHJ4*01 (92.3%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (1-118) -*Homo sapiens* IGHG4*01, G4v5 h P10 (CH1 (119-216), charnière 1-12 S10>P (226) (217-228), CH2 (229-338), CH3 (339-443), CHS K>del (444)) (119-444)], (132-218')-disulfure avec la chaîne légère kappa humanisée (1'-218') [V-KAPPA (*Homo sapiens* IGKV1-39*01 (81.6%) -IGKJ4*01 (100%)) CDR-IMGT [10.3.9] (27-36.54-56.93-101) (1'-111') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (157), V101 (195) (112'-218')]; dimère (224-224":227-227")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa
sabatolimab	inmunoglobulina G4-kappa, anti-[*Homo sapiens* HAVCR2 (receptor celular 2 del virus de la hepatitis A, CD366, miembro 3 de la familia mucina inmunoglobulina de las células T, Tim-3, TIM3, TIMD3, CD366)], anticuerpo monoclonal humanizado; cadena pesada gamma4 humanizada (1-444) [VH (*Homo sapiens* IGHV1-46*01 (87.8%) -(IGHD) -IGHJ4*01 (92.3%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (1-118) -*Homo sapiens* IGHG4*01, G4v5 h P10 (CH1 (119-216), bisagra 1-12 S10>P (226) (217-228), CH2 (229-338), CH3 (339-443), CHS K>del (444)) (119-444)], (132-218')-disulfuro con la cadena ligera kappa humanizada (1'-218') [V-KAPPA (*Homo sapiens* IGKV1-39*01 (81.6%) -IGKJ4*01 (100%)) CDR-IMGT [10.3.9] (27-36.54-56.93-101) (1'-111') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (157), V101 (195) (112'-218')]; dímero (224-224":227-227")-bisdisulfuro, producido por células ováricas de hamster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada
QVQLVQSGAE VKKPGSSVKV SCKASGYTFT SYNMHWVRQA PGQGLEWMGD 50
IYPGNGDTSY NQKFKGRVTI TADKSTSTVY MELSSLRSED TAVYYCARVG 100
GAFPMDYWGQ GTTVTVSSAS TKGPSVFPLA PCSRSTSEST AALGCLVKDY 150
FPEPVTVSWN SGALTSGVHT FPAVLQSSGL YSLSSVVTVP SSSLGTKTYT 200
CNVDHKPSNT KVDKRVESKY GPPCPPCPAP EFLGGPSVFL FPPKPKDTLM 250
ISRTPEVTCV VVDVSQEDPE VQFNWYVDGV EVHNAKTKPR EEQFNSTYRV 300
VSVLTVLHQD WLNGKEYKCK VSNKGLPSSI EKTISKAKGQ PREPQVYTLP 350
PSQEEMTKNQ VSLTCLVKGF YPSDIAVEWE SNGQPENNYK TTPPVLDSDG 400
SFFLYSRLTV DKSRWQEGNV FSCSVMHEAL HNHYTQKSLS LSLG 444

Light chain / Chaîne légère / Cadena ligera
AIQLTQSPSS LSASVGDRVT ITCRASESVE YYGTSLMQWY QQKPGKAPKL 50
LIYAASNVES GVPSRFSGSG SGTDFTLTIS SLQPEDFATY FCQQSRKDPS 100
TFGGGTKVEI 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) 22-96 145-201 259-319 365-423
22"-96" 145"-201" 259"-319" 365"-423"
Intra-L (C23-C104) 23'-92' 138'-198'
23'"-92'" 138'"-198'"
Inter-H-L (CH1 10-CL 126) 132-218' 132"-218'"
Inter-H-H (h 8, h 11) 224-224" 227-227"

N-terminal glutaminyl cyclization to pyroglutamyl (pE, 5-oxoprolyl)
H VH Q1: 1, 1"

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

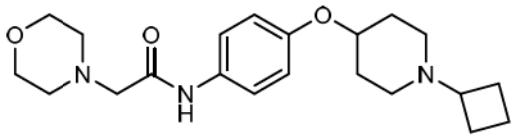
samelisantum

samelisant — *N*-{4-[(1-cyclobutylpiperidin-4-yl)oxy]phenyl}-2-(morpholin-4-yl)acetamide

samélisant — *N*-{4-[(1-cyclobutylpipéridin-4-yl)oxy]phényl}-2-(morpholin-4-yl)acetamide

samelisant — *N*-{4-[(1-ciclobutilpiperidin-4-il)oxi]fenil}-2-(morfolin-4-il)acetamida

$C_{21}H_{31}N_3O_3$



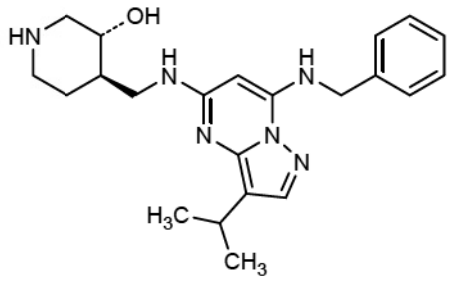
samuraciclibum

samuraciclib — (3*R*,4*R*)-4-({[7-(benzylamino)-3-(propan-2-yl)pyrazolo[1,5-*a*]pyrimidin-5-yl]amino}methyl)piperidin-3-ol

samuraciclib — (3*R*,4*R*)-4-({[7-(benzylamino)-3-(propan-2-yl)pyrazolo[1,5-*a*]pyrimidin-5-yl]amino}méthyl)pipéridin-3-ol

samuraciclib — (3*R*,4*R*)-4-({[7-(benzilamino)-3-(propan-2-il)pirazolo[1,5-*a*]pirimidin-5-il]amino}metil)piperidin-3-ol

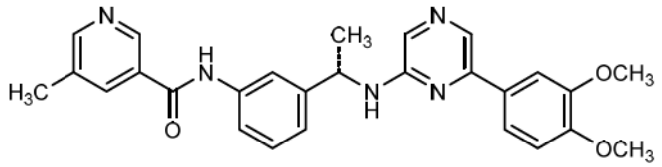
$C_{22}H_{30}N_6O$



seralutinibum

seralutinib	*N*-{3-[(1*S*)-1-{[6-(3,4-dimethoxyphenyl)pyrazin-2-yl]amino}ethyl]phenyl}-5-methylpyridine-3-carboxamide
séralutinib	*N*-{3-[(1*S*)-1-{[6-(3,4-diméthoxyphényl)pyrazin-2-yl]amino}éthyl]phényl}-5-méthylpyridine-3-carboxamide
seralutinib	*N*-{3-[(1*S*)-1-{[6-(3,4-dimetoxifenil)pirazin-2-il]amino}etil]fenil}-5-metilpiridina-3-carboxamida

$C_{27}H_{27}N_5O_3$



simoladagenum autotemcelum #

simoladagene autotemcel	autologous CD34+ hematopoietic stem cells (HSC), obtained by leukapheresis or from bone marrow, transduced *ex vivo* with a non-replicating, self-inactivating (SIN) lentiviral vector encoding codon optimised human adenosine deaminase (ADA) under the internal control of elongation factor 1α short promoter (EFS)
simoladagène autotemcel	cellules souches hématopoïétiques CD34+ autologues obtenues par leucophérèse ou de la moëlle osseuse, transduites *ex vivo* avec un vecteur lentiviral non-répliquant, auto-inactivant (SIN) codant pour l'adénosine déaminase (ADA) humaine codon optimisé sous le contrôle interne d'un promoteur court du facteur d'élongation 1α (EFS)
simoladagén autotemcel	células madre hematopoyéticas CD34+ autólogas obtenidas por leucoaféresis o de médula ósea, transducidas *ex vivo* con un vector lentiviral no replicativo y auto inactivante (SIN), que codifica para la adenosina deaminasa (ADA) humana con codones optimizados bajo el control interno del promotor corto del factor de elongación 1α (EFS)

sisunatovirum

sisunatovir	1'-{[5-(aminomethyl)-1-(4,4,4-trifluorobutyl)-1*H*-benzimidazol-2-yl]methyl}-6'-fluorospiro[cyclopropane-1,3'-indol]-2'(1'*H*)-one

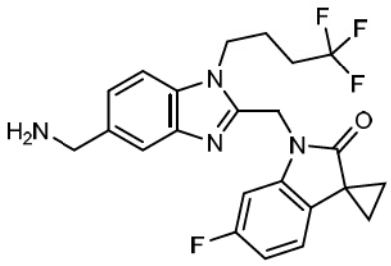
sisunatovir

1'-{[5-(aminométhyl)-1-(4,4,4-trifluorobutyl)-1*H*-benzimidazol-2-yl]méthyl}-6'-fluoro-spiro[cyclopropane-1,3'-[3*H*]indol]-2'(1'*H*)-one

sisunatovir

1'-{[5-(aminometil)-1-(4,4,4-trifluorobutil)-1*H*-benzimidazol-2-il]metil}-6'-fluoro-spiro[ciclopropano-1,3'-[3*H*]indol]-2'(1'*H*)-ona

$C_{23}H_{22}F_4N_4O$



sovesudilum

sovesudil

propyl 2'-(aminomethyl)-5'-[(3-fluoropyridin-4-yl)carbamoyl][1,1'-biphenyl]-3-carboxylate

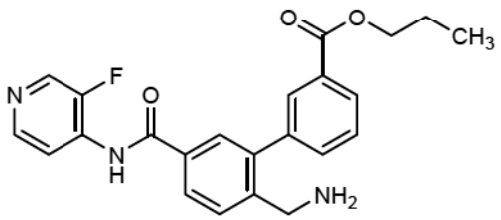
sovésudil

2'-(aminométhyl)-5'-[(3-fluoropyridin-4-yl)carbamoyl][1,1'-biphényl]-3-carboxylate de propyle

sovesudil

2'-(aminometil)-5'-[(3-fluoropiridin-4-il)carbamoil][1,1'-bifenil]-3-carboxilato de propilo

$C_{23}H_{22}FN_3O_3$



sugemalimabum #

sugemalimab

immunoglobulin G4-lambda, anti-[*Homo sapiens* CD274 (programmed death ligand 1, PDL1, PD-L1, B7 homolog 1, B7H1)], *Homo sapiens* monoclonal antibody;
gamma4 heavy chain *Homo sapiens* (1-448) [VH (*Homo sapiens* IGHV3-23*01 (98.0%) -(IGHD) - IGHJ4*01 (100%)) [8.8.14] (1-121) -*Homo sapiens* IGHG4*01, G4v5 h P10 (CH1 (122-219), hinge 1-12 S10>P (229) (220-231), CH2 (232-341), CH3 (342-446), CHS (447-448)) (122-448)], (135-213')-disulfide with lambda light chain *Homo sapiens* (1'-214') [V-LAMBDA (*Homo sapiens* IGLV3-21*02 (100%) - IGLJ2*01 (100%)) [6.3.11] (1'-108') -*Homo sapiens* IGLC2*01 (100%) (109'-214')];
dimer (227-227":230-230")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

sugémalimab

immunoglobuline G4-lambda, anti-[*Homo sapiens* CD274 (ligand 1 de mort programmée, PDL1, PD-L1, homologue 1 de B7, B7H1)], anticorps monoclonal *Homo sapiens*;

chaîne lourde gamma4 *Homo sapiens* (1-448) [VH (*Homo sapiens* IGHV3-23*01 (98.0%) -(IGHD) - IGHJ4*01 (100%)) [8.8.14] (1-121) -*Homo sapiens* IGHG4*01, G4v5 h P10 (CH1 (122-219), charnière 1-12 S10>P (229) (220-231), CH2 (232-341), CH3 (342-446), CHS (447-448)) (122-448)], (135-213')-disulfure avec la chaîne légère lambda *Homo sapiens* (1'-214') [V-LAMBDA (*Homo sapiens* IGLV3-21*02 (100%) - IGLJ2*01 (100%)) [6.3.11] (1'-108') -*Homo sapiens* IGLC2*01 (100%) (109'-214')];
dimère (227-227''':230-230''')-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

sugemalimab

inmunoglobulina G4-lambda, anti-[*Homo sapiens* CD274 (ligando 1 de muerte programada, PDL1, PD-L1, homólogo 1 de B7, B7H1)], anticuerpo monoclonal *Homo sapiens*;
cadena pesada gamma4 *Homo sapiens* (1-448) [VH (*Homo sapiens* IGHV3-23*01 (98.0%) -(IGHD) - IGHJ4*01 (100%)) [8.8.14] (1-121) -*Homo sapiens* IGHG4*01, G4v5 h P10 (CH1 (122-219), bisagra 1-12 S10>P (229) (220-231), CH2 (232-341), CH3 (342-446), CHS (447-448)) (122-448)], (135-213')-disulfuro con la cadena ligera lambda *Homo sapiens* (1'-214') [V-LAMBDA (*Homo sapiens* IGLV3-21*02 (100%) - IGLJ2*01 (100%)) [6.3.11] (1'-108') -*Homo sapiens* IGLC2*01 (100%) (109'-214')];
dímero (227-227''':230-230''')-bisdisulfuro, producido por células ováricas de hamster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLLESGGG LVQPGGSLRL SCAASGFTFS SYAMSWVRQA PGKGLEWVSG  50
ISGSGGFTYY ADSVKGRFTI SRDNSKNTLY LQMNSLRAED TAVYYCAKPP 100
RGYNYGPFDY WGQGTLVTVS SASTKGPSVF PLAPCSRSTS ESTAALGCLV 150
KDYFPEPVTV SWNSGALTSG VHTFPAVLQS SGLYSLSSVV TVPSSSLGTK 200
TYTCNVDHKP SNTKVDKRVE SKYGPPCPPC PAPEFLGGPS VFLFPPKPKD 250
TLMISRTPEV TCVVVDVSQE DPEVQFNWYV DGVEVHNAKT KPREEQFNST 300
YRVVSVLTVL HQDWLNGKEY KCKVSNKGLP SSIEKTISKA KGQPREPQVY 350
TLPPSQEEMT KNQVSLTCLV KGFYPSDIAV EWESNGQPEN NYKTTPPVLD 400
SDGSFFLYSR LTVDKSRWQE GNVFSCSVMH EALHNHYTQK SLSLSLGK   448
```

Light chain / Chaîne légère / Cadena ligera

```
SYVLTQPPSV SVAPGQTARI TCGGNNIGSK SVHWYQQKPG QAPVLVVYDD  50
SDRPSGIPER FSGSNSGNTA TLTISRVEAG DEADYYCQVW DSSSDHVVFG 100
GGTKLTVLGQ PKAAPSVTLF PPSSEELQAN KATLVCLISD FYPGAVTVAW 150
KADSSPVKAG VETTTPSKQS NNKYAASSYL SLTPEQWKSH RSYSCQVTHE 200
GSTVEKTVAP TECS                                        214
```

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

Intra-H (C23-C104)	22-96	148-204	262-322	368-426
	22''-96''	148''-204''	262''-322''	368''-426''
Intra-L (C23-C104)	22'-87'	136'-195'		
	22'''-87'''	136'''-195'''		
Inter-H-L (CH1 10-CL 126)	135-213'	135''-213'''		
Inter-H-H (h 8, h 11)	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-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

Deamidation sites / Sites de déamidation / Posiciones de desamidación
H CH3 N44: 385, 385''
H CH3 N114: 435, 435''
Oxidation sites / Sites de oxydation / Posiciones de oxidación
H CH2 M15.1: 253, 253''
H CH3 M107: 429, 429''

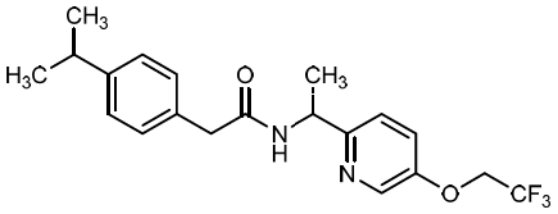
suvecaltamidum

suvecaltamide 2-[4-(propan-2-yl)phenyl]-*N*-{(1*R*)-1-[5-(2,2,2-trifluoroethoxy)pyridin-2-yl]ethyl}acetamide

suvécaltamide 2-[4-(propan-2-yl)phényl]-*N*-{(1*R*)-1-[5-(2,2,2-trifluoroéthoxy)pyridin-2-yl]éthyl}acetamide

suvecaltamida 2-[4-(propan-2-il)fenil]-*N*-{(1*R*)-1-[5-(2,2,2-trifluoroetoxi)piridin-2-il]etil}acetamida

$C_{20}H_{23}F_3N_2O_2$



tebotelimabum #

tebotelimab immunoglobulin G4-kappa, anti-[*Homo sapiens* PDCD1 (programmed cell death 1, PD-1, PD1, CD279)] and anti-[*Homo sapiens* LAG3 (lymphocyte activating 3, lymphocyte-activation 3, CD223)], humanized monoclonal antibody, bispecific tetravalent;
gamma4 heavy chain scFv-h-CH2-CH3 humanized (1-496) [V-KAPPA anti-LAG3 (*Homo sapiens* IGKV1-39*01 (88.4%) -IGKJ4*01 (90.9%)) [6.3.9] (1-107) -8-mer linker (108-115)-VH anti-PDCD1 (*Homo sapiens* IGHV1-46*01 (81.6%) -(IGHD) -IGHJ4*01 (92.9%)) [8.8.12] (116-234) -6-mer diglycyl-cysteinyl-triglycyl linker (235-240)-E-coil motif (241-268) -*Homo sapiens* IGHG4*01, G4v5 h P10, G4v21 CH2 Y15.1, T16, E18 (hinge 1-12 S10>P (278) (269-280), CH2 M15.1>Y (302), S16>T (304), T18>E (306) (281-390), CH3 (391-495), CHS K>del (496) (269-496))], (237-240':245-248')-bisdisulfide with kappa light chain humanized (1'-271')[V-KAPPA anti-PDCD1 (*Homo sapiens* IGKV3D-11*02 (77.7%) -IGKJ4*01 (100%)) [10.3.9] (1'-111') -8-mer linker (112'-119')-VH anti LAG3 (*Homo sapiens* IGHV1-18*01 (86.7%) -(IGHD) -IGHJ4*01 (82.7%)) [8.8.11] (120'-237') -6-mer diglycyl-cysteinyl-triglycyl linker (238'-243') -K-coil motif (244'-271')]; dimer (276-276'':279-279'')-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

tébotélimab immunoglobuline G4-kappa, anti-[*Homo sapiens* PDCD1 (protéine 1 de mort cellulaire programmée, PD-1, PD1, CD279)] et anti-[*Homo sapiens* LAG3 (activateur 3 des lymphocytes, lymphocyte-activation 3, CD223)], anticorps monoclonal humanisé, bispécifique tétravalent;
chaîne lourde gamma4 scFv-h-CH2-CH3 humanisée (1-496) [V-KAPPA anti-LAG3 (*Homo sapiens* IGKV1-39*01 (88.4%) -IGKJ4*01 (90.9%)) [6.3.9] (1-107) -8-mer linker (108-115) -VH anti-PDCD1 (*Homo sapiens* IGHV1-46*01 (81.6%) -(IGHD) -IGHJ4*01 (92.9%)) [8.8.12] (116-234) -6-mer diglycyl-cystéinyl-triglycyl linker (235-240)-E-coil motif (241-268) -*Homo sapiens* IGHG4*01, G4v5 h P10, G4v21 CH2 Y15.1, T16, E18 (charnière 1-12 S10>P (278) (269-280), CH2 M15.1>Y (302), S16>T (304), T18>E (306) (281-390), CH3 (391-495), CHS K>del (496) (269-496))],(237-240':245-248')-bisdisulfure avec la chaîne légère kappa humanisée (1'-271') [V-KAPPA anti-PDCD1 (*Homo sapiens* IGKV3D-11*02 (77.7%) -IGKJ4*01 (100%)) [10.3.9] (1'-111') -8-mer linker (112'-119')-VH anti-LAG3(*Homo sapiens* IGHV1-18*01 (86.7%) -(IGHD) -IGHJ4*01 (82.7%)) [8.8.11] (120'-237') -6-mer diglycyl-cystéinyl-triglycyl linker (238'-243') -K-coil motif (244'-271')];
dimère (276-276'':279-279'')-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

tebotelimab

inmunoglobulina G4-kappa, anti-[*Homo sapiens* PDCD1 (proteína 1 de muerte celular programada, PD-1, PD1, CD279)] y anti-[*Homo sapiens* LAG3 (activador 3 de los linfocitos, linfocito-activación 3, CD223)], anticuerpo monoclonal humanizado, biespecífico tetravalente;
cadena pesada gamma4 scFv-h-CH2-CH3 humanizada (1-496) [V-KAPPA anti-LAG3 (*Homo sapiens* IGKV1-39*01 (88.4%) -IGKJ4*01 (90.9%)) [6.3.9] (1-107) -conector octámero (108-115) -VH anti-PDCD1 (Homo sapiens IGHV1-46*01 (81.6%) -(IGHD) -IGHJ4*01 (92.9%)) [8.8.12] (116-234) -conector sexámero diglicil-cisteinil-triglicil (235-240) -E-coil motif (241-268) -Homo sapiens IGHG4*01, G4v5 h P10, G4v21 CH2 Y15.1, T16, E18 (bisagra 1-12 S10>P (278) (269-280), CH2 M15.1>Y (302), S16>T (304), T18>E (306) (281-390), CH3 (391-495), CHS K>del (496) (269-496))],(237-240':245-248')-bisdisulfuro con la cadena ligera kappa humanizada (1'-271') [V-KAPPA anti-PDCD1 (*Homo sapiens* IGKV3D-11*02 (77.7%) -IGKJ4*01 (100%)) [10.3.9] (1'-111') -conector octámero (112'-119')-VH anti-LAG3(*Homo sapiens* IGHV1-18*01 (86.7%) -(IGHD) -IGHJ4*01 (82.7%)) [8.8.11] (120'-237') -conector sexámero diglicil-cisteinil-triglicil (238'-243') -K-coil motif (244'-271')];
dímero (276-276":279-279")-bisdisulfuro, producido por células ováricas de hamster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
DIQMTQSPSS LSASVGDRVT ITCRASQDVS SVVAWYQQKP GKAPKLLIYS  50
ASYRYTGVPS RFSGSGSGTD FTLTISSLQP EDFATYYCQQ HYSTPWTFGG 100
GTKLEIKGGG SGGGGQVQLV QSGAEVKKPG ASVKVSCKAS GYSFTSYWMN 150
WVRQAPGQGL EWIGVIHPSD SETWLDQKFK DRVTITVDKS TSTAYMELSS 200
LRSEDTAVYY CAREHYGTSP FAYWGQGTLV TVSSGGCGGG EVAACEKEVA 250
ALEKEVAALE KEVAALEKES KYGPPCPPCP APEFLGGPSV FLFPPKPKDT 300
LYITREPEVT CVVVDVSQED PEVQFNWYVD GVEVHNAKTK PREEQFNSTY 350
RVVSVLTVLH QDWLNGKEYK CKVSNKGLPS SIEKTISKAK GQPREPQVYT 400
LPPSQEEMTK NQVSLTCLVK GFYPSDIAVE WESNGQPENN YKTTPPVLDS 450
DGSFFLYSRL TVDKSRWQEG NVFSCSVMHE ALHNHYTQKS LSLSLG     496
```

Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPAT LSLSPGERAT LSCRASESVD NYGMSFMNWF QQKPGQPPKL  50
LIHAASNQGS GVPSRFSGSG SGTDFTLTIS SLEPEDFAVY FCQQSKEVPY 100
TFGGGTKVEI KGGGSGGGGQ VQLVQSGAEV KKPGASVKVS CKASGYTFTD 150
YNMDWVRQAP GQGLEWMGDI NPDNGVTIYN QKFEGRVTMT TDTSTSTAYM 200
ELRSLRSDDT AVYYCAREAD YFYFDYWGQG TTLTVSSGGC GGGKVAACKE 250
KVAALKEKVA ALKEKVAALK E                                271
```

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

Intra-H (C23-C104)	23-88	137-211	311-371	417-475
	23"-88"	137"-211"	311"-371"	417"-475"
Intra-L (C23-C104)	23'-92'	141'-215'		
	23'"-92'"	141'"-215'"		
Inter-H-L	237-240'	245-248'		
	237"-240'"	245"-248'"		
Inter-H-H (h 8, h 11)	276-276"	279-279"		

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
347, 347"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

telazorlimabum #

telazorlimab

immunoglobulin G1-kappa, anti-[*Homo sapiens* TNFRSF4 (tumor necrosis factor receptor (TNFR) superfamily member 4, ACT35, OX40, CD134)], humanized monoclonal antibody;
gamma1 heavy chain humanized (1-448) [VH (*Homo sapiens* IGHV2-70*10 (93.0%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [10.7.10] (26-35.53-59.98-107) (1-118) -*Homo sapiens* IGHG1*01 (100%), G1m17,1 (CH1 K120 (215) (119-216), hinge 1-15 (217-231), CH2 (232-341), CH3 D12 (357), L14 (359) (342-446), CHS (447-448)) (119-448)], (221-213')-disulfide with kappa light chain humanized (1'-213') [V-KAPPA (*Homo sapiens* IGKV3-11*01 (87.4%) -IGKJ1*01 (100%)) CDR-IMGT [5.3.9] (27-31.49-51.38-46) (1'-106') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (152), V101 (190) (107'-213')];
dimer (227-227":230-230")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

télazorlimab	immunoglobuline G1-kappa, anti-[*Homo sapiens* TNFRSF4 (membre 4 de la superfamille des récepteurs du facteur de nécrose tumorale, ACT35, OX40, CD134)], anticorps monoclonal humanisé; chaîne lourde gamma1 humanisée (1-448) [VH (*Homo sapiens* IGHV2-70*10 (93.0%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [10.7.10] (26-35.53-59.98-107) (1-118) -*Homo sapiens* IGHG1*01 (100%), G1m17,1 (CH1 K120 (215) (119-216), charnière 1-15 (217-231), CH2 (232-341), CH3 D12 (357), L14 (359) (342-446), CHS (447-448)) (119-448)], (221-213')-disulfure avec la chaîne légère kappa humanisée (1'-213') [V-KAPPA (*Homo sapiens* IGKV3-11*01 (87.4%) -IGKJ1*01 (100%)) CDR-IMGT [5.3.9] (27-31.49-51.38-46) (1'-106') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (152), V101 (190) (107'-213')]; dimère (227-227":230-230")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa
telazorlimab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* TNFRSF4 (miembro 4 de la superfamilia de los receptores del factor de necrosis tumoral, ACT35, OX40, CD134)], anticuerpo monoclonal humanizado; cadena pesada gamma1 humanizada (1-448) [VH (*Homo sapiens* IGHV2-70*10 (93.0%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [10.7.10] (26-35.53-59.98-107) (1-118) -*Homo sapiens* IGHG1*01 (100%), G1m17,1 (CH1 K120 (215) (119-216), bisagra 1-15 (217-231), CH2 (232-341), CH3 D12 (357), L14 (359) (342-446), CHS (447-448)) (119-448)], (221-213')-disulfuro con la cadena ligera kappa humanizada (1'-213') [V-KAPPA (*Homo sapiens* IGKV3-11*01 (87.4%) -IGKJ1*01 (100%)) CDR-IMGT [5.3.9] (27-31.49-51.38-46) (1'-106') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (152), V101 (190) (107'-213')]; dímero (227-227":230-230")-bisdisulfuro, producido por células ováricas de hamster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVTLKESGPA LVKPTQTLTL TCSFSGFSLS TSGMGVGWIR QPPGKALEWI  50
AHIWWDDDKY YNTALKTRLT ISKDTSKNQV VLTMTNMDPV DTATYYCARI 100
DWDGFAYWGQ GTLVTVSSAS TKGPSVFPLA PSSKSTSGGT AALGCLVKDY 150
FPEPVTVSWN SGALTSGVHT FPAVLQSSGL YSLSSVVTVP SSSLGTQTYI 200
CNVNHKPSNT KVDKKVEPKS CDKTHTCPPC PAPELLGGPS VFLFPPKPKD 250
TLMISRTPEV TCVVVDVSHE DPEVKFNWYV DGVEVHNAKT KPREEQYNST 300
YRVVSVLTVL HQDWLNGKEY KCKVSNKALP APIEKTISKA KGQPREPQVY 350
TLPPSRDELT KNQVSLTCLV KGFYPSDIAV EWESNGQPEN NYKTTPPVLD 400
SDGSFFLYSK LTVDKSRWQQ GNVFSCSVMH EALHNHYTQK SLSLSPGK   448
```

Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPAT LSLSPGERAT LSCRASSSVS YMHWYQQKPG QAPRPWIYAT  50
SNRATGIPAR FSGSGSGTDY TLTISSLEPE DFAVYYCQQW SSNPWTFGQG 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)	22-97	145-201	262-322	368-426
	22"-97"	145"-201"	262"-322"	368"-426"
Intra-L (C23-C104)	23'-87'	133'-193'		
	23'"-87'"	133'"-193'"		
Inter-H-L (h 5-CL 126)	221-213'	221"-213'"		
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-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

C-terminal lysine clipping:

H CHS K2:
448, 448"

WHO Drug Information, Vol. 34, No. 3, 2020 Recommended INN: List 84

tesnatilimabum

tesnatilimab	immunoglobulin G4-kappa, anti-[*Homo sapiens* KLRK1 (killer cell lectin like receptor K1, NKG2D, KLR, NKG2-D, CD314)], *Homo sapiens* monoclonal antibody; gamma4 heavy chain *Homo sapiens* (1-442) [VH (*Homo sapiens* IGHV4-59*01 (93.8%) -(IGHD) - IGHJ3*02 (93.8%)) CDR-IMGT [8.7.9] (26-33.51-57.96-104) (1-115) -*Homo sapiens* IGHG4*01, G4v5 h P10 (CH1 (116-213), hinge S10>P (223) (214-225), CH2 (226-335), CH3 (336-440), CHS (441-442)) (116-442)], (129-215')-disulfide with kappa light chain *Homo sapiens* (1'-215') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (100%) -IGKJ1*01 (100%)) CDR-IMGT [7.3.9] (27-33.51-53.90-98) (1'-108') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (154), V101 (192) (109'-215')]; dimer (221-221'':224-224'')-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa
tesnatilimab	immunoglobuline G4-kappa, anti-[*Homo sapiens* KLRK1 (récepteur lectine like K1 de cellule tueuse, NKG2D, KLR, NKG2-D, CD314)], anticorps monoclonal *Homo sapiens*; chaîne lourde gamma1 *Homo sapiens* (1-442) [VH (*Homo sapiens* IGHV4-59*01 (93.8%) -(IGHD) - IGHJ3*02 (93.8%)) CDR-IMGT [8.7.9] (26-33.51-57.96-104) (1-115) -*Homo sapiens* IGHG4*01, G4v5 h P10 (CH1 (116-213), charnière S10>P (223) (214-225), CH2 (226-335), CH3 (336-440), CHS (441-442)) (116-442)], (129-215')-disulfure avec la chaîne légère kappa *Homo sapiens* (1'-215') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (100%) -IGKJ1*01 (100%)) CDR-IMGT [7.3.9] (21-33.51-53.90-98) (1'-108') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (154), V101 (192) (109'-215')]; dimère (221-221'':224-224'')-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa
tesnatilimab	inmunoglobulina G4-kappa, anti-[*Homo sapiens* KLRK1 (receptor lectina like K1 de célula asesina, NKG2D, KLR, NKG2-D, CD314)], anticuerpo monoclonal *Homo sapiens*; cadena pesada gamma1 *Homo sapiens* (1-442) [VH (*Homo sapiens* IGHV4-59*01 (93.8%) -(IGHD) - IGHJ3*02 (93.8%)) CDR-IMGT [8.7.9] (26-33.51-57.96-104) (1-115) -*Homo sapiens* IGHG4*01, G4v5 h P10 (CH1 (116-213), bisagra S10>P (223) (214-225), CH2 (226-335), CH3 (336-440), CHS (441-442)) (116-442)], (129-215')-disulfuro con la cadena ligera kappa *Homo sapiens* (1'-215') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (100%) -IGKJ1*01 (100%)) CDR-IMGT [7.3.9] (21-33.51-53.90-98) (1'-108') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (154), V101 (192) (109'-215')]; dímero (221-221'':224-224'')-bisdisulfuro, producido por células ováricas de hamster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVHLQESGPG LVKPSETLSL TCTVSDDSIS SYYWSWIRQP PGKGLEWIGH  50
ISYSGSANYN PSLKSRVTIS VDTSKNQFSL KLSSVTAADT AVYYCANWDD 100
AFNIWGQGTM VTVSSASTKG PSVFPLAPCS RSTSESTAAL GCLVKDYFPE 150
PVTVSWNSGA LTSGVHTFPA VLQSSGLYSL SSVVTVPSSS LGTKTYTCNV 200
DHKPSNTKVD KRVESKYGPP CPPCPAPEFL 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 GK         442
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Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPGT LSLSPGERAT LSCRASQSVS SSYLAWYQQK PGQAPRLLIY  50
GASSRATGIP DRFSGSGSGT DFTLTISRLE PEDFAVYYCQ QYGSSPWTFG 100
QGTKVEIKRT VAAPSVFIFP PSDEQLKSGT ASVVCLLNNF YPREAKVQWK 150
VDNALQSGNS QESVTEQDSK DSTYSLSSTL TLSKADYEKH KVYACEVTHQ 200
GLSSPVTKSF NRGEC                                       215
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Post-translational modifications

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

Intra-H (C23-C104)	22-95	142-198	256-316	362-420
	22"-95"	142"-198"	256"-316"	362"-420"
Intra-L (C23-C104)	23'-89'	135'-195'		
	23'"-89'"	135'"-195'"		
Inter-H-L (CH1 10-CL 126)	129-215'	129"-215'"		
Inter-H-H (h 8, h 11)	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

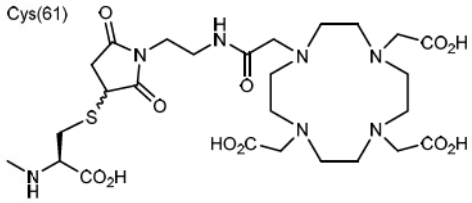
tezatabepum matraxetanum #

tezatabep matraxetan	three-alpha-helix binding protein, derived from an immunoglobulin G (IgG)-binding domain of a staphylococcal protein A (SpA), designed to bind receptor tyrosine-protein kinase erbB-2 (ERBB2, Neu, HER2), produced by peptide synthesis, conjugated at the C-terminal Cys^{61} to one (3*RS*)-2,5-dioxo-1-(2-{2-[4,7,10-tris(carboxymethyl)-1,4,7,10-tetraazacyclododecan-1-yl]acetamido}ethyl)pyrrolidin-3-yl (*matraxetan*) group
tézatabep matraxétan	protéine à trois hélices alpha, dérivée du domaine de l'immunoglobuline G (IgG) se liant à la protéine staphylococcique A (SpA), mise au point pour se lier au récepteur tyrosine-protéine kinase erbB-2 (ERBB2, Neu, HER2), produite par synthèse peptidique, conjuguée sur la Cys^{61} en sa partie C-terminale à un groupe (3*RS*)-2,5-dioxo-1-(2-{2-[4,7,10-tris(carboxyméthyl)-1,4,7,10-tétraazacyclododécan-1-yl]acétamido}éthyl)pyrrolidin-3-yle (*matraxétan*)
tezatabep matraxetán	proteína de tres hélices alfa, derivada del dominio de la inmunoglobulina G (IgG) que se une a la proteína estafilocócica A (SpA), diseñada para unirse al receptor tirosina-proteína kinasa erbB-2 (ERBB2, Neu, HER2), producida por síntesis peptídica, conjugada con la Cys^{61} en su parte C-terminal a un grupo (3*RS*)-2,5-dioxo-1-(2-{2-[4,7,10-tris(carboximetil)-1,4,7,10-tetraazaciclododecan-1-il]acetamido}etil)pirrolidin-3-ilo (*matraxetán*)

Sequence / Séquence / Secuencia

```
AEAKYAKEMR NAYWEIALLP NLTNQQKRAF IRKLYDDPSQ SSELLSEAKK  50
LNDSQAPKVD C*                                           61
```

Potential modified residues / résidus modifiés potentiels / restos modificados pote



tifalibepum #

tifalibep	fusion protein composed of 3 binding domains, each consisting of a three-alpha-helix motif derived from the immunoglobulin (Ig)-binding Z-domain of staphylococcal protein A (SpA), engineered for binding to the human neonatal Fc receptor (FcRn) with the two identical N- and C-terminal domains (1-58, 116-173), and for binding to the domain II of human serum albumin (HSA) with the central domain (59-110), connected via a G_4S peptide linker (111-115); [FcRn-binding engineered SpA peptide (1-58)]-[HSA-binding engineered SpA peptide (59-110)]-[G_4S linker (111-115)]-[FcRn-binding engineered SpA peptide (116-173] fusion protein; produced in *Escherichia coli*
tifalibep	protéine de fusion composée de 3 domaines liants, chacun consistant en un motif à 3 hélices alfa dérivé du domaine Z de la protéine staphylococcique A (SpA) se liant à l'immunoglobuline (Ig), mis au point pour se lier au récepteur Fc néonatal humain (FcRn) avec les deux domaines N- et C-terminaux identiques (1-58, 116-173), et au domaine II de l'albumine sérique humaine (ASH, HSA) avec le domaine central (59-110), connecté via un peptide liant G_4S (111-115) ; protéine de fusion [peptide SpA mis au point pour se lier au FcRn (1-58)]-[peptide SpA mis au point pour se lier au HSA (59-110)]-[peptide liant G_4S (111-115)]-[peptide SpA mis au point pour se lier au FcRn (116-173)]; produite par *Escherichia coli*
tifalibep	proteína de fusión compuesta de 3 dominios de unión, cada uno consistente en un motivo con 3 hélices alfa derivado del dominio Z de la proteína estafilocócica A (SpA) que se une a la inmunoglobulina (Ig), diseñada para unirse al receptor Fc neonatal humano (FcRn) con los dos dominios N- y C-terminal idénticos (1-58, 116-173), y con el dominio II de la albúmina sérica humana (ASH, HSA) con el dominio central (59-110), conectado a través de un péptido linker G_4S (111-115) ; proteína de fusión [péptido SpA diseñado para unirse al FcRn (1-58)]-[péptido SpA diseñado para unirse al HSA (59-110)]-[G_4S linker (111-115)]-[péptido SpA diseñado para unirse al FcRn (116-173)]; producida por *Escherichia coli*

Sequence / Séquence / Secuencia

```
AEAKFAKEWQ QAAHEIRWLP NLTFDQRVAF IHKLRDDPSQ SSELLSEAKK   50
LSESQAPKAS GSLAEAKEAA NAELDSYGVS DFYKRLIDKA KTVEGVEALK  100
DAILAALPGT GGGGSAEAKF AKEWQQAAHE IRWLPNLTFD QRVAFIHKLR  150
DDPSQSSELL SEAKKLSESQ APK                                173
```

Post-translational modifications / Modifications post-traductionnelles / Modificaciones postraduccionales
None / aucune / ninguna

tilogotamabum #

tilogotamab	immunoglobulin G1-kappa, anti-[*Homo sapiens* TNFRSF10B (tumor necrosis factor receptor (TNFR) superfamily member 10B, death receptor 5, DR5, TNF-related apoptosis-inducing ligand receptor 2, TRAILR2, TRAIL-R2, TR-2, CD262)], humanized monoclonal antibody; gamma1 heavy chain humanized (1-447) [VH (*Homo sapiens* IGHV1-3*01 (84.7%) -(IGHD) -IGHJ4*01 (93.3%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (1-118) -*Homo sapiens* IGHG1*03, G1m3, nG1m1, G1v34 CH3 G109 (CH1 R120 (215) (119-216), hinge 1-15 (217-231), CH2 (232-341), CH3 E12 (357), M14 (359), E109>G (431) (342-446), CHS K>del (447)) (119-447)], (221-213')-disulfide with kappa light chain humanized (1'-213') [V-KAPPA (*Homo sapiens* IGKV1-16*01 (83.2%) -IGKJ4*01 (100%)) CDR-IMGT [5.3.9] (27-31.49-51.88-96) (1'-106') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (152), V101 (190) (107'-213')]; dimer (227-227":230-230")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa
tilogotamab	immunoglobuline G1-kappa, anti-[*Homo sapiens* TNFRSF10B (membre 10B de la superfamille des récepteurs du facteur de nécrose tumorale (TNFR), récepteur de mort 5, DR5, TRAILR2, TRAIL-R2, TR-2, CD262)], anticorps monoclonal humanisé; chaîne lourde gamma1 humanisée (1-447) [VH (*Homo sapiens* IGHV1-3*01 (84.7%) -(IGHD) -IGHJ4*01 (93.3%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (1-118) -*Homo sapiens* IGHG1*03, G1m3, nG1m1, G1v34 CH3 G109 (CH1 R120 (215) (119-216), charnière 1-15 (217-231), CH2 (232-341), CH3 E12 (357), M14 (359), E109>G (431) (342-446), CHS K>del (447)) (119-447)], (221-213')-disulfure avec la chaîne légère kappa humanisée (1'-213') [V-KAPPA (*Homo sapiens* IGKV1-16*01 (83.2%) -IGKJ4*01 (100%)) CDR-IMGT [5.3.9] (27-31.49-51.88-96) (1'-106') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (152), V101 (190) (107'-213')]; dimère (227-227":230-230")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa
tilogotamab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* TNFRSF10B (miembro 10B de la superfamilia de los receptores del factor de necrosis tumoral (TNFR), receptor de muerte 5, DR5, TRAILR2, TRAIL-R2, TR-2, CD262)], anticuerpo monoclonal humanizado;

cadena pesada gamma1 humanizada (1-447) [VH (*Homo sapiens* IGHV1-3*01 (84.7%) -(IGHD) - IGHJ4*01 (93.3%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (1-118) -*Homo sapiens* IGHG1*03, G1m3, nG1m1, G1v34 CH3 G109 (CH1 R120 (215) (119-216), bisagra 1-15 (217-231), CH2 (232-341), CH3 E12 (357), M14 (359), E109>G (431) (342-446), CHS K>del (447)) (119-447)], (221-213')-disulfuro con la cadena ligera kappa humanizada (1'-213') [V-KAPPA (*Homo sapiens* IGKV1-16*01 (83.2%) -IGKJ4*01 (100%)) CDR-IMGT [5.3.9] (27-31.49-51.88-96) (1'-106') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (152), V101 (190) (107'-213')];
dímero (227-227":230-230")-bisdisulfuro, producido por células ováricas de hamster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGASVKV SCKASGFNIK DTHMHWVRQA PGQRLEWIGR  50
IDPANGNTEY DQKFQGRVTI TVDTSASTAY MELSSLRSED TAVYYCARWG 100
TNVYFAYWGQ GTLVTVSSAS 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 GALHNHYTQK SLSLSPG    447
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Light chain / Chaîne légère / Cadena ligera

```
DIQLTQSPSS LSASVGDRVT ITCSASSSVS YMYWYQQKPG KAPKPWIYRT  50
SNLASGVPSR FSGSGSGTDF TLTISSLQPE DFATYYCQQY HSYPPTFGGG 100
TKVEIKRTVA APSVFIFPPS DEQLKSGTAS VVCLLNNFYP REAKVQWKVD 150
NALQSGNSQE SVTEQDSKDS TYSLSSTLTL SKADYEKHKV YACEVTHQGL 200
SSPVTKSFNR GEC                                         213
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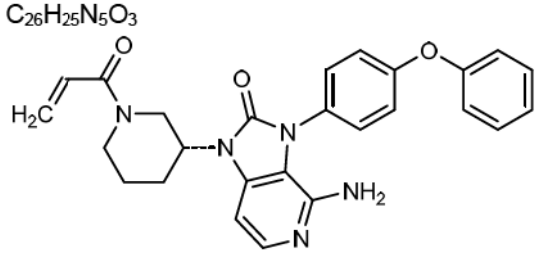
Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro

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'-87'	133'-193'		
	23'"-87'"	133'"-193'"		
Inter-H-L (h 5-CL 126)	221-213'	221"-213'"		
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-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

tolebrutinibum

tolebrutinib	4-amino-3-(4-phenoxyphenyl)-1-[(3*R*)-1-(prop-2-enoyl)piperidin-3-yl]-1,3-dihydro-2*H*-imidazo[4,5-*c*]pyridin-2-one
tolébrutinib	4-amino-3-(4-phénoxyphényl)-1-[(3*R*)-1-(prop-2-énoyl)pipéridin-3-yl]-1,3-dihydro-2*H*-imidazo[4,5-*c*]pyridin-2-one
tolebrutinib	4-amino-3-(4-fenoxifenil)-1-[(3*R*)-1-(prop-2-enoil)piperidin-3-il]-1,3-dihidro-2*H*-imidazo[4,5-*c*]piridin-2-ona



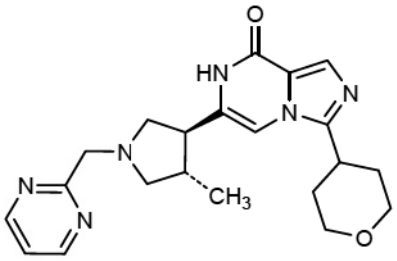
tovinontrinum

tovinontrine — 6-{(3*S*,4*S*)-4-methyl-1-[(pyrimidin-2-yl)methyl]pyrrolidin-3-yl}-3-(oxan-4-yl)imidazo[1,5-*a*]pyrazin-8(7*H*)-one

tovinontrine — 6-{(3*S*,4*S*)-4-méthyl-1-[(pyrimidin-2-yl)méthyl]pyrrolidin-3-yl}-3-(oxan-4-yl)imidazo[1,5-*a*]pyrazin-8(7*H*)-one

tovinontrina — 6-{(3*S*,4*S*)-4-metil-1-[(pirimidin-2-il)metil]pirrolidin-3-il}-3-(oxan-4-il)imidazo[1,5-*a*]pirazin-8(7*H*)-ona

$C_{21}H_{26}N_6O_2$



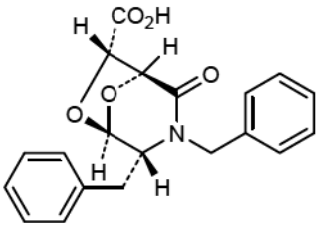
udonitrectagum

udonitrectag — (1*S*,4*R*,5*R*,7*S*)-3,4-dibenzyl-2-oxo-6,8-dioxa-3-azabicyclo[3.2.1]octane-7-carboxylic acid

udonitrectag — acide (1*S*,4*R*,5*R*,7*S*)-3,4-dibenzyl-2-oxo-6,8-dioxa-3-azabicyclo[3.2.1]octane-7-carboxylique

udonitrectag — ácido (1*S*,4*R*,5*R*,7*S*)-3,4-dibencil-2-oxo-6,8-dioxa-3-azabiciclo[3.2.1]octano-7-carboxílico

$C_{20}H_{19}NO_5$



upifitamabum #

upifitamab — immunoglobulin G1-kappa, anti-[*Homo sapiens* SLC34A2 (solute carrier family 34 (sodium phosphate) member 2, sodium/phosphate cotransporter 2B, NaPi2b, NaPi3b)], monoclonal antibody;
gamma1 heavy chain (1-449) [VH (*Homo sapiens* IGHV1-46*01 (81.6%) -(IGHD) -IGHJ4*01 (92.9%)) [8.8.12] (1-119) -glycyl (120) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (217) (121-218), hinge 1-15 (219-233), CH2 (234-343), CH3 E12 (359), M14 (361) (344-448), CHS K>del (449)) (121-449)], (223-215')-disulfide with kappa light chain (1'-215') [V-KAPPA (*Mus musculus* IGKV10-94*01 (84.2%) -IGKJ5*01 (91.7%)/*Homo sapiens* IGKV1-16*01 (83.2%) -IGKJ2*01 (90.9%)) [6.3.9] (1'-107') -arginyl (108') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (154), V101 (192) (109'-215')];
dimer (229-229":232-232")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

upifitamab

immunoglobuline G1-kappa, anti-[*Homo sapiens* SLC34A2 (membre 2 de la famille 34 (phosphate de sodium) de transporteurs de solutés, cotransporteur 2B de sodium/phosphate, NaPi2b, NaPi3b)], anticorps monoclonal; chaîne lourde gamma1 (1-449) [VH (*Homo sapiens* IGHV1-46*01 (81.6%) -(IGHD) -IGHJ4*01 (92.9%)) [8.8.12] (1-119) -glycyl (120) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (217) (121-218), charnière 1-15 (219-233), CH2 (234-343), CH3 E12 (359), M14 (361) (344-448), CHS K>del (449)) (121-449)], (223-215')-disulfure avec la chaîne légère kappa (1'-215') [V-KAPPA (*Mus musculus* IGKV10-94*01 (84.2%) -IGKJ5*01 (91.7%)/*Homo sapiens* IGKV1-16*01 (83.2%) -IGKJ2*01 (90.9%)) [6.3.9] (1'-107') -arginyl (108') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (154), V101 (192) (109'-215')];
dimère (229-229":232-232")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

upifitamab

inmunoglobulina G1-kappa, anti-[*Homo sapiens* SLC34A2 (miembro 2 de la familia 34 (fosfato de sodio) de transportadores de solutos, cotransportador 2B de sodio/fosfato, NaPi2b, NaPi3b)], anticuerpo monoclonal; cadena pesada gamma1 (1-449) [VH (*Homo sapiens* IGHV1-46*01 (81.6%) -(IGHD) -IGHJ4*01 (92.9%)) [8.8.12] (1-119) -glicil (120) -*Homo sapiens* IGHG1*03, G1m3, nG1m1 (CH1 R120 (217) (121-218), bisagra 1-15 (219-233), CH2 (234-343), CH3 E12 (359), M14 (361) (344-448), CHS K>del (449)) (121-449)], (223-215')-disulfuro con la cadena ligera kappa (1'-215') [V-KAPPA (*Mus musculus* IGKV10-94*01 (84.2%) -IGKJ5*01 (91.7%)/*Homo sapiens* IGKV1-16*01 (83.2%) -IGKJ2*01 (90.9%)) [6.3.9] (1'-107') -arginil (108') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (154), V101 (192) (109'-215')];
dímero (229-229":232-232")-bisdisulfuro, producido por células ováricas de hamster chino (CHO), forma glicosilada alfa



Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VVKPGASVKM SCKASGYTFT GYNIHWVKQA PGQGLEWIGA  50
IYPGNGDTSY KQKFRGRATL TADTSTSTVY MELSSLRSED SAVYYCARGE 100
TARATFAYWG QGTLVTVSSG ASTKGPSVFP LAPSSKSTSG GTAALGCLVK 150
DYFPEPVTVS WNSGALTSGV HTFPAVLQSS GLYSLSSVVT VPSSSLGTQT 200
YICNVNHKPS NTKVDKRVEP 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

```
DIQMTQSPSS LSASVGDRVT ITCSASQDIG NFLNWYQQKP GKTVKVLIYY  50
TSSLYSGVPS RFSGSGSGTD YTLTISSLQP EDFATYYCQQ YSKLPLTFGQ 100
GTKLELKRRT 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)	22-96	147-203	264-324	370-428
	22"-96"	147"-203"	264"-324"	370"-428"
Intra-L (C23-C104)	23'-88'	135'-195'		
	23'"-88'"	135'"-195'"		
Inter-H-L (h 5-CL 126)	223-215'	223"-215'"		
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

urabrelimabum #

urabrelimab	immunoglobulin G4-kappa, anti-[*Homo sapiens* CD47 (integrin associated protein, IAP, MER6, OA3)], *Homo sapiens* monoclonal antibody; gamma4 heavy chain *Homo sapiens* (1-452) [VH (*Homo sapiens* IGHV4-4*02 (94.9%) -(IGHD) - IGHJ6*01 (94.7%)) CDR-IMGT [9.7.18] (26-34.52-58.97-114) (1-125)-*Homo sapiens* IGHG4*01 (CH1 (126-223), hinge 1-12 (224-235), CH2 (236-345), CH3 (346-450), CHS (451-452)) (126-452)], (139-212')-disulfide with kappa light chain *Homo sapiens* (1'-212') [V-KAPPA (*Homo sapiens* IGKV3-11*01 (94.7%) - IGKJ4*01 (91.7%)) CDR-IMGT [6.3.8] (27-32.50-52.89-96) (1'-106') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (151), V101 (189) (107'-212')]; dimer (231-231":234-234")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa
urabrélimab	immunoglobuline G4-kappa, anti-[*Homo sapiens* CD47 (protéine associée à l'intégrine, IAP, MER6, OA3)], anticorps monoclonal *Homo sapiens*; chaîne lourde gamma4 *Homo sapiens* (1-452) [VH (*Homo sapiens* IGHV4-4*02 (94.9%) -(IGHD) - IGHJ6*01 (94.7%)) CDR-IMGT [9.7.18] (26-34.52-58.97-114) (1-125)-*Homo sapiens* IGHG4*01 (CH1 (126-223), charnière 1-12 (224-235), CH2 (236-345), CH3 (346-450), CHS (451-452)) (126-452)], (139-212')-disulfure avec la chaîne légère kappa *Homo sapiens* (1'-212') [V-KAPPA (*Homo sapiens* IGKV3-11*01 (94.7%) -IGKJ4*01 (91.7%)) CDR-IMGT [6.3.8] (27-32.50-52.89-96) (1'-106') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (151), V101 (189) (107'-212')]; dimère (231-231":234-234")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa
urabrelimab	inmunoglobulina G4-kappa, anti-[*Homo sapiens* CD47 (proteína asociada a la integrina, IAP, MER6, OA3)], anticuerpo monoclonal *Homo sapiens*; cadena pesada gamma4 *Homo sapiens* (1-452) [VH (*Homo sapiens* IGHV4-4*02 (94.9%) -(IGHD) - IGHJ6*01 (94.7%)) CDR-IMGT [9.7.18] (26-34.52-58.97-114) (1-125)-*Homo sapiens* IGHG4*01 (CH1 (126-223), bisagra 1-12 (224-235), CH2 (236-345), CH3 (346-450), CHS (451-452)) (126-452)], (139-212')-disulfuro con la cadena ligera kappa *Homo sapiens* (1'-212') [V-KAPPA (*Homo sapiens* IGKV3-11*01 (94.7%) -IGKJ4*01 (91.7%)) CDR-IMGT [6.3.8] (27-32.50-52.89-96) (1'-106') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (151), V101 (189) (107'-212')]; dímero (231-231":234-234")-bisdisulfuro, producido por células ováricas de hamster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLQESGPG LVKPSGTLSL TCAVSGVSIR SINWWNWVRQ PPGKGLEWIG  50
EIYHSGSTNY NPSLKSRVTI SVDKSKNQFS LKLNSVTAAD TAVYYCARDG 100
GIAVTDYYYY GLDVWGQGTT VTVSSASTKG PSVFPLAPCS RSTSESTAAL 150
GCLVKDYFPE PVTVSWNSGA LTSGVHTFPA VLQSSGLYSL SSVVTVPSSS 200
LGTKTYTCNV DHKPSNTKVD KRVESKYGPP CPSCPAPEFL GGPSVFLFPP 250
KPKDTLMISR TPEVTCVVVD VSQEDPEVQF NWYVDGVEVH NAKTKPREEQ 300
FNSTYRVVSV LTVLHQDWLN GKEYKCKVSN KGLPSSIEKT ISKAKGQPRE 350
PQVYTLPPSQ EEMTKNQVSL TCLVKGFYPS DIAVEWESNG QPENNYKTTP 400
PVLDSDGSFF LYSRLTVDKS RWQEGNVFSC SVMHEALHNH YTQKSLSLSL 450
GK                                                      452
```

Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPAT LSLSPGERAT LSCRASESVS SNLAWYQQKP GQAPRLLIYG  50
AFNRATGIPA RFSGSGSGTD FTLTISSLEP EDFAVYYCQQ RSDWFTFGGG 100
TKVEIKTVAA PSVFIFPPSD EQLKSGTASV VCLLNNFYPR EAKVQWKVDN 150
ALQSGNSQES VTEQDSKDST YSLSSTLTLS KADYEKHKVY ACEVTHQGLS 200
SPVTKSFNRG EC                                           212
```

Post-translational modifications

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

Intra-H (C23-C104)	22-96	152-208	266-326	372-430
	22"-96"	152"-208"	266"-326"	372"-430"
Intra-L (C23-C104)	23'-88'	132'-192'		
	23'"-88'"	132'"-192'"		
Inter-H-L (CH1 10-CL 126)	139-212'	139"-212'"		
Inter-H-H (h 8, h 11)	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

uzansertibum

uzansertib

N-{(7*R*)-4-[(3*R*,4*R*,5*S*)-3-amino-4-hydroxy-5-methylpiperidin-1-yl]-7-hydroxy-6,7-dihydro-5*H*-cyclopenta[*b*]pyridin-3-yl}-6-(2,6-difluorophenyl)-5-fluoropyridine-2-carboxamide

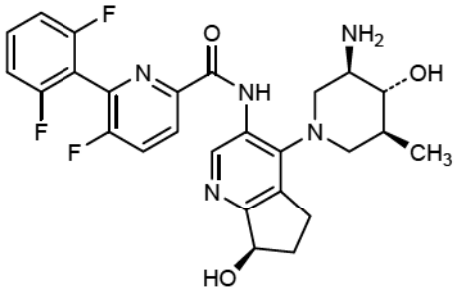
uzansertib

N-{(7*R*)-4-[(3*R*,4*R*,5*S*)-3-amino-4-hydroxy-5-méthylpipéridin-1-yl]-7-hydroxy-6,7-dihydro-5*H*-cyclopenta[*b*]pyridin-3-yl}-6-(2,6-difluorophényl)-5-fluoropyridine-2-carboxamide

uzansertib

N-{(7*R*)-4-[(3*R*,4*R*,5*S*)-3-amino-4-hidroxi-5-metilpiperidin-1-il]-7-hidroxi-6,7-dihidro-5*H*-ciclopenta[*b*]piridin-3-il}-6-(2,6-difluorofenil)-5-fluoropiridina-2-carboxamida

$C_{26}H_{26}F_3N_5O_3$



vebicorvirum

vebicorvir

5,5,11-trioxo-*N*-{[2-(trifluoromethyl)-1,3-thiazol-5-yl]methyl}-10,11-dihydro-5*H*-5λ^6-dibenzo[*b*,*f*][1,4]thiazepine-8-carboxamide

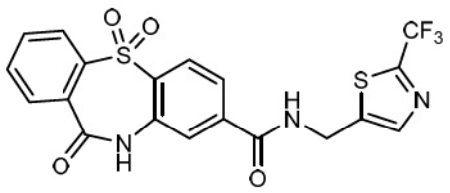
vébicorvir

5,5,11-trioxo-*N*-{[2-(trifluorométhyl)-1,3-thiazol-5-yl]méthyl}-10,11-dihydro-5*H*-5λ^6-dibenzo[*b*,*f*][1,4]thiazépine-8-carboxamide

vebicorvir

5,5,11-trioxo-*N*-{[2-(trifluorometil)-1,3-tiazol-5-il]metil}-10,11-dihidro-5*H*-5λ^6-dibenzo[*b*,*f*][1,4]tiazepina-8-carboxamida

$C_{19}H_{12}F_3N_3O_4S_2$



velmupressinum

velmupressin

1,5-anhydro{4-chloro-L-phenylalanyl-3-(thiophen-2-yl)-L-alanyl-L-valyl-L-asparaginyl-*S*-(3-carboxypropyl)-L-cysteinyl-*N*-[4-(carbamimidoylamino)butyl]-L-prolinamide}

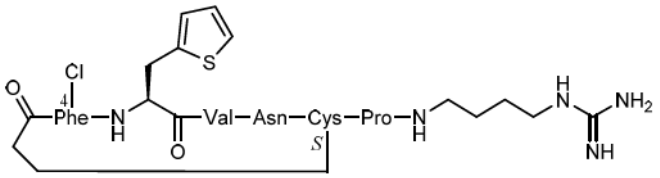
velmupressine

1,5-anhydro{4-chloro-L-phénylalanyl-3-(thiophén-2-yl)-L-alanyl-L-valyl-L-asparaginyl-*S*-(3-carboxypropyl)-L-cystéinyl-*N*-[4-(carbamimidoylamino)butyl]-L-prolinamide}

velmupresina

1,5-anhidro{4-cloro-L-fenilalanil-3-(tiofen-2-il)-L-alanil-L-valil-L-asparaginil-*S*-(3-carboxipropil)-L-cisteinil-*N*-[4-(carbamimidoilamino)butil]-L-prolinamida}

$C_{42}H_{60}ClN_{11}O_8S_2$



velufenacinum

velufenacin

[(3*R*)-1-methylpyrrolidin-3-yl]methyl (3'-chloro-4'-fluoro[1,1'-biphenyl]-2-yl)carbamate

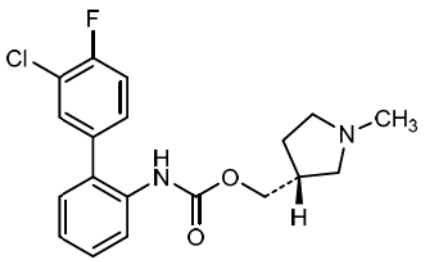
vélufénacine

(3'-chloro-4'-fluoro[1,1'-biphényl]-2-yl)carbamate de [(3*R*)-1-méthylpyrrolidin-3-yl]méthyle

velufenacina

(3'-cloro-4'-fluoro[1,1'-bifenil]-2-il)carbamato de [(3*R*)-1-metilpirrolidin-3-il]metilo

$C_{19}H_{20}ClFN_2O_2$



verbrinacogenum setparvovecum #

verbrinacogene setparvovec	A recombinant non-replicating adeno-associated virus of a modified liver-tropic serotype (S3) (rAAVS3) vector, encoding a gain-of-function variant (R338L; Padua) of codon-optimised human coagulation factor IX (hFIX) under the control of a liver-specific promoter (FRE1) comprising a truncated version of the human apolipoprotein E locus control region (i.e. enhancer) with a truncated version of the human alpha-1-antitrypsin promoter.
verbrinacogène setparvovec	vecteur viral adéno-associé recombinant, non-répliquant, d'un sérotype hépatotropique modifié (S3) (rAAVS3), codant pour le variant Padua (R338L) du facteur de coagulation IX humain (F9, Facteur IX, FIX) dont les codons sont optimisés, sous le contrôle du promoteur spécifique du foie (FRE1) comprenant une version tronquée de la région de contrôle du locus de l'apoprotéine E humaine (c.-à-d. amplificateur) avec une version tronquée du promoteur de l'antitrypsine alpha-1 humaine.
verbrinacogén setparvovec	Un vector de virus adeno-asociado recombinante, no replicativo, de un serotipo hepatotrópico modificado (S3) (rAAVS3), que codifica una variante de ganancia de función (R338L; Padua) del factor de coagulación IX humano (hFIX) con codones optimizados, bajo el control de un promotor específico de hígado (FRE1) que consta de una versión truncada de la región de control del locus de la apolipoproteína E humana (es decir, potenciador) con una versión truncada del promotor de la alfa-1-antitripsina humana.

vilobelimabum #

vilobelimab	immunoglobulin G4-kappa, anti-[*Homo sapiens* C5 (complement 5) anaphylatoxin (C5a, C5 Pr678-751)], chimeric monoclonal antibody; gamma4 heavy chain chimeric (1-446) [VH (*Mus musculus* IGHV1-61*01 (81.6%) -(IGHD) -IGHJ3*01 (92.9%)/*Homo sapiens* IGHV1-46*01 (62.2%) -(IGHD) -IGHJ4*01 (92.9%)) [8.8.13] (1-119) -*Homo sapiens* IGHG4*01 (CH1 (120-217), hinge 1-12 (218-229), CH2 (230-339), CH3 (340-444), CHS (445-446)) (120-446)], (133-218')-disulfide with kappa light chain chimeric (1'-218') [V-KAPPA (*Mus musculus* IGKV3-4*01 (98.0%) -IGKJ2*01 (100%)/*Homo sapiens*IGKV3D-11*02 (69.1%) -IGKJ2*01 (91.7%)) [10.3.9] (1'-111') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (157), V101 (195) (112'-218')]; dimer (225-225":228-228")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa
vilobélimab	immunoglobuline G4-kappa, anti-[*Homo sapiens* C5 (complément 5) anaphylatoxine (C5a, C5 Pr678-751)], anticorps monoclonal chimérique;

chaîne lourde gamma4 chimérique (1-446) [VH (*Mus musculus* IGHV1-61*01 (81.6%) -(IGHD) -IGHJ3*01 (92.9%)/*Homo sapiens* IGHV1-46*01 (62.2%) -(IGHD) -IGHJ4*01 (92.9%)) [8.8.13] (1-119) -*Homo sapiens* IGHG4*01 (CH1 (120-217), charnière 1-12 (218-229), CH2 (230-339), CH3 (340-444), CHS (445-446)) (120-446)], (133-218')-disulfure avec la chaîne légère kappa chimérique (1'-218') [V-KAPPA (*Mus musculus* IGKV3-4*01 (98.0%) -IGKJ2*01 (100%)/*Homo sapiens*IGKV3D-11*02 (69.1%) -IGKJ2*01 (91.7%)) [10.3.9] (1'-111') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (157), V101 (195) (112'-218')]; dimère (225-225":228-228")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

vilobelimab

inmunoglobulina G4-kappa, anti-[*Homo sapiens* C5 (complemento 5) anafilatoxina (C5a, C5 Pr678-751)], anticuerpo monoclonal quimérico;
cadena pesada gamma4 quimérica (1-446) [VH (*Mus musculus* IGHV1-61*01 (81.6%) -(IGHD) -IGHJ3*01 (92.9%)/*Homo sapiens* IGHV1-46*01 (62.2%) -(IGHD) -IGHJ4*01 (92.9%)) [8.8.13] (1-119) -*Homo sapiens* IGHG4*01 (CH1 (120-217), bisagra 1-12 (218-229), CH2 (230-339), CH3 (340-444), CHS (445-446)) (120-446)], (133-218')-disulfuro con la cadena ligera kappa quimérica (1'-218') [V-KAPPA (*Mus musculus* IGKV3-4*01 (98.0%) -IGKJ2*01 (100%)/*Homo sapiens*IGKV3D-11*02 (69.1%) -IGKJ2*01 (91.7%)) [10.3.9] (1'-111') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (157), V101 (195) (112'-218')]; dímero (225-225":228-228")-bisdisulfuro, producido por células ováricas de hamster chino (CHO), forma glicosilada alfa



Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLQQSGPQ LVRPGTSVKI SCKASGYSFT TFWMDWVKQR PGQGLEWIGR  50
IDPSDSESRL DQRFKDRATL TVDKSSSTVY MQLSSPTSED SAVYYCARGN 100
DGYYGFAYWG QGTLVTVSSA STKGPSVFPL APCSRSTSES TAALGCLVKD 150
YFPEPVTVSW NSGALTSGVH TFPAVLQSSG LYSLSSVVTV PSSSLGTKTY 200
TCNVDHKPSN TKVDKRVESK YGPPCPSCPA 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 SLSLGK     446
```

Light chain / Chaîne légère / Cadena ligera

```
DIVLTQSPAS LAVSLGQRAT ISCKASQSVD YDGDSYMKWY QQKPGQPPKL  50
LIYAASNLQS GIPARFSGSG SGTDFTLNIH PVEEEDAATY YCQQSNEDPY 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	260-320	366-424
	22"-96"	146"-202"	260"-320"	366"-424"
Intra-L (C23-C104)	23'-92'	138'-198'		
	23'"-92'"	138'"-198'"		
Inter-H-L (CH1 10-CL 126)	133-218'	133"-218'"		
Inter-H-H (h 8, h 11)	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

C-terminal lysine clipping:
H CHS K2:
446, 446"

WHO Drug Information, Vol. 34, No. 3, 2020 **Recommended INN: List 84**

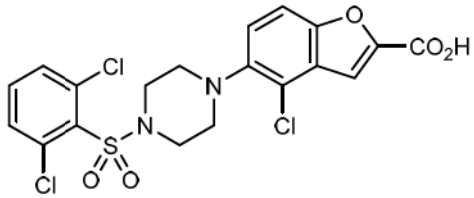
vonafexorum

vonafexor — 4-chloro-5-[4-(2,6-dichlorobenzene-1-sulfonyl)piperazin-1-yl]-1-benzofuran-2-carboxylic acid

vonafexor — acide 4-chloro-5-[4-(2,6-dichlorobenzène-1-sulfonyl)pipérazin-1-yl]-1-benzofuran-2-carboxylique

vonafexor — ácido 4-cloro-5-[4-(2,6-diclorobenceno-1-sulfonil)piperazin-1-il]-1-benzofuran-2-carboxílico

$C_{19}H_{15}Cl_3N_2O_5S$



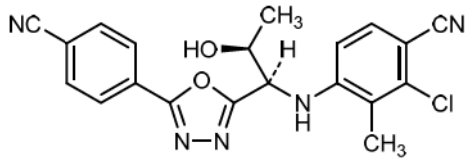
vosilasarmum

vosilasarm — 2-chloro-4-({(1*R*,2*S*)-1-[5-(4-cyanophenyl)-1,3,4-oxadiazol-2-yl]-2-hydroxypropyl}amino)-3-methylbenzonitrile

vosilasarm — 2-chloro-4-({(1*R*,2*S*)-1-[5-(4-cyanophényl)-1,3,4-oxadiazol-2-yl]-2-hydroxypropyl}amino)-3-méthylbenzonitrile

vosilasarm — 4-({(1*R*,2*S*)-1-[5-(4-cianofenil)-1,3,4-oxadiazol-2-il]-2-hidroxipropil}amino)-2-cloro-3-metilbenzonitrilo

$C_{20}H_{16}ClN_5O_2$



vulinacimabum #

vulinacimab — immunoglobulin G1-kappa, anti-[*Homo sapiens* VEGFR2 (vascular endothelial growth factor receptor 2, KDR, kinase insert domain receptor, FLK1, CD309)], *Homo sapiens* monoclonal antibody; gamma1 heavy chain *Homo sapiens* (1-447) [VH (*Homo sapiens* IGHV3-23*04 (90.8%) -(IGHD) -IGHJ1*01 (100%)) [8.8.10] (1-117) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (214) (118-215), hinge 1-15 (216-230), CH2 (231-340), CH3 E12 (356), M14 (358) (341-445), CHS (446-457)) (118-447)], (220-219')-disulfide with kappa light chain *Homo sapiens* (1'-219') [V-KAPPA (*Homo sapiens* IGKV2-30*01 (83.0%) -IGKJ2*01 (100%)) [11.3.9] (1'-112') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (158), V101 (196) (113'-219')];
dimer (226-226":229-229")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

vulinacimab

immunoglobuline G1-kappa, anti-[*Homo sapiens* VEGFR2 (récepteur 2 du facteur de croissance endothélial vasculaire, KDR, récepteur à domaine insert kinase, FLK1, CD309)], *Homo sapiens* anticorps monoclonal;
chaîne lourde gamma1 *Homo sapiens* (1-447) [VH (*Homo sapiens* IGHV3-23*04 (90.8%) -(IGHD) -IGHJ1*01 (100%)) [8.8.10] (1-117) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (214) (118-215), charnière 1-15 (216-230), CH2 (231-340), CH3 E12 (356), M14 (358) (341-445), CHS (446-457)) (118-447)], (220-219')-disulfure avec la chaîne légère kappa *Homo sapiens* (1'-219') [V-KAPPA (*Homo sapiens* IGKV2-30*01 (83.0%) -IGKJ2*01 (100%)) [11.3.9] (1'-112') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (158), V101 (196) (113'-219')];
dimère (226-226":229-229")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

vulinacimab

inmunoglobulina G1-kappa, anti-[*Homo sapiens* VEGFR2 (receptor 2 del factor de crecimiento endotelial vascular, KDR, receptor con dominio inserto kinasa, FLK1, CD309)], *Homo sapiens* anticuerpo monoclonal;
cadena pesada gamma1 *Homo sapiens* (1-447) [VH (*Homo sapiens* IGHV3-23*04 (90.8%) -(IGHD) -IGHJ1*01 (100%)) [8.8.10] (1-117) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 R120>K (214) (118-215), bisagra 1-15 (216-230), CH2 (231-340), CH3 E12 (356), M14 (358) (341-445), CHS (446-457)) (118-447)], (220-219')-disulfuro con la cadena ligera kappa *Homo sapiens* (1'-219') [V-KAPPA (*Homo sapiens* IGKV2-30*01 (83.0%) -IGKJ2*01 (100%)) [11.3.9] (1'-112') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (158), V101 (196) (113'-219')];
dímero (226-226":229-229")-bisdisulfuro, producido por células ováricas de hamster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGGG LVQPGGSLRL SCAASGFSFS TYAMSWVRQA PGKGLEWVSG  50
ISGSGGTTHY ADSVKGRFTI SRDNSKNTVN LQMNSLRAED TAVYYCAKGL 100
WFGEGLWGQG TLVTVSSAST KGPSVFPLAP SSKSTSGGTA ALGCLVKDYF 150
PEPVTVSWNS GALTSGVHTF PAVLQSSGLY SLSSVVTVPS SSLGTQTYIC 200
NVNHKPSNTK VDKKVEPKSC DKTHTCPPCP APELLGGPSV FLFPPKPKDT 250
LMISRTPEVT CVVVDVSHED PEVKFNWYVD GVEVHNAKTK PREEQYNSTY 300
RVVSVLTVLH QDWLNGKEYK CKVSNKALPA PIEKTISKAK GQPREPQVYT 350
LPPSREEMTK NQVSLTCLVK GFYPSDIAVE WESNGQPENN YKTTPPVLDS 400
DGSFFLYSKL TVDKSRWQQG NVFSCSVMHE ALHNHYTQKS LSLSPGK    447
```

Light chain / Chaîne légère / Cadena ligera

```
DVVMTQSPLS LPVTLGQPAS ISCRSSQSLY YRSGYTFLDW YVQKPGQSPQ  50
LLIYQSSKRD SGVPDRISGS GSGTDFTLRI SRVEAEDVGV YYCFQGTHWP 100
YTFGQGTKLE 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	144-200	261-321	367-425
	22"-96"	144"-200"	261"-321"	367"-425"
Intra-L (C23-C104)	23'-93'	139'-199'		
	23'"-93'"	139'"-199'"		
Inter-H-L (h 5-CL 126)	220-219'	220"-219'"		
Inter-H-H (h 11, h 14)	226-226"	229-229"		

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
297, 297"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados

C-terminal lysine clipping:
H CHS K2:
447, 447"

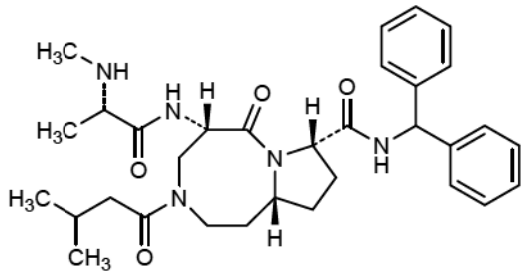
xevinapantum

xevinapant — (5*S*,8*S*,10a*R*)-*N*-(diphenylmethyl)-5-[(2*S*)-2-(methylamino)propanamido]-3-(3-methylbutanoyl)-6-oxodecahydropyrrolo[1,2-*a*][1,5]diazocine-8-carboxamide

xévinapant — (5*S*,8*S*,10a*R*)-*N*-(diphénylméthyl)-5-[(2*S*)-2-(méthylamino)propanamido]-3-(3-méthylbutanoyl)-6-oxodécahydropyrrolo[1,2-*a*][1,5]diazocine-8-carboxamide

xevinapant — (5*S*,8*S*,10a*R*)-*N*-(difenilmetil)-5-[(2*S*)-2-(metilamino)propanamido]-3-(3-metilbutanoil)-6-oxodecahidropirrolo[1,2-*a*][1,5]diazocina-8-carboxamida

$C_{32}H_{43}N_5O_4$



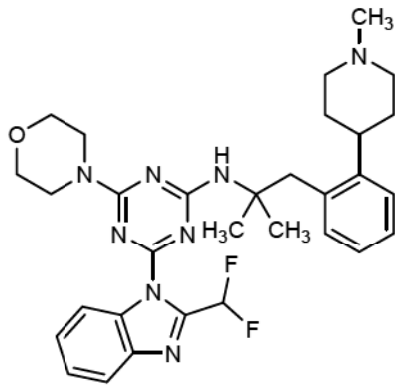
zandelisibum

zandelisib — 4-[2-(difluoromethyl)-1*H*-benzimidazol-1-yl]-*N*-{2-methyl-1-[2-(1-methylpiperidin-4-yl)phenyl]propan-2-yl}-6-(morpholin-4-yl)-1,3,5-triazin-2-amine

zandélisib — 4-[2-(difluorométhyl)-1*H*-benzimidazol-1-yl]-*N*-{2-méthyl-1-[2-(1-méthylpipéridin-4-yl)phényl]propan-2-yl}-6-(morpholin-4-yl)-1,3,5-triazin-2-amine

zandelisib — 4-[2-(difluorometil)-1*H*-benzimidazol-1-il]-*N*-{2-metil-1-[2-(1-metilpiperidin-4-il)fenil]propan-2-il}-6-(morfolin-4-il)-1,3,5-triazin-2-amina

$C_{31}H_{38}F_2N_8O$



zoligratinibum

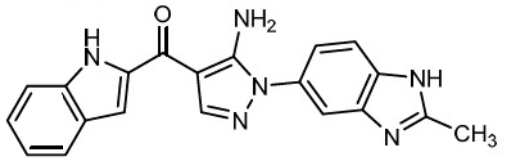
zoligratinib — [5-amino-1-(2-methyl-1*H*-benzimidazol-5-yl)-1*H*-pyrazol-4-yl](1*H*-indol-2-yl)methanone

zoligratinib — [5-amino-1-(2-méthyl-1*H*-benzimidazol-5-yl)-1*H*-pyrazol-4-yl](1*H*-indol-2-yl)méthanone

zoligratinib

[5-amino-1-(2-metil-1*H*-benzimidazol-5-il)-1*H*-pirazol-4-il](1*H*-indol-2-il)metanona

$C_{20}H_{16}N_6O$



zotiraciclibum

zotiraciclib

(8*E*)-6-methyl-12-oxa-3,6-diaza-2(4,2)-pyrimidina-1,4(1,3)-dibenzenacyclododecaphan-8-ene

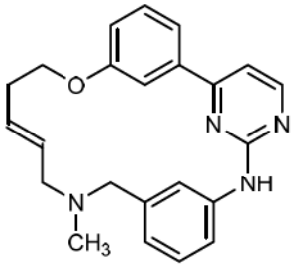
zotiraciclib

(8*E*)-6-méthyl-12-oxa-3,6-diaza-2(4,2)-pyrimidina-1,4(1,3)-dibenzénacyclododécaphan-8-ène

zotiraciclib

(8*E*)-6-metil-12-oxa-3,6-diaza-2(4,2)-pirimidina-1,4(1,3)-dibencenaciclododecafan-8-eno

$C_{23}H_{24}N_4O$



zuberitamabum #

zuberitamab

immunoglobulin G1-kappa, anti-[*Homo sapiens* MS4A1 (membrane spanning 4-domains subfamily A member 1, CD20)], chimeric monoclonal antibody; gamma1 heavy chain chimeric (1-452) [VH (*Mus musculus* IGHV1-12*01 (96.9%) -(IGHD) -IGHJ1*03 (100%)/*Homo sapiens* IGHV1-46*01 (70.4%) -(IGHD) -IGHJ1*03 (85.7%)) [8.8.15] (1-122) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (219) (123-220), hinge 1-15 (221-235), CH2 (236-345), CH3 D12 (361), L14 (363) (346-450), CHS (451-452)) (123-452)], (225-213')-disulfide with kappa light chain chimeric (1'-213') [V-KAPPA (*Mus musculus* IGKV4-72*01 (96.8%) -IGKJ1*01 (90.9 %)/*Homo sapiens* IGKV3-11*01 (64.9%) -IGKJ2*01 (90.9%)) [5.3.9] (1'-106') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (152), V101 (190) (107'-213')];
dimer (231-231":234-234")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

zubéritamab

immunoglobuline G1-kappa, anti-[*Homo sapiens* MS4A1 (membre 1 de la sous-famille A à 4 domaines transmembranaires, CD20)], anticorps monoclonal chimérique;

chaîne lourde gamma1 chimérique (1-452) [VH (*Mus musculus* IGHV1-12*01 (96.9%) -(IGHD) -IGHJ1*03 (100%)/*Homo sapiens* IGHV1-46*01 (70.4%) -(IGHD) -IGHJ1*03 (85.7%)) [8.8.15] (1-122) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (219) (123-220), charnière 1-15 (221-235), CH2 (236-345), CH3 D12 (361), L14 (363) (346-450), CHS (451-452)) (123-452)], (225-213')-disulfure avec la chaîne légère kappa chimérique (1'-213') [V-KAPPA (*Mus musculus* IGKV4-72*01 (96.8%) -IGKJ1*01 (90.9 %)/*Homo sapiens* IGKV3-11*01 (64.9%) -IGKJ2*01 (90.9%)) [5.3.9] (1'-106') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (152), V101 (190) (107'-213')];
dimère (231-231":234-234")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

zuberitamab

inmunoglobulina G1-kappa, anti-[*Homo sapiens* MS4A1 (miembro 1 de la subfamilia A con 4 dominios transmembranarios, CD20)], anticuerpo monoclonal quimérico;
cadena pesada gamma1 quimérica (1-452) [VH (*Mus musculus* IGHV1-12*01 (96.9%) -(IGHD) -IGHJ1*03 (100%)/*Homo sapiens* IGHV1-46*01 (70.4%) -(IGHD) -IGHJ1*03 (85.7%)) [8.8.15] (1-122) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (219) (123-220), bisagra 1-15 (221-235), CH2 (236-345), CH3 D12 (361), L14 (363) (346-450), CHS (451-452)) (123-452)], (225-213')-disulfuro con la cadena ligera kappa quimérica (1'-213') [V-KAPPA (*Mus musculus* IGKV4-72*01 (96.8%) -IGKJ1*01 (90.9 %)/*Homo sapiens* IGKV3-11*01 (64.9%) -IGKJ2*01 (90.9%)) [5.3.9] (1'-106') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (152), V101 (190) (107'-213')];
dímero (231-231":234-234")-bisdisulfuro, producido por células ováricas de hamster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLQQSGAE LVRPGASVKM SCKASGYTFT SYNMHWVKQT PRQGLEWIGA  50
IYPGNGDTSY NQKFKGKATL TVDKSSSTAY MQLSSLTSED SAVYFCARVV 100
YYSNSYWYFD VWGTGTTVTV 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 DELTKNQVSL TCLVKGFYPS DIAVEWESNG QPENNYKTTP 400
PVLDSDGSFF LYSKLTVDKS RWQQGNVFSC SVMHEALHNH YTQKSLSLSP 450
GK                                                      452
```

Light chain / Chaîne légère / Cadena ligera

```
DIELSQSPAI LSASPGEKVT MTCRASSSVS YMHWYQQKPG SSPKPWIYAP  50
SNLASGVPAR FSGSGSGTSY SLTISRVEAE DAATYYCQQW SFNPPTFGAG 100
TKLEIKRTVA 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	149-205	266-326	372-430
	22"-96"	149"-205"	266"-326"	372"-430"
Intra-L (C23-C104)	23'-87'	133'-193'		
	23'"-87""	133'"-193""		
Inter-H-L (h5-CL 126)	225-213'	225"-213""		
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
C-terminal lysine clipping:
H CHS K2:
452, 452"

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

Recommended International Nonproprietary Names (Rec. INN): List 63
Dénominations communes internationales recommandées (DCI Rec.): Liste 63
Denominaciones Comunes Internacionales Recomendadas (DCI Rec.): Lista 63
(WHO Drug Information, Vol. 24, No. 1, 2010)

p.45 **bardoxolonum**

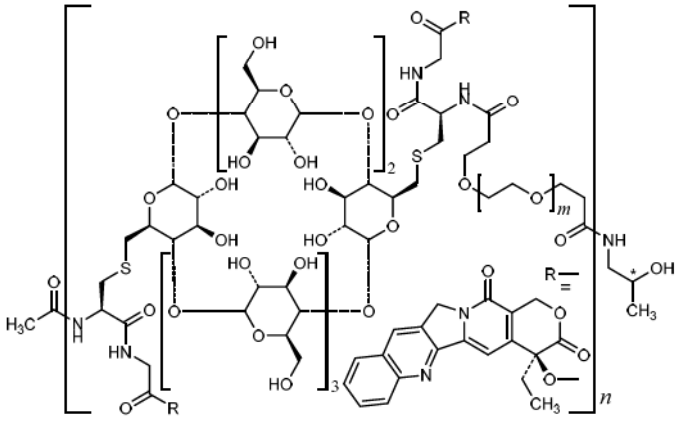
bardoxolone	*replace the molecular formula by the following one*
bardoxolone	*remplacer la formule moléculaire brute par la suivante*
bardoxolona	*sustitúyase la fórmula molecular por la siguiente*

$C_{31}H_{41}NO_4$

Recommended International Nonproprietary Names (Rec. INN): List 79
Dénominations communes internationales recommandées (DCI Rec.): Liste 79
Denominaciones Comunes Internacionales Recomendadas (DCI Rec.): Lista 79
(WHO Drug Information, Vol. 32, No. 1, 2018)

p.112 **davamotecanum pegadexamerum**

davamotecan pegadexamer	*replace the structure by the following one*
davamotécan pégadexamère	*remplacer la structure par la suivante*
davamotecán pegadexámero	*sustitúyase la estructura por la siguiente*



p.123 **ianalumabum #**
-124

ianalumab	*replace the description and the structure by the following ones*
ianalumab	*remplacer la description et la structure par les suivantes*
ianalumab	*sustitúyase la descripción y la estructura por las siguientes*

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 (89.00%) -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;
produced in Chinese hamster ovary (CHO) cells, glycoform alfa

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, CD268], *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 (89.00%) -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,
produit dans des cellules de hamster chinois (CHO), glycoforme alfa

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, CD268], *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 (89.00%) -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,
producido en las células ováricas de hamster chino (CHO), glicoforma alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLQQSGPG LVKPSQTLSL TCAISGDSVS SNSAAWGWIR QSPGRGLEWL  50
GRIYYRSKWY NSYAVSVKSR ITINPDTSKN QFSLQLNSVT PEDTAVYYCA 100
RYDWVPKIGV 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 LSCRASQFIS SSYLSWYQQK PGQAPRLLIY  50
GSSSRATGVP ARFSGSGSGT DFTLTISSLE PEDFAVYYCQ QLYSSPMTFG 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"		

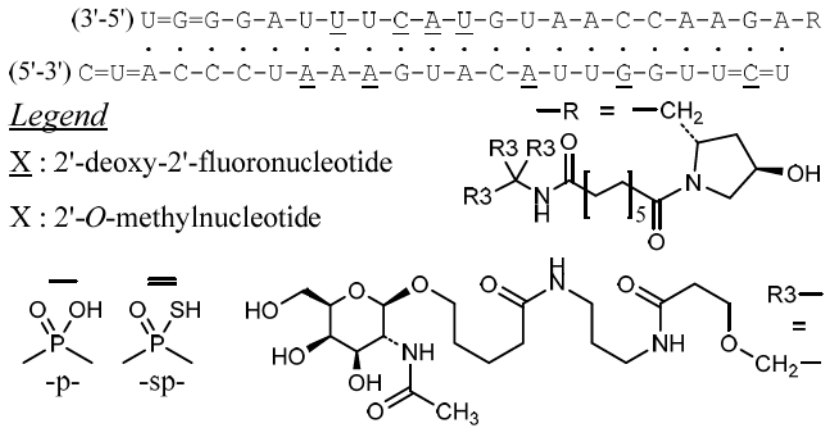
N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
304, 304"
Afucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes afucosylés / glicanos de tipo CHO biantenarios complejos afucosilados
N-terminal glutaminyl cyclization to pyroglutamyl (pE, 5-oxoprolyl)
H VH Q1: 1, 1"

C-terminal lysine clipping
H CHS K2:
454, 454"

Recommended International Nonproprietary Names (Rec. INN): List 81
Dénominations communes internationales recommandées (DCI Rec.): Liste 81
Denominaciones Comunes Internacionales Recomendadas (DCI Rec.): Lista 81
(WHO Drug Information, Vol. 33, No. 1, 2019)

p.128 **vutrisiranum**

vutrisiran	*replace the structure by the following one*
vutrisiran	*remplacer la structure par la suivante*
vutrisirán	*sustitúyase la estructura por la siguiente*



Recommended International Nonproprietary Names (Rec. INN): List 82
Dénominations communes internationales recommandées (DCI Rec.): Liste 82
Denominaciones Comunes Internacionales Recomendadas (DCI Rec.): Lista 82
(WHO Drug Information, Vol. 33, No. 3, 2019)

p.606-607 **adlinacogenum civaparvovecum #**

adlinacogene civaparvovec	*replace the description by the following one*
adlinacogène civaparvovec	*remplacer la description par la suivante*
adlinacogén civaparvovec	*sustitúyase la descripción por la siguiente*

a recombinant non-replicating adeno-associated virus type 2/6 (**rAAV6**) vector, which contains a promoter-less human coagulation factor IX (hF9, Factor IX or FIX) transgene cassette, encoding exons 2-8 and splice acceptor site sequence (SA) from hF9 exon 2, flanked by a sequence homologous to the zinc-finger nuclease (ZFN) cleavage site of the human albumin (hALB) intron 1

vecteur viral adéno-associé de type 2/6 recombinant (**rAAV6**), non-répliquant, contenant la cassette avec le transgène du facteur de coagulation IX humain (hF9, Facteur IX, FIX) sans promoteur, codant pour les exons 2-8 et la séquence du site accepteur (SA) d'épissage de l'exon 2 de hF9, flanqué par une séquence homologue au site de clivage de la nucléase à doigts de zinc (ZFN) de l'intron 1 l'albumine humaine (hALB).

un vector de virus adeno asociado tipo 2/6 recombinante (**rAAV6**), no replicativo, que contiene un casete con el transgen del factor de coagulación IX (hF9, Factor IX o FIX) humano sin promotor, que codifica para los exones 2-8 y la secuencia del sitio aceptor (SA) del splicing del exon 2 de hf9, flanqueado por una secuencia homóloga al sitio de rotura por la nuclease con dedos de zinc (ZFN) del intron 1 de la albúmina humana (hALB)

p.625-626 **devafidugenum civaparvovecum #**

devafidugene civaparvovec — *replace the description by the following one*
devafidugène civaparvovec — *remplacer la description par la suivante*
devafidugén civaparvovec — *sustitúyase la descripción por la siguiente*

a recombinant non-replicating adeno-associated virus type 2/6 (**rAAV6**) vector, which contains a promoter-less human alpha-L-iduronidase (hIDUA) transgene cassette, encoding partial exon 1 and full exons 2-14 with the first 28 amino acids removed, and splice acceptor site sequence (SA) from hIDUA exon 2, flanked by a sequence homologous to the zinc-finger nuclease (ZFN) cleavage site of the human albumin (hALB) intron 1

vecteur viral adéno-associé de type 2/6 recombinant (**rAAV6**), non-répliquant, contenant la cassette du transgène de l'alpha-L-iduronidase humaine (hIDUA) sans promoteur, codant partiellement l'exon 1 et entièrement les exons 2-14 dont la partie correspondant aux 28 premiers acides aminés a été retirée, et la séquence du site accepteur (SA) d'épissage de l'exon 2 de l'hIDUA, flanqué d'une séquence homologue au site de clivage de la nucléase à doigts de zinc (ZFN) de l'intron 1 de l'albumine humaine (hALB)

un vector de virus adeno asociado tipo 2/6 recombinante (**rAAV6**), no replicativo, que contiene un casete con el transgen de la alfa-L-iduronidasa humana (hIDUA) sin promotor, que codifica para el exón 1 parcial y los exones 2-14 completos con los primeros 28 amino ácidos eliminados, y la secuencia del sitio aceptor (SA) del splicing del exón 2 de hIDUA, flanqueado por una secuencia homóloga al sitio de rotura por la nuclease con dedos de zinc (ZFN) del intron 1 de la albúmina humana (hALB)

p.645 **inlezifigenum civaparvovecum #**

inlezifigene civaparvovec — *replace the description by the following one*
inlezifigène civaparvovec — *remplacer la description par la suivante*
inlezifigén civaparvovec — *sustitúyase la descripción por la siguiente*

a recombinant non-replicating adeno-associated virus type 2/6 (**rAAV6**) vector, expressing a cDNA that targets 447-461 bp of the albumin locus (relative to the transcription initiation site), fused to the obligate heterodimeric FokI nuclease domain ELD, under the control of an apolipoprotein E hepatic control region and human alpha-1-antitrypsin promoter (ApoE/hAAT)

vecteur viral adéno-associé de type 2/6 recombinant (**rAAV6**), non-répliquant, exprimant un ADNc ciblant les paires de bases 447-461 du locus de l'albumine (en relation avec le site initial de transcription), fusionné au domaine hétérodimérique ELD de la nucléase FokI, sous le contrôle d'une région de contrôle de l'apolipoprotéine E (ApoE) spécifique du foie et du promoteur de l'alpha1-antitrypsine humaine (ApoE/hAAT)

un vector de virus adeno asociado tipo 2/6 recombinante (**rAAV6**), no replicativo, que expresa un cDNA dirigido a unirse a los pares de bases 447-461 (en relación al sitio de iniciación de la transcripción) del locus de la albúmina, fusionado al dominio heterodimérico ELD de la nuclease FokI, bajo el control de una región de control hepático de la apolipoproteína E y el promotor de la alfa 1 antitripsina humana (ApoE/hAAT)

p.669 -670 **ranuzifigenum civaparvovecum #**

ranuzifigene civaparvovec — *replace the description by the following one*
ranuzifigène civaparvovec — *remplacer la description par la suivante*
ranuzifigén civaparvovec — *sustitúyase la descripción por la siguiente*

a recombinant non-replicating adeno-associated virus type 2/6 (**rAAV6**) vector, expressing a cDNA that targets 468-485 bp of the albumin locus (relative to the transcription initiation site), fused to the obligate heterodimeric FokI nuclease domain ELD, under the control of an apolipoprotein E hepatic control region and human alpha-1-antitrypsin promoter (ApoE/hAAT)

vecteur viral adéno-associé de type 2/6 recombinant (**rAAV6**), non-répliquant, exprimant un ADNc ciblant les paires de bases 468-485 du locus de l'albumine (en relation avec le site initial de transcription), fusionné au domaine hétérodimérique ELD de la nucléase FokI, sous le contrôle d'une région de contrôle de l'apolipoprotéine E (ApoE) spécifique du foie et du promoteur de l'alpha1-antitrypsine humaine (ApoE/hAAT)

un vector de virus adeno asociado tipo 2/6 recombinante (**rAAV6**), no replicativo, que expresa un cDNA dirigido a unirse a los pares de bases 468-485 (en relación al sitio de iniciación de la transcripción) del locus de la albúmina, fusionado al dominio heterodimérico ELD de la nuclease FokI, bajo el control de una región de control hepático de la apolipoproteína E y el promotor de la alfa 1 antitripsina humana (ApoE/hAAT)

p.676 **selitrectinibum**

selitrectinib — *replace the chemical name by the following one*
sélitrectinib — *remplacer le nom chimique par le suivant*
selitrectinib — *sustitúyase el nombre químico por el siguiente*

(2^2R,6*R*)-3^5-fluoro-6-methyl-**7-aza-**1(5,3)-pyrazolo[1,5-*a*]pyrimidina-3(3,2)-pyridina-2(1,2)-pyrrolidinacyclooctaphan-8-one

(2^2R,6*R*)-3^5-fluoro-6-méthyl-**7-aza-**1(5,3)-pyrazolo[1,5-*a*]pyrimidina-3(3,2)-pyridina-2(1,2)-pyrrolidinacyclooctaphan-8-one

(2^2R,6*R*)-3^5-fluoro-6-metil-**7-aza-**1(5,3)-pirazolo[1,5-*a*]pirimidina-3(3,2)-piridina-2(1,2)-pirrolidinaciclooctafan-8-ona

p.688 -689 **tefidsogenum civaparvovecum #**

tefidsogene civaparvovec — *replace the description by the following one*
tefidsogène civaparvovec — *remplacer la description par la suivante*
tefidsogén civaparvovec — *sustitúyase la descripción por la siguiente*

a recombinant non-replicating adeno-associated virus type 2/6 (**rAAV6**) vector, which contains a promoter-less human iduronate 2-sulfatase (hIDS) transgene cassette, encoding parts of exon 1 plus exons 2-9 from hIDS and a splice acceptor site (SA) derived from human coagulation factor IX (hF9, factor IX or FIX) exon 2, flanked by a sequence homologous to the zinc-finger nuclease (ZFN) cleavage site of the human albumin (hALB) intron 1

vecteur viral adéno-associé de type 2/6 recombinant (**rAAV6**), non-répliquant, contenant la cassette du transgène de l'iduronate 2-sulfatase humaine (hIDS) sans promoteur, codant partiellement l'exon 1 et les exons 2-9 de hIDS, et la séquence du site accepteur (SA) d'épissage dérivé de l'exon 2 du facteur de coagulation IX humain (hF9, facteur IX, FIX), flanqué d'une séquence homologue au site de clivage de la nucléase à doigts de zinc (ZFN) de l'intron 1 de l'albumine humaine (hALB)

un vector de virus adeno asociado tipo 2/6 recombinante (**rAAV6**), no replicativo, que contiene un casete con el transgen de la iduronato 2-sulfatasa humana (hIDS) sin promotor, que codifica para partes del exón 1 más los exones 2-9 de hIDS y un sitio aceptor del splicing derivado del exón 2 del factor de coagulación IX humano (hF9, factor IX o FIX), flanqueado por una secuencia homóloga al sitio de rotura por la nuclease con dedos de zinc (ZFN) del intron 1 de la albúmina humana (hALB)

Recommended International Nonproprietary Names (Rec. INN): List 83
Dénominations communes internationales recommandées (DCI Rec.): Liste 83
Denominaciones Comunes Internacionales Recomendadas (DCI Rec.): Lista 83
(WHO Drug Information, Vol. 34, No. 1, 2020)

p.25 **avalotcagenum ontaparvovecum #**
-26 avalotcagene ontaparvovec *replace the description by the following one*
avalotcagène ontaparvovec *remplacer la description par la suivante*
avalotcagén ontaparvovec *sustitúyase la descripción por la siguiente*

A recombinant non-replicating adeno-associated virus type 2/8 (**rAAV8**) vector, encoding codon-optimized, wild-type human ornithine transcarbamylase (OTC) under the control of a hybrid human thyroxine-binding globulin (TBG) / human alpha 1-microglobulin/bikunin precursor (AMBP) promoter/enhancer. The vector genome is a head-to-head dimer, with the vector genome cassette located 5' of the mutated internal inverted terminal repeat (ITR) in a reverse orientation and the vector genome cassette located 3' of the mutated internal ITR in a forward orientation.

vecteur viral adéno-associé de type 2/8 recombinant non-répliquant (**rAAV8**), codant pour l'ornithine transcarbamylase humaine sauvage (OTC) avec des codons optimisés, sous le contrôle de l'activateur/promoteur hybride de la globuline liant la thyroxine (TBP) humaine /précurseur de microglobuline alpha 1 / bikunine (AMBP). Le génome du vecteur est un dimère en tête à tête avec la cassette contenant le génome du vecteur en position 5´ de la séquence inverse terminale répétée (ITR) interne et mutée dont l'orientation est inverse et la cassette contenant le vecteur du génome en position 3´ de l'ITR interne et mutée dont l'orientation est vers l'avant

Un vector de virus adenoasociado recombinante no replicativo del serotipo 2/8 (**rAAV8**), que codifica para la ornitina transcarbamilasa silvestre humana (OTC) con codones optimizados, bajo el control de un promotor/potenciador híbrido de la globulina fijadora de tiroxina humana (TBG) / precursor de microglobulina alfa 1 humana/bicunina (AMBP). El genoma del vector es un dímero de cabeza con cabeza, con el casete del genoma del vector en posición 5' a la repetición terminal invertida (ITR) interna y mutada localizado en orientación inversa. y el casete del genoma del vector en posición 3' a la ITR localizado en orientación hacia adelante.

p.49 **epcoritamabum #**

epcoritamab *replace the structure by the following one*
épcoritamab *remplacer la structure par la suivante*
epcoritamab *sustitúyase la estructura por la siguiente*

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

```
EVKLVESGGG LVQPGGSLRL SCAASGFTFN TYAMNWVRQA PGKGLEWVAR  50
IRSKYNNYAT YYADSVKDRF TISRDDSKSS LYLQMNNLKT EDTAMYYCVR 100
HGNFGNSYVS WFAYWGQGTL VTVSSASTKG PSVFPLAPSS KSTSGGTAAL 150
GCLVKDYFPE PVTVSWNSGA LTSGVHTFPA VLQSSGLYSL SSVVTVPSSS 200
LGTQTYICNV NHKPSNTKVD KRVEPKSCDK THTCPPCPAP EFEGGPSVFL 250
FPPKPKDTLM ISRTPEVTCV VVAVSHEDPE VKFNWYVDGV EVHNAKTKPR 300
EEQYNSTYRV VSVLTVLHQD WLNGKEYKCK VSNKALPAPI EKTISKAKGQ 350
PREPQVYTLP PSREEMTKNQ VSLTCLVKGF YPSDIAVEWE SNGQPENNYK 400
TTPPVLDSDG SFLLYSKLTV DKSRWQQGNV FSCSVMHEAL HNHYTQKSLS 450
LSPG                                                    454
```

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

```
QAVVTQEPSF SVSPGGTVTL TCRSSTGAVT TSNYANWVQQ TPGQAFRGLI  50
GGTNKRAPGV PARFSGSLIG DKAALTITGA QADDESIYFC ALWYSNLWVF 100
GGGTKLTVLG QPKAAPSVTL FPPSSEELQA NKATLVCLIS DFYPGAVTVA 150
WKADSSPVKA GVETTTPSKQ SNNKYAASSY LSLTPEQWKS HRSYSCQVTH 200
EGSTVEKTVA PTECS                                        215
```

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

```
EVQLVESGGG LVQPDRSLRL SCAASGFTFH DYAMHWVRQA PGKGLEWVST  50
ISWNSGTIGY ADSVKGRFTI SRDNAKNSLY LQMNSLRAED TALYYCAKDI 100
QYGNYYYGMD VWGQGTTVTV SSASTKGPSV FPLAPSSKST SGGTAALGCL 150
VKDYFPEPVT VSWNSGALTS GVHTFPAVLQ SSGLYSLSSV VTVPSSSLGT 200
QTYICNVNHK PSNTKVDKRV EPKSCDKTHT CPPCPAPEFE GGPSVFLFPP 250
KPKDTLMISR TPEVTCVVVA VSHEDPEVKF NWYVDGVEVH NAKTKPREEQ 300
YNSTYRVVSV LTVLHQDWLN GKEYKCKVSN KALPAPIEKT ISKAKGQPRE 350
PQVYTLPPSR EEMTKNQVSL TCLVKGFYPS DIAVEWESNG QPENNYKTTP 400
PVLDSDGSFF LYSRLTVDKS RWQQGNVFSC SVMHEALHNH YTQKSLSLSP 450
G                                                       451
```

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

```
EIVLTQSPAT LSLSPGERAT LSCRASQSVS SYLAWYQQKP GQAPRLLIYD  50
ASNRATGIPA RFSGSGSGTD FTLTISSLEP EDFAVYYCQQ RSNWPITFGQ 100
GTRLEIKRTV 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) 22-98 152-208 269-329 375-433
22"-96" 149"-205" 266"-326" 372"-430"
Intra-L (C23-C104) 22'-90' 137'-196'
23'"-88'" 134'"-194'"
Inter-H-L (h 5-CL 126) 228-214' 225"-214'"
Inter-H-H (h 11, h 14) 234-231" 237-234"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
305, 302"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados.

p.55 **giroctocogenum fitelparvovecum #**

giroctocogene fitelparvovec *replace the description by the following one*
giroctocogène fitelparvovec *remplacer la description par la suivante*
giroctocogén fitelparvovec *sustitúyase la descripción por la siguiente*

A recombinant non-replicating adeno-associated virus type 2/6 (**rAAV6**) vector, encoding human B-domain-deleted blood coagulation factor VIII (hF8, FVIII) under the control of a synthetic liver-specific promoter.

Vecteur viral adéno-associé de type 2/6 recombinant non-répliquant (**rAAV6**), codant pour le facteur de coagulation sanguine VIII humain (hF8, FVIII), dont le domaine B a été supprimé, sous le contrôle d'un promoteur synthétique spécifique du foie.

Un vector de virus adenoasociado recombinante no replicativo del tipo 2/6 (**rAAV6**), que codifica para el factor de coagulación sanguíneo VIII humano (hF8, FVIII) con el dominio B delecionado, bajo el control de un promotor sintético específico del hígado.

p.63

supprimer	*insérer*
lététresgéne autoleucel	lététresgène autoleucel

p.132 **zildistrogenum varoparvovecum #**

zildistrogene varoparvovec	*replace the description by the following one*
zildistrogène varoparvovec	*remplacer la description par la suivante*
zildistrogén varoparvovec	*sustitúyase la descripción por la siguiente*

A recombinant non-replicating adeno-associated virus type 2/9 (**rAAV9**) vector, encoding human microdystrophin 5 (h-μD5) under control of CK8 muscle creatine kinase promoter and enhancer elements

vecteur viral adéno-associé de type 2/9 recombinant non-répliquant (**rAAV9**) codant pour la microdystrophine 5 humaine (h-mD5) sous le contrôle de l'activateur/promoteur de la créatine kinase musculaire CK8

Un vector de virus adenoasociado recombinante no replicativo del tipo 2/9 (**rAAV9**), que codifica para la microdistrofina 5 humana (h-mD5) bajo el control del promotor y elementos potenciadores (enhancer) de la creatina quinasa CK8 de músculo.

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/

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.

1.10 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>レカネマブは，遺伝子組換え抗ヒトアミロイドベータペプチド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 IgG1 に由来する。レカネマブは，チャイニーズハムスター卵巣細胞により産生される。レカネマブは，454 個のアミノ酸残基からなる H 鎖（γ1 鎖）2 本及び 219 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 150,000）である。</td></tr>
<tr><td>構造式</td><td>アミノ酸配列及びジスルフィド結合並びに主な糖鎖の推定構造を別紙に示す。</td></tr>
<tr><td>効能・効果</td><td>アルツハイマー病による軽度認知障害及び軽度の認知症の進行抑制</td></tr>
<tr><td>用法・用量</td><td>通常，レカネマブ（遺伝子組換え）として 10 mg/kg を，2 週間に 1 回，約 1 時間かけて点滴静注する。</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：レカネマブ（遺伝子組換え）
製剤：レケンビ点滴静注 200 mg（1 バイアル中にレカネマブ［遺伝子組換え］を 200 mg 含有）
レケンビ点滴静注 500 mg（1 バイアル中にレカネマブ［遺伝子組換え］を 500 mg 含有）</td></tr>
<tr><td>毒性</td><td>(1)急性（投与経路：静脈内）
<table>
<tr><th>動物種</th><th>概略の致死量</th></tr>
<tr><td>ラット♂♀</td><td>>100 mg/kg</td></tr>
<tr><td>カニクイザル♂</td><td>>50 mg/kg</td></tr>
</table>
(2)亜急性・慢性（投与経路：静脈内）
<table>
<tr><th>動物種</th><th>投与期間
[試験番号]</th><th>投与量
(mg/kg)</th><th>主な所見</th></tr>
<tr><td rowspan="2">カニクイザル</td><td>4 週間
[B090486]</td><td>0, 5, 15, 50</td><td>無毒性量: 50 mg/kg
5: 特になし
15: 脾臓重量の増加・脾臓の胚中心の大きさと数の増加（雄）
50: 脾臓の絶対重量の増加（雌），脾臓の胚中心の大きさと数の増加（雌雄）</td></tr>
<tr><td>39 週間
[B100068]</td><td>0, 15, 50, 100</td><td>無毒性量: 100 mg/kg
15: 特になし
50: 特になし
100: 脾臓重量の増加・胚中心のわずかな増加（雌）</td></tr>
</table></td></tr>
<tr><td>副作用</td><td>早期アルツハイマー病を対象とした国際共同第Ⅲ相試験において，本剤を投与した 898 例（日本人 87 例を含む）中 401 例（44.7%）に副作用が認められた。主な副作用（発現率 1%以上）は，注入に伴う反応 234 例（26.1%），ARIA-H 148 例（16.5%），ARIA-E 113 例（12.6%），頭痛 16 例（1.8%），過敏症 15 例（1.7%）であった。</td></tr>
<tr><td>会社</td><td>エーザイ株式会社
共同開発会社：Biogen Inc.</td></tr>
</table>

【別紙】

アミノ酸配列及びジスルフィド結合

L鎖

DVVMTQSPLS LPVTPGAPAS ISCRSSQSIV HSNGNTYLEW YLQKPGQSPK

LLIYKVSNRF SGVPDRFSGS GSGTDFTLRI SRVEAEDVGI YYCFQGSHVP

PTFGPGTKLE IKRTVAAPSV FIFPPSDEQL KSGTASVVCL LNNFYPREAK

VQWKVDNALQ SGNSQESVTE QDSKDSTYSL SSTLTLSKAD YEKHKVYACE

VTHQGLSSPV TKSFNRGEC

H鎖

EVQLVESGGG LVQPGGSLRL SCSASGFTFS SFGMHWVRQA PGKGLEWVAY

ISSGSSTIYY GDTVKGRFTI SRDNAKNSLF LQMSSLRAED TAVYYCAREG

GYYYGRSYYT MDYWGQGTTV TVSSASTKGP SVFPLAPSSK STSGGTAALG

CLVKDYFPEP VTVSWNSGAL TSGVHTFPAV LQSSGLYSLS SVVTVPSSSL

GTQTYICNVN HKPSNTKVDK RVEPKSCDKT HTCPPCPAPE LLGGPSVFLF

PPKPKDTLMI SRTPEVTCVV VDVSHEDPEV KFNWYVDGVE VHNAKTKPRE

EQYNSTYRVV SVLTVLHQDW LNGKEYKCKV SNKALPAPIE KTISKAKGQP

REPQVYTLPP SREEMTKNQV SLTCLVKGFY PSDIAVEWES NGQPENNYKT

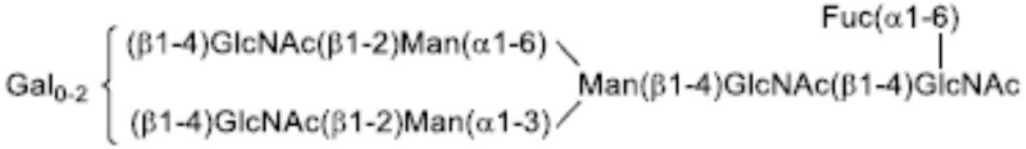
TPPVLDSDGS FFLYSKLTVD KSRWQQGNVF SCSVMHEALH NHYTQKSLSL

SPGK

H 鎖 N304：糖鎖結合；H 鎖 K454：部分的プロセシング

L 鎖 C219－H 鎖 C227，H 鎖 C233－H 鎖 C233，H 鎖 C236－H 鎖 C236：ジスルフィド結合

主な糖鎖の推定構造



別紙様式１

生物由来製品又は特定生物由来製品の指定資料のまとめ

一般名：	レカネマブ（遺伝子組換え）
販売名：	レケンビ点滴静注 200mg レケンビ点滴静注 500mg
申請者：	エーザイ株式会社
効能・効果：	アルツハイマー病による軽度認知障害及び軽度の認知症の進行抑制
用法・用量：	通常，レカネマブ（遺伝子組換え）として 10mg/kg を，2 週間に 1 回，約 1 時間かけて点滴静注する。
生物由来原料等の使用の有無	☑使用 ☐不使用
使用した生物由来原料等	☐ヒト由来細胞・組織、☐ヒト由来成分（血液、尿、その他）、☑動物由来細胞・組織、☐動物由来成分（血液、その他） 原材料名；チャイニーズハムスター卵巣細胞（CHO-[redacted]細胞株）
生物由来原料等の使用目的	☑宿主細胞、☐培地添加物、☐その他の製造原材料、☐製剤添加物、☐その他（　　）
原料等の由来となるヒト・動物のスクリーニング・管理の内容：	別紙様式 2 参照
生物由来原料等に対する不活化処理等の内容：	別添 2 参照
ウイルスクリアランス試験結果の概要：	別添 3 参照
製造工程の概要（フローチャート）： （不活化処理には下線を付し、処理条件を具体的に記載）	別添 2 参照

別紙様式２

使用した生物由来原料等の名称 注1），注2）	チャイニーズハムスター卵巣細胞（CHO-[redacted]細胞株）
使用した生物由来原料等の分類	□ヒト血液由来成分、□ヒト細胞組織、□ヒト尿由来成分、□ヒト由来成分（血液、細胞組織又は尿を除くもの）、□反芻動物由来成分、☑動物細胞組織、□動物由来成分、□その他（　　）
生物由来原料等の使用目的	□有効成分、☑宿主細胞、□培地添加物、□その他の製造原料等（　　）、□製剤添加物、□その他（　　）
生物由来原料等の由来となるヒト・動物のスクリーニング・管理の内容注3）	別添 1 参照 「ヒト又は動物細胞株を用いて製造されるバイオテクノロジー応用医薬品のウイルス安全性評価」について（医薬審第 329 号　平成 12 年 2 月 22 日）及び「生物薬品（バイオテクノロジー応用医薬品／生物起源由来医薬品）製造用細胞基剤の由来，調製及び特性解析」について（医薬審第 873 号　平成 12 年 7 月 14 日）に従い評価を実施した。
生物由来原料等のウイルス等の不活化及び除去処理等の内容注4）	別添 2 参照
製造工程の概要（フローチャート）注5）注6） （不活化及び除去処理には下線を付し、条件を具体的に記載）	別添 2 参照
ウイルスクリアランス試験結果の概要注7）	別添 3 参照

注１）複数の生物由来原料等を使用している場合、別紙様式２は当該原料等ごとに作成する。

注２）動物種及び使用部位も記載する。

注３）合致する告示・通知等がある場合は引用する。

注４）生物由来原料等の製造工程におけるすべての不活化処理等の内容を記載する。なお、別紙として記載してもよい。

注５）滅菌工程については、方法・条件も含めて記載する。なお、別紙として記載してもよい。また、複数の生物由来原料等を使用している場合には本欄は共通となるので、「○○（共通となる原材料名）と同じ」と記載してもよい。

注６）生物由来原料等の製造工程については、記載する必要はない。

注７）ウイルスクリアランス試験を行っている場合には全て記載する。生物由来原料等の製造工程での結果と製品の製造工程での結果に分けられるものは分けて記載する。なお、別紙として記載してもよい。

別添 1

CHO-[redacted]細胞株よりマスター・セル・バンク（MCB）及びワーキング・セル・バンク（WCB）を作製した。MCB 及び WCB の特性解析結果を表 1 に示す。

表 1　MCB 及び WCB の特性解析結果

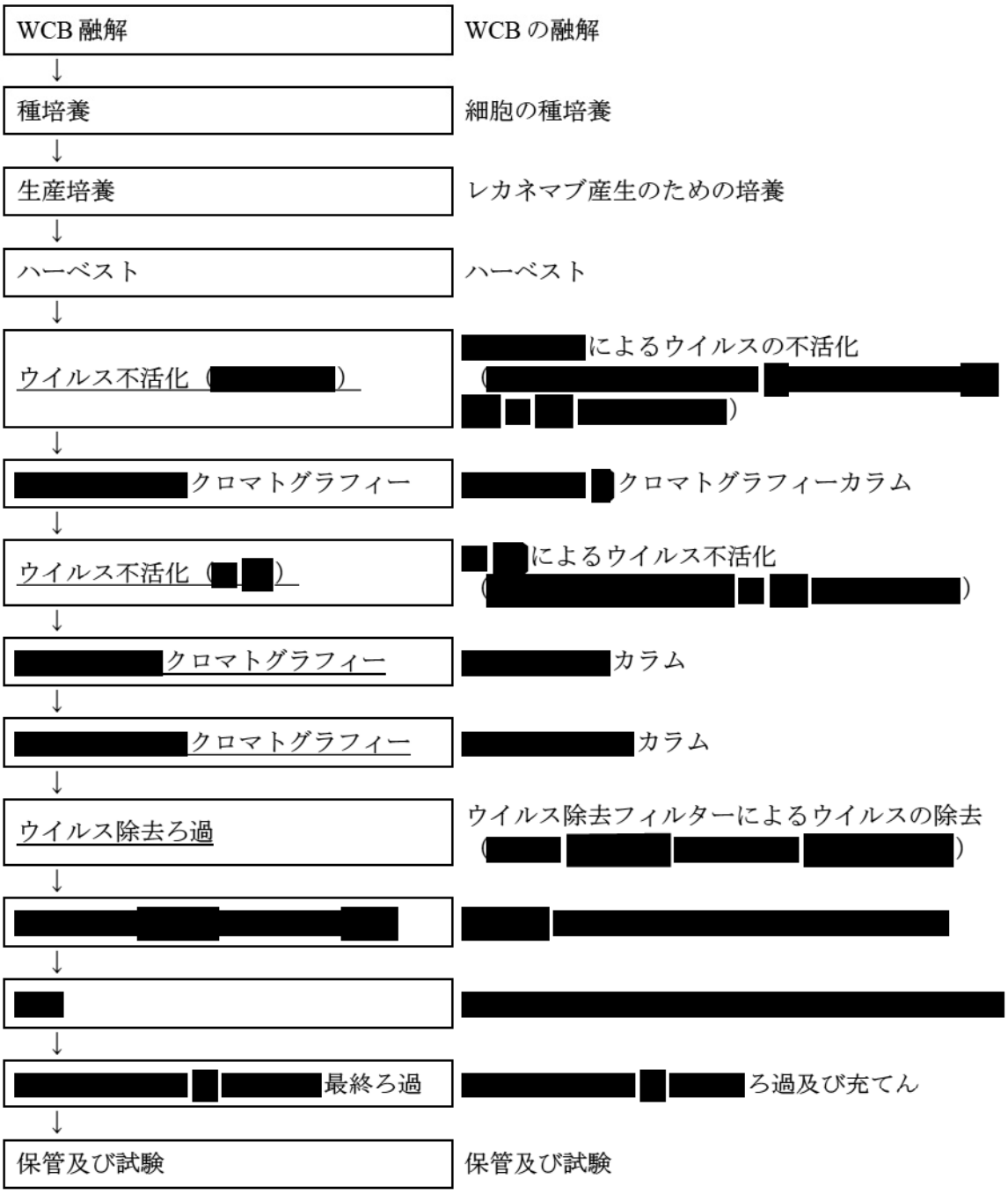
試験項目	MCB	WCB
マイコプラズマ （MCB：培養法，Points to Consider (FDA)，Ph.Eur.） （WCB：培養法，USP，Ph.Eur.）	検出されず	検出されず
無菌試験	増殖せず	増殖せず
確認試験	チャイニーズハムスターと一致	チャイニーズハムスターと一致
In vitro外来性ウイルス（[redacted]日間）[1)]	検出されず	検出されず
[redacted]ウイルス（PCR）	検出されず	検出されず
In vivo外来性ウイルス[2)]	検出されず	試験実施せず
In vitro[redacted]ウイルス	検出されず	試験実施せず
[redacted]ウイルス（PCR）	検出されず	試験実施せず
In vitro[redacted]ウイルス	検出されず	試験実施せず
[redacted]ウイルス（PCR）	検出されず	試験実施せず
ハムスター抗体産生試験	検出されず	試験実施せず
[redacted]抗体産生試験	検出されず	試験実施せず
[redacted]	検出されず	試験実施せず
[redacted]試験	検出されず	試験実施せず
逆転写酵素試験	逆転写酵素活性に対し陰性	試験実施せず
透過型電子顕微鏡	細胞質内A型粒子：[redacted] C型レトロウイルス粒子：[redacted] マイコプラスマ，真菌，酵母，細菌，その他のウイルス又はウイルス様粒子：観察されず	試験実施せず

1) MCB に対する指標細胞：[redacted]
　WCB に対する指標細胞：[redacted]

2) 被験動物：[redacted]

別添 2

原薬の製造工程の概要を以下に示す。不活化及び除去処理を下線で示す。



別添 3

原薬の製造工程のうち，下記の工程について，ウイルスクリアランス試験を実施した。

- ウイルス不活化（[redacted]）工程
- ウイルス不活化（[redacted]）工程
- [redacted]クロマトグラフィー工程
- [redacted]クロマトグラフィー工程
- ウイルス除去ろ過工程

1. モデルウイルス選定

潜在的な外来性ウイルスを除去又は不活化するための精製工程の頑健性を評価することを目的として，出発物質中に含まれる可能性のあるウイルス及び幅広い潜在的汚染源の物理的及び化学的特性を示すウイルスのうち，代表的なウイルスを低減することを示すためのモデルウイルスを選定した。モデルウイルスの物理化学的特性を表 1 に示す。

表 1　選定したモデルウイルスの特性

ウイルス名	ゲノム	外被	ウイルス科	サイズ（nm）	抵抗性
XMuLV	一本鎖 RNA	有	レトロウイルス科	80～110	低い
MMV	一本鎖 DNA	無	パルボウイルス科	18～24	非常に高い
PRV	二本鎖 DNA	有	ヘルペスウイルス科	120～200	低い
REO3	二本鎖 RNA	無	レオウイルス科	60～80	中程度

MMV＝マウス微小ウイルス，PRV＝仮性狂犬病ウイルス，REO3＝レオウイルス 3 型，XMuLV＝異種指向性マウス白血病ウイルス関連ウイルス

2. ウイルスクリアランス試験の結果

以下の式に従い，各ウイルスについて，各精製工程におけるウイルス対数減少値（LRV）を求めた。

$$R = log_{10} \frac{V1 \times T1}{V2 \times T2}$$

R：ウイルス対数減少値
V1：工程前の容量
V2：工程後の容量
T1：工程前のウイルス濃度
T2：工程後のウイルス濃度

各工程について[redacted]回ずつ試験を行い，[redacted]し，製造工程の総 LRV を算出した。各工程における[redacted]95%信頼区間を算出した。ウイルスクリアランスの結果の概要を表 2 に示す。

表 2　プロセス C 精製工程のウイルス対数減少値の概要

工程	ウイルス対数減少値			
	XMuLV	**MMV**	**PRV**	**REO3**
ウイルス不活化（[redacted]）工程	≥[redacted]	[redacted]	[redacted]	[redacted]
ウイルス不活化（[redacted]）工程	≥[redacted]	[redacted]	≥[redacted]	[redacted]
[redacted]クロマトグラフィー工程	≥[redacted]	[redacted]	≥[redacted]	[redacted]
[redacted]クロマトグラフィー工程	≥[redacted]	[redacted]	≥[redacted]	≥[redacted]
ウイルス除去ろ過工程	≥[redacted]	≥[redacted]	≥[redacted]	≥[redacted]
総ウイルス対数減少値	≥21.94±0.20	≥10.43±0.09	≥20.59±0.88	≥9.77±0.06

MMV＝マウス微小ウイルス，PRV＝仮性狂犬病ウイルス，REO3＝レオウイルス 3 型，XMuLV＝異種指向性マウス白血病ウイルス関連ウイルス

[redacted]

第3部　品質に関する文書

番号	添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	評価資料・参考資料
1	3.2.S.1.1	Nomenclature	—	—	—	評価資料
2	3.2.S.1.2	Structure	—	—	—	評価資料
3	3.2.S.1.3	General Properties	—	—	—	評価資料
4	3.2.S.2.1	Manufacturer(s)	—	—	—	評価資料
5	3.2.S.2.2	Description of Manufacturing Process and Process Controls	—	—	—	評価資料
6	3.2.S.2.3	Control of Materials - Raw Materials	—	—	—	評価資料
7	3.2.S.2.3	Control of Materials - Source, History, and Generation of the Cell Substrate	—	—	—	評価資料
8	3.2.S.2.3	Control of Materials - Preparation and Testing of the Cell Banks	—	—	—	評価資料
9	3.2.S.2.4	Controls of Critical Steps and Intermediates	—	—	—	評価資料
10	3.2.S.2.5	Process Validation and /or Evaluation - Overview	—	—	—	評価資料
11	3.2.S.2.5	Process Validation and /or Evaluation - Biogen Solothurn	—	—	—	評価資料
12	3.2.S.2.5	Process Validation and /or Evaluation - Clearance of Process-related Impurities	—	—	—	評価資料
13	3.2.S.2.5	Process Validation and /or Evaluation - Process Hold Times	—	—	—	評価資料
14	3.2.S.2.5	Process Validation and /or Evaluation - Column Lifetime Validation and Membrane Verification	—	—	—	評価資料
15	3.2.S.2.5	Process Validation and /or Evaluation - Shipping Validation	—	—	—	評価資料
16	3.2.S.2.6	Manufacturing Process Development - Overview	—	—	—	評価資料
17	3.2.S.2.6	Manufacturing Process Development - Critical Quality Attributes	—	—	—	評価資料
18	3.2.S.2.6	Manufacturing Process Development - Manufacturing Development Studies	—	—	—	評価資料
19	3.2.S.2.6	Manufacturing Process Development - Process Development History	—	—	—	評価資料
20	3.2.S.2.6	Manufacturing Process Development - Comparability	—	—	—	評価資料
21	3.2.S.3.1	Elucidation of Structure and Other Characteristics	—	—	—	評価資料
22	3.2.S.3.2	Impurities	—	—	—	評価資料
23	3.2.S.4.1	Specification	—	—	—	評価資料

番号	添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	評価資料・参考資料
24	3.2.S.4.2	Analytical Procedures - Overview	—	—	—	評価資料
25	3.2.S.4.2	Analytical Procedures - Oligosaccharide Profile	—	—	—	評価資料
26	3.2.S.4.2	Analytical Procedures - Capillary Electrophoresis	—	—	—	評価資料
27	3.2.S.4.2	Analytical Procedures - Size Exclusion Chromatography (SEC)	—	—	—	評価資料
28	3.2.S.4.2	Analytical Procedures - Ion Exchange Chromatography	—	—	—	評価資料
29	3.2.S.4.2	Analytical Procedures - Host Cell DNA	—	—	—	評価資料
30	3.2.S.4.2	Analytical Procedures - Host Cell Protein	—	—	—	評価資料
31	3.2.S.4.2	Analytical Procedures - Protein A ELISA	—	—	—	評価資料
32	3.2.S.4.2	Analytical Procedures - Polysorbate 80	—	—	—	評価資料
33	3.2.S.4.2	Analytical Procedures - Antigen Binding ELISA	—	—	—	評価資料
34	3.2.S.4.2	Analytical Procedures - FcγRIIa Binding Assay	—	—	—	評価資料
35	3.2.S.4.2	Analytical Procedures - Protein Concentration	—	—	—	評価資料
36	3.2.S.4.3	Validation of Analytical Procedures - Overview	—	—	—	評価資料
37	3.2.S.4.3	Validation of Analytical Procedures - Oligosaccharide Profiling	—	—	—	評価資料
38	3.2.S.4.3	Validation of Analytical Procedures - Reduced Capillary Electrophoresis	—	—	—	評価資料
39	3.2.S.4.3	Validation of Analytical Procedures - Non-Reduced Capillary Electrophoresis	—	—	—	評価資料
40	3.2.S.4.3	Validation of Analytical Procedures - Size Exclusion Chromatography (SEC)	—	—	—	評価資料
41	3.2.S.4.3	Validation of Analytical Procedures - Ion Exchange Chromatography	—	—	—	評価資料
42	3.2.S.4.3	Validation of Analytical Procedures - Host Cell DNA	—	—	—	評価資料
43	3.2.S.4.3	Validation of Analytical Procedures - Host Cell Protein	—	—	—	評価資料
44	3.2.S.4.3	Validation of Analytical Procedures - Protein A ELISA	—	—	—	評価資料
45	3.2.S.4.3	Validation of Analytical Procedures - Polysorbate 80	—	—	—	評価資料
46	3.2.S.4.3	Validation of Analytical Procedures - Antigen Binding ELISA	—	—	—	評価資料
47	3.2.S.4.3	Validation of Analytical Procedures - CD32a (FcγRIIa) Binding Assay	—	—	—	評価資料
48	3.2.S.4.3	Validation of Analytical Procedures - Protein Concentration	—	—	—	評価資料
49	3.2.S.4.4	Batch Analyses	—	—	—	評価資料
50	3.2.S.4.5	Justification of Specification	—	—	—	評価資料

番号	添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	評価資料・参考資料
51	3.2.S.5	Reference Standards or Materials	—	—	—	評価資料
52	3.2.S.6	Container Closure System	—	—	—	評価資料
53	3.2.S.7.1	Stability Summary and Conclusions	—	—	—	評価資料
54	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment	—	—	—	評価資料
55	3.2.S.7.3	Stability Data	—	—	—	評価資料
56	3.2.P.1	Description and Composition of the Drug Product	—	—	—	評価資料
57	3.2.P.2.1	Components of the Drug Product	—	—	—	評価資料
58	3.2.P.2.2	Drug Product	—	—	—	評価資料
59	3.2.P.2.3	Manufacturing Process Development - Process Development History	—	—	—	評価資料
60	3.2.P.2.3	Manufacturing Process Development - Manufacturing Development Studies	—	—	—	評価資料
61	3.2.P.2.3	Manufacturing Process Development - Comparability	—	—	—	評価資料
62	3.2.P.2.4	Container Closure System	—	—	—	評価資料
63	3.2.P.2.5	Microbiological Attributes	—	—	—	評価資料
64	3.2.P.2.6	Compatibility	—	—	—	評価資料
65	3.2.P.3.1	Manufacturer(s)	—	—	—	評価資料
66	3.2.P.3.2	Batch Formula	—	—	—	評価資料
67	3.2.P.3.3	Description of Manufacturing Process and Process Controls	—	—	—	評価資料
68	3.2.P.3.4	Controls of Critical Steps and Intermediates	—	—	—	評価資料
69	3.2.P.3.5	Process Validation and /or Evaluation - Overview	—	—	—	評価資料
70	3.2.P.3.5	Process Validation and /or Evaluation - Biogen RTP-PF	—	—	—	評価資料
71	3.2.P.3.5	Process Validation and /or Evaluation - Equipment and Component Sterilization	—	—	—	評価資料
72	3.2.P.3.5	Process Validation and /or Evaluation - General Validation Studies Introduction	—	—	—	評価資料
73	3.2.P.4	Control of Excipients	—	—	—	評価資料
74	3.2.P.5.1	Specification(s)	—	—	—	評価資料
75	3.2.P.5.2	Analytical Procedures - Overview	—	—	—	評価資料
76	3.2.P.5.2	Analytical Procedures - Identity by Peptide Mapping	—	—	—	評価資料
77	3.2.P.5.2	Analytical Procedures - FcγRIIa Binding Assay	—	—	—	評価資料
78	3.2.P.5.3	Validation of Analytical Procedures - Overview	—	—	—	評価資料

番号	添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	評価資料・参考資料
79	3.2.P.5.3	Validation of Analytical Procedures - Identity by Peptide	－	－	－	評価資料
80	3.2.P.5.3	Validation of Analytical Procedures - CD32a (FcgRIIa) Binding Assay	－	－	－	評価資料
81	3.2.P.5.4	Batch Analyses	－	－	－	評価資料
82	3.2.P.5.5	Characterization of Impurities	－	－	－	評価資料
83	3.2.P.5.6	Justification of Specification(s)	－	－	－	評価資料
84	3.2.P.6	Reference Standards or Materials	－	－	－	評価資料
85	3.2.P.7	Container Closure System	－	－	－	評価資料
86	3.2.P.8.1	Stability Summary and Conclusion	－	－	－	評価資料
87	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment	－	－	－	評価資料
88	3.2.P.8.3	Stability Data	－	－	－	評価資料
89	3.2.A.1	Facilities and Equipment [Biogen Solothurn, Switzerland]	－	－	－	評価資料
90	3.2.A.1	Facilities and Equipment [Biogen Solothurn Floorplans]	－	－	－	評価資料
91	3.2.A.1	Facilities and Equipment [Biogen RTP-PF, USA]	－	－	－	評価資料
92	3.2.A.1	Facilities and Equipment [Biogen RTP-PF Floorplans]	－	－	－	評価資料
93	3.2.A.2	Adventitious Agents Safety Evaluation	－	－	－	評価資料
94	3.2.A.3	Excipients	－	－	－	評価資料

第4部　非臨床試験報告書

4.2.1　薬理試験

番号	添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	評価資料・参考資料
1	4.2.1.1.1	In vitro characterization of binding profiles to different Aβ species of lecanemab and competitor antibodies (AD-TR-445)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
2	4.2.1.1.2	Compiled In Vitro Data on Human Aβ Protofibril Specificity and Affinity of mAb158/BAN2401 (AD-TR-006)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
3	4.2.1.1.3	ABBA: Binding Activity of mAb158 to Aβ Protofibrils and Oligomers (W-20090268)	20[redacted]-20[redacted]	Eisai Co., Ltd.	国内	参考資料
4	4.2.1.1.4	Lecanemab and competitor antibodies binding to Aβ protofibrils in human alzheimer's disease brain (AD-TR-461)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
5	4.2.1.1.5	BAN2401 Binding Studies: An Amino Terminal Binding Epitope in Beta Amyloid (BR-035)	20[redacted] （報告書作成年月）	Eisai Inc.	海外	参考資料
6	4.2.1.1.6	Production of Fab158 and $F(ab')_2$-2401 Fragments and Analysis of Binding to Amyloid β Protofibrils (AD-TR-085)	20[redacted]-20[redacted]	[redacted]	海外	参考資料

番号	添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	評価資料・参考資料
7	4.2.1.1.7	X-ray structure analysis of human anti-Aβ antibody (Lecanemab) Fab fragment in complex with Aβ-peptide (W-20210274)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
8	4.2.1.1.8	ABBA: In Vitro Inhibition of Beta-Sheet Formation (W-20090273)	20[redacted]-20[redacted]	Eisai Co., Ltd.	国内	参考資料
9	4.2.1.1.9	BAN2401: Effects of BAN2401 on Amyloid β Protofibril Binding to Dendritic Spines in Rat Primary Hippocampal Neuron Culture (W-20090258)	20[redacted]-20[redacted]	Eisai Co., Ltd.	国内	参考資料
10	4.2.1.1.10	BAN2401: Effects of BAN2401 on Amyloid β Protofibril Binding to Rat Primary Hippocampal Neurons in Culture (M09007)	20[redacted]-20[redacted]	Eisai Co., Ltd.	国内	評価資料
11	4.2.1.1.11	Evaluation of the Protective Effect of BAN2401 on Aβ1-42 Induced Toxicity In Vitro (CO18660)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
12	4.2.1.1.12	ABBA: In Vitro Inhibition of Neuronal Toxicity (W-20090274)	20[redacted]-20[redacted]	Eisai Co., Ltd.	国内	参考資料
13	4.2.1.1.13	BAN2401: The Effects of BAN2401 to Neuronal Cell Toxicity of Amyloid Beta Protofibrils in Cultured Neuronal Cells Derived From Fetal Rat Septa (M09010)	20[redacted]-20[redacted]	Eisai Co., Ltd.	国内	参考資料

番号	添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	評価資料・参考資料
14	4.2.1.1.14	1. Optimization Experiments to Obtain Correct Stoichiometry of BAN2401 and Abeta Aggregates 2. Effect of BAN2401 on Abeta Aggregates 3. Effects of BAN2401-Abeta Adducts in an Ex-Vivo Assay Using Hippocampal Slices for LTP Measurement Using Multi Electrode Array (MEA) for Electrophysiology (CO16640)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
15	4.2.1.1.15	BAN2401 and mAb158 Interactions With Human and Murine FcγRI (AD-TR-019)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
16	4.2.1.1.16	Development of Fc Receptor Binding Assays Using the Forte Bio Octet (BR-034)	20[redacted] （報告書作成年月）	Eisai Inc.	海外	参考資料
17	4.2.1.1.17	Study of BAN2401 Interaction With the Human Neonatal Fc Receptor Using Surface Plasmon Resonance (AD-TR-058)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
18	4.2.1.1.18	Microglia Potency Assay for BAN2401: Preliminary Data on Dose-dependence of BAN2401 and on Inhibition of Fcγ Receptors (AD-TR-123)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
19	4.2.1.1.19	Effects of BAN2401 on Amyloid β Peptide Protofibril Uptake and Inflammatory Responses in Cultured Alzheimer's Disease and Normal Elderly Control Microglia (LMS 0432-02-26207)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
20	4.2.1.1.20	Exploratory Report on Short-Term Efficacy of mAb158 in Tg-APP_{ArcSwe} Mice (AD-TR-008)	20[redacted]-20[redacted]	[redacted]	海外	参考資料

番号	添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	評価資料・参考資料
21	4.2.1.1.21	Analysis of Aβ Species in CSF and Brain at Different Time-Points Following Short-Term Treatment With mAb158 in Tg-APP$_{ArcSwe}$ Mice (AD-TR-014)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
22	4.2.1.1.22	Short-Term Dose-Finding of mAb158 in Tg-APP$_{ArcSwe}$ Mice (AD-TR-010)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
23	4.2.1.1.23	Long-Term Efficacy of mAb158 in Tg-APP$_{ArcSwe}$ Mice (AD-TR-007)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
24	4.2.1.1.24	BIO08: Mass Spectrometry Analysis of Different Aβ Species in CSF From Tg-APP$_{ArcSwe}$ Mice After mAb158 Treatment (AD-TR-070)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
25	4.2.1.1.25	Long-Term Efficacy of mAb158 in Old Tg-APP$_{ArcSwe}$ Mice (AD-TR-009)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
26	4.2.1.1.26	Long-Term Dose-Finding of mAb158 in Tg-APP$_{ArcSwe}$ Mice (AD-TR-011)	20[redacted]-20[redacted]	[redacted]	海外	参考資料
27	4.2.1.1.27	Time Course Study to Evaluate the Effects of mAb158 on Amyloid-β Protofibril Levels and Plaque Load in Aged Female Tg2576 Mice (AD-TR-443)	20[redacted]-20[redacted]	[redacted]	海外	参考資料

番号	添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	評価資料・参考資料
28	4.2.1.1.28	ABBA mAb158: Acute/Sub-Chronic Effects on Brain Aβ Protofibrils/Oligomers in 14-Month-Old Tg2576 Mice (W-20090278)	20[redacted]-20[redacted]	Eisai Co., Ltd.	国内	参考資料
29	4.2.1.1.29	A Pharmacological Study: The Effect of mAb158 on Amyloid Protofibril in Brain of Aged Tg2576 Mouse (W-20100295)	20[redacted]-20[redacted]	Eisai Co., Ltd.	国内	参考資料
30	4.2.1.1.30	ABBA mAb158: Effects on Aβ Protofibrils/Oligomers of Brain and Cerebrospinal Fluid in 4-Month-Old Tg2576 Mice (W-20090277)	20[redacted]-20[redacted]	Eisai Co., Ltd.	国内	参考資料
31	4.2.1.1.31	ABBA mAb158: Effects on Brain Aβ Protofibrils/Oligomers, Aβ Plaques, Aβx-42 and Aβx-40 in 12.5-Month-Old Tg2576 Mice (W-20090276)	20[redacted]-20[redacted]	Eisai Co., Ltd.	国内	参考資料
32	4.2.1.1.32	ABBA: A Behavioral Study by Treatment of mAb158, Antiamyloid-β Protofibril Antibody, in Tg2576 Mice (NSEA2014-015)	20[redacted] （報告書作成年月）	Eisai Co., Ltd.	国内	参考資料
33	4.2.1.1.33	A Pharmacological Study With Supplemental Histopathological Examination: The Effect of mAb158 on Amyloid Protofibril in Tg2576 Mouse Brains (W-20100318)	20[redacted]-20[redacted]	Eisai Co., Ltd.	国内	参考資料
34	4.2.1.1.34	SEC04: Short Term Efficacy of rec158 in Tg-APP$_{ArcSwe}$ Mice Shown by 82El-MSD Assay (AD-TR-055)	20[redacted]-20[redacted]	[redacted]	海外	参考資料