ロカメッツキット
に関する資料

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略号一覧

略号	省略していない表現 (英)	省略していない表現 (日)
CT	computerized tomography	コンピュータ断層撮影
EANM	European Association of Nuclear Medicine	欧州核医学会
MBq	megabecquerel	メガベクレル
mCi	Millicurie	ミリキュリー
PET	positron emission tomography	陽電子放出断層撮影
PSMA	prostate-specific membrane antigen	前立腺特異的膜抗原
QOL	quality of life	生活の質
RI	radioisotope	放射性同位体
SNMMI	Society of nuclear medicine & molecular imaging	核医学・分子イメージング学会

1 起原又は発見の経緯

当該内容については，「2.3 品質に関する概括資料」，「2.4 非臨床試験の概括評価」，「2.5 臨床に関する概括評価」に記載した。

2 本剤の治療上の位置づけ

セラノスティクス（Theranostics）とは，治療（Therapy）と画像診断（Diagnostics）を融合させた新たな概念である。同じ標的分子に対して特異的な親和性を有する抗体やペプチド等の薬剤を，診断時には診断用放射性同位体（診断用 RI），治療時には治療用 RI で標識することで，ベースとなる薬剤を変えずに診断と治療を行う。セラノスティクスでは，診断用 RI で標識した薬剤の体内動態等から，病巣を可視化する。その後，治療用 RI で標識した薬剤を投与することで，ターゲット細胞で薬効を発揮する一方，周囲の正常組織での傷害は限定的である。このため，がん患者にとってより有効かつ安全な医療の実現につながると期待されている。

PSMA-11（以下，本剤）は，前立腺特異的膜抗原（PSMA）を標的とした，セラノスティクスによる新しい診断アプローチに使用する薬剤である。PSMA は前立腺癌に多く発現するタンパク質であり，放射性リガンドによる前立腺癌の診断及び治療の標的分子として期待されている。本剤は，放射性診断薬である[^{68}Ga]Ga-PSMA-11（以下，^{68}Ga-PSMA-11）溶液の調製に使用するバイアルキットであり，ガリウム（^{68}Ga） ジェネレータから溶出した塩化ガリウム（^{68}Ga）溶液で溶解した後，^{68}Ga 標識した ^{68}Ga-PSMA-11 を静脈内投与し，PET/CT スキャンで前立腺癌患者の PSMA 発現病変を画像化する。

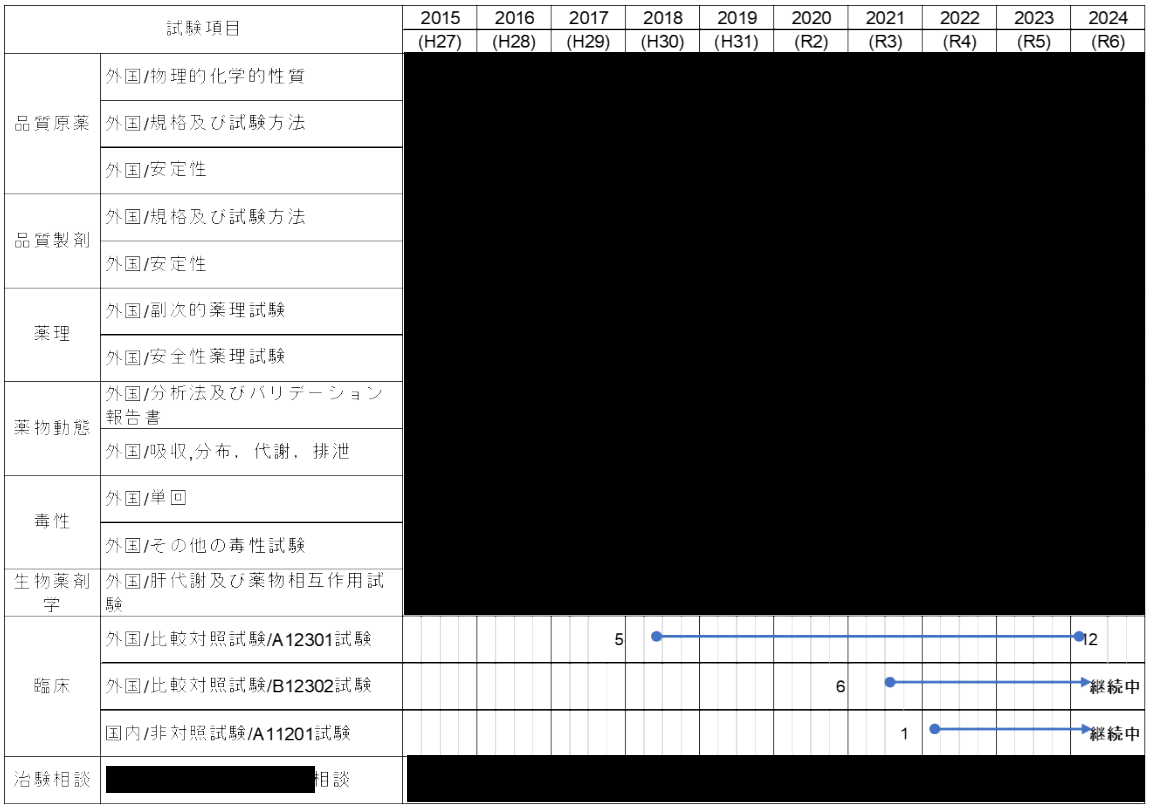
本剤は，前立腺癌患者に対する PSMA 標的療法の適応判定のための PET 診断に不可欠な薬剤である。本邦では，現在，同様の目的で使用可能な薬剤は承認されておらず，本剤が PSMA を標的とした国内初の放射性診断薬である。

3 開発の経緯図

開発の経緯の詳細については「2.3 品質に関する概括資料」，「2.4 非臨床試験の概括評価」，「2.5 臨床に関する概括評価」を参照のこと。

開発の経緯図を Figure 3-1 に示す。

Figure 3-1　　開発の経緯図



4　　特徴及び有用性

PSMA 陽性病変を有する前立腺癌を対象とした国内初のセラノスティクスの放射性診断薬である

本剤を利用した PSMA を標的とする画像診断と，PSMA 標的療法の組み合わせは，PSMA 陽性病変を有する前立腺癌を対象とした国内で最初のセラノスティクスであり，新たなタイプのプレシジョンメディシンである。^{68}Ga-PSMA-11 PET/CT 検査で PSMA 陽性病変が特定された患者では，その作用機序から PSMA 標的療法による高い有効性が期待できる。

^{68}Ga-PSMA-11 PET/CT 検査は，前立腺癌における PSMA 陽性病変を検出可能な国内初の PET/CT 検査であり，PSMA 標的治療の患者選択に不可欠である

^{68}Ga-PSMA-11 PET/CT 検査は，欧米で既に承認され，欧州核医学会（EANM）及び核医学・分子イメージング学会（SNMMI）共同のガイドラインにも明記された実績のある診断方法であり，海外でその有用性が多数報告されている [2.5-1.1.2 項]。本邦では，前立腺癌における PSMA 陽性病変を検出可能な画像診断は承認されておらず，本剤をガリウム（^{68}Ga）標識した ^{68}Ga-PSMA-11 を用いた PET/CT 検査が国内初となる。本剤を用いた ^{68}Ga-PSMA-11 PET/CT 検査は，PSMA 標

的治療の患者選択に不可欠であるとともに，検査による適正な患者選択によって，副作用の低減，患者の生活の質（QOL）の向上，医療資源の有効な利用等へも貢献が期待される。

ガリウム（^{68}Ga）ジェネレータを用いて医療施設で簡便にガリウム（^{68}Ga）標識可能である

本剤は，ガリウム（^{68}Ga）ジェネレータを用いて医療施設内で用時調製が可能である。本剤はガリウム（^{68}Ga）標識されておらず，非放射性医薬品と同様に取り扱われるため，保管や輸送における利便性及び安全性が高い。

5 まとめ

以上を踏まえ，以下のとおり本剤の製造販売承認申請を行う。

【申請品目】

ロカメッツキット

【効能又は効果（案）】

ガリウム（^{68}Ga）を用いた標識後に、前立腺癌を有する成人の前立腺特異的膜抗原（PSMA）陽性病変の陽電子放出断層撮影（PET）による PSMA 標的療法の適応となる前立腺癌患者の選択

【用法及び用量（案）】

通常、成人にはガリウム（^{68}Ga）ゴゼトチドとして 111MBq（3mCi）～259MBq（7mCi）を静脈内投与する。

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表 一 覧

Table 1-1　主要国での承認状況 3

1 外国における使用状況等

2025 年 6 月現在，PSMA-11（商標名：Locametz）は，ガリウム（^{68}Ga）を用いた標識後，前立腺癌患者での PSMA 陽性病変を検出する PET 用放射性診断薬として，米国では 2022 年 3 月に，欧州では 2022 年 12 月にそれぞれ承認されている。主要国での承認状況を，Table 1-1 に示す。

Table 1-1 主要国での承認状況

国名	承認年月日	効能・効果
米国	2022 年 3 月 23 日	LOCAMETZ は，ガリウム（^{68}Ga）で標識した後，以下の前立腺癌男性患者における前立腺特異的膜抗原（PSMA）陽性病変の陽電子放出断層撮影（PET）診断のための放射性診断薬である • 初回根治的治療の対象であり転移が疑われる患者 • 血清前立腺特異抗原（PSA）値の上昇に基づき再発が疑われる患者 • 治療薬の添付文書に記載されている PSMA 標的療法の適応となる転移性前立腺癌患者の選択
欧州	2022 年 12 月 9 日	Locametz は，ガリウム（^{68}Ga）を用いた標識後に，以下の臨床状況において，成人前立腺癌患者の陽電子放出断層撮影（PET）による前立腺特異的膜抗原（PSMA）陽性病変の検出を適応とする • 一次根治治療前の高リスク前立腺癌患者の一次病期分類 • 一次根治治療後に血清前立腺特異抗原（PSA）値が上昇した患者における前立腺癌の再発疑い • 進行性の PSMA 陽性転移性去勢抵抗性前立腺癌（mCRPC）を有し，PSMA 標的療法の適応となる患者の特定
英国	2022 年 8 月 10 日	Locametz は，ガリウム（^{68}Ga）で標識した後，成人前立腺癌患者の陽電子放出断層撮影（PET）による前立腺特異的膜抗原（PSMA）陽性病変の同定を適応とする放射性診断薬である
カナダ	2023 年 4 月 5 日	LOCAMETZ［ガリウム（^{68}Ga）ゴゼトチド調製用キット］は，ガリウム（^{68}Ga）で標識した後，以下の前立腺癌男性患者における前立腺特異的膜抗原（PSMA）陽性病変の陽電子放出断層撮影（PET）診断のための放射性診断薬である • 初回根治的治療の対象であり転移が疑われる患者 • 血清前立腺特異抗原（PSA）値の上昇に基づき再発が疑われる患者 • 進行性の PSMA 陽性転移性去勢抵抗性前立腺癌（mCRPC）を有し，PSMA 標的療法の適応となる患者の特定

2 外国の添付文書等の概要

スイス・ノバルティス社の企業中核データシート（CCDS）を提出する。また 2025 年 6 月時点で最新の米国，欧州の添付文書を提出する。

2ページ目以降は，非公表のため削除

NOVARTIS

[redacted]

LOCAMETZ®/™ (gozetotide)
25 micrograms, kit for radiopharmaceutical preparation of gallium (^{68}Ga) gozetotide solution for injection

Core Data Sheet (CDS)

[redacted]

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use LOCAMETZ safely and effectively. See full prescribing information for LOCAMETZ.

LOCAMETZ® (kit for the preparation of gallium Ga 68 gozetotide injection), for intravenous use
Initial U.S. Approval: 2020

----------RECENT MAJOR CHANGES----------

Indications and Usage (1)	3/2025
Dosage and Administration, Image Interpretation (2.8)	3/2025
Warnings and Precautions, Risk for Misinterpretation (5.1)	3/2025

----------INDICATIONS AND USAGE----------

LOCAMETZ, after radiolabeling with gallium-68, is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA)-positive lesions in men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level
- for selection of patients who are indicated for PSMA-directed therapy as described in the prescribing information of the therapeutic products. (1)

----------DOSAGE AND ADMINISTRATION----------

- Use appropriate radiation safety measures and aseptic precautions while handling and administering gallium Ga 68 gozetotide injection. (2.1)
- The recommended amount of radioactivity is 111 MBq to 259 MBq (3 mCi to 7 mCi). Administered as slow intravenous injection. (2.2)
- Advise patients to be well hydrated prior to the administration and to void immediately prior to and frequently after image acquisition. (2.3)
- A diuretic expected to act within the uptake time period may be administered at the time of radiotracer injection. (2.6)
- Acquire PET whole body images 50 minutes to 100 minutes after administration. (2.7)
- See the full prescribing information for detailed instructions on preparation, administration, imaging, and radiation dosimetry. (2)

----------DOSAGE FORMS AND STRENGTHS----------

- Kit for the preparation of gallium Ga 68 gozetotide injection supplied in a multiple-dose vial containing 25 mcg of gozetotide as a white lyophilized powder. After radiolabeling with gallium-68, the vial contains a sterile solution of gallium Ga 68 gozetotide at a strength up to 2,590 MBq (70 mCi) in up to 10 mL at calibration date and time. (3)

----------CONTRAINDICATIONS----------

None. (4)

----------WARNINGS AND PRECAUTIONS----------

- Risk for Misinterpretation: Gallium Ga 68 gozetotide uptake may occur in other tumor types and in non-malignant processes. Interpretation of LOCAMETZ PET imaging with histopathology and/or other diagnostic procedures is recommended. (5.1)
- Radiation Risk: Gallium Ga 68 gozetotide contributes to a patient's overall long-term cumulative radiation exposure. Ensure safe handling and preparation procedures to protect patients and health care workers from unintentional radiation exposure. (5.2)

----------ADVERSE REACTIONS----------

The adverse reactions (incidence ≥ 0.5%) are fatigue, nausea, constipation, and vomiting. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Novartis Pharmaceuticals Corporation at 1-888-669-6682 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 3/2025

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*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

LOCAMETZ, after radiolabeling with gallium-68, is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA)-positive lesions in men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy.
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.
- for selection of patients who are indicated for PSMA-directed therapy as described in the prescribing information of the therapeutic products.

2 DOSAGE AND ADMINISTRATION

2.1 Radiation Safety – Drug Handling

After reconstitution and radiolabeling of LOCAMETZ, the vial contains gallium Ga 68 gozetotide injection. Handle the gallium Ga 68 gozetotide injection with appropriate safety measures to minimize radiation exposure *[see Warnings and Precautions (5.2)]*. Use waterproof gloves, effective radiation shielding, and other appropriate safety measures when preparing and handling gallium Ga 68 gozetotide injection.

Radiopharmaceuticals should be used by or under the control of health care providers who are qualified by specific training and experience in the safe use and handling of radionuclides, and whose experience and training have been approved by the governmental agency authorized to license the use of radionuclides.

2.2 Recommended Dosage

In adults, the recommended amount of radioactivity to be administered for PET is 111 MBq to 259 MBq (3 mCi to 7 mCi) by slow intravenous injection.

2.3 Patient Preparation

Advise patients to be well hydrated prior to gallium Ga 68 gozetotide injection administration and to void immediately prior to and frequently during the first hours after image acquisition to reduce radiation exposure *[see Warnings and Precautions (5.2)]*.

2.4 Drug Preparation

LOCAMETZ allows the direct preparation of gallium Ga 68 gozetotide injection with the eluate from one of the following generators (see below for specific instruction for use with each generator):

- Eckert & Ziegler GalliaPharm germanium-68/gallium-68 (^{68}Ge/^{68}Ga) generator
- IRE ELiT Galli Eo germanium-68/gallium-68 (^{68}Ge/^{68}Ga) generator
- ITM Medical Isotopes GeGant germanium-68/gallium-68 (^{68}Ge/^{68}Ga) generator

The instructions for use provided by the germanium-68/gallium-68 generator manufacturer should also be followed.

Prepare gallium Ga 68 gozetotide injection according to the following aseptic procedure:

a. Use suitable shielding to reduce radiation exposure.
b. Wear waterproof gloves.
c. Flip the cap off the LOCAMETZ vial and swab the septum with an appropriate antiseptic, then allow the septum to dry.
d. Pierce the LOCAMETZ vial septum with a sterile needle connected to a 0.2-micron sterile air venting filter to maintain atmospheric pressure within the vial during the reconstitution process.
e. Place the LOCAMETZ vial in a lead shield container.
f. Follow the generator specific procedures below. Schematic diagrams are provided in Figures 1, 2 and 3.

<u>Preparation with Eckert & Ziegler GalliaPharm Generator</u>

1) Connect the male luer of the outlet line of the generator to a sterile elution needle (size 21G to 23G).
2) Connect the LOCAMETZ vial directly to the outlet line of the generator by pushing the elution needle through the rubber septum.

3) Elute directly from the generator into the LOCAMETZ vial.
4) Perform the elution manually or by means of a pump according to the generator instructions for use.
5) Reconstitute the lyophilized powder with 5 mL of eluate.
6) At the end of the elution, disconnect the LOCAMETZ vial from the generator by removing the elution needle and the vent needle with the 0.2-micron sterile air venting filter from the rubber septum. Then, invert LOCAMETZ vial once and place it upright.
7) Incubate the LOCAMETZ vial upright between 20°C to 30°C (68°F to 86°F) for at least 5 minutes without agitation or stirring.
8) After 5 minutes, assay the vial containing the gallium Ga 68 gozetotide injection for total radioactivity using a dose calibrator, calculate the radioactivity concentration and record the result.
9) After radiolabeling, gallium Ga 68 gozetotide injection may be diluted with Sterile Water for Injection, USP or 0.9% Sodium Chloride Injection, USP up to a final volume of 10 mL.
10) Perform quality controls according to the recommended methods in order to check compliance with the specifications *[see Dosage and Administration (2.5)]*.
11) Store the LOCAMETZ vial containing the gallium Ga 68 gozetotide injection upright in a lead shield container below 30°C (86°F) until use.
12) After addition of gallium-68 chloride to the LOCAMETZ vial, use gallium Ga 68 gozetotide injection within 6 hours.

Preparation with IRE ELiT Galli Eo Generator

1) Connect the male luer of the outlet line of the generator to a sterile elution needle (size 21G to 23G).
2) Connect the LOCAMETZ vial directly to the outlet line of the generator by pushing the elution needle through the rubber septum.
3) Connect the LOCAMETZ vial through the vent needle with 0.2-micron sterile air venting filter to a vacuum vial (25 mL minimum volume) by means of a sterile needle (size 21G to 23G) or to a vacuum pump to start the elution.
4) Elute directly from the generator into the LOCAMETZ vial.
5) Reconstitute the lyophilized powder with 1.1 mL of eluate.
6) At the end of the elution, first withdraw the sterile needle from the vacuum vial or disconnect the vacuum pump in order to establish atmospheric pressure into the LOCAMETZ vial, then disconnect the vial from the generator by removing both the elution needle and the vent needle with the 0.2-micron sterile air venting filter needle from the rubber septum. Inversion of the LOCAMETZ vial is not needed.
7) Incubate the LOCAMETZ vial upright between 20°C to 30°C (68°F to 86°F) for at least 5 minutes without agitation or stirring.
8) After 5 minutes, assay the vial containing the gallium Ga 68 gozetotide injection for total radioactivity using a dose calibrator, calculate the radioactivity concentration and record the result.
9) After radiolabeling, gallium Ga 68 gozetotide injection may be diluted with Sterile Water for Injection, USP or 0.9% Sodium Chloride Injection, USP up to a final volume of 10 mL.
10) Perform quality controls according to the recommended methods in order to check compliance with the specifications *[see Dosage and Administration (2.5)]*.
11) Store the LOCAMETZ vial containing the gallium Ga 68 gozetotide injection upright in a lead shield container below 30°C (86°F) until use.
12) After addition of gallium-68 chloride to the LOCAMETZ vial, use gallium Ga 68 gozetotide injection within 6 hours.

Preparation with ITM Medical Isotopes GeGant Generator

1) Connect the male luer of the outlet line of the generator to a sterile elution needle (size 21G to 23G).
2) Connect the LOCAMETZ vial directly to the outlet line of the generator by pushing the elution needle through the rubber septum.
3) Elute directly from the generator into the LOCAMETZ vial.

4) Perform the elution manually or by means of a pump according to the generator instructions for use.
5) Reconstitute the lyophilized powder with 4 mL of eluate.
6) At the end of the elution, disconnect the LOCAMETZ vial from the generator by removing the elution needle and the vent needle with the 0.2-micron sterile air venting filter from the rubber septum. Then, invert LOCAMETZ vial once and place it upright.
7) Incubate the LOCAMETZ vial upright between 20°C to 30°C (68°F to 86°F) for at least 5 minutes without agitation or stirring.
8) After 5 minutes, assay the vial containing the gallium Ga 68 gozetotide injection for total radioactivity using a dose calibrator, calculate the radioactivity concentration and record the result.
9) After radiolabeling, gallium Ga 68 gozetotide injection may be diluted with Sterile Water for Injection, USP or 0.9% Sodium Chloride Injection, USP up to a final volume of 10 mL.
10) Perform quality controls according to the recommended methods in order to check compliance with the specifications *[see Dosage and Administration (2.5)]*.
11) Store the LOCAMETZ vial containing the gallium Ga 68 gozetotide injection upright in a lead shield container below 30°C (86°F) until use.
12) After addition of gallium-68 chloride to the LOCAMETZ vial, use gallium Ga 68 gozetotide injection within 6 hours.

Figure 1. Preparation with Eckert & Ziegler GalliaPharm Generator

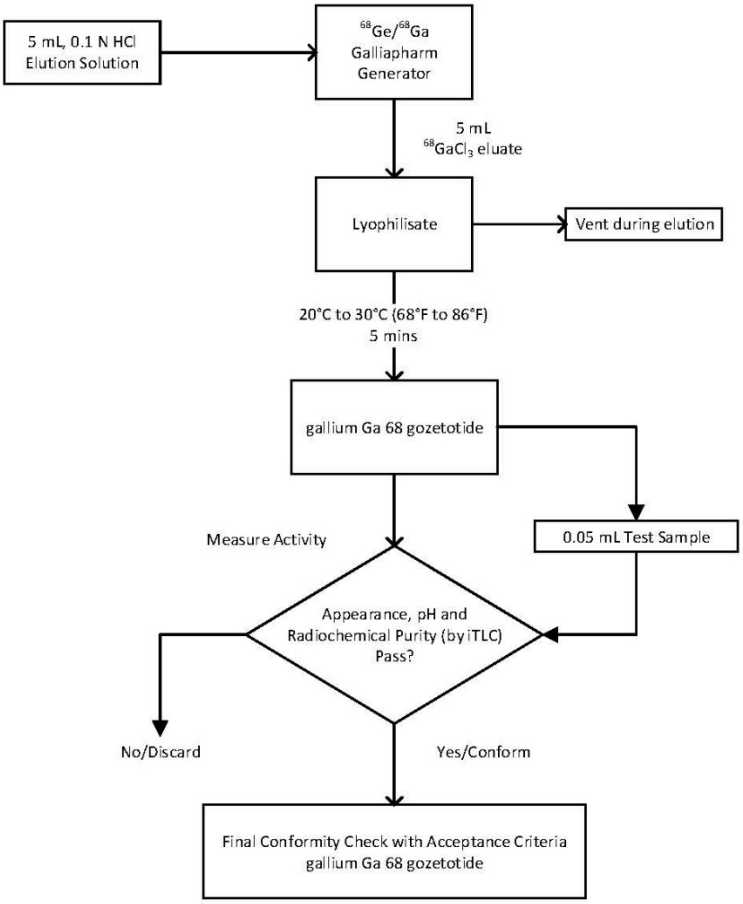


Figure 2. Preparation with IRE ELiT Galli Eo Generator

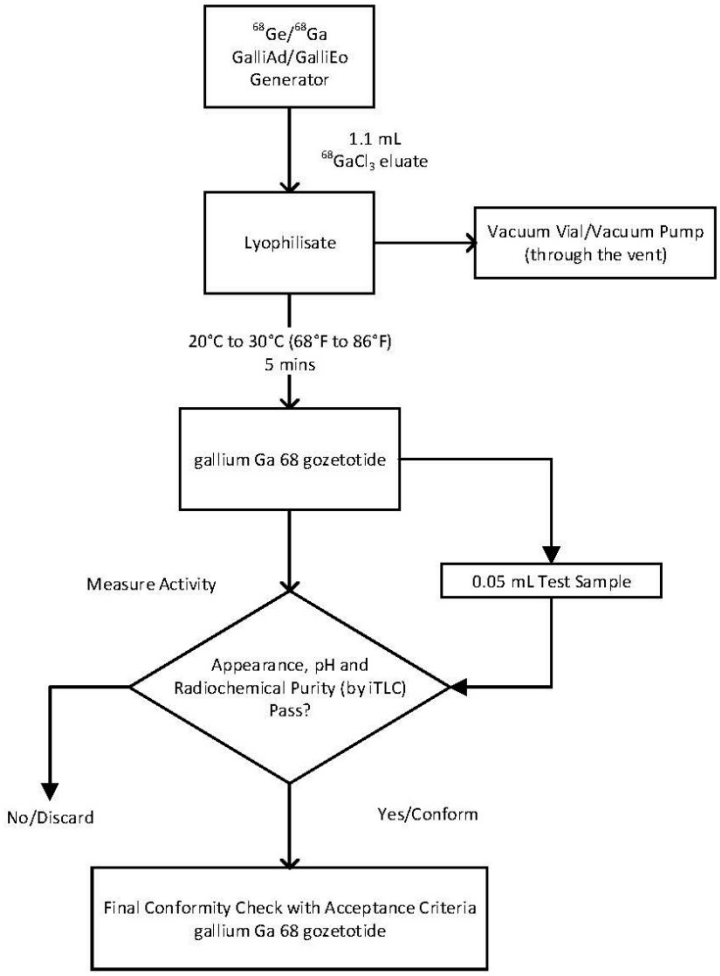
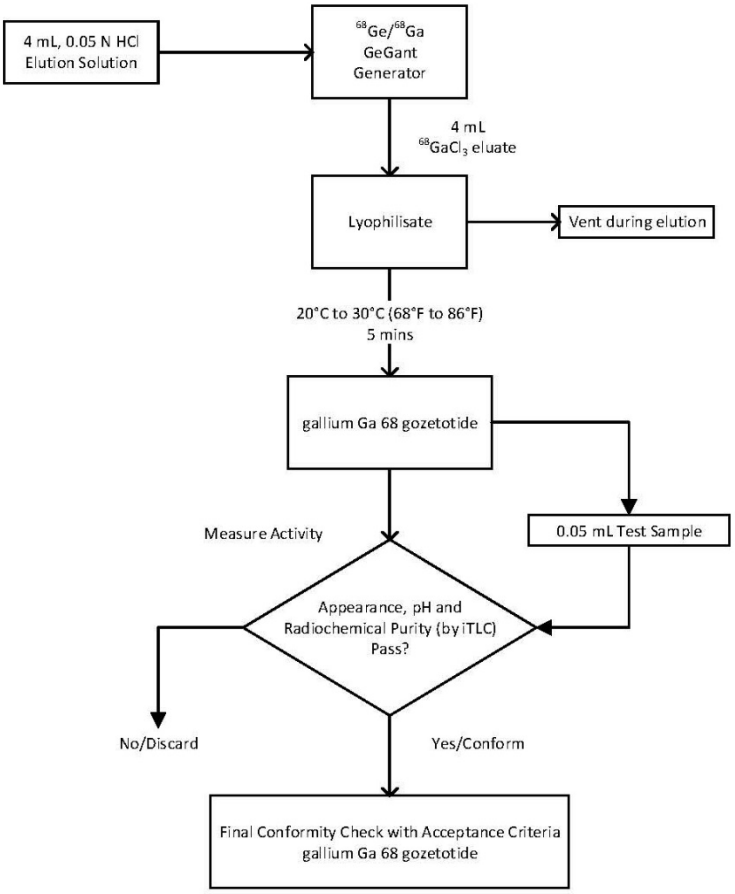


Figure 3. Preparation with ITM Medical Isotopes GeGant Generator



2.5 Specifications and Quality Control

Perform the quality controls in Table 1 behind a lead glass shield for radioprotection purposes.

Table 1. Specifications of Gallium Ga 68 Gozetotide Injection

Test	Acceptance criteria	Method
Appearance	Clear, colorless and free from particulate matter	Visual inspection
pH	3.2 to 6.5	pH-indicator strips
Radiochemical purity	gallium Ga 68 gozetotide ≥ 95% Non-complexed gallium-68 species ≤ 5%	Instant thin layer chromatography (ITLC, see details below)

Determine radiochemical purity of gallium Ga 68 gozetotide injection by performing instant thin layer chromatography (ITLC).

Perform ITLC using ITLC SG strips and using ammonium acetate 1M: Methanol (1:1 V/V) as mobile phase.

ITLC Method

a. Develop the ITLC SG strip for a distance of 6 cm from the point of application (i.e., to 7 cm from the bottom of the ITLC strip).
b. Scan the ITLC SG strip with a radiometric ITLC scanner.
c. Calculate radiochemical purity by integration of the peaks on the chromatogram. Do not use the reconstituted product if the percentage (%) of non-complexed gallium-68 species is higher than 5%.

The retention factor (Rf) specifications are as follows:

- Non-complexed gallium-68 species, Rf = 0 to 0.2;
- Gallium Ga 68 gozetotide, Rf = 0.8 to 1.

2.6 Administration

a. Use aseptic technique and radiation shielding when withdrawing and administering gallium Ga 68 gozetotide injection.
b. Calculate the necessary volume to administer based on calibration time and required dose.
c. Inspect the prepared gallium Ga 68 gozetotide injection for particulate matter and discoloration behind a lead glass shield for radioprotection purposes. Use only solutions that are clear, colorless and free from particulate matter.
d. Using a single-dose syringe fitted with a sterile needle (size 21G to 23G) and protective shielding, aseptically withdraw the prepared gallium Ga 68 gozetotide injection.
e. Verify the total radioactivity in the syringe with a dose calibrator immediately before and after gallium Ga 68 gozetotide injection administration to the patient. The dose calibrator must be calibrated with NIST traceable standards.
f. After injection of gallium Ga 68 gozetotide, administer an intravenous flush of sterile 0.9% Sodium Chloride Injection, USP to ensure full delivery of the dose.
g. Dispose of any unused gallium Ga 68 gozetotide injection in a safe manner in compliance with applicable regulations.
h. If clinically necessary, a diuretic expected to act within the uptake time period may be administered at the time of radiotracer injection to potentially decrease artifact from radiotracer accumulation in the urinary bladder and ureters.

2.7 Image Acquisition

Begin PET scanning 50 minutes to 100 minutes after the intravenous administration of gallium Ga 68 gozetotide injection. Patients should void immediately prior to image acquisition and image acquisition should begin at the mid-thighs and proceed cranially to the skull base or skull vertex. Adapt imaging technique according to the equipment used and patient characteristics in order to obtain the best image quality possible.

2.8 Image Interpretation

Gallium Ga 68 gozetotide binds to PSMA. Based on the intensity of the signals, PET images obtained using gallium Ga 68 gozetotide injection indicate the presence of PSMA in tissues.

Imaging Prior to Initial Definitive or Suspected Recurrence Therapy

Lesions should be considered suspicious if uptake is greater than physiologic uptake in that tissue or greater than adjacent background if no physiologic uptake is expected. Tumors that do not bear PSMA will not be visualized. Increased uptake in tumors is not specific for prostate cancer *[see Warnings and Precautions (5.1)]*.

Imaging to Select Patients for PSMA-Directed Therapy

For instructions on patient selection, refer to the prescribing information of the PSMA-directed therapeutic product.

2.9 Radiation Dosimetry

Estimated radiation absorbed doses per injected activity for organs and tissues of 13 adult male patients with an early stage of disease following an intravenous bolus of gallium Ga 68 gozetotide injection are shown in Table 2.

The effective radiation dose resulting from the administration of 259 MBq (7 mCi) is 4.4 mSv. The radiation doses for this administered dose to the critical organs, which are the kidneys, urinary bladder, and spleen, are 96.2 mGy, 25.4 mGy, and 16.8 mGy, respectively.

These radiation doses are for gallium Ga 68 gozetotide injection alone. If CT or a transmission source are used for attenuation correction, the radiation dose will increase by an amount that varies by technique.

Table 2. Estimated Mean Radiation Absorbed Doses per Activity of Intravenously Administered Gallium Ga 68 Gozetotide Injection in Selected Organs and Tissues

	Absorbed dose (mGy/MBq)	
Organ	**Mean**	**SD**
Adrenals	0.0156	0.0014
Brain	0.0104	0.0011
Breasts	0.0103	0.0011
Gallbladder	0.0157	0.0012
Lower colon	0.0134	0.0009
Small intestine	0.014	0.002
Stomach	0.0129	0.0008
Heart	0.012	0.0009
Kidneys	0.3714	0.0922
Liver	0.0409	0.0076
Lungs	0.0111	0.0007
Muscle	0.0103	0.0003
Pancreas	0.0147	0.0009
Red marrow	0.0114	0.0016
Skin	0.0091	0.0003
Spleen	0.065	0.018
Testes	0.0111	0.0006
Thymus	0.0105	0.0006
Thyroid	0.0104	0.0006
Urinary bladder	0.0982	0.0286
Total body	0.0143	0.0013
Effective dose (mSv/MBq)	**0.0169**	**0.0015**

3 DOSAGE FORMS AND STRENGTHS

LOCAMETZ is a kit for the preparation of gallium Ga 68 gozetotide injection supplied in a multiple-dose vial containing 25 micrograms of gozetotide as a white lyophilized powder.

Gallium-68 is obtained from one of the following generators:

- Eckert & Ziegler GalliaPharm (Ge 68/Ga 68) generator
- IRE ELiT Galli Eo (Ge 68/Ga 68) generator
- ITM Medical Isotopes GeGant (Ge 68/Ga 68) generator

After radiolabeling with gallium-68, each vial contains a sterile, clear, colorless solution free from particulate matter of gallium Ga 68 gozetotide at an activity of up to 2,590 MBq (70 mCi) in up to 10 mL at calibration date and time.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Risk for Misinterpretation

Image interpretation errors can occur with LOCAMETZ PET. Negative imaging does not rule out the presence of prostate cancer and positive imaging does not confirm the presence of prostate cancer. Gallium Ga 68 gozetotide uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes, such as Paget's disease, fibrous dysplasia, and osteophytosis. Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended.

The performance of LOCAMETZ for imaging of biochemically recurrent prostate cancer seems to be affected by serum PSA levels and by site of disease. The performance of LOCAMETZ for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by Gleason score *[see Clinical Studies (14.1, 14.2)]*.

5.2 Radiation Risk

Gallium Ga 68 gozetotide contributes to the patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Ensure safe handling to minimize radiation exposure to the patient and health care workers. Advise patients to be well hydrated prior to gallium Ga 68 gozetotide injection administration and to void immediately prior to and frequently during the first hours after image acquisition to reduce radiation exposure *[see Dosage and Administration (2.1, 2.3)]*.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of LOCAMETZ has been established based on three prospective studies of gallium Ga 68 gozetotide in patients with prostate cancer (i.e., Studies 1, 2, and 3). Adverse reactions from these studies are reported below.

In Studies 1 and 2 using another formulation of gallium Ga 68 gozetotide injection, 960 patients received one dose of gallium Ga 68 gozetotide intravenously with the amount (mean ± SD) of radioactivity 188.7 ± 40.7 MBq (5.1 ± 1.1 mCi) *[see Clinical Studies (14.1, 14.2)]*. The most commonly reported adverse reactions were nausea, diarrhea and dizziness, occurring at a rate of < 1%.

In a randomized, multicenter, open-label clinical study (NCT03511664, referred to as Study 3) in which gallium Ga 68 gozetotide was used to identify PSMA-positive patients on PET imaging to determine eligibility for PSMA-directed therapy, 1,003 patients with progressive metastatic castration-resistant prostate cancer (mCRPC) received one dose of gallium Ga 68 gozetotide intravenously with the amount of radioactivity 167.1 ± 23.1 MBq (4.52 ± 0.62 mCi). Patients were males with median age of 70 years (range, 40 to 94 years), were White (87%), Black or African American (7%), or Asian (2.4%), and had median baseline PSA levels of 74 ng/mL (range, 0 to 8995 ng/mL).

Adverse reactions occurring at ≥ 0.5% in patients with metastatic prostate cancer who received gallium Ga 68 gozetotide injection in Study 3 are presented in Table 3.

Table 3. Adverse Reactions (≥ 0.5%) in Patients with Metastatic Prostate Cancer Who Received Gallium Ga 68 Gozetotide Injection in Study 3

Adverse reactions	Gallium Ga 68 Gozetotide Injection N = 1003 n (%)
General disorders	
Fatigue	12 (1.2)
Gastrointestinal disorders	
Nausea	8 (0.8)
Constipation	5 (0.5)
Vomiting	5 (0.5)

Adverse reactions occurring at a rate of < 0.5% in the study were diarrhea, dry mouth, injection site reactions including injection site hematoma and injection site warmth, and chills.

7 DRUG INTERACTIONS

Androgen Deprivation Therapy and Other Therapies Targeting the Androgen Pathway

Androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, can result in changes in uptake of gallium Ga 68 gozetotide in prostate cancer. The effect of these therapies on performance of LOCAMETZ PET has not been established.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

LOCAMETZ is not indicated for use in females. There are no available data with gallium Ga 68 gozetotide use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. All radiopharmaceuticals, including LOCAMETZ, have the potential to cause fetal harm depending on the fetal stage of development and the magnitude of radiation dose. Animal reproduction studies have not been conducted with gallium Ga 68 gozetotide.

8.2 Lactation

Risk Summary

LOCAMETZ is not indicated for use in females. There are no data on the presence of gallium Ga 68 gozetotide in human milk, the effect on the breastfed infant, or the effect on milk production.

8.4 Pediatric Use

The safety and effectiveness of gallium Ga 68 gozetotide in pediatric patients have not been established.

8.5 Geriatric Use

The efficacy of LOCAMETZ in geriatric patients with prostate cancer is based on data from three prospective studies.

Of the total number of patients in Studies 1 and 2 *[see Clinical Studies (14.1, 14.2)]*, 691 of 960 (72%) were 65 years of age and older while 195 (20%) were 75 years of age and older.

Of the total number of patients in Study 3 *[see Adverse Reactions (6.1)]*, 752 of 1,003 (75%) were 65 years of age and older while 284 (28%) were 75 years of age and older.

The efficacy and safety profiles of gallium Ga 68 gozetotide appeared similar in younger adult and geriatric patients with prostate cancer and other reported clinical experience has not identified differences in responses between the elderly and younger patients.

10 OVERDOSAGE

In the event of an overdose of gallium Ga 68 gozetotide, reduce the radiation absorbed dose to the patient where possible by increasing the elimination of the radioactivity from the body by hydration and frequent bladder voiding. A diuretic might also be considered. If possible, an estimate of the effective radiation dose exposure to the patient should be made.

11 DESCRIPTION

11.1 Chemical Characteristics

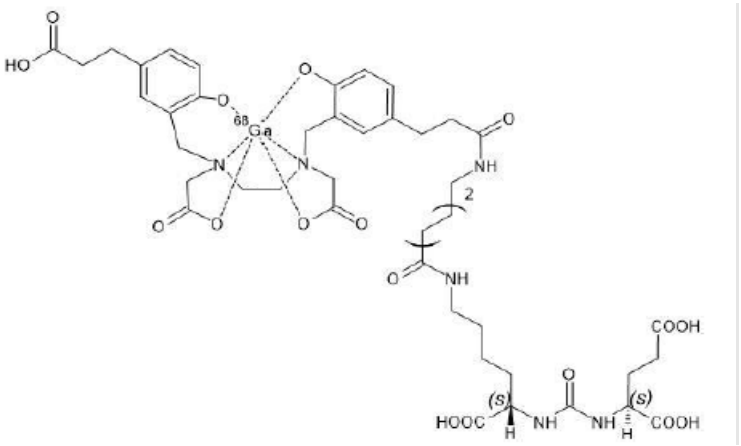
LOCAMETZ (kit for the preparation of gallium Ga 68 gozetotide injection) is a sterile, radioactive diagnostic agent for intravenous administration after radiolabeling. Each vial contains 25 micrograms of gozetotide, 1 mg gentisic acid, 78 mg of sodium acetate trihydrate, and 40 mg sodium chloride. Gozetotide is also known as PSMA-11.

After reconstitution and radiolabeling of LOCAMETZ, the vial contains gallium Ga 68 gozetotide injection at a radioactivity of up to 2,590 MBq (70 mCi) in up to 10 mL at calibration date and time. The vial also contains hydrochloric acid derived from the gallium-68 chloride solution. Gallium Ga 68 gozetotide injection has a pH between 3.2 to 6.5.

Gallium Ga 68 gozetotide is a urea based peptidomimetic that has a covalently bound chelator (HBED-CC). The peptide has amino acid sequence OH-Glu-CO-Lys(Ahx-CC-HBED)-OH.

Gallium Ga 68 gozetotide has a molecular weight of 1011.91 g/mol. The chemical structure is shown in Figure 4.

Figure 4. Chemical Structure of Gallium Ga 68 Gozetotide



11.2 Physical Characteristics

Gallium-68 decays with a half-life of 68 minutes to stable zinc-68. Table 4 and Table 5 display the principle radiation emission data, and physical decay of gallium-68.

Table 4. Principal Radiation Emission Data (> 1%) for Gallium-68

Radiation/Emission	% Disintegration	Mean energy (MeV)
beta+	88%	0.8360
beta+	1.1%	0.3526
Gamma	178%	0.5110
Gamma	3%	1.0770
X-ray	2.8%	0.0086
X-ray	1.4%	0.0086

Table 5. Physical Decay Chart for Gallium-68

Minutes	Fraction remaining
0	1
15	0.858
30	0.736
60	0.541
90	0.398
120	0.293
180	0.158
240	0.086
360	0.025

11.3 Radiation Attenuation

Table 6 displays the radiation attenuation by lead shielding of gallium-68.

Table 6. Radiation Attenuation of 511 keV Photons by Lead (Pb) Shielding

Shield thickness (Pb) mm	Coefficient of attenuation
6	0.5
12	0.25
17	0.1
34	0.01
51	0.001

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Gallium Ga 68 gozetotide binds to PSMA. It binds to cells that express PSMA, including malignant prostate cancer cells, which usually overexpress PSMA. Gallium-68 is a β+ emitting radionuclide that allows PET.

12.2 Pharmacodynamics

The relationship between gallium Ga 68 gozetotide plasma concentrations and successful imaging was not explored in clinical trials.

12.3 Pharmacokinetics

Distribution

Intravenously injected gallium Ga 68 gozetotide is cleared from the blood and is accumulated preferentially in the liver (15%), kidneys (7%), spleen (2%), and salivary glands (0.5%). Gallium Ga 68 gozetotide uptake is also seen in the adrenals and prostate. There is no uptake in the cerebral cortex or in the heart, and usually lung uptake is low.

Gozetotide exhibits a mean blood-to-plasma ratio (% CV) of 0.71 (26%) and is approximately 33% bound to human plasma proteins at 1 mcg/mL to 5 mcg/mL *in vitro*.

Elimination

A total of 14% of the injected dose is excreted in urine in the first 2 hours post-injection.

In Vitro Drug Interaction Studies

CYP450 enzymes

Gozetotide is not a substrate of cytochrome P450 (CYP450) enzymes, not an inhibitor of CYP1A2, CYP2B6, CYP2C8, CYP2C19, CYP2D6 and CYP3A4, and not an inducer of CYP1A2, CYP2B6 and CYP3A4 *in vitro*.

Transporters

Gozetotide is not a substrate of BCRP, P-gp, MATE1, MATE2-K, OAT1, OAT3 or OCT2. Gozetotide is not an inhibitor of BCRP, P-gp, MATE1, MATE2-K, OAT1, OAT3, OATP1B1, OATP1B3, OCT1 or OCT2 *in vitro*.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No studies on mutagenic, carcinogenic potential or fertility have been conducted with gallium Ga 68 gozetotide.

14 CLINICAL STUDIES

14.1 Imaging Prior to Initial Definitive Therapy

The efficacy of LOCAMETZ for PET of PSMA-positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy has been established based on a study of another formulation of gallium Ga 68 gozetotide injection. Below is a display of the results of the prospective, open label study PSMA-PreRP (NCT03368547 and NCT02919111, referred to as Study 1).

This two-center study enrolled 325 patients with biopsy-proven prostate cancer who were considered candidates for prostatectomy and pelvic lymph node dissection. All enrolled patients met at least one of the following criteria: serum PSA of at least 10 ng/mL, tumor stage cT2b or greater, or Gleason score greater than 6. Each patient received a single gallium Ga 68 gozetotide PET/CT or PET/MR from mid-thigh to skull base.

A total of 123 patients (38%) proceeded to standard-of-care prostatectomy and template pelvic lymph node dissection and had sufficient histopathology data for evaluation (evaluable patients). Three members of a pool of six central readers independently interpreted each PET scan for the presence of abnormal gallium Ga 68 gozetotide uptake in pelvic lymph nodes located in the common iliac, external iliac, internal iliac, and obturator subregions bilaterally as well as in any other pelvic location. The readers were blinded to all clinical information except for the history of prostate cancer prior to definitive treatment. Extrapelvic sites and the prostate gland itself were not analyzed in this study. For each patient, gallium Ga 68 gozetotide PET results and reference standard histopathology obtained from dissected pelvic lymph nodes were compared by region (left hemipelvis, right hemipelvis, and other).

For the 123 evaluable patients, the mean age was 65 years (range, 45 to 76 years), and 89% were White. The median serum PSA was 11.8 ng/mL. The summed Gleason score was 7 for 44%, 8 for 20%, and 9 for 31% of the patients, with the remainder of the patients having Gleason scores of 6 or 10.

Table 7 compares majority PET reads to pelvic lymph node histopathology results at the patient-level with region matching, such that at least one true positive region defines a true positive patient. As shown, approximately 24% of patients studied were found to have pelvic nodal metastases based on histopathology (95% CI: 17, 32).

Table 7. Patient-Level Performance of Gallium Ga 68 Gozetotide PET for Detection of Pelvic Lymph Node Metastasis[a] in Men with Prostate Cancer with Suspected Metastasis in Study 1 (n = 123)

		Histopathology		Predictive value % (95% CI)
		Positive	Negative	
PET scan	Positive	14	9	PPV 61% (41, 81)
	Negative	16	84	NPV 84% (79, 91)
Total		30	93	
Diagnostic performance % (95% CI)		Sensitivity 47% (29, 65)	Specificity 90% (84, 96)	

Abbreviations: CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value.
[a]With region matching where at least one true positive region defines a true positive patient.

Among the pool of six readers, sensitivity ranged from 36% to 60%, specificity from 83% to 96%, positive predictive value from 38% to 80%, and negative predictive value from 80% to 88%.

In an exploratory subgroup analysis based on summed Gleason score, there was a numerical trend toward more true positives in patients with Gleason score of 8 or higher compared to those with Gleason score of 7 or lower.

An exploratory analysis was performed to estimate the sensitivity and specificity for pelvic nodal metastasis detection in all scanned patients, including the patients who were lacking histopathology reference standard. An imputation method was used based on patient-specific factors. This exploratory analysis resulted in an imputed sensitivity of 47%, with a

95% confidence interval (CI) ranging from 38% to 55%, and an imputed specificity of 74%, with a 95% CI ranging from 68% to 80% for all patients imaged with gallium Ga 68 gozetotide PET.

14.2 Imaging Prior to Suspected Recurrence Therapy

The efficacy of LOCAMETZ for PET of PSMA-positive lesions in men with prostate cancer with suspected recurrence based on elevated serum PSA level has been established based on studies of another formulation of gallium Ga 68 gozetotide injection. Below is a display of the result of the prospective, open label study PSMA-BCR (NCT02940262 and NCT02918357, referred to as Study 2).

This two-center study enrolled 635 patients with biochemical evidence of recurrent prostate cancer after definitive therapy, defined by serum PSA of > 0.2 ng/mL more than 6 weeks after prostatectomy or by an increase in serum PSA of at least 2 ng/mL above nadir after definitive radiotherapy. All patients received a single gallium Ga 68 gozetotide PET/CT or PET/MR from mid-thigh to skull base. Three members of a pool of nine independent central readers evaluated each scan for the presence and regional location (20 subregions grouped into four regions) of abnormal gallium Ga 68 gozetotide uptake suggestive of recurrent prostate cancer. The readers were blinded to all clinical information other than type of primary therapy and most recent serum PSA level.

A total of 469 patients (74%) had at least one positive region detected by gallium Ga 68 gozetotide PET majority read. The distribution of gallium Ga 68 gozetotide PET positive regions was 34% bone, 25% prostate bed, 25% pelvic lymph node, and 17% extrapelvic soft tissue. Two hundred and ten patients had composite reference standard information collected in a PET positive region (evaluable patients), consisting of at least one of the following: histopathology, imaging (bone scintigraphy, CT, or MRI) acquired at baseline or within 12 months after gallium Ga 68 gozetotide PET, or serial serum PSA. Composite reference standard information for gallium Ga 68 gozetotide PET negative regions was not systematically collected in this study.

In the 210 evaluable patients, the mean age was 70 years (range, 49 to 88 years) and 82% were 65 years of age or older. White patients made up 90% of the group. The median serum PSA was 3.6 ng/mL. Prior treatment included radical prostatectomy in 64% and radiotherapy in 73%.

Of the 210 evaluable patients, 192 patients (91%) were found to be true positive in one or more regions against the composite reference standard (95% CI: 88%, 95%). Among the pool of nine readers used in the study, the proportion of patients who were true positive in one or more regions ranged from 82% to 97%. The prostate bed had the lowest proportion of true positive results at the region-level (76% versus 96% for non-prostate regions).

An exploratory analysis was also performed in which gallium Ga 68 gozetotide PET positive patients who lacked reference standard information were imputed using an estimated likelihood that at least one location-matched PET positive lesion was reference standard positive based on patient-specific factors. In this exploratory analysis, 340 of 475 patients (72%) were imputed as true positive in one or more regions (95% CI: 68%, 76%).

In another exploratory analysis using the same imputation approach for PET positive patients who lacked reference standard information, 340 of 635 patients (54%) were correctly detected as true positive (95% CI: 50%, 57%) among all BCR patients who received a PET scan, whether it was read as positive or negative. The likelihood of identifying a gallium Ga 68 gozetotide PET positive lesion in this study generally increased with higher serum PSA level. Table 8 shows the patient-level gallium Ga 68 gozetotide PET results stratified by serum PSA level. The mean time between PSA measurement and PET scan was 40 days with a range of 0 to 367 days. Percent PET positivity was calculated as the proportion of patients with a positive gallium Ga 68 gozetotide PET out of all patients scanned. Percent PET positivity includes patients determined to be either true positive or false positive as well as those in whom such determination was not made due to the absence of composite reference standard data.

Table 8. Patient-Level Gallium Ga 68 Gozetotide PET Results and Percent PET Positivity Stratified by Serum PSA Level in Men with Prostate Cancer with Suspected Recurrence in Study 2 (n = 628)[a]

PSA (ng/mL)	PET-positive patients				PET-negative patients	PET positivity %[b] (95% CI)
	Total	TP	FP	Without reference standard		
		With reference standard				
< 0.5	48	11	1	36	87	36% (27, 44)
		12				
≥ 0.5 and < 1	44	15	3	26	35	56% (45, 67)
		18				
≥ 1 and < 2	71	29	1	41	15	83% (75, 91)
		30				
≥ 2	299	137	13	149	29	91% (88, 94)
		150				
Total	462	192	18	252	166	74% (70, 77)
		210				

Abbreviations: PET, positron emission tomography; PSA, prostate-specific antigen; PSMA, prostate-specific membrane antigen; BCR, biochemical recurrence; TP, true positive; FP, false positive.
[a]7 patients were excluded from this table due to protocol deviations.
[b]Percent PET positivity: PET positive patients/total patients scanned.

14.3 Imaging to Select Patients for PSMA-Directed Therapy

Refer to the prescribing information of the PSMA-directed therapy for description of the studies in which the efficacy of LOCAMETZ for selecting patients has been established.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

LOCAMETZ is supplied as a kit for the preparation of gallium Ga 68 gozetotide injection in a carton of 1 vial (NDC# 69488-017-61).

Each multiple-dose vial contains 25 micrograms of gozetotide as white lyophilized powder packaged in a 10 mL type I Plus glass vial closed with a rubber stopper and sealed with a flip-off cap.

Storage and Handling

Before radiolabeling, store at 2°C to 25°C (36°F to 77°F). Do not freeze.

After radiolabeling, store upright with an appropriate lead shielding to protect from radiation, below 30°C (86°F). Do not freeze. After radiolabeling, use within 6 hours.

This preparation is approved for use by persons under license by the Nuclear Regulatory Commission or the relevant regulatory authority of an Agreement State.

17 PATIENT COUNSELING INFORMATION

Adequate Hydration

Advise patients to be well hydrated prior to the administration of gallium Ga 68 gozetotide injection and urge them to urinate immediately prior to image acquisition and frequently during the first hours following administration to reduce radiation exposure *[see Dosage and Administration (2.3), Warnings and Precautions (5.2)]*.

Distributed by:
Novartis Pharmaceuticals Corporation

East Hanover, NJ 07936

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U.S. Patent 11369590

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

Locametz 25 micrograms kit for radiopharmaceutical preparation

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The vial contains 25 micrograms of gozetotide.

The radionuclide is not part of the kit.

Excipient with known effect

The vial contains 28.97 mg of sodium.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Kit for radiopharmaceutical preparation
One vial of white lyophilised powder (powder for solution for injection).

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.

Locametz, after radiolabelling with gallium-68, is indicated for the detection of prostate-specific membrane antigen (PSMA)-positive lesions with positron emission tomography (PET) in adults with prostate cancer (PCa) in the following clinical settings:

- Primary staging of patients with high-risk PCa prior to primary curative therapy,
- Suspected PCa recurrence in patients with increasing levels of serum prostate-specific antigen (PSA) after primary curative therapy,
- Identification of patients with PSMA-positive progressive metastatic castration-resistant prostate cancer (mCRPC) for whom PSMA-targeted therapy is indicated (see section 4.4).

4.2 Posology and method of administration

This medicinal product should only be administered by trained healthcare professionals with technical expertise in using and handling nuclear medicine imaging agents and only in a designated nuclear medicine facility.

Posology

The recommended dose of gallium (^{68}Ga) gozetotide is 1.8-2.2 MBq/kg of body weight, with a minimum dose of 111 MBq up to a maximum dose of 259 MBq.

Special populations
Elderly
No dose adjustment is required in patients aged 65 years and above.

Renal impairment
There are no data with gallium (^{68}Ga) gozetotide in patients with moderate to severe/end-stage renal impairment. No dose adjustment is considered necessary in patients with renal impairment (see section 5.2).

Hepatic impairment
No dose adjustment is required in patients with hepatic impairment (see section 5.2).

Paediatric population
There is no relevant use of Locametz in the paediatric population for the identification of PSMA-positive lesions in prostate cancer.

Method of administration

This medicinal product is for intravenous and multidose use. It should be reconstituted and radiolabelled before administration to the patient.

After reconstitution and radiolabelling, gallium (^{68}Ga) gozetotide solution should be administered by slow intravenous injection. Local extravasation resulting in inadvertent radiation exposure to the patient and imaging artefacts should be avoided. The injection should be followed by an intravenous flush of sterile sodium chloride 9 mg/ml (0.9%) solution for injection to ensure full delivery of the dose.

The total radioactivity in the syringe should be verified with a dose calibrator immediately before and after administration to the patient. The dose calibrator must be calibrated and comply with international standards. Instructions regarding the dilution of the gallium (^{68}Ga) gozetotide solution should be followed (see section 12).

For patient preparation, see section 4.4.

For instructions on reconstitution and radiolabelling of the medicinal product before administration, see section 12.

Image acquisition
Gallium (^{68}Ga) gozetotide PET image acquisition should be performed by scanning the whole body starting at mid-thigh and proceeding to skull base. PET images should be acquired 50 to 100 minutes after the intravenous administration of gallium (^{68}Ga) gozetotide solution.

Image acquisition start time and duration should be adapted to the equipment used, the patient and the tumour characteristics, in order to obtain the best image quality possible.

Use of computer tomography (CT) or magnetic resonance imaging (MRI) for attenuation correction is recommended.

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients listed in section 6.1 or to any of the components of the labelled radiopharmaceutical.

4.4 Special warnings and precautions for use

Individual benefit/risk justification

For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information.

To date no outcome data exist to inform subsequent management of patients with high-risk disease when PSMA PET/CT is utilised for primary staging.

Experience of use of gallium (^{68}Ga) gozetotide PET for selection of patients for PSMA-based therapy is limited to patients with progressive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy, and to selection of patients for treatment with lutetium (^{177}Lu) vipivotide tetraxetan. Benefit-risk ratio may not be generalisable to other types of PSMA-based therapy and patients with mCRPC with different prior treatments.

Radiation risk

Gallium (^{68}Ga) gozetotide contributes to the patient's overall long-term cumulative radiation exposure, which is associated with an increased risk of cancer. Safe handling, reconstitution and radiolabelling procedures should be ensured to protect patients and healthcare professionals from unintentional radiation exposure (see sections 6.6 and 12).

Interpretation of gallium (^{68}Ga) gozetotide images

PET images with gallium (^{68}Ga) gozetotide should be interpreted by visual assessment. Suspicion of malignant lesions is based on gallium (^{68}Ga) gozetotide uptake in comparison with tissue background.

Gallium (^{68}Ga) gozetotide uptake is not specific to prostate cancer and may occur in normal tissues (see section 5.2), other types of cancers and non-malignant processes, potentially leading to false positive findings. Moderate to high physiological PSMA uptake is noted in the kidneys, lacrimal glands, liver, salivary glands and urinary bladder wall. False positive findings include, but are not limited to, renal cell carcinoma, hepatocellular carcinoma, breast cancer, lung cancer, benign bone diseases (e.g. Paget's disease), pulmonary sarcoidosis/granulomatosis, gliomas, meningiomas, paragangliomas and neurofibromas. Ganglia can mimic lymph nodes.

The diagnostic performance of gallium (^{68}Ga) gozetotide may be affected by serum PSA levels, androgen-receptor-targeting treatments, disease stage and size of malignant lymph nodes (see section 5.1).

Gallium (^{68}Ga) gozetotide PET images should be interpreted only by readers trained in the interpretation of PET images with gallium (^{68}Ga) gozetotide PET. Findings on gallium (^{68}Ga) gozetotide PET images should always be interpreted in conjunction with and be confirmed by other diagnostic methods (including histopathology) before subsequent change in patient management is initiated.

Patient preparation

Patients should be well hydrated prior to gallium (^{68}Ga) gozetotide administration and should be advised to void immediately prior to and frequently during the first hours after image acquisition in order to reduce radiation exposure.

Specific warnings

Sodium content
This medicinal product contains 28.97 mg sodium per injection, equivalent to 1.5% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Acidic pH and extravasation
Low pH of gallium (^{68}Ga) gozetotide may lead to injection site reactions after administration. Accidental extravasation may cause local irritation, due to the acidic pH of the solution. Cases of extravasation should be managed as per institutional guidelines.

4.5 Interaction with other medicinal products and other forms of interaction

Based on *in vitro* interaction studies, gallium (^{68}Ga) gozetotide is not expected to have any clinically significant interaction with other medicinal products (see section 5.2). No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy

Locametz is not indicated for use in females. There are no data on the use of gallium (^{68}Ga) gozetotide in females. Reproductive toxicity studies in animals have not been conducted with gallium (^{68}Ga) gozetotide. However, all radiopharmaceuticals, including gallium (^{68}Ga) gozetotide, have the potential to cause foetal harm.

Breast-feeding

Locametz is not indicated for use in females. There are no data on the effects of gallium (^{68}Ga) gozetotide on the breast-fed newborn/infant or on milk production. Lactation studies have not been conducted in animals with gallium (^{68}Ga) gozetotide.

Fertility

There are no data on the effect of gallium (^{68}Ga) gozetotide on human fertility.

4.7 Effects on ability to drive and use machines

Gallium (^{68}Ga) gozetotide has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of safety profile

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 0.0166 mSv/MBq, with a maximal recommended dose of 259 MBq (4.3 mSv), these adverse reactions are expected to occur with a low probability.

Mild to moderate adverse reactions occurred in patients receiving gallium (^{68}Ga) gozetotide, with the exception of a grade 3 fatigue event (0.1%).

The most common adverse reactions are fatigue (1.2%), nausea (0.8%), constipation (0.5%) and vomiting (0.5%).

Tabulated list of adverse reactions

The safety profile of gallium (^{68}Ga) gozetotide at median dose per body weight of 1.9 MBq/kg (range: 0.9-3.7 MBq/kg) was evaluated in 1 003 patients with metastatic castration-resistant prostate cancer receiving physician's discretion for best standard of care (VISION study).

Adverse reactions (Table 1) are listed by MedDRA system organ class. Within each system organ class, the adverse reactions are ranked by frequency, with the most frequent reactions first. Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness. In addition, the corresponding frequency category for each adverse reaction is based on the following convention (CIOMS III): very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1 000 to <1/100); rare (≥1/10 000 to <1/1 000); very rare (<1/10 000).

Table 1 Adverse reactions observed with gallium (^{68}Ga) gozetotide

System organ class	Frequency category	Adverse reaction
Gastrointestinal disorders	Uncommon	Nausea
	Uncommon	Constipation
	Uncommon	Vomiting
	Uncommon	Diarrhoea
	Uncommon	Dry mouth
General disorders and administration site conditions	Common	Fatigue
	Uncommon	Injection site reactions[1]
	Uncommon	Chills

[1] Injection site reactions includes: injection site haematoma, injection site warmth, injection site pruritus

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

In the event of administration of a radiation overdose with gallium (^{68}Ga) gozetotide, the radiation absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body by hydration and frequent bladder voiding. It might be helpful to estimate the effective radiation dose that was applied.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Diagnostic radiopharmaceuticals, other diagnostic radiopharmaceuticals for tumour detection, ATC code: V09IX14

Mechanism of action

Gallium (^{68}Ga) gozetotide binds to cells that express PSMA, including malignant prostate cancer cells, which overexpress PSMA. Gallium-68 is a radionuclide with an emission yield that allows PET imaging. Based on the intensity of the signals, PET images obtained with gallium (^{68}Ga) gozetotide indicate the presence of PSMA protein in tissues.

Pharmacodynamic effects

At the chemical concentrations used for diagnostic examinations, gallium (^{68}Ga) gozetotide does not have any pharmacodynamic activity.

Clinical efficacy and safety

The sensitivity and specificity of gallium (^{68}Ga) gozetotide were evaluated in the two following prospective studies:

In van Kalmthout et al, 2020, 103 adult male patients with biopsy-proven prostate cancer and intermediate- and high-risk features indicated for extended pelvic lymph node dissection (ePLND) underwent gallium (^{68}Ga) gozetotide PET/CT imaging. PET/CT scans were read by two independent blinded readers and ePLND was the histopathology reference standard for 96 out of 103 (93%) patients. Patient-based sensitivity, specificity, positive and negative predictive value (PPV and NPV, respectively) of gallium (^{68}Ga) gozetotide PET/CT imaging to detect lymph node metastasis (LNM) are summarised in Table 2.

Table 2 Efficacy results in primary staging in patients with biopsy-proven prostate cancer

	Patient-based N=96[1]
Sensitivity (95% CI)	42% (27, 58)
Specificity (95% CI)	91% (79, 97)
PPV	77% (54, 91)
NPV	68% (56, 78)

[1] Evaluable population

Inter-reader agreement was $\kappa = 0.67$ for the 2 independent blinded readers. Of the 67 LNM analysed, 26 were detected by gallium (^{68}Ga) gozetotide PET/CT, resulting in 38.8% node-based sensitivity. Median diameter of the metastatic deposit in these detected LNM was 7 mm (range: 0.3-35). The PET reading missed 41 LNM with a median metastatic deposit of 3.0 mm (range: 0.5 to 35.0).

In Fendler et al, 2019, 635 adult male patients with histopathology-proven and biochemical recurrence (BCR) prostate cancer after prostatectomy (N=262), radiation therapy (N=169) or both (N=204) underwent gallium (^{68}Ga) gozetotide PET/CT or PET/MRI imaging. BCR was defined by serum PSA of ≥0.2 ng/mL more than 6 weeks after prostatectomy or by an increase in serum PSA of at least 2 ng/mL above nadir after definitive radiotherapy. Patients had median PSA level of 2.1 ng/mL above nadir after radiation therapy (range: 0.1-1 154 ng/mL). A composite reference standard, including histopathology, serial serum PSA levels and imaging (CT, MRI, and/or bone scan) findings was available for 223 of 635 (35.1%) patients, while histopathology reference standard alone was available for 93 (14.6%) patients. PET/CT scans were read by 3 independent readers blinded to clinical information other than the type of primary therapy and most recent serum PSA level.

Detection of PSMA-positive lesions occurred in 475 of 635 (75%) patients receiving gallium (^{68}Ga) gozetotide and the detection rate was significantly increased with PSA levels. The detection rate of gallium (^{68}Ga) gozetotide PET positive lesion increased with increasing serum PSA levels (see section 4.4). Sensitivity and positive predictive value (PPV) of gallium (^{68}Ga) gozetotide PET/CT imaging are summarised in Table 3. Inter-reader Fleiss κ for gallium (^{68}Ga) gozetotide PET/CT imaging ranged from 0.65 (95% CI: 0.61, 0.70) to 0.78 (95% CI: 0.73, 0.82) across the assessed regions (prostate bed, pelvic nodes, extrapelvic soft tissues and bones).

Table 3 Efficacy results in patients with histopathology-proven and BCR prostate cancer

	Composite reference standard N=223[1]	**Histopathology reference standard N=93[1]**
Sensitivity per-patient (95% CI)	NA	92% (84, 96)
Sensitivity per-region (95% CI)	NA	90% (82, 95)
PPV per-patient (95% CI)	92% (88, 95)	84% (75, 90)
PPV per-region (95% CI)	92% (88, 95)	84% (76, 91)
[1] Evaluable population		

Gallium (^{68}Ga) gozetotide PET/CT imaging was used to identify adult patients with progressive, PSMA-positive mCRPC cancer for the randomised, multicentre, open-label, phase III study VISION, which tested efficacy of Pluvicto plus best standard of care or best standard of care alone. A total of 1 003 male patients, who had been treated with at least one androgen receptor (AR) pathway inhibitor and 1 or 2 prior taxane-based chemotherapy regimens, were selected based on the PSMA expression of their prostate cancer lesions. Patients underwent a gallium (^{68}Ga) gozetotide PET/CT scan to evaluate PSMA expression in lesions defined by central read criteria. Improved overall survival and radiographic progression-free survival were reported in the PSMA-targeted therapy arm.

Paediatric population

The European Medicines Agency has waived the obligation to submit the results of studies with Locametz in all subsets of the paediatric population for visualisation of PSMA in prostate cancer (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

Distribution

Gallium (^{68}Ga) gozetotide exhibits bi-exponential behaviour in blood, with a biological half-life of 6.5 minutes for the fast component and a terminal half-life of 4.4 hours for the slower component. Based on *in vitro* data, gozetotide mainly distributes to plasma, with a mean blood-to-plasma ratio of 0.71. Gozetotide is 33% bound to human plasma proteins.

Organ uptake

The highest radiation absorbed dose of gallium (^{68}Ga) gozetotide occurred in the kidneys, lacrimal glands, salivary glands, urinary bladder wall and liver.

The estimated radiation absorbed doses to these organs for an administered activity of 259 MBq are 62.1 mGy (kidneys), 28.5 mGy (lacrimal glands), 23.1 mGy (salivary glands), 14.8 mGy (urinary bladder wall) and 13.7 mGy (liver).

Biotransformation

Based on *in vitro* data, gallium (^{68}Ga) gozetotide undergoes negligible hepatic and renal metabolism.

Elimination

Gallium (^{68}Ga) gozetotide is mainly eliminated via the renal route. Approximately 14% of the gallium (^{68}Ga) gozetotide dose administered is excreted in the urine after 2 hours post-injection.

Half-life

Based on the gallium (^{68}Ga) gozetotide biological and terminal half-life of 4.4 hours and on the gallium-68 physical half-life of 68 minutes, the resulting gallium (^{68}Ga) gozetotide effective half-life is 54 minutes.

In vitro evaluation of drug interaction potential

CYP450 enzymes
Gozetotide is not a substrate, inhibitor or inducer of cytochrome P450 (CYP450) enzymes. Gallium (^{68}Ga) gozetotide is not expected to have any drug interactions with CYP450 substrates, inhibitors or inducers.

Transporters
Gozetotide is not a substrate of BCRP, P-gp, MATE1, MATE2-K, OAT1, OAT3 or OCT2. Gozetotide is not an inhibitor of BCRP, BSEP, P-gp, MATE1, MATE2-K, OAT1, OAT3, OATP1B1, OATP1B3, OCT1 or OCT2. Gallium (^{68}Ga) gozetotide is not expected to have any drug interactions with the substrates of these transporters.

Special populations

Elderly
In the VISION clinical study, 752 of 1 003 (75%) patients were aged 65 years or older. No overall differences in safety and efficacy were observed between these patients and younger patients.

Renal impairment / hepatic impairment
Gallium (^{68}Ga) gozetotide pharmacokinetics and biodistribution are not expected to be affected by renal/hepatic impairment to any clinically relevant extent.

5.3 Preclinical safety data

Gozetotide was evaluated in safety pharmacology and single-dose toxicity studies. Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology and single-dose toxicity.

Carcinogenicity and mutagenicity

Mutagenicity studies and carcinogenicity studies have not been carried out with gallium (^{68}Ga) gozetotide.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gentisic acid
Sodium acetate trihydrate
Sodium chloride

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in sections 6.6 and 12.

6.3 Shelf life

Unopened vial: 1 year.

After reconstitution and radiolabelling, chemical and physical in-use stability have been demonstrated for 6 hours at 30°C (see section 6.4). Store upright.

From a microbiological point of view, unless the method of opening, reconstitution, radiolabelling, or dilution precludes the risk of microbial contamination, the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage

Before reconstitution, store below 25°C.

For storage conditions after reconstitution and radiolabelling of the medicinal product, see section 6.3.

Storage of radiopharmaceuticals should be in accordance with national regulations on radioactive materials.

6.5 Nature and contents of container

Locametz is supplied as a multidose kit for the radiopharmaceutical preparation of gallium (^{68}Ga) gozetotide solution for injection (see sections 2 and 3). Locametz contains one 10 mL type I Plus glass vial closed with a rubber stopper and sealed with a flip-off cap.

6.6 Special precautions for disposal and other handling

General warning

Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the competent official organisation.

Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

The content of the vial is intended only for use in the preparation of gallium (^{68}Ga) gozetotide solution for injection and is not to be administered directly to the patient without first undergoing the preparative procedure (see sections 4.2 and 12).

Precautions to be taken before handling or administration of the medicinal product

Before reconstitution, the content of Locametz is not radioactive. After reconstitution and radiolabelling, effective radiation shielding of the gallium (^{68}Ga) gozetotide solution for injection must be maintained (see section 3).

After reconstitution and radiolabelling, Locametz contains a sterile solution for injection of gallium (^{68}Ga) gozetotide at an activity of up to 1 369 MBq. The gallium (^{68}Ga) gozetotide solution for injection also contains hydrochloric acid derived from the gallium-68 chloride solution.

Gallium (^{68}Ga) gozetotide solution for injection is a sterile, clear, colourless solution for intravenous administration, without undissolved matter and with pH between 3.2 to 6.5.

Appropriate aseptic precautions should be taken when withdrawing and administering gallium (^{68}Ga) gozetotide solution for injection.

Administration procedures should be carried out in a way to minimise risk of contamination of the medicinal product and irradiation of the operators. Effective radiation shielding is mandatory.

If at any time in the preparation of this medicinal product the integrity of the vial is compromised it should not be used.

For instructions on reconstitution and radiolabelling of the medicinal product before administration, see section 12.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Novartis Europharm Limited
Vista Building
Elm Park, Merrion Road
Dublin 4
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1692/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09 December 2022

10. DATE OF REVISION OF THE TEXT

11. DOSIMETRY

Gallium-68 is produced by means of a germanium-68/gallium-68 (^{68}Ge/^{68}Ga) generator and decays with a half-life of 68 min to stable zinc-68. Gallium-68 decays as follows:

- 89% through positron emission with a mean energy of 836 keV, followed by photonic annihilation radiations of 511 keV (178%).
- 10% through orbital electron capture (X-ray or Auger emissions), and
- 3% through 13 gamma transitions from 5 excited levels.

The effective radiation dose of gallium (^{68}Ga) gozetotide is 0.022 mSv/MBq, resulting in an approximate effective radiation dose of 5.70 mSv for an administered maximum activity of 259 MBq.

Median radiation absorbed doses for organs and tissues of adult patients (N=6) following intravenous injection of gallium (^{68}Ga) gozetotide including observed ranges were calculated by Sandgren et al, 2019, using ICRP/ICRU voxel phantom with the software IDAC-Dose 2.1. Median radiation absorbed doses of gallium (^{68}Ga) gozetotide are shown in Table 4.

Table 4 Estimated median radiation absorbed doses of gallium (^{68}Ga) gozetotide

	Radiation absorbed dose (mGy/MBq)[1] N=6	
Organ	**Median (mGy/MBq)**	**Range (mGy/MBq)**
Adrenals	0.048	0.0405 – 0.0548
Brain	0.008	0.0065 – 0.0079
Breast	0.008	0.0077 – 0.0087
Endosteum (bone surface)*	0.011	0.0095 – 0.0110
Eye lenses*	0.0051	0.0047 – 0.0054
Gallbladder wall	0.027	0.0212 – 0.0343
Heart wall	0.026	0.0236 – 0.0317
Kidneys*	0.240	0.2000 – 0.2800
Lacrimal glands*	0.110	0.0430 – 0.2000
Left colon wall**	0.014	0.0120 – 0.0140
Liver*	0.053	0.0380 – 0.0710
Lungs*	0.016	0.0130 – 0.0170
Muscle	0.0083	0.0073 – 0.0086
Oesophagus*	0.014	0.0110 – 0.0150
Pancreas	0.019	0.0173 – 0.0209
Recto-sigmoid colon wall	0.013	0.0108 – 0.0149
Red (active) bone marrow*	0.015	0.0140 – 0.0150
Right colon wall**	0.014	0.0120 – 0.0140
Salivary glands*	0.089	0.0740 – 0.1500
Skin*	0.007	0.0059 – 0.0069
Small intestine wall	0.014	0.0129 – 0.0149
Spleen*	0.046	0.0300 – 0.1000
Stomach wall*	0.015	0.0150 – 0.0170
Testes*	0.009	0.0074 – 0.0089
Thymus	0.0081	0.0072 – 0.0085
Thyroid*	0.010	0.0090 – 0.0100
Urinary bladder wall*	0.057	0.0280 – 0.0840
Effective dose (mSv/MBq)*[2]	0.022	0.0204 – 0.0242

* as reported by Sandgren et al, 2019; all other organ estimates were estimated based on the time-integrated activity coefficients of the source organs published in the paper

** reported in Sandgren as a single value labelled "Colon"

[1] doses were calculated using the software IDAC-Dose 2.1.

[2] derived according to ICRP Publication 103

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Method of preparation

Step 1: Reconstitution and radiolabelling

Locametz allows the direct preparation of gallium (^{68}Ga) gozetotide solution for injection with the eluate from one of the following generators (see below for specific instructions for use with each generator):

- Eckert & Ziegler GalliaPharm germanium-68/gallium-68 (^{68}Ge/^{68}Ga) generator
- IRE ELiT Galli Ad germanium-68/gallium-68 (^{68}Ge/^{68}Ga) generator

The instructions for use provided by the germanium-68/gallium-68 generator manufacturer should also be followed.

Gallium (^{68}Ga) gozetotide solution for injection should be prepared according to the following aseptic procedure:

a. Flip the cap off the Locametz vial and swab the septum with an appropriate antiseptic, then allow the septum to dry.
b. Pierce the Locametz vial septum with a sterile needle connected to a 0.2 micron sterile air venting filter to maintain atmospheric pressure within the vial during the reconstitution process. Place the Locametz vial in a lead shield container.

Follow the generator-specific reconstitution and radiolabelling procedures as shown in Table 5 and in Figures 1 and 2. Then continue with Step 2.

Table 5 Reconstitution and radiolabelling with Eckert & Ziegler GalliaPharm and IRE ELiT Galli Ad generators

If Eckert & Ziegler GalliaPharm generator is used	**If IRE ELiT Galli Ad generator is used**
• Connect the male luer of the outlet line of the generator to a sterile elution needle (size 21G-23G). • Connect the Locametz vial directly to the outlet line of the generator by pushing the elution needle through the rubber septum. • Elute directly from the generator into the Locametz vial.	
Perform the elution manually or by means of a pump according to the generator instructions for use.	Connect the Locametz vial through the vent needle with 0.2 micron sterile air venting filter to a vacuum vial (25 mL minimum volume) by means of a sterile needle (size 21G-23G) or to a pump to start the elution.
Reconstitute the lyophilised powder with 5 mL of eluate.	Reconstitute the lyophilised powder with 1.1 mL of eluate.
At the end of the elution, disconnect the Locametz vial from the generator by removing the elution needle and the vent needle with the 0.2 micron sterile air venting filter from the rubber septum. Then, invert the Locametz vial once and place it upright.	At the end of the elution, first withdraw the sterile needle from the vacuum vial or disconnect the vacuum pump in order to establish atmospheric pressure into the Locametz vial, then disconnect the vial from the generator by removing both the elution needle and the vent needle with the 0.2 micron sterile air venting filter needle from the rubber septum.

Figure 1 Reconstitution and radiolabelling procedure for Eckert & Ziegler GalliaPharm generator

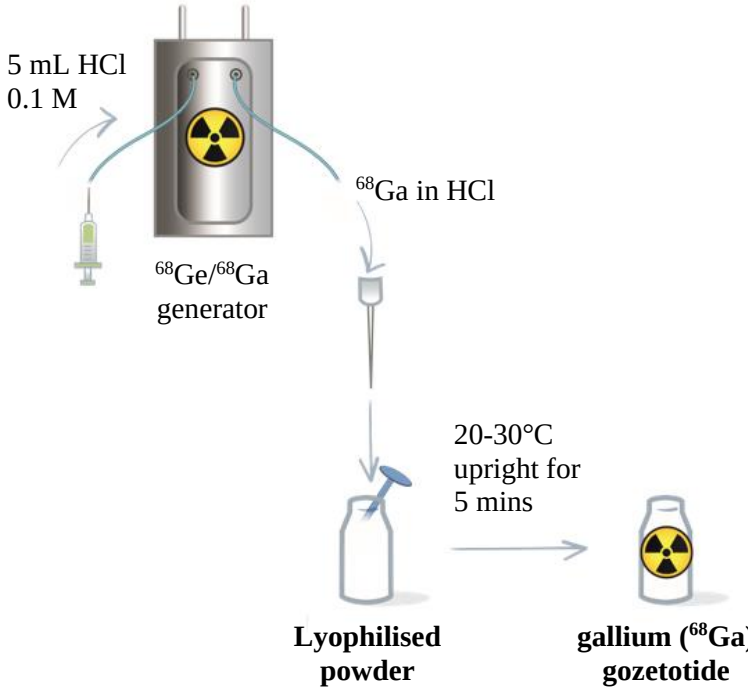
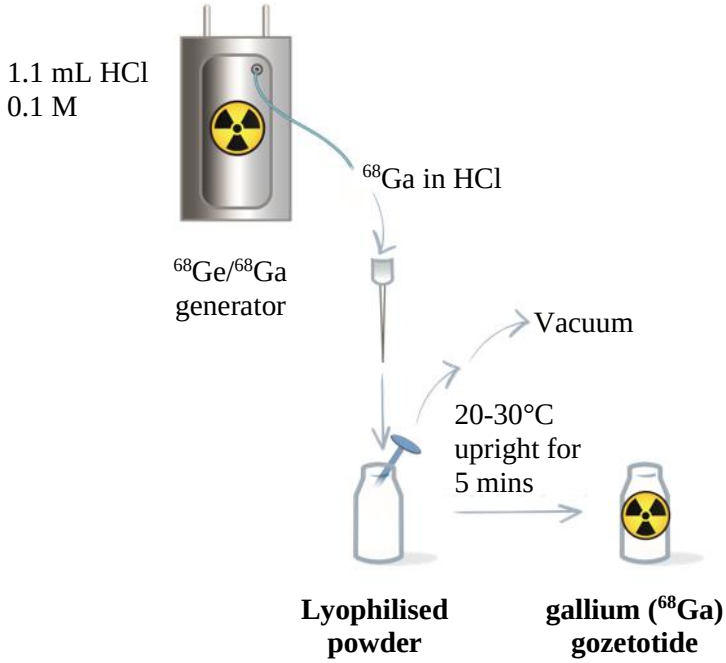


Figure 2 Reconstitution and radiolabelling procedure for IRE ELiT Galli Ad generator



Step 2: Incubation

a. Incubate the Locametz vial upright at room temperature (20-30°C) for at least 5 minutes without agitation or stirring.
b. After 5 minutes, assay the vial containing the gallium (^{68}Ga) gozetotide solution for injection for total radioactivity concentration using a dose calibrator and record the result.
c. Perform quality controls according to the recommended methods in order to check compliance with the specifications (see Step 3).
d. Store the Locametz vial containing the gallium (^{68}Ga) gozetotide solution for injection upright in a lead shield container below 30°C until use.

e. After addition of gallium-68 chloride to the Locametz vial, use gallium (^{68}Ga) gozetotide solution for injection within 6 hours.

Step 3: Specifications and quality control
Perform the quality controls in Table 6 behind a lead glass shield for radioprotection purposes.

Table 6 Specifications of the gallium (68Ga) gozetotide solution for injection

Test	Acceptance criteria	Method
Appearance	Clear, colourless and without undissolved matter	Visual inspection
pH	3.2 – 6.5	pH-indicator strips
Labelling efficiency	Non-complexed gallium-68 species ≤3%	Instant thin layer chromatography (ITLC, see details below)

Determine labelling efficiency of gallium (^{68}Ga) gozetotide solution for injection by performing instant thin layer chromatography (ITLC).
Perform ITLC using ITLC SG strips and using ammonium acetate 1M: Methanol (1:1 V/V) as mobile phase.

ITLC method
a. Develop the ITLC SG strip for a distance of 6 cm from the point of application (i.e. to 7 cm from the bottom of the ITLC strip).
b. Scan the ITLC SG strip with a radiometric ITLC scanner.
c. Calculate labelling efficiency by integration of the peaks on the chromatogram. Do not use the reconstituted and radiolabelled product if the percentage (%) of non-complexed gallium-68 species is higher than 3%.

The retention factor (Rf) specifications are as follows:
- Non-complexed gallium-68 species, Rf = 0 to 0.2;
- Gallium (^{68}Ga) gozetotide, Rf = 0.8 to 1

Step 4: Administration
a. Aseptic technique and radiation shielding should be used when withdrawing and administering gallium (^{68}Ga) gozetotide solution for injection (see sections 4.2 and 6.6).
b. Prior to use, visually inspect the prepared gallium (^{68}Ga) gozetotide solution for injection behind a lead glass shield for radioprotection purposes. Only solutions that are clear, colourless and without undissolved matter should be used (see sections 4.2 and 6.6).
c. After reconstitution and radiolabelling, gallium (^{68}Ga) gozetotide solution for injection can be diluted with water for injections or sodium chloride 9 mg/mL (0.9%) solution for infusion up to a final volume of 10 mL. For the IRE ELiT Galli Ad generator, dilution to a minimum volume of 4 mL is required in order to reduce osmolality.
d. Using a single-dose syringe fitted with a sterile needle (size 21G-23G) and protective shielding, aseptically withdraw the prepared gallium (^{68}Ga) gozetotide solution for injection prior to administration (see sections 4.2 and 6.6).
e. The total radioactivity in the syringe should be verified with a dose calibrator immediately before and after gallium (^{68}Ga) gozetotide administration to the patient. The dose calibrator must be calibrated and comply with international standards (see section 4.2).

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Advanced Accelerator Applications (Italy) S.R.L.
Via Crescentino snc
13040 Saluggia (VC)
Italy

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to restricted medical prescription (see Annex I: Summary of Product Characteristics, section 4.2).

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

The marketing authorisation holder (MAH) shall submit the first PSUR for this product within 6 months following authorisation.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:
- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

Locametz 25 micrograms kit for radiopharmaceutical preparation
gozetotide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

The vial contains 25 micrograms of gozetotide.

3. LIST OF EXCIPIENTS

Sodium chloride, gentisic acid, sodium acetate trihydrate. See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Kit for radiopharmaceutical preparation

1 vial.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For multidose use.
To be reconstituted and radiolabelled with gallium-68 chloride solution provided by a germanium-68/gallium-68 generator.
Read the package leaflet before use.
Intravenous use after reconstitution and radiolabelling.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Medicinal product radioactive after reconstitution.

8. EXPIRY DATE

EXP
After reconstitution and radiolabelling, store upright below 30°C and use within 6 hours.

9. SPECIAL STORAGE CONDITIONS

Before reconstitution, store below 25°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Novartis Europharm Limited
Vista Building
Elm Park, Merrion Road
Dublin 4
Ireland

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1692/001

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

POWDER VIAL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Locametz 25 mcg kit for radiopharmaceutical preparation
gozetotide
Intravenous use after reconstitution and radiolabelling

2. METHOD OF ADMINISTRATION

To be reconstituted and radiolabelled with gallium-68 chloride solution provided by a germanium-68/gallium-68 generator.
Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

25 mcg

6. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SHIELD LABEL TO BE APPLIED AFTER RADIOLABELLING

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Locametz 25 micrograms
gallium (^{68}Ga) gozetotide solution for injection
Intravenous use

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP____ Time/Date

After radiolabelling, use within 6 hours.

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

Total activity: _____MBq
Total volume: _____mL
Calibration time: _____ Time/Date

6. OTHER

Store upright below 30°C.

Radioactive imaging agent



B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Locametz 25 micrograms kit for radiopharmaceutical preparation
gozetotide

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Locametz is and what it is used for
2. What you need to know before Locametz is used
3. How Locametz is used
4. Possible side effects
5. How Locametz is stored
6. Contents of the pack and other information

1. What Locametz is and what it is used for

What Locametz is
This medicine is a radiopharmaceutical product for diagnostic use only.

Locametz contains a substance called gozetotide. Before use, gozetotide (the powder in the vial) is coupled with a radioactive substance called gallium-68 to make gallium (^{68}Ga) gozetotide solution (this procedure is called radiolabelling).

What Locametz is used for
After radiolabelling with gallium-68, Locametz is used in a medical imaging procedure called positron emission tomography (PET) to detect specific types of cancer cells with a protein called prostate-specific membrane antigen (PSMA) in adults with prostate cancer. This is done:
- to find out whether prostate cancer has spread to lymph nodes and other tissues outside the prostate, before primary curative therapy (e.g. therapy involving surgical removal of the prostate, radiation therapy)
- to identify cancer cells when recurrence of prostate cancer is suspected in patients who have received primary curative therapy
- to find out whether patients with progressive metastatic castration-resistant prostate cancer may be suitable for a specific therapy, called PSMA-targeted therapy

How Locametz works
When given to the patient, gallium (^{68}Ga) gozetotide binds to the cancer cells that have PSMA on their surface and makes them visible to your nuclear medicine doctor during the PET medical imaging procedure. This gives your doctor and nuclear medicine doctor valuable information about your disease.

The use of gallium (^{68}Ga) gozetotide involves exposure to a small amount of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

If you have any questions about how Locametz works or why this medicine has been prescribed for you, ask your nuclear medicine doctor.

2. What you need to know before Locametz is used

Locametz must not be used
- if you are allergic to gozetotide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your nuclear medicine doctor before you receive Locametz if you have any other type of cancer, as this could affect the interpretation of the image.

The use of Locametz involves exposure to a small amount of radioactivity. Repeated exposure to radiation may increase the risk of cancer. Your nuclear medicine doctor will explain necessary radioprotection measures to you (see section 3).

Before administration of Locametz you should
- Drink plenty of water so that you remain hydrated and urinate immediately before the PET medical imaging procedure, and as often as possible during the first hours after administration.

Children and adolescents
This medicine should not be given to children or adolescents aged under 18 years because no data are available in this age group.

Pregnancy and breast-feeding
Locametz is not intended for use in women. All radiopharmaceuticals, including Locametz, have the potential to cause harm to an unborn baby.

Driving and using machines
It is considered unlikely that Locametz will affect your ability to drive or to use machines.

Locametz contains sodium
This medicine contains 28.97 mg sodium (main component of cooking/table salt) in each injection. This is equivalent to 1.5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Locametz is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Locametz will only be used in special controlled areas. This radiopharmaceutical product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this radiopharmaceutical product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of Locametz to be used in your case. It will be the smallest quantity necessary to get the desired information.

The quantity to be administered usually recommended for an adult is 1.8-2.2 MBq (megabecquerel, the unit used to express radioactivity) per kg of body weight, with a minimum amount of 111 MBq and a maximum of 259 MBq.

Administration of Locametz and conduct of the procedure
After reconstitution and radiolabelling, Locametz is given as a slow injection into a vein. You will undergo a PET scan starting 50 to 100 minutes after you have received Locametz.

Duration of the procedure
Your nuclear medicine doctor will inform you about the usual duration of the procedure.

After administration of Locametz, you should
- Continue to drink plenty of water so that you remain hydrated and urinate as often as possible to eliminate the radiopharmaceutical product from your body.

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more Locametz than you should
An overdose of Locametz is unlikely because you will only receive a single dose that is precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the event of an overdose, you will receive the appropriate treatment. You may be asked to drink and urinate frequently in order to eliminate the radiopharmaceutical product from your body.

Should you have any further question on the use of Locametz, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects include the following listed below. If these side effects become severe, please tell your nuclear medicine doctor.

Common (may affect up to 1 in every 10 people)
- tiredness (fatigue)

Uncommon (may affect up to 1 in every 100 people)
- nausea
- constipation
- vomiting
- diarrhoea
- dry mouth
- reactions at the site of injection, such as bruising, itching and warmth (injection site reactions)
- chills

This radiopharmaceutical product will deliver low amounts of ionising radiation associated with the least risk of cancer and hereditary abnormalities.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How Locametz is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceutical products will be in accordance with national regulations on radioactive materials.

The following information is intended for the specialist only:
- Locametz must not be used after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.
- Before reconstitution, store below 25°C.
- After reconstitution and radiolabelling, store upright below 30°C. Use within 6 hours.

6. Contents of the pack and other information

What Locametz contains
- The active substance is gozetotide. One vial contains 25 micrograms of gozetotide. The other ingredients are: gentisic acid, sodium acetate trihydrate and sodium chloride (see "Locametz contains sodium" in section 2).

What Locametz looks like and contents of the pack
Locametz is a multidose kit for radiopharmaceutical preparation containing one vial of white freeze-dried powder (powder for solution for injection).

Gallium-68 is not part of the kit.

After reconstitution and radiolabelling, Locametz contains a sterile solution for injection of gallium (^{68}Ga) gozetotide at an activity of up to 1 369 MBq.

After reconstitution, the gallium (^{68}Ga) gozetotide solution for injection also contains hydrochloric acid.

Pack size: 1 vial.

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This leaflet was last revised in

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

The following information is intended for healthcare professionals only:

The complete SmPC of Locametz is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.

国内ではロカメッツキットの同種同効薬が承認されていないが，ロカメッツキットと同様な有効成分を持つ前立腺癌画像診断薬[^{68}Ga]Ga-PSMA-11 が国内で開発されているため，その公開情報を記載する。

販売名	ロカメッツキット	未定
一般名	本剤のガリウム（^{68}Ga）標識後の医薬品一般的名称は，ガリウム（^{68}Ga）ゴゼトチドである。 なお本剤の一般的名称としては，これより必要な部分を切り取った以下の名称を使用する。 日本名：ゴゼトチド 英名：Gozetotide	本剤のガリウム（^{68}Ga）標識後の医薬品一般的名称は，ガリウム（^{68}Ga）ゴゼトチドである。
会社名	ノバルティスファーマ株式会社	テリックスファーマジャパン株式会社
効能又は効果	ガリウム（^{68}Ga）を用いた標識後に、前立腺癌を有する成人の前立腺特異的膜抗原（PSMA）陽性病変の陽電子放出断層撮影（PET）による PSMA 標的療法の適応となる前立腺癌患者の選択	未定
備考	—	[プレスリリース：前立腺がん PET 画像診断薬第 1 相試験で日本人の安全性と忍容性を確認　2022 年 2 月 8 日]

前立腺がんPET画像診断薬第１相試験で日本人の安全性と忍容性を確認

前立腺がんPET画像診断薬第１相試験で日本人の安全性と忍容性を確認

東京（日本）- 2022年2月8日。

テリックス・ファーマシューティカルズ・リミテッド（ASX：TLX、以下「テリックス」）の100%子会社であるテリックスファーマジャパン株式会社（以下「テリックスジャパン」）は、金沢大学との共同研究のもと日本で初めて行われたテリックスの前立腺がん画像診断薬「TLX591-CDx（gallium-68(^{68}Ga)-PSMA-11調製用キット)」の第I相医師主導治験において、日本人の安全性と忍容性を確認したことをお知らせします。

本試験は、日本人の患者を対象にTLX591-CD x の安全性、忍容性、放射線量、薬物動態を評価するものです。重篤な有害事象は認められず、全身および臓器別照射線量は日本人と外国人の間で差が無いことが示されました。また、日本人の患者におけるTLX591-CDxの薬物動態は、欧米人集団で報告された過去の試験と同様でした。

本試験は、金沢大学附属病院で実施され、金沢大学附属病院の各部門の密接な協働によりトップラインレポート（TLR）が作成されました。2021年5月から8月にかけて、前立腺がん患者計10名が登録されました。全ての患者はTLX591-CDxの投与後、陽電子放射断層撮影（PET）による撮影を行い、9月には試験が終了しました。

金沢大学附属病院臨床開発部長の村山敏典教授は、**「我々は、この重要な第I相試験の最初の解析を早期に終了できたことを誇りに思います。日本人における^{68}Ga-PSMA-11の安全性と忍容性のプロファイルが確認できたこと、および薬物動態と線量測定において日本人と外国人の成績が同様であることを見出したことに非常に勇気づけられています。」**と述べています。

の表れと受け止めさせていただきました。本治験の結果は、日本を含むアジア全域での本剤の開発促進のための重要な基盤となるものです。先日米国や豪州で承認された本剤を一日も早く日本で上市できるように引き続き努力して参ります。」と述べています。

プレスリリース

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最新の添付文書を参照する事

20XX年X月作成（第１版）

日本標準商品分類番号
877290

貯法：室温保存
有効期間：12ヵ月

承認番号	XXXXXXXXXX
販売開始	20XX年XX月

PSMA放射性リガンド診断薬
ガリウム(68Ga)ゴゼトチド注射液 調製用

ロカメッツ®キット
LOCAMETZ® Kit

処方箋医薬品
（注意－医師等の処方箋により使用すること）

NOVARTIS

2. 禁忌（次の患者には投与しないこと）
本剤の成分に対し過敏症の既往歴のある患者

3. 組成・性状

3.1 組成

販売名	ロカメッツキット
有効成分	（1バイアル中）ゴゼトチド25μg
添加剤	（1バイアル中）酢酸ナトリウム水和物78mg、塩化ナトリウム40mg、ゲンチジン酸1mg

3.2 製剤の性状

販売名	ロカメッツキット
性状	白色の粉末又は塊（凍結乾燥ケーキ）

4. 効能又は効果

PSMA標的療法の前立腺癌患者への適応判定の補助

5. 効能又は効果に関連する注意

本剤で調製したガリウム（68Ga）ゴゼトチドを用いたPET検査は、PSMA標的療法の適応となる前立腺癌患者への適応判定においてPSMA陽性病変の有無に関する情報を得る目的でのみ実施すること。前立腺癌の再発又は転移の診断における有用性は確立していない。

6. 用法及び用量

通常、成人にはガリウム（68Ga）ゴゼトチドとして111～259MBqを静脈内投与し、投与50～100分後に陽電子放出断層撮影（PET）法により撮像を開始する。

7. 用法及び用量に関連する注意

7.1 ガリウム（68Ga）ゴゼトチドの調製には、放射性医薬品基準に収載されたガリウム（68Ga）ジェネレータから溶出した塩化ガリウム(68Ga)溶液を用いること。

7.2 撮像時間は、投与量、撮像機器、データ収集条件、画像再構成のアルゴリズム及びパラメータ等を考慮して決定すること。

8. 重要な基本的注意

検査上の有益性が被曝による不利益を上回ると判断される場合にのみ投与すること。

9. 特定の背景を有する患者に関する注意

9.7 小児等

小児等を対象とした臨床試験は実施していない。

11. 副作用

次の副作用があらわれることがあるので、観察を十分に行い、異常が認められた場合には投与を中止するなど適切な処置を行うこと。

11.2 その他の副作用

	0.5%未満	頻度不明
胃腸障害	口内乾燥、悪心、便秘	嘔吐、下痢
一般・全身障害及び投与部位の状態	－	疲労、注射部位反応、悪寒

14. 適用上の注意

14.1 薬剤調製時の注意

14.1.1 ガリウム（68Ga）ジェネレータから塩化ガリウム（68Ga）溶液を本剤のバイアルに直接溶出し、混和した後、立てた状態に置きインキュベーション（20～30℃で5分間以上）することにより、ガリウム（68Ga）ゴゼトチドを得ること。なお、ガリウム（68Ga）ゴゼトチドの調製手順、品質管理のための試験等の詳細は製造販売業者が提供する注射液調製の手引きを参照すること。

14.1.2 ガリウム（68Ga）ゴゼトチドの品質管理規格は次のとおりである。

外観：無色澄明の液、異物を認めない
pH：3.2～6.5
標識率：非標識ガリウム（68Ga）≦5%

14.1.3 調製後の注射液は、立てた状態のまま室温で保存し、6時間以内に投与すること。

14.1.4 他の薬剤と混合しないこと。

14.2 薬剤投与時の注意

14.2.1 局所血管外漏出による被曝及び画像アーチファクトを避けるため、溶解後は緩徐に静脈内投与すること。ガリウム(68Ga)ゴゼトチドは酸性のため、血管外漏出により局所刺激が発現することがある。血管外漏出が発現した場合は、直ちに投与を中止し、適切な処置を行うこと。

14.2.2 膀胱部の被曝を軽減させるため、撮像前後にできるだけ患者に水分を摂取させ、排尿させることが望ましい。

14.3 検査上の注意

ガリウム（68Ga）ゴゼトチドの取込みは他のがん種、非悪性腫瘍及び正常組織でも生じる可能性がある。病理組織学的診断法又はその他の診断法を参照し、ガリウム（68Ga）ゴゼトチドを用いたPET画像所見を解釈することが推奨される。

16. 薬物動態

16.1 血中濃度

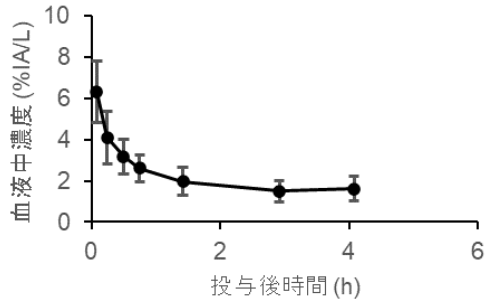
16.1.1 単回投与

日本人去勢抵抗性前立腺癌患者3例にガリウム（68Ga）ゴゼトチド111～259MBqを単回静脈内投与したときの血液中濃度推移及び薬物動態パラメータは以下のとおりであった。

日本人患者にガリウム（^{68}Ga）ゴゼトチド111～259MBqを
単回静脈内投与したときの薬物動態パラメータ

n	Cmax（%IA/L）	AUClast（h·%IA/L）	T1/2（h）
3	6.45 (18.5)	8.93 (29.6)	3.93 (38.1)

幾何平均値（幾何CV%）



日本人患者にガリウム（^{68}Ga）ゴゼトチド111～259MBqを
単回静脈内投与したときの血液中濃度推移（平均値±標準偏差）

16.3 分布

16.3.1 吸収線量

日本人去勢抵抗性前立腺癌患者3例にガリウム（^{68}Ga）ゴゼトチド111～259MBqを単回静脈内投与したときの各臓器の吸収線量推定値は以下のとおりであった[1]。吸収線量推定値は、腎臓、肝臓、涙腺及び唾液線で高かった。

臓器	平均値（mGy/MBq）	標準偏差
副腎	0.046	0.0074
膀胱壁	0.10	0.12
脳	0.0079	0.0023
骨	0.013	0.0023
左結腸	0.024	0.0038
右結腸	0.054	0.010
食道	0.014	0.0024
眼球	0.0078	0.0022
胆嚢壁	0.032	0.023
心臓壁	0.045	0.0089
腎臓	0.23	0.14
涙腺	0.13	0.11
肝臓	0.17	0.19
肺	0.013	0.0030
膵臓	0.019	0.0038
前立腺	0.025	0.0097
直腸	0.013	0.0042
赤色骨髄	0.017	0.0023
唾液腺	0.12	0.068
小腸	0.059	0.016
脾臓	0.065	0.022
胃	0.035	0.011
精巣	0.013	0.0075
胸腺	0.011	0.00036
甲状腺	0.013	0.0073
全身	0.015	0.0013
実効線量（mSv/MBq）	0.030	0.0070

16.3.2 血漿蛋白結合率

ゴゼトチドのヒト血漿蛋白結合率は約33%であった[2]（*in vitro*）。

16.5 排泄

ガリウム（^{68}Ga）ゴゼトチドは主に腎臓を介して排泄される。前立腺癌の再発が疑われる被験者9例にガリウム（^{68}Ga）ゴゼトチド（平均投与量：112.5MBq）を単回静脈内投与したとき、投与後2時間までの放射能としての尿中累積排泄率は投与量の14%であった[3]（外国人データ）。

17. 臨床成績

ガリウム(^{68}Ga)ゴゼトチドPET/CTスキャンは、成人の遠隔転移を有する前立腺癌患者でのPSMA陽性病変を同定し、以下に示す臨床試験への適格性を確認するために使用された。

17.1 有効性及び安全性に関する試験

17.1.1 国内第Ⅱ相試験（A11201 試験）

PSMA陽性[注1)]の遠隔転移を有する去勢抵抗性前立腺癌（mCRPC）患者のうち、①1剤以上の新規アンドロゲン受容体シグナル阻害薬（ARSI）及び1[注2)]又は2剤のタキサン系抗悪性腫瘍剤による治療歴のある患者12例、②1剤のARSIによる治療歴があり、タキサン系抗悪性腫瘍剤による治療歴のない[注3)]患者18例を対象に、①ではルテチウムビピボチドテトラキセタン（^{177}Lu）（7.4GBqを6週間間隔で最大6回静脈内投与）とBSC/BSoC[注4)]との併用投与の有効性、安全性等を、②ではルテチウムビピボチドテトラキセタン（^{177}Lu）の有効性、安全性等を検討することを目的とした非盲検非対照試験を実施した。

主要評価項目である治験担当医師判定による奏効率[注5)]［90%信頼区間］（%）はそれぞれ、①25.0［7.2, 52.7］、②33.3［15.6, 55.4］であった。

注1）ガリウム（^{68}Ga）ゴゼトチド（111～259MBq）を用いたPET/CT検査で、中央判定によりPSMA陽性と診断された患者。計35例が適格性確認を受けた。

注2）2剤目のタキサン系抗悪性腫瘍剤による治療が適応にならないと治験担当医師に判断された場合に、組入れ可能とされた。

注3）2剤目のARSIによる治療が適切と治験担当医師に判断された患者が対象とされた。

注4）アンドロゲン除去療法（ADT）、ARSIの使用は可とされ、他の治験薬、細胞傷害性抗悪性腫瘍剤、免疫療法、他の放射性医薬品、半身放射線療法、PARP阻害剤及びAKT阻害剤の使用は不可とされた。

注5）前立腺癌ワーキンググループ3（PCWG3）基準に基づく奏効率

ルテチウムビピボチドテトラキセタン（^{177}Lu）の副作用は30例中20例（66.7%）に認められた。主な副作用は便秘及び血小板数減少各6例（20.0%）、貧血5例（16.7%）、口内乾燥及び倦怠感各4例（13.3%）、悪心、食欲減退及び味覚不全各3例（10.0%）であった。ガリウム（^{68}Ga）ゴゼトチドの副作用は35例中2例（5.7%）に認められた。主な副作用は血小板減少症及び白血球減少症各1例（2.9%）であった（2023年12月8日データカットオフ）[1]。

17.1.2 海外第Ⅲ相試験（B12302/PSMAfore 試験）

1剤のARSIによる治療歴があり、タキサン系抗悪性腫瘍剤による治療歴のない[注1)] PSMA陽性[注2)]のmCRPC患者469例を対象に、BSC[注3)]の併用下で、ルテチウムビピボチドテトラキセタン（^{177}Lu）（7.4GBqを6週間間隔で最大6回静脈内投与）と治験担当医師により選択された2剤目のARSIの有効性及び安全性を検討することを目的とした無作為化非盲検比較試験を実施した。

主要評価項目であるPCWG3基準に基づく盲検下独立中央判定によるrPFSは、ARSI群と比較してルテチウムビピボチドテトラキセタン（^{177}Lu）群で統計学的に有意な延長を示した（2022年10月2日データカットオフ）。

注1）タキサン系抗悪性腫瘍剤による治療を延期することが適切と治験担当医師に判断された場合に、組入れ可能とされた。

注2）ガリウム（^{68}Ga）ゴゼトチド（111～185MBq）を用いたPET/CT検査で、中央判定によりPSMA陽性と診断された患者。計547例が適格性確認を受けた。

注3）ADTの使用は可とされ、他の治験薬、生物学的製剤、免疫療法、細胞傷害性抗悪性腫瘍剤、他の放射性医薬品、PARP阻害剤及び半

身放射線療法の使用は不可とされた。また、ルテチウムビピボチドテトラキセタン（^{177}Lu）群ではARSIの使用は不可とされた。

PSMAfore試験：主要評価項目の成績

画像診断に基づく無増悪生存期間（rPFS）*1	ルテチウムビピボチドテトラキセタン(^{177}Lu)群 N = 233	ARSI群 N = 234
イベント数（%）	60（25.8）	106（45.3）
中央値（月）［95%信頼区間］*2	9.30［6.77, -］	5.55［4.04, 5.95］
ハザード比［95%信頼区間］*3	0.41［0.29, 0.56］	
P値*4	<0.0001	

-：推定不能
*1 PCWG3基準に従った盲検下独立中央判定（データカットオフ 2022年10月2日）
*2 Kaplan-Meier法
*3 層別Cox比例ハザードモデル
*4 層別log-rank検定、有意水準（片側）0.025

ルテチウムビピボチドテトラキセタン（^{177}Lu）の副作用は227例中199例（87.7%）に認められた。主な副作用は口内乾燥126例（55.5%）、悪心59例（26.0%）、無力症55例（24.2%）、疲労42例（18.5%）、貧血33例（14.5%）、食欲減退32例（14.1%）であった。ガリウム(68Ga)ゴゼトチドの副作用は547例中9例(1.6%)に認められた。主な副作用は口内乾燥2例(0.4%)であった(2024年2月27日データカットオフ)[4]。

18. 薬効薬理

18.1 測定法

ガリウム（^{68}Ga）ゴゼトチドの放射性核種から放出される放射線（ガンマ線）が核医学検査装置により計数化又は画像化される。

18.2 集積機序

ガリウム（^{68}Ga）ゴゼトチドは、PSMAを高発現する前立腺癌を含むPSMA発現細胞に結合する。

19. 有効成分に関する理化学的知見

調製前の化合物

ゴゼトチド

一般的名称

ガリウム(68Ga)ゴゼトチド

Gallium(68Ga)Gozetotide

化学名

{*N*-[(*N*^{6}-{6-[3-(3-{[{2-[{[5-(2-carboxyethyl)-2-hydroxy-κ*O*-phenyl]methyl}(carboxy-κ*O*-methyl)amino-κ*N*]ethyl}(carboxy-κ*O*-methyl)amino-κ*N*]methyl}-4-hydroxy-κ*O*-phenyl)propanamido]hexanoyl}-L-lysin-*N*^{ε}-yl)carbonyl]-L-glutamato(3-)}(^{68}Ga)gallium

分子式

$C_{44}H_{59}{}^{68}GaN_6O_{17}$

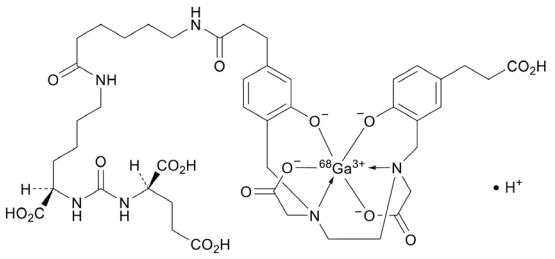
分子量

1011.90

性　状

無色澄明の液

化学構造式



核物理学的特性（^{68}Gaとして）[5]

・物理的半減期：67.71分

・主なβ+線エネルギー：1,899.01keV(87.94%)、821.71keV(1.20%)

・主なγ線エネルギー：1,833.16keV(0.14%)、1,260.97keV(0.09%)、1,077.34keV(3.22%)、805.83keV(0.09%)、578.55keV(0.03%)、511keV(178.28%)

・減衰表

時間（分）	残存放射能
0	1
15	0.858
30	0.736
60	0.541
90	0.398
120	0.293
180	0.158
360	0.025

22. 包装

1バイアル

23. 主要文献

1) 社内資料：国内第Ⅱ相試験（A11201試験）（CTD2.7.6-4.2.1, CTD2.7.2-2.3.1）
2) 社内資料：ヒト蛋白結合（CTD2.7.2-2.1.1）
3) Green MA et al.： Nucl Med Biol.：2017；46：32-35
4) 社内資料：海外第Ⅲ相試験（B12302試験）（CTD2.7.6-4.1.2）
5) Data derived from nudat（www.nndc.bnl.gov）

24. 文献請求先及び問い合わせ先

ノバルティスファーマ株式会社　ノバルティスダイレクト
〒105-6333　東京都港区虎ノ門1-23-1
NOVARTIS DIRECT
0120-003-293
受付時間： 月～金 9：00～17：30
（祝日及び当社休日を除く）
www.novartis.co.jp

26. 製造販売業者等

26.1 製造販売（輸入）

ノバルティスファーマ株式会社
東京都港区虎ノ門1-23-1

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略号一覧

略号	省略していない表現 (英)	省略していない表現 (日)
CRPC	castration-resistant prostate cancer	去勢抵抗性前立腺癌
EANM	European Association of Nuclear Medicine	欧州核医学会
MBq	megabecquerel	メガベクレル
mCi	millicurie	ミリキュリー
mCRPC	metastatic castration-resistant prostate cancer	転移性去勢抵抗性前立腺癌
PET	positron emission tomography	陽電子放出断層撮影
PSMA	prostate-specific membrane antigen	前立腺特異的膜抗原
RADAR	radiation dose assessment resource	－
SNMMI	Society of nuclear medicine & molecular imaging	核医学・分子イメージング学会

1 効能又は効果欄

1.1 効能又は効果

ガリウム（^{68}Ga）を用いた標識後に、前立腺癌を有する成人の前立腺特異的膜抗原（PSMA）陽性病変の陽電子放出断層撮影（PET）による PSMA 標的療法の適応となる前立腺癌患者の選択

1.2 効能又は効果の設定根拠

[^{68}Ga]Ga-PSMA-11（以下，^{68}Ga-PSMA-11）は，前立腺特異的膜抗原（PSMA）に特異的に結合し，PET/CT スキャンにより前立腺癌における PSMA 陽性病変を同定することができる放射性診断薬である。PSMA-11（以下，本剤）は，放射性診断薬である ^{68}Ga-PSMA-11 溶液の調製に使用するバイアルキットであり，ガリウム（^{68}Ga）ジェネレータから溶出した塩化ガリウム（^{68}Ga）溶液で溶解した後，標識した ^{68}Ga-PSMA-11 を静脈内投与し，PET/CT スキャンにより前立腺癌患者の PSMA 陽性病変を検出する。セラノスティクスでは，診断薬と治療薬が同一の標的分子に特異的に結合するため， ^{68}Ga-PSMA-11 による検査で PSMA 陽性病変が特定された患者では，その作用機序から PSMA 標的療法による高い有効性が期待できる。

^{68}Ga-PSMA-11 による検査で PSMA 陽性病変が確認されたタキサン既治療の転移性去勢抵抗性前立腺癌（mCRPC）患者を対象とした外国第 III 相試験（VISION 試験）及び国内第 II 相試験（A11201 試験）の結果から， 放射性治療薬である[^{177}Lu]Lu-PSMA-617（以下，AAA617）の PSMA 陽性 mCRPC 患者に対する有効性及び安全性が確認された。また，同様に PSMA 陽性が確認されたタキサン未治療の mCRPC 患者を対象とした外国第 III 相試験（PSMAfore 試験）及び A11201 試験の結果からも，PSMA 陽性 mCRPC 患者に対する AAA617 の有効性及び安全性が確認された [2.5-1.2.1.2 項]。なお，ノバルティスファーマ株式会社は， PSMA 陽性の mCRPC 患者を対象に，PSMA 標的療法に用いる放射性治療薬である「プルヴィクト静注」を本剤と同時に承認申請している。

上記以外の臨床試験でも，^{68}Ga-PSMA-11 PET/CT は PSMA 標的療法の患者選択ツールとして世界的に使用されており，ノバルティス社が実施中の他の臨床試験｛[^{225}Ac]Ac-PSMA-617（CRPC 患者対象，AcTION 試験），[^{225}Ac]Ac -PSMA-R2（mCRPC 患者対象，SatisfACtion 試験）｝のほか，^{177}Lu-PSMA-I&T 及び ^{177}Lu-DOTA-rosopatamab の第 III 相試験においても使用されている。また，ノバルティス社が実施する臨床試験以外でも[^{225}Ac]Ac-PSMA-617 等の臨床試験で適格性を確認するために ^{68}Ga-PSMA-11 PET/CT スキャンが用いられ，その結果が公表文献でも複数報告されている [2.5-1.1.2.1 項]。

各種ガイドラインでも ^{68}Ga-PSMA-11 PET/CT 検査は推奨されており，NCCN ガイドライン version 4 2024，EAU ガイドライン 2024，及び欧州核医学会（EANM）及び核医学・分子イメージング学会（SNMMI） PET/CT ガイドライン Version 2.0 においては，^{68}Ga-PSMA-11 PET/CT 検査は

前立腺癌の診断ツールとしてのみならず，AAA617 等の PSMA 標的療法の患者選択ツールとしての使用が支持されている。2022 年に報告された RADAR VI でも PSMA 標的療法の治療の適格性確認のために PSMA-PET 画像検査の実施が推奨されている [2.5-1.1.2.1 項]。

以上を踏まえ，本剤の効能又は効果（案）を「ガリウム（^{68}Ga）を用いた標識後に，前立腺癌を有する成人の前立腺特異的膜抗原（PSMA）陽性病変の陽電子放出断層撮影（PET）による PSMA 標的療法の適応となる前立腺癌患者の選択」と設定した。

審査の過程で，医薬品医療機器総合機構との協議を踏まえ，効能又は効果を以下のとおり設定することとした。

PSMA 標的療法の前立腺癌患者への適応判定の補助

2 効能又は効果に関連する注意欄

2.1 効能又は効果に関連する注意

放射性医薬品基準に収載されたガリウム（^{68}Ga）ジェネレータから溶出した塩化ガリウム（^{68}Ga）溶液で標識の上、使用すること。

2.2 効能又は効果に関連する注意の設定根拠

上述のとおり，本剤は，放射性診断薬である ^{68}Ga-PSMA-11 溶液の調製に使用するバイアルキットであり，ガリウム（^{68}Ga）ジェネレータから溶出した塩化ガリウム（^{68}Ga） 溶液で溶解した後，^{68}Ga 標識した ^{68}Ga-PSMA-11 を静脈内投与し，PET/CT スキャンで前立腺癌患者の PSMA 発現病変を画像化する。本剤の使用にあたり，その有効性及び安全性を担保するために，放射性医薬品基準に収載されたガリウム（^{68}Ga）ジェネレータを使用するよう注意喚起する目的で本項を設定した。

審査の過程で，医薬品医療機器総合機構との協議を踏まえ，効能又は効果に関連する注意を以下のとおり設定することとした。

本剤で調製したガリウム（^{68}Ga）ゴゼトチドを用いた PET 検査は、PSMA 標的療法の適応となる前立腺癌患者への適応判定において PSMA 陽性病変の有無に関する情報を得る目的でのみ実施すること。前立腺癌の再発又は転移の診断における有用性は確立していない。

3 用法及び用量欄

3.1 用法及び用量

通常、成人にはガリウム（^{68}Ga）ゴゼトチドとして 111MBq（3mCi）～259MBq（7mCi）を静脈内投与する。

3.2 用法及び用量の設定根拠

本剤をガリウム（^{68}Ga）標識した ^{68}Ga-PSMA-11 の用法及び用量は 111～259 MBq（3～7 mCi）に設定した。この用法・用量は，EANM 及び SNMMI のガイドラインで推奨されている 1.8～2.2 MBq/kg の用量範囲に準じており，米国で承認された ^{68}Ga-PSMA-11 の添付文書の用法・用量と合致している。この推奨用法・用量を下回る場合，画質及び病変検出が低下することが示されている。また，設定した用法・用量は，^{68}Ga-PSMA-11 投与により PSMA 陽性と確認された mCRPC 患者を対象とした臨床試験（VISION 試験，PSMAfore 試験，及び A11201 試験）の成績からも支持された [2.7.3-4.2 項]。

審査の過程で，医薬品医療機器総合機構との協議を踏まえ，用法及び用量を以下のとおり設定することとした。

通常、成人にはガリウム（^{68}Ga）ゴゼトチドとして 111～259MBq を静脈内投与し、投与 50～100 分後に陽電子放出断層撮影（PET）法により撮像を開始する。

4 用法及び用量に関連する注意欄

4.1 用法及び用量に関連する注意

7.1 ガリウム（^{68}Ga）ゴゼトチドを静脈内投与し、50～100 分後に陽電子放出断層撮影（PET）画像を得ること。
7.2 ガリウム（^{68}Ga）ゴゼトチドの調製手順の詳細は、製造販売業者が提供するマニュアル等を参照すること。

4.2 用法及び用量に関連する注意の設定根拠

ガリウム（^{68}Ga）ゴゼトチドの静脈内投与から PET による画像撮影までの時間は，臨床試験での経験，文献報告，及び EANM 及び SNMMI のガイドラインでの推奨に準じて設定し，その注意喚起のため 7.1 項を設定した。

また，本剤の使用にあたっては，各医療施設において放射性医薬品基準に収載されたガリウム（^{68}Ga）ジェネレータを用いた調製が必要であり，適切な調製手順を注意喚起するために 7.2 項を設定した。

審査の過程で，医薬品医療機器総合機構との協議を踏まえ，用法及び用量に関連する注意を以下のとおり設定することとした。

7.1 ガリウム（^{68}Ga）ゴゼトチドの調製には、放射性医薬品基準に収載されたガリウム（^{68}Ga）ジェネレータから溶出した塩化ガリウム(^{68}Ga)溶液を用いること。
7.2 撮像時間は、投与量、撮像機器、データ収集条件、画像再構成のアルゴリズム及びパラメータ等を考慮して決定すること。

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2. 禁忌欄 3
8. 重要な基本的注意欄 3
9. 特定の背景を有する患者に関する注意欄 3
9.7 小児等欄 3
11. 副作用欄 3
14. 適用上の注意欄 4

2. 禁忌欄

2. 禁忌（次の患者には投与しないこと）

本剤の成分に対し過敏症の既往歴のある患者

2. 禁忌の設定根拠

本剤の成分に対し過敏症の既往歴のある患者に本剤を投与した場合，重篤な過敏症症状が発現する可能性が考えられることから，一般的な注意として記載した。

8. 重要な基本的注意欄

8. 重要な基本的注意

検査上の有益性が被曝による不利益を上回ると判断される場合にのみ投与すること。

8. 重要な基本的注意の設定根拠

本剤は標識後に投与するため，他の放射性医薬品の診断薬の電子添文を参考に設定した。

9. 特定の背景を有する患者に関する注意欄

9.7 小児等欄

9.7 小児等

小児等を対象とした臨床試験は実施していない。

9.7 小児等の設定根拠

小児等に対する有効性及び安全性が確立していないことから記載した。

11. 副作用欄

11. 副作用

次の副作用があらわれることがあるので、観察を十分に行い、異常が認められた場合には投与を中止するなど適切な処置を行うこと。

11.2 その他の副作用

	0.5%未満	頻度不明
胃腸障害	口内乾燥、悪心、便秘	嘔吐、下痢
一般・全身障害及び投与部位の状態	—	疲労、注射部位反応、悪寒

11. 副作用の設定根拠

冒頭は添付文書新記載要領の Q&A に基づき記載した。

本項に記載した副作用は，本剤の企業中核データシート（CCDS）に基づき設定した。発現頻度は，海外第 III 相試験（B12302/PSMAfore 試験）及び国内第 II 相試験（A11201 試験）の本剤群における併合解析結果に基づき記載した。

14. 適用上の注意欄

14. 適用上の注意

14.1 薬剤調製時の注意

14.1.1 ガリウム（^{68}Ga）ジェネレータから塩化ガリウム（^{68}Ga）溶液を本剤のバイアルに直接溶出し、混和した後、立てた状態に置きインキュベーション（20～30℃で 5 分間以上）することにより、ガリウム（^{68}Ga）ゴゼトチドを得ること。なお、ガリウム（^{68}Ga）ゴゼトチドの調製手順、品質管理のための試験等の詳細は製造販売業者が提供する注射液調製の手引きを参照すること。

14.1.2 ガリウム（^{68}Ga）ゴゼトチドの品質管理規格は次のとおりである。

外観：無色澄明の液、異物を認めない

pH：3.2～6.5

標識率：非標識ガリウム（^{68}Ga）≦5%

14.1.3 調製後の注射液は、立てた状態のまま室温で保存し、6 時間以内に投与すること。

14.1.4 他の薬剤と混合しないこと。

14.2 薬剤投与時の注意

14.2.1 局所血管外漏出による被曝及び画像アーチファクトを避けるため、溶解後は緩徐に静脈内投与すること。ガリウム（^{68}Ga）ゴゼトチドは酸性のため、血管外漏出により局所刺激が発現することがある。血管外漏出が発現した場合は、直ちに投与を中止し、適切な処置を行うこと。

14.2.2 膀胱部の被曝を軽減させるため、撮像前後にできるだけ患者に水分を摂取させ、排尿させることが望ましい。

14.3 検査上の注意

ガリウム（^{68}Ga）ゴゼトチドの取込みは他のがん種、非悪性腫瘍及び正常組織でも生じる可能性がある。病理組織学的診断法又はその他の診断法を参照し、ガリウム（^{68}Ga）ゴゼトチドを用いた PET 画像所見を解釈することが推奨される。

14. 適用上の注意の設定根拠

14.1，14.2.1 本剤の臨床試験及び CCDS に基づき設定した。

14.2.2 本剤は腎排泄されることから，排尿により膀胱部への被曝を軽減させることができるため設定した。
14.3 PET 画像上における Ga 標識した本剤の取込みは，前立腺癌に特異的ではなく，PSMA 発現の生体内分布に従い，他のがん種や非悪性腫瘍及び正常組織でも生じる可能性があるため設定した。

1 医薬品一般的名称（JAN）

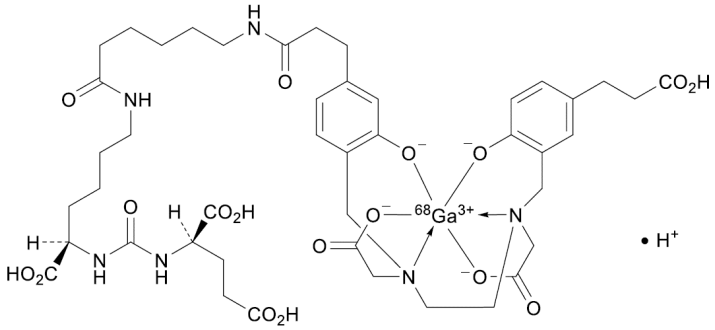
本剤のガリウム（^{68}Ga）標識後の医薬品一般的名称は，令和 6 年 5 月 7 日付医薬薬審発 0507 第 1 号により，以下のとおり通知された。

登録番号：305-2-B3

JAN（日本名）：ガリウム（^{68}Ga）ゴゼトチド

JAN（英　名）：Gallium (^{68}Ga) Gozetotide

構造式：



なお本剤の一般的名称としては，これより必要な部分を切り取った以下の名称を使用する。

日本名：ゴゼトチド

英名：Gozetotide

2 International Nonproprietary Names for Pharmaceutical Substances (INN)

gallium (^{68}Ga) gozetotidum：本剤のガリウム（^{68}Ga）標識後の INN は，WHO Drug Information Vol. 35, No. 1, 2021, Recommended INN List 85 の 148 頁に r-INN として収載されている。

医薬薬審発 0507 第１号
令 和 ６ 年 ５ 月 ７ 日

各都道府県衛生主管部（局）長　殿

厚生労働省医薬局医薬品審査管理課長
（　　公　　印　　省　　略　　）

医薬品の一般的名称について

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

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

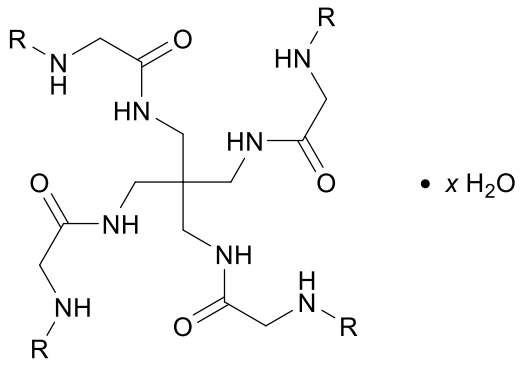
（別表２）INN に収載された品目の我が国における医薬品一般的名称

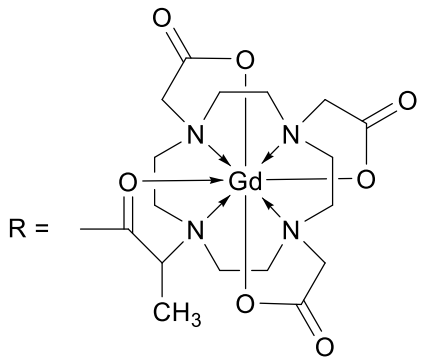
（平成 18 年 3 月 31 日薬食審査発第 0331001 号厚生労働省医薬食品局審査管理課長通知に示す別表２）

登録番号 305-1-B11

JAN（日本名）：ガドクアトラン水和物

JAN（英　名）：Gadoquatrane Hydrate





$C_{81}H_{128}Gd_4N_{24}O_{32}$・$xH_2O$

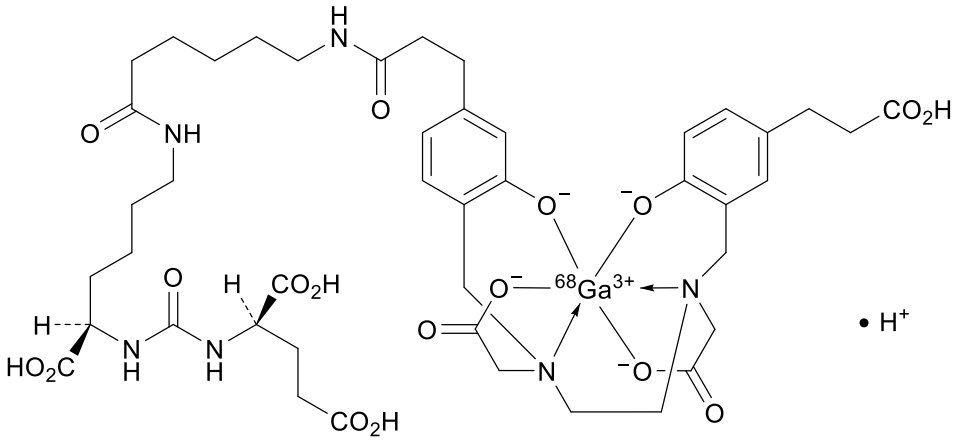
rac-[{μ$_4$-2,2',2'',2''',2'''',2'''''-[{(2*R*,16*Ξ*)-3,6,12,15-テトラオキソ-1κ*O*^{3}:2κ*O*^{15}-9,9-ビス[(2-{(2*Ξ*)-2-[4,7,10-トリス(カルボキシ-3κ^3*O*^{4},*O*^{7},*O*^{10}:4κ^3*O*$^{4'}$,*O*$^{7'}$,*O*$^{10'}$-メチル)-1,4,7,10-テトラアザシクロドデカン-1-イル-3κ^4*N*^{1},*N*^{4},*N*^{7},*N*^{10}:4κ^4*N*$^{1'}$,*N*$^{4'}$,*N*$^{7'}$,*N*$^{10'}$]-プロパンアミド-3κ*O*:4κ*O*'}アセトアミド)メチル]-4,7,11,14-テトラアザヘプタデカン-2,16-ジイル}ビス(1,4,7,10-テトラアザシクロドデカン-10,1,4,7-テトライル-1κ^4*N*^{1},*N*^{4},*N*^{7},*N*^{10}:2κ^4*N*$^{1'}$,*N*$^{4'}$,*N*$^{7'}$,*N*$^{10'}$)]ヘキサアセタト-1κ^3*O*^{1},*O*^{4},*O*^{7}:2κ^3*O*$^{1'}$,*O*$^{4'}$,*O*$^{7'}$}(12−)]四ガドリニウム　水和物

rac-[{μ$_4$-2,2',2'',2''',2'''',2'''''-[{(2*R*,16*Ξ*)-3,6,12,15-Tetraoxo-1κ*O*^{3}:2κ*O*^{15}-9,9-bis[(2-{(2*Ξ*)-2-[4,7,10-tris(carboxy-3κ^3*O*^{4},*O*^{7},*O*^{10}:4κ^3*O*$^{4'}$,*O*$^{7'}$,*O*$^{10'}$-methyl)-1,4,7,10-tetraazacyclododecan-1-yl-3κ^4*N*^{1},*N*^{4},*N*^{7},*N*^{10}:4κ^4*N*$^{1'}$,*N*$^{4'}$,*N*$^{7'}$,*N*$^{10'}$]-propanamido-3κ*O*:4κ*O*'}acetamido)methyl]-4,7,11,14-tetraazaheptadecane-2,16-diyl}bis(1,4,7,10-tetraazacyclododecane-10,1,4,7-tetrayl-1κ^4*N*^{1},*N*^{4},*N*^{7},*N*^{10}:2κ^4*N*$^{1'}$,*N*$^{4'}$,*N*$^{7'}$,*N*$^{10'}$)]hexaacetato-1κ^3*O*^{1},*O*^{4},*O*^{7}:2κ^3*O*$^{1'}$,*O*$^{4'}$,*O*$^{7'}$}(12−)]tetragadolinium hydrate

登録番号 305-2-B3

JAN（日本名）：ガリウム（^{68}Ga）ゴゼトチド

JAN（英　名）：Gallium (^{68}Ga) Gozetotide



$C_{44}H_{59}{}^{68}GaN_6O_{17}$

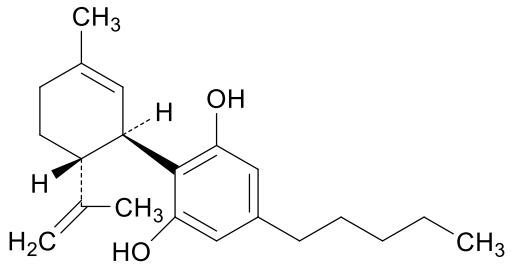
{*N*-[(*N*^{6}-{6-[3-(3-{[{2-[{[5-(2-カルボキシエチル)-2-ヒドロキシ-κ*O*-フェニル]メチル}(カルボキシ-κ*O*-メチル)アミノ-κ*N*]エチル}(カルボキシ-κ*O*-メチル)アミノ-κ*N*]メチル}-4-ヒドロキシ-κ*O*-フェニル)プロパンアミド]ヘキサノイル}-L-リシン-*N*^{2}-イル)カルボニル]-L-グルタマト(3−)}(^{68}Ga)ガリウム

{*N*-[(*N*^{6}-{6-[3-(3-{[{2-[{[5-(2-Carboxyethyl)-2-hydroxy-κ*O*-phenyl]methyl}(carboxy-κ*O*-methyl)amino-κ*N*]ethyl}(carboxy-κ*O*-methyl)amino-κ*N*]methyl}-4-hydroxy-κ*O*-phenyl)propanamido]hexanoyl}-L-lysin-*N*^{2}-yl)carbonyl]-L-glutamato(3−)}(^{68}Ga)gallium

登録番号 305-3-B5

JAN（日本名）：カンナビジオール

JAN（英　名）：Cannabidiol



$C_{21}H_{30}O_2$

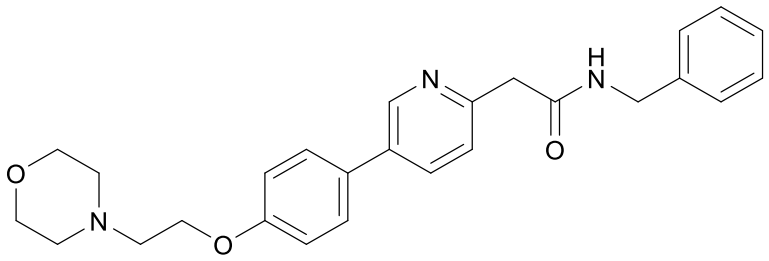
2-[(1*R*,6*R*)-3-メチル-6-(プロパ-1-エン-2-イル)シクロヘキサ-2-エン-1-イル]-5-ペンチルベンゼン-1,3-ジオール

2-[(1*R*,6*R*)-3-Methyl-6-(prop-1-en-2-yl)cyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol

登録番号 305-3-B6

JAN（日本名）：チルバニブリン

JAN（英　名）：Tirbanibulin



$C_{26}H_{29}N_3O_3$

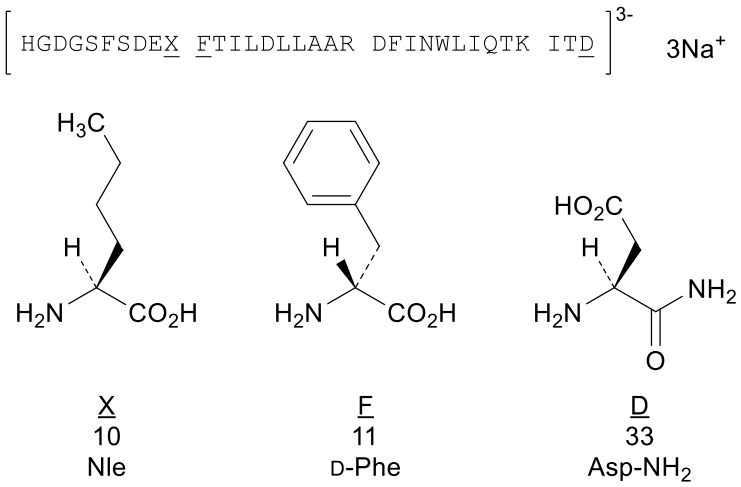
N-ベンジル-2-(5-{4-[2-(モルホリン-4-イル)エトキシ]フェニル}ピリジン-2-イル)アセトアミド

N-Benzyl-2-(5-{4-[2-(morpholin-4-yl)ethoxy]phenyl}pyridin-2-yl)acetamide

登録番号 305-4-B2

JAN（日本名）：アプラグルチドナトリウム

JAN（英　名）：Apraglutide Sodium



$C_{172}H_{260}N_{43}Na_3O_{52}$

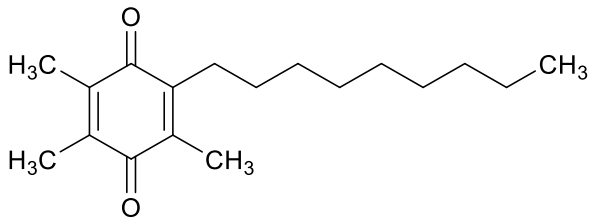
アプラグルチドナトリウムは，ヒトグルカゴン様ペプチド-2（GLP-2）類縁体（Ala2Gly，Met10Nle，Asn11D-Phe，Asn16Leu）であり，C 末端はアミド化されている．アプラグルチドナトリウムは，33 個のアミノ酸残基からなる合成ペプチドのナトリウム塩である．

Apraglutide Sodium is a human glucagon-like peptide-2 (GLP-2) analog (Ala2Gly, Met10Nle, Asn11D-Phe, Asn16Leu), whose C-terminus is amidated. Apraglutide Sodium is a sodium salt of a synthetic peptide consisting of 33 amino acid residues.

登録番号 305-4-B3

JAN（日本名）：ウトレロキサスタット

JAN（英　名）：Utreloxastat



$C_{18}H_{28}O_2$

2,3,5-トリメチル-6-ノニルシクロヘキサ-2,5-ジエン-1,4-ジオン

2,3,5-Trimethyl-6-nonylcyclohexa-2,5-diene-1,4-dione

※　JAN 以外の情報は、参考として掲載しました。

International Nonproprietary Names for Pharmaceutical Substances (INN)

RECOMMENDED International Nonproprietary Names: List 85

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

Dénominations communes internationales des Substances pharmaceutiques (DCI)

Dénominations communes internationales RECOMMANDÉES: Liste 85

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

Denominaciones Comunes Internacionales para las Sustancias Farmacéuticas (DCI)

Denominaciones Comunes Internacionales RECOMENDADAS: Lista 85

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

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

Please find the names from proposed **INN List 124 – COVID-19 (special edition)** that have reached the status of recommended INN in annex.
Veuillez trouver les noms de la **Liste 124 des DCI proposées – COVID-19 (édition spéciale)** ayant atteint le statut de DCI recommandées en annexe.
Por favor, abajo se encuentran los nombres de la **Lista 124 de DCI propuestas – COVID-19 (edición especial)** que han alcanzado el estatus de DCI recomendadas.

acapatamabum #

acapatamab	immunoglobulin scFv-scFv-scFc, anti-[*Homo sapiens* FOLH1 (folate hydrolase, prostate specific membrane antigen, PSMA)] and anti-[*Homo sapiens* CD3E (CD3 epsilon, Leu-4)], monoclonal antibody single chain (scFv)2-scFc, bispecific; IG single chain scFv-scFv-scFc, anti FOLH1 and anti-CD3E (1-986) [scFv-VH-V-kappa anti-FOLH1 (1-243) [VH (*Homo sapiens* IGHV3-11*01 G49>C (44) (84.7%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -15-mer-tris(tetraglycyl-seryl) linker (122-136)-V-KAPPA (*Homo sapiens* IGKV1-16*01 (79.3%) -IGKJ2*01 Q120>C (236) (90.9%)) CDR-IMGT [6.3.9] (163-168.186-188.225-233) (137-243)] -6-mer seryl-tetraglycyl-seryl linker (244-249) -scFv-VH-V-lambda anti-CD3E (250-498) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87.0%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (275-282.300-309.348-363) (250-374) -15-mer-tris(tetraglycyl-seryl) linker (375-389) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (415-423.441-443.480-488) (390-498)] -4-mer- tetraglycyl linker (499-502) -scFc (h-CH2-CH3)-(h-CH2-CH3) (503-986) [*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (hinge 6-15 (503-512), CH2 R83>C (574), N84.4>G (579), V85>C (584) (513-622), CH3 E12 (638), M14 (640) (623-727), CHS (728-729)) (503-729) -30-mer hexakis(tetraglycyl-seryl) linker (730-759) -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (hinge 6-15 (760-769), CH2 R83>C (831), N84.4>G (836), V85>C (841) (770-879), CH3 E12 (895), M14 (897) (880-984), CHS (985-986)) (760-986)]], non-glycosylated, produced in Chinese hamster ovary (CHO) cells
acapatamab	immunoglobuline scFv-scFv-scFc, anti-[*Homo sapiens* FOLH1 (folate hydrolase, antigène membranaire spécifique de la prostate, PSMA)], et anti-[*Homo sapiens* CD3E (CD3 epsilon, Leu-4)], anticorps monoclonal à chaîne unique (scFv)2-scFc, bispécifique;

	IG à chaîne unique scFv-scFv-scFc, anti FOLH1 et anti-CD3E (1-986) [scFv-VH-V-kappa anti-FOLH1 (1-243) [VH (*Homo sapiens* IGHV3-11*01 G49>C (84.7%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -15-mer-tris(tétraglycyl-séryl) linker (122-136)-V-KAPPA (*Homo sapiens* IGKV1-16*01 (79.3%) -IGKJ2*01 Q120>C (236) (90.9%)) CDR-IMGT [6.3.9] (163-168.186-188.225-233) (137-243)] -6-mer-séryl-tétraglycyl-séryl linker (244-249) -scFv-VH-V-lambda anti-CD3E (250-498) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87.0%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (275-282.300-309.348-363) (250-374) -15-mer-tris(tétraglycyl-séryl) linker (375-389) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (415-423.441-443.480-488) (390-498)] -4-mer-tétraglycyl linker (499-502) -scFc (h-CH2-CH3)-(h-CH2-CH3) (503-986) [*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (charnière 6-15 (503-512), CH2 R83>C (574), N84.4>G (579), V85>C (584) (513-622), CH3 E12 (638), M14 (640) (623-727), CHS (728-729)) (503-729) -30-mer-hexakis(tétraglycyl-séryl) linker (730-759) -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (charnière 6-15 (760-769), CH2 R83>C (831), N84.4>G (836), V85>C (841) (770-879), CH3 E12 (895), M14 (897) (880-984), CHS (985-986)) (760-986)]], non-glycosylé, produit dans des cellules ovariennes de hamster chinois (CHO)
acapatamab	inmunoglobulina scFv-scFv-scFc, anti-[*Homo sapiens* FOLH1 (folato hidrolasa, antígeno membranario específico de la prostata, PSMA)], y anti-[*Homo sapiens* CD3E (CD3 épsilon, Leu-4)], anticuerpo monoclonal con cadena única (scFv)2-scFc, biespecífica; IG con cadena única scFv-scFv-scFc, anti FOLH1 y anti-CD3E (1-986) [scFv-VH-V-kappa anti-FOLH1 (1-243) [VH (*Homo sapiens* IGHV3-11*01 G49>C (84.7%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -15-mer-tris(tetraglicil-seril) linker (122-136)-V-KAPPA (*Homo sapiens* IGKV1-16*01 (79.3%) -IGKJ2*01 Q120>C (236) (90.9%)) CDR-IMGT [6.3.9] (163-168.186-188.225-233) (137-243)] -6-mer-seril-tetraglicil-seril linker (244-249) -scFv-VH-V-lambda anti-CD3E (250-498) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87.0%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (275-282.300-309.348-363) (250-374) -15-mer-tris(tetraglicil-seril) linker (375-389) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (415-423.441-443.480-488) (390-498)] -4-mer- tetraglicil linker (499-502) -scFc (h-CH2-CH3)-(h-CH2-CH3) (503-986) [*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (bisagra 6-15 (503-512), CH2 R83>C (574), N84.4>G (579), V85>C (584) (513-622), CH3 E12 (638), M14 (640) (623-727), CHS (728-729)) (503-729) -30-mer-hexakis(tetraglicil-seril) linker (730-759) -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (bisagra 6-15 (760-769), CH2 R83>C (831), N84.4>G (836), V85>C (841) (770-879), CH3 E12 (895), M14 (897) (880-984), CHS (985-986)) (760-986)]], no glicosilado, producido en las células ováricas de hámster chino (CHO)

Heavy chain / Chaîne lourde / Cadena pesada

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QVQLVESGGG LVKPGESLRL SCAASGFTFS DYYMYWVRQA PGKCLEWVAI  50
ISDGGYYTYY SDIIKGRFTI SRDNAKNSLY LQMNSLKAED TAVYYCARGF 100
PLLRHGAMDY WGQGTLVTVS SGGGGSGGGG SGGGGSDIQM TQSPSSLSAS 150
VGDRVTITCK ASQNVDTNVA WYQQKPGQAP KSLIYSASYV YWDVPSRFSG 200
SASGTDFTLT ISSVQSEDFA TYYCQQYDQQ LITFGCGTKL EIKSGGGGSE 250
VQLVESGGGL VQPGGSLKLS CAASGFTFNK YAMNWVRQAP GKGLEWVARI 300
RSKYNNYATY YADSVKDRFT ISRDDSKNTA YLQMNNLKTE DTAVYYCVRH 350
GNFGNSYISY WAYWGQGTLV TVSSGGGGSG GGGSGGGGSQ TVVTQEPSLT 400
VSPGGTVTLT CGSSTGAVTS GNYPNWVQQK PGQAPRGLIG GTKFLAPGTP 450
ARFSGSLLGG KAALTLSGVQ PEDEAEYYCV LWYSNRWVFG GGTKLTVLGG 500
GGDKTHTCPP CPAPELLGGP SVFLFPPKPK DTLMISRTPE VTCVVVDVSH 550
EDPEVKFNWY VDGVEVHNAK TKPCEEQYGS TYRCVSVLTV LHQDWLNGKE 600
YKCKVSNKAL PAPIEKTISK AKGQPREPQV YTLPPSREEM TKNQVSLTCL 650
VKGFYPSDIA VEWESNGQPE NNYKTTPPVL DSDGSFFLYS KLTVDKSRWQ 700
QGNVFSCSVM HEALHNHYTQ KSLSLSPGKG GGGSGGGGSG GGGSGGGGSG 750
GGGSGGGGSD KTHTCPPCPA PELLGGPSVF LFPPKPKDTL MISRTPEVTC 800
VVVDVSHEDP EVKFNWYVDG VEVHNAKTKP CEEQYGSTYR CVSVLTVLHQ 850
DWLNGKEYKC KVSNKALPAP IEKTISKAKG QPREPQVYTL PPSREEMTKN 900
QVSLTCLVKG FYPSDIAVEW ESNGQPENNY KTTPPVLDSD GSFFLYSKLT 950
VDKSRWQQGN VFSCSVMHEA LHNHYTQKSL SLSPGK               986
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Post-translational modifications

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

Intra-V (C23 C104)	22-96	159-224	271-347	411-479	
Intra-C (C23-C104)	543-603	649-707	800-860	906-964	
Intra-CH2 (C83-C85)	574-584	831-841			
Inter-VH-VL (C49-C120)	44-236				
Inter-h11 (h 11 - h 11)	508-765				
Inter-h14 (h 14 - h 14)	511-768				

No N-glycosylation sites / pas de sites de N-glycosylation / ningún posición de N-glicosilación
CH2 N84.4>G:
579, 836
Aglycosylated

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
CHS K2:
986

adrenomedullinum pegolum #

adrenomedullin pegol

human adrenomedullin, C-terminal L-tyrosil amide, pegylated at *O*^{4} of Y^{1} with [(3*S*)-3-amino-4-{[(2R)-1-amino-3-{[(3*RS*)-2,5-dioxo-1-{3-oxo-3-[α-methyl(polyoxyethylene)-ω-amino]propyl}pyrrolidin-3-yl]sulfanyl}-1-oxopropan-2-yl]amino}-4-oxobutyl]carbamoyl; *O*$^{4.1}$-{[(3*S*)-3-amino-4-{[(2*R*)-1-amino-3-{[(3*RS*)-1-{3-[α-methylpoly(oxyethylene)-ω-amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl]sulfanyl}-1-oxopropan-2-yl]amino}-4-oxobutyl]carbamoyl}adrenomedullin (human)

adrénomedulline pégol

adrénomédulline humaine, L-tyrosil amide C-terminal, pégylée en *O*^{4} de Y^{1} avec [(3*S*)-3-amino-4-{[(2R)-1-amino-3-{[(3*RS*)-2,5-dioxo-1-{3-oxo-3-[α-méthyl(polyoxyéthylène)-ω-amino]propyl}pyrrolidin-3-yl]sulfanyl}-1-oxopropan-2-yl]amino}-4-oxobutyl]carbamoyle; *O*$^{4.1}$-({(3*S*)-3-amino-4-[(2*R*)-1-amino-3-{[(3*RS*)-1-{3-[α-méthylpoly(oxyéthylène)-ω-amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl]sulfanyl}-1-oxopropan-2-yl]-4-oxobutyl}carbamoyl)adrénomédulline (humaine)

adrenomedulina pegol

adrenomedulina humana, C-terminal L-tirosil amida, pegilada en *O*^{4} de Y^{1} con [(3*S*)-3-amino-4-{[(2R)-1-amino-3-{[(3*RS*)-2,5-dioxo-1-{3-oxo-3-[α-metil(polioxietileno)-ω-amino]propil}pirrolidin-3-il]sulfanil}-1-oxopropan-2-il]amino}-4-oxobutil]carbamoilo; *O*$^{4.1}$-({(3*S*)-3-amino-4-[(2*R*)-1-amino-3-{[(3*RS*)-1-{3-[α-metilpoli(oxietileno)-ω-amino]-3-oxopropil}-2,5-dioxopirrolidin-3-il]sulfanil}-1-oxopropan-2-il]-4-oxobutil}carbamoil)adrenomedulina (humana)

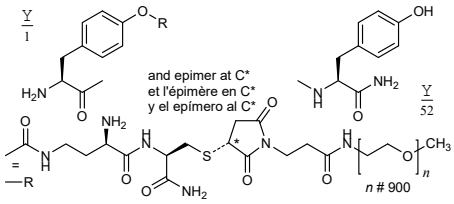
$C_{280}H_{430}N_{86}O_{83}S_4(C_2H_4O)_{\approx 900}$

Sequence / Séquence / Secuencia

YRQSMNNFQG LRSFGCRFGT CTVQKLAHQI YQFTDKDKDN VAPRSKISPQ 50
GY 52

Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
36-86 43-89

Modified residues / Résidus modifiés / Restos modificados



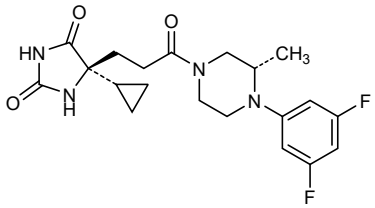
aldumastatum

aldumastat — (5*S*)-5-cyclopropyl-5-{3-[(3*S*)-4-(3,5-difluorophenyl)-3-methylpiperazin-1-yl]-3-oxopropyl}imidazolidine-2,4-dione

aldumastat — (5*S*)-5-cyclopropyl-5-{3-[(3*S*)-4-(3,5-difluorophényl)-3-méthylpipérazin-1-yl]-3-oxopropyl}imidazolidine-2,4-dione

aldumastat — (5*S*)-5-ciclopropil-5-{3-[(3*S*)-4-(3,5-difluorofenil)-3-metilpiperazin-1-il]-3-oxopropil}imidazolidina-2,4-diona

$C_{20}H_{24}F_2N_4O_3$



alnuctamabum #

alnuctamab — immunoglobulin G1-kappa/lambda with domain crossover, anti-[*Homo sapiens* TNFRSF17 (TNF receptor superfamily member 17, tumor necrosis factor receptor superfamily, member 17, B cell maturation antigen, BCMA, BCM, TNFRSF13A, CD269)] and anti-[*Homo sapiens* CD3E (CD3 epsilon, Leu-4)], monoclonal antibody, bispecific, trivalent; gamma1-lambda heavy chain anti-TNFRSF17 and anti-CD3E (VH-CH1-V-lambda-CH1-h-CH2-CH3) (1-671) [VH anti-TNFRSF17 (*Homo sapiens* IGHV3-23*01 (94.9%) -(IGHD) -IGHJ5*01 (93.3%)) CDR-IMGT [8.8.9] (26-33.51-58.97-105) (1-116) -*Homo sapiens* IGHG1*01, G1m17 (CH1 K26>E (146), K119>E (212), K120 (213) (117-214), hinge 1-6 (215-220)) (117-220) -10-mer bis(tetraglycyl-seryl) linker (221-230) -V-LAMBDA anti-CD3E (*Mus musculus* IGLV1*01 (81.2%) -IGLJ1*01 (100%)/*Homo sapiens* IGLV7-46*01 (80.0%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (256-264.282-284.321-329) (231-339)) -2-mer diseryl linker (340-341) -*Homo sapiens* IGHG1*01 G1m17,1, G1v14 CH2 A1.3, A1.2, G1v32 CH3 W22 (CH1 K120 (438) (342-439), hinge 1-15 (440-454), CH2 L1.3>A (458), L1.2>A (459), P114>G (553) (455-564), CH3 S10>C (578), D12 (580), L14 (582), T22>W (590) (565-669), CHS (670-671)) (342-671)],

	(219-216')-disulfide with kappa light chain anti-TNFRSF17 (1'-216') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (90.6%) -IGKJ1*01 (91.7%)) CDR-IMGT [7.3.10] (27-33.51-53.90-99) (1'-109') -*Homo sapiens* IGKC*01 (98.1%) E12>R (125), Q13>K (126), Km3 A45.1 (155), V101 (193) (110'-216')]; (444-232''')-disulfide with VH-C-kappa light chain anti-CD3E, (1'''-232''') [VH (*Homo sapiens* IGHV3-23*03 (87.0%) -(IGHD) -IGHJ6*01 (90.9%)) CDR-IMGT [8.10.16] (26-33.51-60.99-114) (1'''-125''') -*Homo sapiens* IGKC*01 (99.1%) T1.3>S (127), Km3 A45.1 (171), V101 (209) (126'''-232''')]; gamma1 heavy chain anti-TNFRSF17 (1''-446'') [VH (*Homo sapiens* IGHV3-23*01 (94.9%) -(IGHD) -IGHJ5*01 (93.3%)) CDR-IMGT [8.8.9] (26-33.51-58.97-105) (1''-116'') -*Homo sapiens* IGHG1*01 G1m17,1, G1v14 CH2 A1.3, A1.2, G1v33 CH3 S22, A24, V86 (CH1 K26>E (146), K119>E (212), K120 (213) (117''-214''), hinge 1-15 (215''-229''), CH2 L1.3>A (233), L1.2>A (234), P114>G (328) (230''-339''), CH3 Y5>C (348), D12 (355), L14 (357), T22>S (365), L24>A (367), Y86>V (406) (340''-444''), CHS (445''-446'')) (117''-446'')], (219''-216'''')-disulfide with kappa light chain anti-TNFRSF17 (1''''-216'''') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (90.6%) -IGKJ1*01 (91.7%)) CDR-IMGT [7.3.10] (27-33.51-53.90-99) (1''''-109'''') -*Homo sapiens* IGKC*01 (98.1%) E12>R (125), Q13>K (126), Km3 A45.1 (155), V101 (193) (110''''-216'''')]; dimer (450-225'':453-228'':578-348'')-trisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa
alnuctamab	immunoglobuline G1-kappa/lambda avec domaines échangés, anti-[*Homo sapiens* TNFRSF17 (membre 17 de la superfamille des récepteurs du TNF, membre 17 de la superfamille des récepteurs du facteur de nécrose tumorale, antigène de maturation de cellule B, BCMA, BCM, TNFRSF13A, CD269)] et anti-[*Homo sapiens* CD3E (CD3 epsilon, Leu-4)], anticorps monoclonal, bispécifique, trivalent; chaîne lourde gamma1 anti-TNFRSF17 et anti-CD3E (VH-CH1-V-lambda-CH1-h-CH2-CH3) (1-671) [VH anti-TNFRSF17 (*Homo sapiens* IGHV3-23*01 (94.9%) -(IGHD) -IGHJ4*01 (93.3%)) CDR-IMGT [8.8.9] (26-33.51-58.97-105) (1-116) -*Homo sapiens* IGHG1*01 G1m17 (CH1 K26>E (146), K119>E (212), K120 (213) (117-214), charnière 1-6 (215-220)) (117-220) -10-mer bis(tétraglycyl-séryl) linker (221-230) -V-LAMBDA anti-CD3E (*Mus musculus* IGLV1*01 (81.2%) -IGLJ1*01 (100%)/*Homo sapiens* (IGLV7-46*01 (80.0%) -IGLJ3*02 (100%) CDR-IMGT [9.3.9] (256-264.282-284.321-329) (231-339)) -2-merdiséryl linker (340-341) -*Homo sapiens* IGHG1*01 G1m17,1,G1v14 CH2 A1.3, A1.2, G1v32 CH3 W22 (CH1 K120 (438) (342-439), charnière 1-15 (440-454), CH2 L1.3>A (458), L1.2>A (459), P114>G (553) (455-564), CH3 S10>C (578), D12 (580), L14 (582), T22>W (590) (565-669), CHS (670-671)) (342-671)], (219-216')-disulfure avec la chaîne légère kappa anti-TNFRSF17 (1'-216') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (90.6%) -IGKJ1*01 (91.7%)) CDR-IMGT [7.3.10] (27-33.51-53.90-99) (1'-109') -*Homo sapiens* IGKC*01 (98.1%) E12>R (125), Q13>K (126), Km3 A45.1 (155), V101 (193) (110'-216')]; (444-232')-disulfure avec la chaîne légère VH-C-kappa anti-CD3E (1'''-232''') [VH (*Homo sapiens* IGHV3-23*03 (87.0%) -IGHJ6*01 (90.9%)) CDR-IMGT [8.10.16] (26-33.51-60.99-114) (1'''-125''') -*Homo sapiens* IGKC*01 (99.1%) T1.3>S (127), Km3 A45.1 (171), V101 (209) (126'''-232''')];

	chaîne lourde gamma1 anti-TNFRSF17 (1''-446'') [VH (*Homo sapiens* IGHV3-23*01 (94.9%) -(IGHD) -IGHJ4*01 (93.3%)) CDR-IMGT [8.8.9] (26-33.51-58.97-105) (1''-116'') -*Homo sapiens* IGHG1*01 G1m17,1, G1v14 CH2 A1.3, A1.2, G1v33 CH3 S22, A24, V86 (CH1 K26>E (146), K119>E (212), K120 (213) (117''-214''), charnière 1-15 (215''-229''), CH2 L1.3>A (233), L1.2>A (234), P114>G (328) (230''-339''), CH3 Y5>C (348), D12 (355), L14 (357), T22>S (365), L24>A (367), Y86>V (406) (340''-444''), CHS (445''-446'')) (117''-446'')], (219''-216'''')-disulfure avec la chaîne légère kappa anti-TNFRSF17 (1''''-216'''') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (90.6%) -IGKJ1*01 (91.7%)) CDR-IMGT [7.3.10] (27-33.51-53.90-99) (1''''-109'''') -*Homo sapiens* IGKC*01 (98.1%) E12>R (125), Q13>K (126), Km3 A45.1 (155), V101 (193) (110''''-216'''')]; dimère (450-225'':453-228'':578-348'')-trisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa
alnuctamab	inmunoglobulina G1-kappa/lambda con dominios cruzados, anti-[*Homo sapiens* TNFRSF17 (miembro 17 de la superfamilia de los receptores del TNF, miembro 17 de la superfamilia de los receptores del factor de necrosis tumoral, antígeno de maduración de célula B, BCMA, BCM, TNFRSF13A, CD269)] y anti-[*Homo sapiens* CD3E (CD3 épsilon, Leu-4)], anticuerpo monoclonal, biespecífico, trivalente; cadena pesada gamma1 anti-TNFRSF17 y anti-CD3E (VH-CH1-V-lambda-CH1-h-CH2-CH3) (1-671) [VH anti-TNFRSF17 (*Homo sapiens* IGHV3-23*01 (94.9%) -(IGHD) -IGHJ4*01 (93.3%)) CDR-IMGT [8.8.9] (26-33.51-58.97-105) (1-116) -*Homo sapiens* IGHG1*01 G1m17 (CH1 K26>E (146), K119>E (212), K120 (213) (117-214), bisagra 1-6 (215-220)) (117-220) -10-mer bis(tetraglicil-seril) linker (221-230) -V-LAMBDA anti-CD3E (*Mus musculus* IGLV1*01 (81.2%) -IGLJ1*01 (100%)/*Homo sapiens* (IGLV7-46*01 (80.0%) -IGLJ3*02 (100%) CDR-IMGT [9.3.9] (256-264.282-284.321-329) (231-339)) -2-merdiseril linker (340-341) -*Homo sapiens* IGHG1*01 G1m17,1,G1v14 CH2 A1.3, A1.2, G1v32 CH3 W22 (CH1 K120 (438) (342-439), bisagra 1-15 (440-454), CH2 L1.3>A (458), L1.2>A (459), P114>G (553) (455-564), CH3 S10>C (578), D12 (580), L14 (582), T22>W (590) (565-669), CHS (670-671)) (342-671)], (219-216')-disulfuro con la cadena ligera kappa anti-TNFRSF17 (1'-216') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (90.6%) -IGKJ1*01 (91.7%)) CDR-IMGT [7.3.10] (27-33.51-53.90-99) (1'-109') -*Homo sapiens* IGKC*01 (98.1%) E12>R (125), Q13>K (126), Km3 A45.1 (155), V101 (193) (110'-216')]; (444-232')-disulfuro con la cadena ligera VH-C-kappa anti-CD3E (1'''-232''') [VH (*Homo sapiens* IGHV3-23*03 (87.0%) -IGHJ6*01 (90.9%)) CDR-IMGT [8.10.16] (26-33.51-60.99-114) (1'''-125''') -*Homo sapiens* IGKC*01 (99.1%) T1.3>S (127), Km3 A45.1 (171), V101 (209) (126'''-232''')]; cadena pesada gamma1 anti-TNFRSF17 (1''-446'') [VH (*Homo sapiens* IGHV3-23*01 (94.9%) -(IGHD) -IGHJ4*01 (93.3%)) CDR-IMGT [8.8.9] (26-33.51-58.97-105) (1''-116'') -*Homo sapiens* IGHG1*01 G1m17,1, G1v14 CH2 A1.3, A1.2, G1v33 CH3 S22, A24, V86 (CH1 K26>E (146), K119>E (212), K120 (213) (117''-214''), bisagra 1-15 (215''-229''), CH2 L1.3>A (233), L1.2>A (234), P114>G (328) (230''-339''), CH3 Y5>C (348), D12 (355), L14 (357), T22>S (365), L24>A (367), Y86>V (406) (340''-444''), CHS (445''-446'')) (117''-446'')], (219''-216'''')-disulfuro con la cadena ligera kappa anti-TNFRSF17 (1''''-216'''') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (90.6%) -IGKJ1*01 (91.7%)) CDR-IMGT [7.3.10] (27-33.51-53.90-99) (1''''-109'''') -*Homo sapiens* IGKC*01 (98.1%) E12>R (125), Q13>K (126), Km3 A45.1 (155), V101 (193) (110''''-216'''')]; dímero (450-225'':453-228'':578-348'')-trisdisulfuro, producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada (1-671 anti-TNFRSF17 and anti-CD3)

```
EVQLLESGGG LVQPGGSLRL SCAASGFTFS DNAMGWVRQA PGKGLEWVSA  50
ISGPGSSTYY ADSVKGRFTI SRDNSKNTLY LQMNSLRAED TAVYYCAKVL 100
GWFDYWGQGT LVTVSSASTK GPSVFPLAPS SKSTSGGTAA LGCLVEDYFP 150
EPVTVSWNSG ALTSGVHTFP AVLQSSGLYS LSSVVTVPSS SLGTQTYICN 200
VNHKPSNTKV DEKVEPKSCD GGGGSGGGGS QAVVTQEPSL TVSPGGTVTL 250
TCGSSTGAVT TSNYANWVQE KPGQAFRGLI GGTNKRAPGT PARFSGSLLG 300
GKAALTLSGA QPEDEAEYYC ALWYSNLWVF GGGTKLTVLS SASTKGPSVF 350
PLAPSSKSTS GGTAALGCLV KDYFPEPVTV SWNSGALTSG VHTFPAVLQS 400
SGLYSLSSVV TVPSSSLGTQ TYICNVNHKP SNTKVDKKVE PKSCDKTHTC 450
PPCPAPEAAG GPSVFLFPPK PKDTLMISRT PEVTCVVVDV SHEDPEVKFN 500
WYVDGVEVHN AKTKPREEQY NSTYRVVSVL TVLHQDWLNG KEYKCKVSNK 550
ALGAPIEKTI SKAKGQPREP QVYTLPPCRD ELTKNQVSLW CLVKGFYPSD 600
IAVEWESNGQ PENNYKTTPP VLDSDGSFFL YSKLTVDKSR WQQGNVFSCS 650
VMHEALHNHY TQKSLSLSPG K                                 671
```

Heavy chain / Chaîne lourde / Cadena pesada (1"-446" anti-TNFRSF17)

```
EVQLLESGGG LVQPGGSLRL SCAASGFTFS DNAMGWVRQA PGKGLEWVSA  50
ISGPGSSTYY ADSVKGRFTI SRDNSKNTLY LQMNSLRAED TAVYYCAKVL 100
GWFDYWGQGT LVTVSSASTK GPSVFPLAPS SKSTSGGTAA LGCLVEDYFP 150
EPVTVSWNSG ALTSGVHTFP AVLQSSGLYS LSSVVTVPSS SLGTQTYICN 200
VNHKPSNTKV DEKVEPKSCD KTHTCPPCPA PEAAGGPSVF LFPPKPKDTL 250
MISRTPEVTC VVVDVSHEDP EVKFNWYVDG VEVHNAKTKP REEQYNSTYR 300
VVSVLTVLHQ DWLNGKEYKC KVSNKALGAP IEKTISKAKG QPREPQVCTL 350
PPSRDELTKN QVSLSCAVKG FYPSDIAVEW ESNGQPENNY KTTPPVLDSD 400
GSFFLVSKLT VDKSRWQQGN VFSCSVMHEA LHNHYTQKSL SLSPGK     446
```

Light chain / Chaîne légère / Cadena ligera (1'-216' and 1'"-216"" anti-TNFRSF17)

```
EIVLTQSPGT LSLSPGERAT LSCRASQSVS DEYLSWYQQK PGQAPRLLIH  50
SASTRATGIP DRFSGSGSGT DFTLAISRLE PEDFAVYYCQ QYGYPPDFTF 100
GQGTKVEIKR TVAAPSVFIF PPSDRKLKSG TASVVCLLNN FYPREAKVQW 150
KVDNALQSGN SQESVTEQDS KDSTYSLSST LTLSKADYEK HKVYACEVTH 200
QGLSSPVTKS FNRGEC                                      216
```

Light chain / Chaîne légère / Cadena ligera (1'"-232"" anti-CD3E)

```
EVQLLESGGG LVQPGGSLRL SCAASGFTFS TYAMNWVRQA PGKGLEWVSR  50
IRSKYNNYAT YYADSVKGRF TISRDDSKNT LYLQMNSLRA EDTAVYYCVR 100
HGNFGNSYVS WFAYWGQGTL VTVSSASVAA PSVFIFPPSD EQLKSGTASV 150
VCLLNNFYPR EAKVQWKVDN ALQSGNSQES VTEQDSKDST YSLSSTLTLS 200
KADYEKHKVY ACEVTHQGLS SPVTKSFNRG EC                    232
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 143-199 252-320 368-424 485-545 591-649
22"-96" 143"-199" 260"-320" 366"-424"
Intra-L (C23-C104) 23'-89' 136'-196'
22'"-98"" 152'"-212'"
23'"-89'"" 136'"-196'""
Inter-H-L (h 5-CL 126) 219-216' 444-232'" 219"-216""
Inter-H-H (h 11, h 14) 450-225" 453-228"
Inter-H-H engineered 578-348"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
521, 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 / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
671, 446"

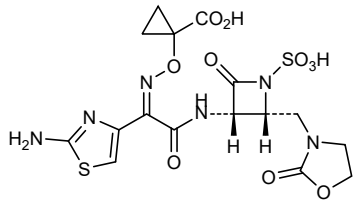
ancremonamum

ancremonam — 1-({(*Z*)-[1-(2-amino-1,3-thiazol-4-yl)-2-oxo-2-({(3*S*,4*R*)-2-oxo-4-[(2-oxo-1,3-oxazolidin-3-yl)methyl]-1-sulfoazetidin-3-yl}amino)ethylidene]amino}oxy) cyclopropane-1-carboxylic acid

ancrémonam — acide1-({(*Z*)-[1-(2-amino-1,3-thiazol-4-yl)-2-oxo-2-({(3*S*,4*R*)-2-oxo-4-[(2-oxo-1,3-oxazolidin-3-yl)méthyl]-1-sulfoazétidin-3-yl}amino)éthylidène]amino}oxy) cyclopropane-1-carboxylique

ancremonam — ácido1-({(*Z*)-[1-(2-amino-1,3-tiazol-4-il)-2-oxo-2-({(3*S*,4*R*)-2-oxo-4-[(2-oxo-1,3-oxazolidin-3-il)metil]-1-sulfoazetidin-3-il}amino)etilideno]amino}oxi) ciclopropano-1-carboxílico

$C_{16}H_{18}N_6O_{10}S_2$



apitegromabum #

apitegromab	immunoglobulin G4-lambda, anti-[*Homo sapiens* pro-MSTN (pro-growth differentiation factor 8, pro-GDF8, pro-myostatin, pro-GDF-8)], *Homo sapiens* monoclonal antibody; gamma4 heavy chain *Homo sapiens* (1-452) [VH (*Homo sapiens* IGHV3-30*03 (100%) -(IGHD) - IGHJ6*01 (94.4%)) CDR-IMGT [8.8.19] (26-33.51-58.97-115) (1-126)-*Homo sapiens* IGHG4*01, G4v5 h P10 (CH1 (127-224), hinge 1-12 S10>P (234) (225-236), CH2 (237-346), CH3 (347-451), CHS K>del (452)) (127-452)], (140-214')-disulfide with lambda light chain *Homo sapiens* (1'-215') [V-LAMBDA (*Homo sapiens* IGLV1-44*01 (98%) -IGLJ2*01 (100%)) CDR-IMGT [8.3.10] (26-33.51-53.90-99) (1'-109') -*Homo sapiens* IGLC2*01 (100%) (110'-215')]; dimer (232-232":235-235")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa
apitégromab	immunoglobuline G4-lambda, anti-[*Homo sapiens* pro-MSTN (pro-facteur de croissance et de différenciation 8, pro-GDF8, pro-myostatine, pro-GDF-8)], anticorps monoclonal *Homo sapiens*; chaîne lourde gamma4 *Homo sapiens* (1-452) [VH (*Homo sapiens* IGHV3-30*03 (100%) -(IGHD) - IGHJ6*01 (94.4%)) CDR-IMGT [8.8.19] (26-33.51-58.97-115) (1-126)-*Homo sapiens* IGHG4*01, G4v5 h P10 (CH1 (127-224), charnière 1-12 S10>P (234) (225-236), CH2 (237-346), CH3 (347-451), CHS K>del (452)) (127-452)], (140-214')-disulfure avec la chaîne légère lambda *Homo sapiens* (1'-215') [V-LAMBDA (*Homo sapiens* IGLV1-44*01 (98%) -IGLJ2*01 (100%)) CDR-IMGT [8.3.10] (26-33.51-53.90-99) (1'-109') -*Homo sapiens* IGLC2*01 (100%) (110'-215')]; dimère (232-232":235-235")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa
apitegromab	inmunoglobulina G4-lambda, anti-[*Homo sapiens* pro-MSTN (pro-factor de crecimiento y de diferenciación 8, pro-GDF8, pro-miostatina, pro-GDF-8)], anticuerpo monoclonal *Homo sapiens*;

cadena pesada gamma4 *Homo sapiens* (1-452) [VH (*Homo sapiens* IGHV3-30*03 (100%) -(IGHD) - IGHJ6*01 (94.4%)) CDR-IMGT [8.8.19] (26-33.51-58.97-115) (1-126)-*Homo sapiens* IGHG4*01, G4v5 h P10 (CH1 (127-224), bisagra 1-12 S10>P (234) (225-236), CH2 (237-346), CH3 (347-451), CHS K>del (452)) (127-452)], (140-214')-disulfuro con la cadena ligera lambda *Homo sapiens* (1'-215') [V-LAMBDA (*Homo sapiens* IGLV1-44*01 (98%) -IGLJ2*01 (100%)) CDR-IMGT [8.3.10] (26-33.51-53.90-99) (1'-109') - *Homo sapiens* IGLC2*01 (100%) (110'-215')]; dímero (232-232":235-235")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVESGGG VVQPGRSLRL SCAASGFTFS SYGMHWVRQA PGKGLEWVAV  50
ISYDGSNKYY ADSVKGRFTI SRDNSKNTLY LQMNSLRAED TAVYYCARDL 100
LVRFLEWSHY YGMDVWGQGT TVTVSSASTK GPSVFPLAPC SRSTSESTAA 150
LGCLVKDYFP EPVTVSWNSG ALTSGVHTFP AVLQSSGLYS LSSVVTVPSS 200
SLGTKTYTCN VDHKPSNTKV DKRVESKYGP PCPPCPAPEF LGGPSVFLFP 250
PKPKDTLMIS RTPEVTCVVV DVSQEDPEVQ FNWYVDGVEV HNAKTKPREE 300
QFNSTYRVVS VLTVLHQDWL NGKEYKCKVS NKGLPSSIEK TISKAKGQPR 350
EPQVYTLPPS QEEMTKNQVS LTCLVKGFYP SDIAVEWESN GQPENNYKTT 400
PPVLDSDGSF FLYSRLTVDK SRWQEGNVFS CSVMHEALHN HYTQKSLSLS 450
LG                                                      452
```

Light chain / Chaîne légère / Cadena ligera

```
QSVLTQPPSA SGTPGQRVTI SCSGSSSNIG SNTVHWYQQL PGTAPKLLIY  50
SDNQRPSGVP DRFSGSKSGT SASLAISGLQ SEDEADYYCA AWDDSLNGVF 100
GGGTKLTVLG QPKAAPSVTL FPPSSEELQA NKATLVCLIS DFYPGAVTVA 150
WKADSSPVKA GVETTTPSKQ SNNKYAASSY LSLTPEQWKS HRSYSCQVTH 200
EGSTVEKTVA PTECS                                        215
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 153-209 267-327 373-431
22"-96" 153"-209" 267"-327" 373"-431"
Intra-L (C23-C104) 22'-89' 137'-196'
22'"-89'" 137'"-196'"
Inter-H-L (h 10-CL 126) 140-214' 140"-214'"
Inter-H-H (h 8, h 11) 232-232" 235-235"

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

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
303, 303"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados.

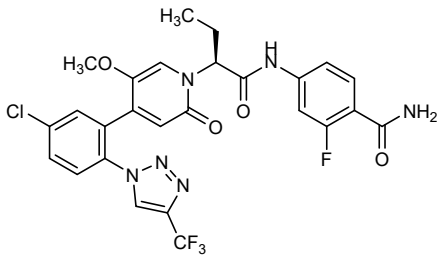
asundexianum

asundexian — (4*S*)-2^4-chloro-4-ethyl-7^3-fluoro-3^5-methoxy-3^2,5-dioxo-1^4-(trifluoromethyl)-3^2*H*-6-aza-3(4,1)-pyridina-1(1)-[1,2,3]triazola-2(1,2),7(1)-dibenzenaheptaphane-7^4-carboxamide

asundexian — (4*S*)-2^4-chloro-4-éthyl-7^3-fluoro-3^5-méthoxy-3^2,5-dioxo-1^4-(trifluorométhyl)-3^2*H*-6-aza-3(4,1)-pyridina-1(1)-[1,2,3]triazola-2(1,2),7(1)-dibenzénaheptaphane-7^4-carboxamide

asundexián — (4*S*)-2^4-cloro-4-etil-7^3-fluoro-3^5-metoxi-3^2,5-dioxo-1^4-(trifluorometil)-3^2*H*-6-aza-3(4,1)-piridina-1(1)-[1,2,3]triazola-2(1,2),7(1)-dibencenaheptafano-7^4-carboxamida

$C_{26}H_{21}ClF_4N_6O_4$



atidarsagenum autotemcelum #

atidarsagene autotemcel

Autologous CD34+ hematopoietic stem and progenitor cells transduced *ex vivo* with a replication-incompetent lentiviral vector encoding human arylsulfatase A (ARSA). Autologous CD34+ hematopoietic stem and progenitor cells (HSPC), obtained from bone marrow (BM) or mobilised peripheral blood (mPB), transduced *ex vivo* with a replication-incompetent pseudotyped HIV-1 based lentiviral vector encoding the human arylsulfatase A (ARSA) transgene under the control of a human phosphoglycerate kinase (PGK) promoter. The vector is pseudotyped with the vesicular stomatitis virus (VSV) envelope glycoprotein. The vector genome also contains a mutated Woodchuck hepatitis virus post-transcriptional regulatory element (WPRE), a fragment of the HIV-1 *gag,* the HIV-1 Rev response element (RRE), the HIV-1 central polypurine tract (cPPT) and a fragment of *nef*. The CD34+ cell population corresponds to an heterogenous population of stem and progenitor cells, some expressing the CD90 and/or CD133 markers.

atidarsagène autotemcel

Des cellules souches et progénitrices hématopoïétiques CD34+ autologues ont été transduites *ex vivo* avec un vecteur lentiviral incompétent à la réplication codant pour l'arylsulfatase A humaine (ARSA).
Des cellules souches et progénitrices hématopoïétiques CD34+ autologues (HSPC), obtenues à partir de moelle osseuse (BM) ou de sang périphérique mobilisé (mPB), ont été transduites *ex vivo* avec un vecteur lentiviral, à base de VIH-1 pseudotypé et incompétent à la réplication, codant pour le transgène de l'arylsulfatase A humaine (ARSA), sous le contrôle d'un promoteur de la phosphoglycérate kinase (PGK) humaine. Le vecteur est pseudotypé avec la glycoprotéine d'enveloppe du virus de la stomatite vésiculeuse (VSV). Le génome du vecteur contient également l'élément régulateur post-transcriptionnel Woodchuck (WPRE) du virus de l'hépatite, un fragment du *gag* du VIH-1, l'élément de réponse post-transcriptionnel (RRE) du VIH-1 et le tractus central de polypurine du VIH-1 (cPPT), ainsi qu'un fragment de *nef*. La population de cellules CD34+ correspond à une population hétérogène de cellules souches et progénitrices, certaines exprimant les marqueurs CD90 et/ou CD133.

atidarsagén autotemcel	Células troncales y progenitoras hematopoyéticas CD34+ autólogas transducidas *ex vivo* con un vector lentiviral incompetente en replicación que codifica para la arilsulfatasa A humana (ARSA). Las células troncales y progenitoras hematopoyéticas CD34+ autólogas, obtenidas de médula ósea o movilizadas de sangre periférica, se transducen *ex vivo* con un vector lentiviral basado en VIH-1 seudotipado y incompetente en replicación, que codifica el transgen de la arilsulfatasa A humana (ARSA) bajo el control de un promotor de la fosfoglicerato quinasa humana (PGK). El vector está seudotipado con la glicoproteína de la envuelta del virus de la estomatitis vesicular (VSV). El genoma del vector también contiene el elemento regulador post-transcipcional del virus de la hepatitis de la marmota (WPRE), un fragmento de *gag* del VIH-1, un elemento de respuesta post-transcripcional (RRE) del VIH-1 y un tramo central de poli-purinas (cPPT) de VIH-1, así como un fragmento de *nef*. La población de células CD34+corresponde en una población de celulas troncales y progenitoras, algunas expressando los marcadores CD90 y/o CD133.
avipendekinum pegolum #	
avipendekin pegol	human L-methionyl-interleukin 15, produced in *Escherichia coli*, pegylated at N^2 of Met^1 and N^6 of Lys residues with 4-[α-methylpoly(oxyethylene)-ω-oxy]butanoyl groups; L-methionyl-interleukin 15 (human, non-glycosylated), produced in *Escherichia coli*, substituted on an average of one site among N^2 of Met^1 and/or N^6 of lysyl residues with 4-[α-methylpoly(oxyethylene)-ω-oxy]butanoyl groups (~40 kDa each)
avipendékine pégol	L-méthionyl-interleukine 15 humaine, produite par *Escherichia coli*, pégylée en N^2 de Met^1 et N^6 des résidus Lys avec des groupes 4-[α-méthylpoly(oxyéthylène)-ω-oxy]butanoyle; L-méthionyl-interleukine 15 (humaine, non-glycosylée), produite dans *Escherichia coli*, substituée sur une moyenne d'un site parmi le N^2 du Met^1 et/ou N^6 des résidus lysyl par des groupes 4-[α-méthylpoly(oxyéthylène)-ω-oxy]butanoyle (~40 kDa chacun)
avipendekina pegol	L-metionil-interleukina 15 humana, producida en *Escherichia coli*, pegilada en N^2 de Met^1 y N^6 de residuos Lis con grupos 4-[α-metilpoli(oxietileno)-ω-oxi]butanoilo; L-metionil-interleukina 15 (humana, no glicosilada), producida en *Escherichia coli*, sustituida pro término medio de un sitio entre el N^2 del Met^1 y/o el N^6 de los residuos lisil por grupos 4-[α-metilpoli(oxietileno)-ω-oxi]butanoilo (~40 kDa cada uno)

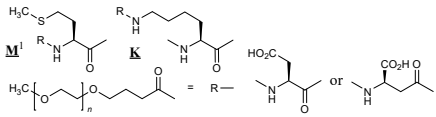
$C_{563}H_{898}N_{144}O_{185}S_8[C_5H_8O_2(C_2H_4O)_n]_x$ n ≈ 900, x ≈ 1

Sequence / Séquence / Secuencia

MNWVNVISDL **KK**IEDLIQSM HIDATLYTES DVHPSC**K**VTA M**K**CFLLELQV 50
ISLESGDASI HDTVENLIIL ANNSLSSNGN VTESGC**K**ECE ELEE**K**NI**K**EF 100
LQSFVHIVQM FINTS 115

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
36-86, 43-89
Partial deamidation / Désamidation partielle / Desamidación parcial
N78 (Asn>Asp, isoaspartyl)

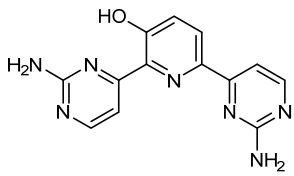
Modified residues / Résidus modifiés / Restos modificados
avipendekin : pegol ~ 1:1
M[1] (Met 1: ~32-40 %), **K** (Lys 11, 37, 42, 87: ~33-42 %; Lys 12, 95, 98: ~18-35 %)



avotaciclibum

avotaciclib	2,6-bis(2-aminopyrimidin-4-yl)pyridin-3-ol
avotaciclib	2,6-bis(2-aminopyrimidin-4-yl)pyridin-3-ol
avotaciclib	2,6-bis(2-aminopirimidin-4-il)piridin-3-ol

$C_{13}H_{11}N_7O$



azercabtagenum zapreleucelum #

azercabtagene zapreleucel

Adult allogeneic CD4+ and CD8+ enriched T cells transduced with an anti-CD19 chimeric antigen receptor (CAR) that is site-specific integrated into the cellular genome.
Adult allogeneic CD4+ and CD8+ enriched T cells, gene edited through the electroporation of homing endonuclease mRNA, which is translated into endonuclease protein that introduces a double-stranded DNA break in exon 1 of the endogenous T cell receptor alpha constant (TRAC) locus. Cells are subsequently transduced with a recombinant non-replicating adeno-associated virus type 6 (rAAV6) vector, encoding an anti-CD19 CAR transgene consisting of a murine CD19-specific scFv (clone FMC63), a CD8 hinge/transmembrane domain, a novel 6 (N6) co-stimulatory domain and CD3 zeta signaling domain, under the control of the synthetic promoter JeT and the SV40 poly(A) signal. CAR transgene integration is achieved via homology directed recombination at the endonuclease target site (exon 1 of TRAC). Depletion of CD3+ cells is performed on the

	transduced cells to remove cells with functional endogenous T cell receptor (TCR). The substance is a mixture of non-effector (naive, stem cell memory, central memory) (CCR7+) and effector memory and effector (CCR7-) CD4+ and CD8+ T cells with generally ≥99% T cell receptor knockout, and ≥40% anti-CD19 CAR knock-in. Activation of the cells is accompanied *in vitro* by release of IFNγ, IL-2, IL-6, and TNFα in an antigen-dependent manner.
azercabtagène zapréleucel	Lymphocytes T adultes allogéniques de type CD4+ et CD8+ transduits avec un récepteur d'antigène chimérique (CAR) anti-CD19 qui est intégré de manière spécifique au site. Lymphocytes T allogéniques enrichies en cellules de type CD4+ et CD8+, dont les gènes ont été édités par l'électroporation du mRNA de l'endonucléase de ciblage, qui est traduite en une protéine endonucléase qui introduit une rupture d'ADN double brin dans l'exon 1 du locus du récepteur alpha endogène aux cellules T (TRAC). Les cellules sont transduites ensuite avec un vecteur du virus recombinant adéno-associé, non réplicatif de type 6 (rAAV6), qui code pour un trangène anti-CD19 CAR, qui consiste en un scFv spécifique à CD19 (clone FMC63), un domaine CD8 transmembranaire/charnière, en un nouveau domaine de co-stimulation 6 (N6) et en un domaine de signalisation CD3 zêta, sous le contrôle du promoteur synthétique JeT et d'un signal poly(A) SV40. L'intégration du transgène CAR est obtenue via la recombinaison homologue dirigée au site de ciblage de l'endonucléase (l'exon 1 du TRAC). La déplétion des cellules CD3+ est effectuée sur les cellules transduites pour éliminer les cellules avec des récepteurs T (TCR) endogènes. La substance est un mélange de lymphocytes T non-effecteurs (naïfs, cellules souches mémoire, mémoire centrale) (CCR7+) et lymphocytes T mémoire effecteurs et effecteurs (CCR7-) CD4+ et CD8+ avec en général ≥99% de récepteurs des lymphocytes T knock-out et ≥40% de CAR anti-CD19 knock-in. L'activation des cellules est accompagnée *in vitro* par le relâchement d'IFNγ, IL-2, IL-6, et TNFα d'une manière antigène-dépendante.
azercabtagén zapreleucel	Linfocitos T adultos, alogénicos, enriquecidos en CD4+ y CD8+, transducidos con un receptor de antígenos quimérico (CAR) anti-CD19 que se integra en el genoma celular de forma específica de sitio. Linfocitos T adultos, alogénicos, enriquecidos en CD4+ y CD8+, con genes editados mediante la electroporación del ARNm de una endonucleasa de homing, que se traduce a una proteína endonucleasa que introduce una rotura en el ADN de doble cadena en el exón 1 del locus de la región constante del receptor alfa de células T endógenas (TRAC). Las células son posteriormente transducidas con un vector recombinante, no replicativo, de virus adeno-asociado tipo 6 (rAAV6) que codifica para un transgén de CAR anti-CD19 que consiste en un scFv murino nti-CD19 (clon FMC63), un dominio bisagra/transmenbrana

	CD8, un nuevo dominio de co-estimulación 6 (N6) y el dominio de señalización CD3 zeta, bajo el control del promotor sintético JeT y la señal poly(A) del SV40. La integración del transgén CAR se consigue mediante recombinación homóloga dirigida en el sitio diana de la endonucleasa (exón 1 de TRAC). Se realiza la depleción de células CD3+ en las células transducidas para eliminar las células con un receptor de células T (TCR) endógeno funcional. La sustancia es una mezcla de linfocitos T no efectores (ingenuos, células troncales memoria, memoria central) (CCR7+) y linfocitos T memoria efectores y efectores (CCR7-) CD4+ y CD8+ con en general ≥99% de receptores de linfocitos T (TCR) knock-out y ≥40% de CAR anti-CD19 knock-in. La activación de las células está acompañada *in vitro* por la liberación de IFNγ, IL-2, IL-6, y TNFα de una manera antígeno-dependiente.
bapotulimabum #	
bapotulimab	immunoglobulin G2-kappa, anti-[*Homo sapiens* ILDR2 (immunoglobulin like domain containing receptor 2, C1orf32)], *Homo sapiens* monoclonal antibody; gamma2 heavy chain *Homo sapiens* (1-445) [VH (*Homo sapiens* IGHV1-69*10 (100%) -(IGHD) -IGHJ5*01 (81.2%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG2*01, G2m.. CH2 V45.1 (CH1 (121-218), hinge 1-12 (219-230), CH2 V45.1 (281) (231-339), CH3 (340-444), CHS K>del (445)) (121-445)], (134-219')-disulfide with kappa light chain *Homo sapiens* (1'-219') [V-KAPPA (*Homo sapiens* IGKV2-28*01 (99%) -IGKJ4*01 (83.3%)) CDR-IMGT [11.3.9] (27-37.55-57.94-102) (1'-112') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (158), V101 (196) (113'-219')]; dimer (222-222":223-223":226-226":229-229")-tetrakisdisulfide, produced in a Chinese hamster ovary (CHO)-derived cell line, glycoform alfa
bapotulimab	immunoglobuline G2-kappa, anti-[*Homo sapiens* ILDR2 (récepteur 2 contenant un domaine immunoglobuline-like, C1orf32)], anticorps monoclonal *Homo sapiens*; chaîne lourde gamma2 *Homo sapiens* (1-445) [VH (*Homo sapiens* IGHV1-69*10 (100%) -(IGHD) -IGHJ5*01 (81.2%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG2*01, G2m.. CH2 V45.1 (CH1 (121-218), charnière 1-12 (219-230), CH2 V45.1 (281) (231-339), CH3 (340-444), CHS K>del (445)) (121-445)], (134-219')-disulfure avec la chaîne légère kappa *Homo sapiens* (1'-219') [V-KAPPA (*Homo sapiens* IGKV2-28*01 (99%) -IGKJ4*01 (83.3%)) CDR-IMGT [11.3.9] (27-37.55-57.94-102) (1'-112') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (158), V101 (196) (113'-219')]; dimère (222-222":223-223":226-226":229-229")-tétrakisdisulfure, produite dans une lignée cellulaire dérivée des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

bapotulimab

inmunoglobulina G2-kappa, anti-[*Homo sapiens* ILDR2 (receptor 2 que contiene un dominio inmunoglobulina-like, C1orf32)], anticuerpo monoclonal *Homo sapiens*;
cadena pesada gamma2 *Homo sapiens* (1-445) [VH (*Homo sapiens* IGHV1-69*10 (100%) -(IGHD) -IGHJ5*01 (81.2%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG2*01, G2m.. CH2 V45.1 (CH1 (121-218), bisagra 1-12 (219-230), CH2 V45.1 (281) (231-339), CH3 (340-444), CHS K>del (445)) (121-445)], (134-219')-disulfuro con la cadena ligera kappa *Homo sapiens* (1'-219') [V-KAPPA (*Homo sapiens* IGKV2-28*01 (99%) -IGKJ4*01 (83.3%)) CDR-IMGT [11.3.9] (27-37.55-57.94-102) (1'-112') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (158), V101 (196) (113'-219')];
dímero (222-222":223-223":226-226":229-229")-tetrakisdisulfuro, producido en una línea celular derivada de las células ováricas de hamster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGSSVKV SCKASGGTFS SYAISWVRQA PGQGLEWMGG  50
IIPILGIANY AQKFQGRVTI TADKSTSTAY MELSSLRSED TAVYYCARGR 100
LPYGDFWDSW GQGTLVTVSS ASTKGPSVFP LAPCSRSTSE STAALGCLVK 150
DYFPEPVTVS WNSGALTSGV HTFPAVLQSS GLYSLSSVVT VPSSNFGTQT 200
YTCNVDHKPS NTKVDKTVER KCCVECPPCP APPVAGPSVF LFPPKPKDTL 250
MISRTPEVTC VVVDVSHEDP EVQFNWYVDG VEVHNAKTKP REEQFNSTFR 300
VVSVLTVVHQ DWLNGKEYKC KVSNKGLPAP IEKTISKTKG QPREPQVYTL 350
PPSREEMTKN QVSLTCLVKG FYPSDIAVEW ESNGQPENNY KTTPPMLDSD 400
GSFFLYSKLT VDKSRWQQGN VFSCSVMHEA LHNHYTQKSL SLSPG      445
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Light chain / Chaîne légère / Cadena ligera

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DIVMTQSPLS LPVTPGEPAS ISCRSSQSLL YSNGYNYLDW YLQKPGQSPQ  50
LLIYLGSNRA SGVPDRFSGS GSGTDFTLKI SRVEAEDVGV YYCMQALQTP 100
LTFGGGTKLE IRRTVAAPSV FIFPPSDEQL KSGTASVVCL LNNFYPREAK 150
VQWKVDNALQ SGNSQESVTE QDSKDSTYSL SSTLTLSKAD YEKHKVYACE 200
VTHQGLSSPV TKSFNRGEC                                   219
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 147-203 260-320 366-424
22"-96" 147"-203" 260"-320" 366"-424"
Intra-L (C23-C104) 23'-93' 139'-199'
23'"-93'" 139'"-199'"
Inter-H-L (CH1 10-CL 126)* 134-219' 134"-219'"
Inter-H-H (h 4, h 5, h 8, h 11)* 222-222" 223-223" 226-226" 229-229"
*A-isoform, predominant

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:
296, 296"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados.

barecetamabum #
barecetamab

immunoglobulin G1-lambda, anti-[*Homo sapiens* ERBB3 (receptor tyrosine-protein kinase erbB-3, HER3)], *Homo sapiens* monoclonal antibody;
gamma1 heavy chain *Homo sapiens* (1-451) [VH (*Homo sapiens* IGHV3-23*01 (90.8%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -*Homo sapiens* IGHG1*01, nG1m1, G1m17 (CH1 K120 (218) (122-219), hinge 1-15 (220-234), CH2 (235-344), CH3 E12 (360), M14 (362) (345-449), CHS (450-451)) (122-451)], (224-215')-disulfide with lambda light chain *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV1-47*02 (92.9%) -IGLJ2*01 (100%)) CDR-IMGT [8.3.11] (26-33.51-53.90-100) (1'-110') -*Homo sapiens* IGLC3*03 (100%) (111'-216')];
dimer (230-230":233-233")-bisdisulfide, produced in Chinese hamster ovary (CHO)-K1 cell line, glycoform alfa

barécétamab

immunoglobuline G1-lambda, anti-[*Homo sapiens* ERBB3 (récepteur à activité tyrosine kinase erbB-3, HER3)], *Homo sapiens* anticorps monoclonal;
chaîne lourde gamma1 *Homo sapiens* (1-451) [VH (*Homo sapiens* IGHV3-23*01 (90.8%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -*Homo sapiens* IGHG1*01, nG1m1, G1m17 (CH1 K120 (218) (122-219), charnière 1-15 (220-234), CH2 (235-344), CH3 E12 (360), M14 (362) (345-449), CHS (450-451)) (122-451)], (225-215')-disulfure avec la chaîne légère lambda *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV1-47*02 (92.9%) -IGLJ2*01 (100%)) CDR-IMGT [8.3.11] (26-33.51-53.90-100) (1'-110') -*Homo sapiens* IGLC3*03 (100%) (111'-216')]; dimère (230-230":233-233")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) lignée cellulaire CHO-K1, glycoforme alfa

barecetamab

inmunoglobulina G1-lambda, anti-[*Homo sapiens* ERBB3 (receptor de la actividad tirosina kinasa erbB-3, HER3)], *Homo sapiens* anticuerpo monoclonal;
cadena pesada gamma1 *Homo sapiens* (1-451) [VH (*Homo sapiens* IGHV3-23*01 (90.8%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -*Homo sapiens* IGHG1*01, nG1m1, G1m17 (CH1 K120 (218) (122-219), bisagra 1-15 (220-234), CH2 (235-344), CH3 E12 (360), M14 (362) (345-449), CHS (450-451)) (122-451)], (225-215')-disulfuro con la cadena ligera lambda *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV1-47*02 (92.9%) -IGLJ2*01 (100%)) CDR-IMGT [8.3.11] (26-33.51-53.90-100) (1'-110') -*Homo sapiens* IGLC3*03 (100%) (111'-216')]; dímero (230-230":233-233")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular CHO-K1, forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLLESGGG LVQPGGSLRL SCAASGFTFS DYDMSWVRQA PGKGLEWVST  50
IDLDSGSIYY ADSVQGRFTI SRDNSKNTLY LQMNSLRAED TAVYYCAKDL 100
HMGPEGPFDY WGQGTLVTVS SASTKGPSVF PLAPSSKSTS GGTAALGCLV 150
KDYFPEPVTV SWNSGALTSG VHTFPAVLQS SGLYSLSSVV TVPSSSLGTQ 200
TYICNVNHKP SNTKVDKKVE PKSCDKTHTC PPCPAPELLG GPSVFLFPPK 250
PKDTLMISRT PEVTCVVVDV SHEDPEVKFN WYVDGVEVHN AKTKPREEQY 300
NSTYRVVSVL TVLHQDWLNG KEYKCKVSNK ALPAPIEKTI SKAKGQPREP 350
QVYTLPPSRE EMTKNQVSLT CLVKGFYPSD IAVEWESNGQ PENNYKTTPP 400
VLDSDGSFFL YSKLTVDKSR WQQGNVFSCS VMHEALHNHY TQKSLSLSPG 450
K                                                       451
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Light chain / Chaîne légère / Cadena ligera

```
QSVLTQPPSA SGTPGQRVTI SCSGSSSNIG SNSVSWYQQL PGTAPKLLIY  50
SDNHRPSGVP DRFSGSKSGT SASLAISGLR SEDEADYYCQ GWDTSLSGHV 100
FGGGTKLTVL GQPKAAPSVT LFPPSSEELQ ANKATLVCLI SDFYPGAVTV 150
AWKADSSPVK AGVETTTPSK QSNNKYAASS YLSLTPEQWK SHKSYSCQVT 200
HEGSTVEKTV APTECS                                       216
```

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) 22'-89' 138'-197'
22'"-89'" 138'"-197'"
Inter-H-L (h 5-CL 126) 224-215' 224"-215'"
Inter-H-H (h 11, h 14) 230-230" 233-233"

N-terminal glutaminyl cyclization to pyroglutamyl (pE, 5-oxoprolyl)
L VL Q1:
1', 1'"

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.

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
451, 451"

batiraxceptum #

batiraxcept

human tyrosine-protein kinase receptor UFO (AXL oncogene) fragment (8-202, 1-195 in the current sequence), variant ($G^{14}>S^{7}$, $A^{54}>V^{47}$, $D^{69}>G^{62}$, $V^{74}>A^{67}$, $G^{109}>R^{102}$), fused via peptidyl linker (^{196}GGGGS^{200}) to a human immunoglobulin G1 Fc fragment (201-426, C-terminal Lys residue deleted), dimer, glycosylated, produced in Chinese hamster ovary (CHO) cells;
[$G^{14}>S(7)$, $A^{54}>V(47)$, $D^{69}>G(62)$, $V^{74}>A(67)$, $G^{109}>R(102)$] human AXL receptor tyrosine kinase (AXL oncogene, tyrosine-protein kinase receptor UFO) (8-202)-peptide (1-195), fused via a G_4S linker (196-200) to a human immunoglobulin G1 C-terminal K>del Fc fragment (201-426), dimer (206-206':209-209')-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

batiraxcept

récepteur de la tyrosine kinase-protéine UFO (oncogène AXL), fragment (8-202, 1-195 dans la séquence présente), variant ($G^{14}>S^{7}$, $A^{54}>V^{47}$, $D^{69}>G^{62}$, $V^{74}>A^{67}$, $G^{109}>R^{102}$), fusionné via un peptide liant (^{196}GGGGS^{200}) à un fragment Fc de l'immunoglobuline humaine G1 (201-426, résidu Lys C-terminal supprimé), dimère, glycosylé, produit par des cellules ovariennes de hamsters chinois (CHO);
[$G^{14}>S(7)$, $A^{54}>V(47)$, $D^{69}>G(62)$, $V^{74}>A(67)$, $G^{109}>R(102)$] tyrosine kinase du récepteur AXL humaine (oncogène AXL, récepteur de la tyrosine kinase-protéine UFO) (8-202)-peptide (1-195), fusionné via un peptide liant G_4S (196-200) au fragment Fc C-terminal K>del de l'immunoglobuline G1 humaine (201-426), dimère (206-206':209-209')-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

batiraxcept

receptor de la proteína tirosina kinasa humana UFO (oncogén AXL) fragmento (8-202, 1-195 en la secuencia actual), variante ($G^{14}>S^{7}$, $A^{54}>V^{47}$, $D^{69}>G^{62}$, $V^{74}>A^{67}$, $G^{109}>R^{102}$), fusionado a través de un conector peptidil (^{196}GGGGS^{200}) a una inmunoglobulina humana G1 Fc fragmento (201-426, residuo Lis C-terminal eliminado), dímero, glicosilado, producido en células ováricas de hámster Chino (CHO);
[$G^{14}>S(7)$, $A^{54}>V(47)$, $D^{69}>G(62)$, $V^{74}>A(67)$, $G^{109}>R(102)$] AXL receptor tirosina kinasa humana (oncogén AXL, receptor de la proteína tirosina-kinasa UFO) (8-202)-péptido (1-195), fusionado a través de un péptido G_4S (196-200) con un fragmento Fc C-terminal K>del de la inmunoglobulina G1 humana (201-426), dímero (206-206':209-209')-bisdisulfuro, producido en células ováricas de hámster Chino (CHO), glicosilada alfa

Sequence / Séquence / Secuencia

```
EESPFVSNPG NITGARGLTG TLRCQLQVQG EPPEVHWLRD GQILELVDST   50
QTQVPLGEDE QGDWIVASQL RITSLQLSDT GQYQCLVFLG HQTFVSQPGY  100
VRLEGLPYFL EEPEDRTVAA NTPFNLSCQA QGPPEPVDLL WLQDAVPLAT  150
APGHGPQRSL HVPGLNKTSS FSCEAHNAKG VTTSRTATIT VLPQQGGGGS  200
DKTHTCPPCP APELLGGPSV FLFPPKPKDT LMISRTPEVT CVVVDVSHED  250
PEVKFNWYVD GVEVHNAKTK PREEQYNSTY RVVSVLTVLH QDWLNGKEYK  300
CKVSNKALPA PIEKTISKAK GQPREPQVYT LPPSREEMTK NQVSLTCLVK  350
GFYPSDIAVE WESNGQPENN YKTTPPVLDS DGSFFLYSKL TVDKSRWQQG  400
NVFSCSVMHE ALHNHYTQKS LSLSPG                            426
```

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

intra-AXL	24-85	128-173	intra-Fc	241-301	347-405
	24'-85'	128'-173'		241'-301'	347'-405'
inter-Fc	206-206'	209-209'			

Glycosylation sites / Sites de glycosylation / Posiciones de glicosilación
AXL: N11, N125, N166, N11', N125', N166';
Fc: N277, N277'

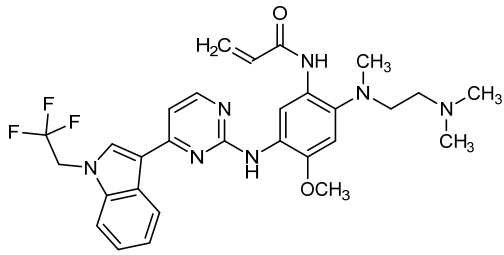
befotertinibum

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

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

befotertinib — *N*-[2-{[2-(dimetilamino)etil](metil)amino}-4-metoxi-5-({4-[1-(2,2,2-trifluoroetil)-1*H*-indol-3-il]pirimidin-2-il}amino)fenil]prop-2-enamida

$C_{29}H_{32}F_3N_7O_2$



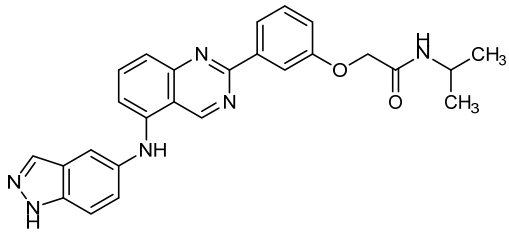
belumosudilum

belumosudil — 2-(3-{4-[(1*H*-indazol-5-yl)amino]quinazolin-2-yl}phenoxy)-*N*-(propan-2-yl)acetamide

bélumosudil — 2-(3-{4-[(1*H*-indazol-5-yl)amino]quinazolin-2-yl}phénoxy)-*N*-(propan-2-yl)acetamide

belumosudil — 2-(3-{4-[(1*H*-indazol-5-il)amino]quinazolin-2-il}fenoxi)-*N*-(propan-2-il)acetamida

$C_{26}H_{24}N_6O_2$



bentracimabum #

bentracimab — immunoglobulin Fab G1-lambda, anti-[*ticagrelor* and its active metabolite AR-C124910XX], *Homo sapiens* monoclonal antibody; VH-(CH1-hinge) gamma1 heavy chain *Homo sapiens* (1-234) [VH (*Homo sapiens* IGHV1-69*06 (85.7%) -(IGHD) -IGHJ1*01 (100%)) CDR-IMGT [8.7.14] (26-33.51-58.97-118) (1-129) -*Homo sapiens* IGHG1*03 (100%) G1m3 (CH1 R120 (226) (130-227), hinge 1-7 (228-234)) (130-234)], (232-215')-disulfide with lambda light chain *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV1-51*01 (94.6%) -IGLJ2*01 (81.8%)) CDR-IMGT [8.3.11] (26-33.51-53.90-100) (1'-110') -*Homo sapiens* IGLC2*01(100%) (111'-216')], non-glycosylated, produced in the bacteria *Escherichia coli* (*E. coli*)

bentracimab

immunoglobuline Fab G1-lambda, anti-[*ticagrelor* et son métabolite actif AR-C124910XX], anticorps monoclonal *Homo sapiens*;
VH-(CH1-charnière) chaîne lourde gamma1 *Homo sapiens* (1-234) [VH (*Homo sapiens* (1-234) [VH (*Homo sapiens* IGHV1-69*06 (85.7%) -(IGHD) -IGHJ1*01 (100%)) CDR-IMGT [8.7.14] (26-33.51-58.97-118) (1-129) -*Homo sapiens* IGHG1*03 (100%) G1m3 (CH1 R120 (226) (130-227), charnière 1-7 (228-234)) (130-234)], (232-215')-disulfure avec la chaîne légère lambda *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV1-51*01 (94.6%) -IGLJ2*01 (81.8%)) CDR-IMGT [8.3.11] (26-33.51-53.90-100) (1'-110') -*Homo sapiens* IGLC2*01(100%) (111'-216')], non-glycosylé, produit dans la bactérie *Escherichia coli* (*E. coli*)

bentracimab

inmunoglobulina Fab G1-lambda, anti-[*ticagrelor* y su metabolito activo AR-C124910XX], anticuerpo monoclonal *Homo sapiens*;
VH-(CH1-bisagra) cadena pesada gamma1 *Homo sapiens* (1-234) [VH (*Homo sapiens* (1-234) [VH (*Homo sapiens* IGHV1-69*06 (85.7%) -(IGHD) -IGHJ1*01 (100%)) CDR-IMGT [8.7.14] (26-33.51-58.97-118) (1-129) -*Homo sapiens* IGHG1*03 (100%) G1m3 (CH1 R120 (226) (130-227), bisagra 1-7 (228-234)) (130-234)], (232-215')-disulfuro con la cadena ligera lambda *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV1-51*01 (94.6%) -IGLJ2*01 (81.8%)) CDR-IMGT [8.3.11] (26-33.51-53.90-100) (1'-110') -*Homo sapiens* IGLC2*01(100%) (111'-216')], no glicosilado, producido en la bacteria *Escherichia coli* (*E. coli*)

Heavy chain / Chaîne lourde / Cadena pesada
```
QVQLQESGAE VKKPGSSVRV SCKASGGTFD SYSIHWVRQA PGQGLEWMGG  50
IIPAFGTLSS AQDFQARVTI SADKSTSTAY MELSGLRSED TAVYYCARGS 100
FDYYFWSASH PPNDALAIWG QGTLVTVSSA STKGPSVFPL APSSKSTSGG 150
TAALGCLVKD YFPEPVTVSW NSGALTSGVH TFPAVLQSSG LYSLSSVVTV 200
PSSSLGTQTY ICNVNHKPSN TKVDKRVEPK SCDK                  234
```

Light chain / Chaîne légère / Cadena ligera
```
QSVVTQPPSV SAAPGQKVTI SCSGSNSDIG NNYVSWYQQL PGTAPKLLIY  50
DNNKRPSGIP DRFSGSKSGT SATLAITGLQ AGDEADYYCG TWLYDRAVGL 100
FGGGTKVTVL GQPKAAPSVT LFPPSSEELQ ANKATLVCLI SDFYPGAVTV 150
AWKADSSPVK AGVETTTPSK QSNNKYAASS YLSLTPEQWK SHRSYSCQVT 200
HEGSTVEKTV APTECS                                      216
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 156-212
Intra-L (C23-C104) 22'-89' 138'-197'
Inter-H-L (h 5-CL 126) 232-215'

N-terminal glutaminyl cyclization to pyroglutamyl (pE, 5-oxoprolyl)
L VH Q1:
1
L VL Q1:
1'

No N-glycosylation site / pas de sites de N-glycosylation / ningùm posición de N-glycosilación
Agycosylated

bepirovirsenum

bepirovirsen

all-P-ambo-2'-*O*-(2-methoxyethyl)-*P*-thioguanylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-5-methyl-*P*-thiocytidylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-*P*-thioadenylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-*P*-thioguanylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-*P*-thioadenylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-*P*-

thiothymidylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-2'-deoxy-5-methyl-*P*-thiocytidylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-*P*-thioadenylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-*P*-thioguanylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-5-methyl-*P*-thiouridylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-*P*-thioguanylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-5-methylcytidine

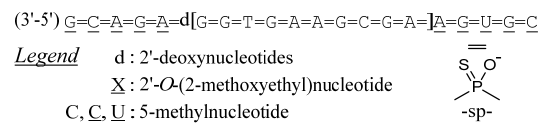
bépirovirsen

tout-P-ambo-2'-*O*-(2-méthoxyéthyl)-*P*-thioguanylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-5-méthyl-*P*-thiocytidylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-*P*-thioadénylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-*P*-thioguanylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-*P*-thioadénylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-2'-désoxy-5-méthyl-*P*-thiocytidylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-*P*-thioadénylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-*P*-thioguanylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-5-méthyl-*P*-thiouridylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-*P*-thioguanylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-5-méthylcytidine

bepirovirsén

todo-P-ambo-2'-*O*-(2-metoxietil)-*P*-tioguanilil-(3'→5')-5-metil-2'-*O*-(2-metoxietil)-*P*-tiocitidilil-(3'→5')-2'-*O*-(2-metoxietil)-*P*-tioadenilil-(3'→5')-2'-*O*-(2-metoxietil)-*P*-tioguanilil-(3'→5')-2'-*O*-(2-metoxietil)-*P*-tioadenilil-(3'→5')-2'-desoxi-*P*-tioguanilil-(3'→5')-2'-desoxi-*P*-tioguanilil-(3'→5')-*P*-tiotimidilil-(3'→5')-2'-desoxi-*P*-tioguanilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-2'-desoxi-*P*-tioguanilil-(3'→5')-2'-desoxi-5-metil-*P*-tiocitidilil-(3'→5')-2'-desoxi-*P*-tioguanilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-2'-*O*-(2-metoxietil)-*P*-tioadenilil-(3'→5')-2'-*O*-(2-metoxietil)-*P*-tioguanilil-(3'→5')-5-metil-2'-*O*-(2-metoxietil)-*P*-tiouridilil-(3'→5')-2'-*O*-(2-metoxietil)-*P*-tioguanilil-(3'→5')-2'-*O*-(2-metoxietil)-5-metilcitidina

$C_{230}H_{309}N_{88}O_{115}P_{19}S_{19}$



beremagenum geperpavecum #

beremagene geperpavec

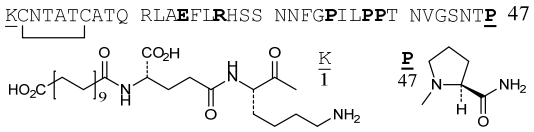
A replication-defective herpes simplex virus encoding human collagen type VII alpha 1 chain (COL7A1).

	A recombinant replication-defective, non-integrating herpes simplex virus-1 (HSV-1) (KOS strain) encoding two copies of human collagen type VII alpha 1 chain (COL7A1), inserted into the immediate early (IE) infected cell protein 4 (ICP4) gene regions after deletion of both copies of ICP4 genes, under the control of the human cytomegalovirus (hCMV) immediate early promoter and bovine growth hormone polyadenylation signal (bGHpA). The infected cell protein 22 (ICP22) gene is also deleted.
bérémagène géperpavec	Un virus herpès simplex à réplication défectueuse codant pour la chaîne du collagène humain de type VII alpha 1 (COL7A1). Un virus recombinant de l'herpès simplex-1 (HSV-1) (souche KOS), non intégrateur et à défaut de réplication, codant pour deux copies de la chaîne du collagène humain de type VII alpha 1 (COL7A1), insérées dans les régions du gène de la protéine d'infection cellulaire précoce 4 (ICP4) après délétion des deux copies des gènes ICP4, sous le contrôle du promoteur précoce immédiat du cytomégalovirus humain (hCMV) et du signal de polyadénylation de l'hormone de croissance bovine (bGHpA). Le gène de la protéine d'infection cellulaire précoce 22 (ICP22) est également supprimé.
beremagén geperpavec	Un virus herpes simplex deficiente para replicación que codifica para la cadena de colágeno humano de tipo VII alfa 1 (COL7A1). Un virus herpes simplex -1 (HSV-1) (cepa KOS) recombinante, no integrativo y deficiente en replicación, que codifica dos copias de la cadena de colágeno humano de tipo VII alfa 1 (COL7A1), insertadas en las regiones del gen de la proteína de infección celular inmediatamente temprana 4 (ICP4) tras la deleción de las dos copias de genes ICP4, bajo el control del promotor inmediatamente temprano del citomeglovirus humano (hCMV) y la señal de poliadenilación de la hormona de crecimiento bovina (bGHpA). El gen de la proteína de infección celular 22 (ICP22) está también delecionado.

cagrilintidum

cagrilintide	$N^{2.1}$-[*N*-(19-carboxynonadecanoyl)-L-γ-glutamyl]-[N^{14}>E, V^{17}>R, A^{25}>P, S^{28}>P, S^{29}>P, Y^{37}>P]-human amylin (islet amyloid polypeptide, IAPP, diabetes-associated peptide, DAP, insulinoma amyloid peptide, *INN: amlintide*), (35-40)-disulfide
cagrilintide	$N^{2.1}$-[*N*-(19-carboxynonadécanoyl)-L-γ-glutamyl]-[N^{14}>E, V^{17}>R, A^{25}>P, S^{28}>P, S^{29}>P, Y^{37}>P]-amyline humaine (polypeptide amyloïde des ilots, IAPP, peptide associé au diabète, DAP, polypeptide amyloïde de l'insulinome, *DCI: amlintide*), (35-40)-disulfure
cagrilintida	$N^{2.1}$-[*N*-(19-carboxinonadecanoil)-L-γ-glutamil]-[N^{14}>E, V^{17}>R, A^{25}>P, S^{28}>P, S^{29}>P, Y^{37}>P]-amilina humana (polipéptido amiloide de los islotes, IAPP, péptido asociado a la diabetes, DAP, polipéptido amiloide insulinoma, *DCI: amlintida*), (35-40)-disulfuro

$C_{194}H_{312}N_{54}O_{59}S_2$



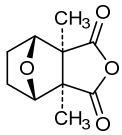
cantharidinum

cantharidin — (3a*R*,4*S*,7*R*,7a*S*)-3a,7a-dimethylhexahydro-4,7-epoxy-2-benzofuran-1,3-dione

cantharidine — (3a*R*,4*S*,7*R*,7a*S*)-3a,7a-diméthylhexahydro-4,7-époxy-2-benzofurane-1,3-dione

cantaridina — (3a*R*,4*S*,7*R*,7a*S*)-3a,7a-dimetilhexahidro-4,7-epoxi-2-benzofurano-1,3-diona

$C_{10}H_{12}O_4$



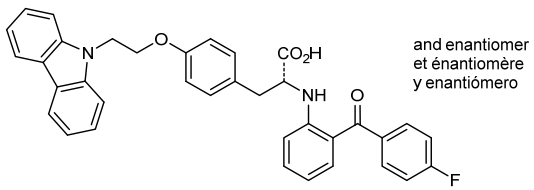
carfloglitazarum

carfloglitazar — *O*-[2-(9*H*-carbazol-9-yl)ethyl]-*N*-[2-(4-fluorobenzoyl)phenyl]-DL-tyrosine

carfloglitazar — *O*-[2-(9*H*-carbazol-9-yl)éthyl]-*N*-[2-(4-fluorobenzoyl)phényl]-DL-tyrosine

carfloglitazar — *O*-[2-(9*H*-carbazol-9-il)etil]-*N*-[2-(4-fluorobenzoil)fenil]-DL-tirosina

$C_{36}H_{29}FN_2O_4$



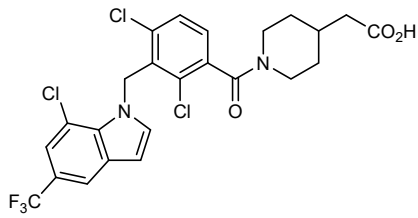
cedirogantum

cedirogant — [1-(2,4-dichloro-3-{[7-chloro-5-(trifluoromethyl)-1*H*-indol-1-yl]methyl}benzoyl)piperidin-4-yl]acetic acid

cédirogant — acide [1-(2,4-dichloro-3-{[7-chloro-5-(trifluorométhyl)-1*H*-indol-1-yl]méthyl}benzoyl)pipéridin-4-yl]acétique

cedirogant — ácido [1-(2,4-dicloro-3-{[7-cloro-5-(trifluorometil)-1*H*-indol-1-il]metil}benzoil)piperidin-4-il]acético

$C_{24}H_{20}Cl_3F_3N_2O_3$



cevaretigenum ritoparvovecum #

cevaretigene ritoparvovec

A non-replicating adeno-associated viral vector serotype 5 vector encoding human retinoid isomerohydrolase (RPE65).
A recombinant non-replicating adeno-associated viral vector serotype 5 (rAAV5), encoding codon-optimised human retinoid isomerohydrolase (retinal pigment epithelium-specific 65 kDa protein [RPE65]), under the control of the human RPE65 promoter and an SV40 poly(A) signal, flanked by AAV2 inverted terminal repeats (ITR).

cévarétigène ritoparvovec

Un vecteur adénoviral à réplication défectueuse de sérotype 5 et codant pour l'isomérohydrolase rétinoïde humaine (RPE65).
Un vecteur adénoviral recombinant à réplication défectueuse de sérotype 5 (rAAV5), codant pour une isomérohydrolase rétinoïde humaine, avec des codons optimisés (protéine de 65 kDa spécifique de l'épithélium pigmentaire rétinien [RPE65]), sous le contrôle du promoteur RPE65 humain et d'un signal SV40 poly(A), flanqué de répétitions terminales inversées (ITR) AAV2.

cevaretigén ritoparvovec

Un vector de virus adeno-asociado serotipo 5, no replicativo, que codifica para la isomerohidrolasa retinoide humana (RPE65).
Un vector de virus adeno-asociado recombinante serotipo 5, (rAAV5) no replicativo, que codifica para la isomerohidrolasa retinoide humana (proteína de 65 kDa específica del epitelio pigmentario retiniano [RPE65]) con los codones optimizados, bajo el control del promotor de RPE65 humano y una señal poly(A) de SV40, flanqueado por las repeticiones terminales invertidas (ITR) del AAV2.

cipaglucosidasum alfa #

cipaglucosidase alfa

human lysosomal α-glucosidase (acid alpha-glucosidase, acid maltase) fragment (57-952, 57-69 from the propeptide sequence), (1-896, 1-13 in the current sequence), produced in Chinese hamster ovary (CHO) cells, glycosylated;
human lysosomal α-glucosidase (acid alpha-glucosidase, GAA, acid maltase; EC 3.2.1.20) pre-pro-protein (57-952)-peptide (with 13 residues (57-69) of the propeptide (28-69)), produced in Chinese hamster ovary (CHO) cells, glycoform alfa

cipaglucosidase alfa

α-glucosidase lysosomale humaine (alpha-glucosidase acide, maltase acide) fragment (57-952, 57-69 de la séquence du propeptide), (1-896, 1-13 dans la séquence actuelle), produit dans des cellules ovariennes de hamster chinois (CHO), glycosylée;
α-glucosidase lysosomale humaine (alpha-glucosidase acide, GAA, maltase acide; EC 3.2.1.20) pré-pro-protéine (57-952)-peptide (avec 13 résidus (57-69) du propeptide (28-69)), produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

cipaglucosidasa alfa

α-glucosidasa humana lisosomal (ácido alfa-glucosidasa, ácido maltasa) fragmento (57-952, 57-69 de la secuencia propétido), (1-896, 1-13 en la secuencia actual), producido en células ováricas de hámster Chino (CHO), glisosiladas;
α-glucosidasa lisosomal humana (alfa glucosidasa ácida, GAA, maltasa ácida; EC 3.2.1.20) pre-pro-proteína (57-952)-péptido, (con 13 residuos (57-69) del propéptido (28-69)), producido en las células ováricas de hámster Chino (CHO), glicosilada alfa

Sequence / Séquence / Secuencia

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

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

Glycosylation sites / Sites de glycosylation / Posiciones de glicosilación
N84, N177, N334, N414, N596, N826, N869

cirtuvivintum

cirtuvivint

2-(4-methylpiperazin-1-yl)-*N*-[6-(1-methyl-1*H*-pyrazol-4-yl)isoquinolin-3-yl]pyridine-4-carboxamide

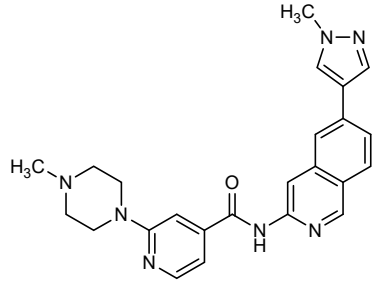
cirtuvivint

2-(4-méthylpipérazin-1-yl)-*N*-[6-(1-méthyl-1*H*-pyrazol-4-yl)isoquinoléin-3-yl]pyridine-4-carboxamide

cirtuvivint

2-(4-metilpiperazin-1-il)-*N*-[6-(1-metil-1*H*-pirazol-4-il)isoquinolein-3-il]piridina-4-carboxamida

$C_{24}H_{25}N_7O$



coprelotamabum #

coprelotamab	immunoglobulin G1-kappa, anti-[*Homo sapiens* ERBB2 (epidermal growth factor receptor 2, receptor tyrosine protein kinase erbB-2, EGFR2, HER2, HER-2, p185cerbB2, NEU, CD340)], humanized monoclonal antibody; gamma1 heavy chain humanized (1-450) [VH humanized (*Homo sapiens* IGHV3-66*01 (81.6%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (217) (121-218), hinge 1-15 (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-214')-disulfide with kappa light chain humanized (1'-214') [V-KAPPA humanized (*Homo sapiens* IGKV1-39*01 (86.3%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (229-229":232-232")-bisdisulfide, produced in Chinese hamster ovary (CHO)-DG44 cell line, glycoform alfa
coprélotamab	immunoglobuline G1-kappa, anti-[*Homo sapiens* ERBB2 (récepteur 2 du facteur de croissance épidermique, récepteur tyrosine-protéine kinase erbB-2, EGFR2, HER2, HER-2, p185c-erbB2, NEU, CD340)], anticorps monoclonal humanisé; chaîne lourde gamma1 humanisée (1-450) [VH humanisé (*Homo sapiens* IGHV3-66*01 (81.6%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (217) (121-218), charnière 1-15 (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-214')-disulfure avec la chaîne légère kappa humanisée (1'-214') [V-KAPPA humanisé (*Homo sapiens* IGKV1-39*01 (86.3%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (229-229":232-232")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) lignée cellulaire CHO-DG44, glycoforme alfa
coprelotamab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* ERBB2 (receptor 2 del factor de crecimiento epidérmico, receptor tirosina-proteína kinasa erbB-2, EGFR2, HER2, HER-2, p185c-erbB2, NEU, CD340)], anticuerpo monoclonal humanizado; cadena pesada gamma1 humanizada (1-450) [VH humanizado (*Homo sapiens* IGHV3-66*01 (81.6%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (217) (121-218), bisagra 1-15 (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-214')-disulfuro con la cadena ligera kappa humanizada (1'-214') [V-KAPPA humanizado (*Homo sapiens* IGKV1-39*01 (86.3%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (229-229":232-232")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular CHO-DG44, forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVESGGG LVQPGGSLRL SCAASGFNIK DTYIHWVRQA PGKGLEWVAR  50
IYPTNGYTRY ADSVKGRFTI SADTSKNTAY LQMNSLRAED TAVYYCSRWG 100
GDGFYAMDYW GQGTLVTVSS ASTKGPSVFP LAPSSKSTSG GTAALGCLVK 150
DYFPEPVTVS WNSGALTSGV HTFPAVLQSS GLYSLSSVVT VPSSSLGTQT 200
YICNVNHKPS NTKVDKKVEP KSCDKTHTCP PCPAPELLGG PSVFLFPPKP 250
KDTLMISRTP EVTCVVVDVS HEDPEVKFNW YVDGVEVHNA KTKPREEQYN 300
STYRVVSVLT VLHQDWLNGK EYKCKVSNKA LPAPIEKTIS KAKGQPREPQ 350
VYTLPPSRDE LTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPV 400
LDSDGSFFLY SKLTVDKSRW QQGNVFSCSV MHEALHNHYT QKSLSLSPGK 450
```

Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS LSASVGDRVT ITCRASQDVN TAVAWYQQKP GKAPKLLIYS  50
ASFLYSGVPS RFSGSRSGTD FTLTISSLQP EDFATYYCQQ HYTTPPTFGQ 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

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

Intra-H (C23-C104)	22-96	147-203	264-324	370-428
	22"-96"	147"-203"	264"-324"	370"-428"
Intra-L (C23-C104)	23'-88'	134'-194'		
	23'"-88'"	134'"-194'"		
Inter-H-L (h 5-CL 126)	223-214'	223"-214'"		
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 / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
450, 450"

cotoretigenum toliparvovecum

cotoretigene toliparvovec

A replication-defective adeno-associated viral vector encoding codon-optimised human retinitis pigmentosa GTPase regulator (RPGR).
A recombinant replication-defective adeno-associated viral vector serotype 8 (rAAV8) encoding codon-optimised human retinitis pigmentosa GTPase regulator (RPGR), under the control of human rhodopsin kinase (RK) promoter and bovine growth hormone poly(A) sequence, flanked by AAV2 inverted terminal repeats (ITR).

cotoretigène toliparvovec

Un vecteur adénoviral défectueux en terme de réplication et codant pour le régulateur de la GTPase de la rétinite pigmentaire humaine avec des codons optimisés (RPGR).
Un vecteur adénoviral recombinant de sérotype 8 (rAAV8) à réplication défectueuse codant pour un régulateur de la GTPase de la rétinite pigmentaire humaine (RPGR) avec des codons optimisés, sous contrôle du promoteur de la kinase de la rhodopsine humaine et de la séquence poly(A) de l'hormone de croissance bovine, flanqué de répétitions terminales inversées (ITR) de l'AAV2.

cotoretigén toliparvovec

Un vector de virus adeno-asociado, deficiente de replicación, que codifica para el regulador de la GTPasa implicado en la retinosis pigmentaria humana (RPGR) con los codones optimizados.
Un vector de virus adeno-asociado recombinante de serotipo 8 (rAAV8), deficiente de replicación, que codifica para el regulador de la GTPasa implicado en la retinosis pigmentaria humana (RPGR) con los codones optimizados, bajo el control del promotor de la rodopsin quinasa (RK) humana y la secuencia poly(A) de la hormona de crecimiento bovina, flanqueado por las repeticiones terminales invertidas (ITR) del AAV2.

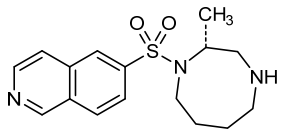
cotosudilum

cotosudil — 6-[(2*R*)-2-methyl-1,4-diazocane-1-sulfonyl]isoquinoline

cotosudil — 6-[(2*R*)-2-méthyl-1,4-diazocane-1-sulfonyl]isoquinoléine

cotosudil — 6-[(2*R*)-2-metil-1,4-diazocano-1-sulfonil]isoquinoleína

$C_{16}H_{21}N_3O_2S$



dafsolimabum #

dafsolimab — immunoglobulin G2B-kappa, anti-[CD3E (CD3 epsilon, Leu-4)], *Mus musculus* monoclonal antibody;
gamma2b heavy chain *Mus musculus* (1-456) [VH (*Mus musculus* IGHV1-4*01 (95.9%) -(IGHD) -IGHJ4*01 (94.1%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Mus musculus* IGHG2B*02 (100%) (CH1 (121-217), hinge 1-22 (218-239), CH2 (240-349), CH3 (350-454), CHS (455-456)) (121-456)], (135-213')-disulfide with kappa light chain *Mus musculus* (1'-213') [V-KAPPA (*Mus musculus* IGKV4-59*01 (100%) -IGKJ5*01 (100%)) CDR-IMGT [5.3.9] (27-31.49-51.88-96) (1'-106') -*Mus musculus* IGKC1*01 (100%) (107'-213')];
dimer (229-229":232-232":235-235":238-238")-tetrakisdisulfide, produced in SP2/0-derived mouse myeloma cells, glycoform alfa

dafsolimab — immunoglobuline G2B-kappa, anti-[CD3E (CD3 epsilon, Leu-4)], anticorps monoclonal *Mus musculus*;
chaîne lourde gamma2b *Mus musculus* ((1-456) [VH (*Mus musculus* IGHV1-4*01 (95.9%) -(IGHD) -IGHJ4*01 (94.1%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Mus musculus* IGHG2B*02 (100%) (CH1 (121-217), charnière 1-22 (218-239), CH2 (240-349), CH3 (350-454), CHS (455-456)) (121-456)], (135-213')-disulfure avec la chaîne légère kappa *Mus musculus* (1'-213') [V-KAPPA (*Mus musculus* IGKV4-59*01 (100%) -IGKJ5*01 (100%)) CDR-IMGT [5.3.9] (27-31.49-51.88-96) (1'-106') -*Mus musculus* IGKC1*01 (100%) (107'-213')];
dimère (229-229":232-232":235-235":238-238")-tétrakisdisulfure, produit par une ligne cellulaire dérivée de myélome murin SP2/0, glycoforme alfa

dafsolimab — inmunoglobulina G2B-kappa, anti-[CD3E (CD3 épsilon, Leu-4)], anticuerpo monoclonal *Mus musculus*;
cadena pesada gamma2b *Mus musculus* ((1-456) [VH (*Mus musculus* IGHV1-4*01 (95.9%) -(IGHD) -IGHJ4*01 (94.1%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Mus musculus* IGHG2B*02 (100%) (CH1 (121-217), bisagra 1-22 (218-239), CH2 (240-349), CH3 (350-454), CHS (455-456)) (121-456)], (135-213')-disulfuro con la cadena ligera kappa *Mus musculus* (1'-213') [V-KAPPA (*Mus musculus* IGKV4-59*01 (100%) -IGKJ5*01 (100%)) CDR-IMGT [5.3.9] (27-31.49-51.88-96) (1'-106') -*Mus musculus* IGKC1*01 (100%) (107'-213')];
dímero (229-229":232-232":235-235":238-238")-tetrakisdisulfuro, producido en una línea celular de mieloma murino SP2/0, forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLQQSGAE LARPGASVKM SCKASGYTFT SYTMHWVKQR PGQGLEWIGY  50
INPSSGYTNY IQRFKDKATL TADKSSSTAY MQVSSLTSED SAVYYCARGS 100
RYDYYGMDYW GQGTSVTVSS AKTTPPSVYP LAPGCGDTTG SSVTLGCLVK 150
GYFPESVTVT WNSGSLSSSV HTFPALLQSG LYTMSSSVTV PSSTWPSQTV 200
TCSVAHPASS TTVDKKLEPS GPISTINPCP PCKECHKCPA PNLEGGPSVF 250
IFPPNIKDVL MISLTPKVTC VVVDVSEDDP DVQISWFVNN VEVHTAQTQT 300
HREDYNSTIR VVSTLPIQHQ DWMSGKEFKC KVNNKDLPSP IERTISKIKG 350
LVRAPQVYIL PPPAEQLSRK DVSLTCLVVG FNPGDISVEW TSNGHTEENY 400
KDTAPVLDSD GSYFIYSKLN MKTSKWEKTD SFSCNVRHEG LKNYYLKKTI 450
SRSPGK                                                  456
```

Light chain / Chaîne légère / Cadena ligera

```
QIVLTQSPAI MSASPGEKVT MTCSASSSVS YMHWYQQKSG TSPKRWIYDT  50
SKLASGVPAR FSGSGSGTSY SLTISSMEAE DAATYYCQQW SSNPLTFGAG 100
TKLELKRADA APTVSIFPPS SEQLTSGGAS VVCFLNNFYP KDINVKWKID 150
GSERQNGVLN SWTDQDSKDS TYSMSSTLTL TKDEYERHNS YTCEATHKTS 200
TSPIVKSFNR NEC                                         213
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Post-translational modifications

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

Intra-H (C23-C104) 22-96 147-202 270-330 376-434
22"-96" 147"-202" 270"-330' 376"-434"
Intra-L (C23-C104) 23'-87" 133'-193'
23'"-87"" 133'"-193'"
Inter-H-L (CH1 11-CL 126) 135-213' 135"-213'"
Inter-H-H (h 12, h 15, h 18, h 21) 229-229" 232-232" 235-235" 238-238"

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

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
306, 306"

Fucosylated complex bi-antennary SP2/0-type glycans / glycanes de type SP2/0 bi-antennaires complexes fucosylés / glicanos de tipo SP2/0 biantenarios complejos fucosilados
C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
456, 456"

dafsolimabum setaritoxum

dafsolimab setaritox — immunoglobulin G2B-kappa, anti-[CD3E (CD3 epsilon, Leu-4)], *Mus musculus* monoclonal antibody conjugated to aglycosylated ricin toxin A (RTA);
gamma2b heavy chain *Mus musculus* (1-456) [VH (*Mus musculus* IGHV1-4*01 (95.9%) -(IGHD) -IGHJ4*01 (94.1%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Mus musculus* IGHG2B*02 (100%) (CH1 (121-217), hinge 1-22 (218-239), CH2 (240-349), CH3 (350-454), CHS (455-456)) (121-456)], (135-213')-disulfide with kappa light chain *Mus musculus* (1'-213') [V-KAPPA (*Mus musculus* IGKV4-59*01 (100%) -IGKJ5*01 (100%)) CDR-IMGT [5.3.9] (27-31.49-51.88-96) (1'-106') -*Mus musculus* IGKC1*01 (100%) (107'-213')];
dimer (229-229":232-232":235-235":238-238")-tetrakisdisulfide, produced in SP2/0-derived mouse myeloma cells, glycoform alfa, substituted at N^6 of an average of 1.6 lysyl residues with 4-[(1*RS*)-1-{[L-methionyl-ricin toxin A-chain (Met-RTA, non-glycosylated, produced in *Escherichia coli*)-S^{260}-yl]sulfanyl}ethyl]benzoyl groups

dafsolimab sétaritox — immunoglobuline G2B-kappa, anti-[CD3E (CD3 epsilon, Leu-4)], anticorps monoclonal *Mus musculus* conjugué à la toxine A de la ricine aglycosylée (RTA);
chaîne lourde gamma2b *Mus musculus* -(1-456) [VH (*Mus musculus* IGHV1-4*01 (95.9%) -(IGHD) -IGHJ4*01 (94.1%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Mus musculus* IGHG2B*02 (100%) (CH1 (121-217), charnière 1-22 (218-239), CH2 (240-349), CH3 (350-454), CHS (455-456)) (121-456)], (135-213')-disulfure avec la chaîne légère kappa *Mus musculus* (1'-213') [V-KAPPA (*Mus musculus* IGKV4-59*01 (100%) -IGKJ5*01 (100%)) CDR-IMGT [5.3.9] (27-31.49-51.88-96) (1'-106') -*Mus musculus* IGKC1*01 (100%) (107'-213')];
dimère (229-229":232-232":235-235":238-238")-tétrakisdisulfure, produit par une lignée cellulaire dérivée de myélome murin SP2/0, glycoforme alfa, substitué en N^6 sur un moyenne de 1.6 résidus lysyl par des groupes 4-[(1*RS*)-1-{[L-méthionyl-chaîne A de la toxine de ricine (Met-RTA, non-glycosylée, produite par *Escherichia coli*)-S^{260}-yl]sulfanyl}éthyl]benzoyle

dafsolimab setaritox

inmunoglobulina G2B-kappa, anti-[CD3E (CD3 épsilon, Leu-4)], anticuerpo monoclonal *Mus musculus* conjugado con la toxina A de la ricina aglicosilada (RTA);
cadena pesada gamma2b *Mus musculus* -(1-456) [VH (*Mus musculus* IGHV1-4*01 (95.9%) -(IGHD) -IGHJ4*01 (94.1%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Mus musculus* IGHG2B*02 (100%) (CH1 (121-217), bisagra 1-22 (218-239), CH2 (240-349), CH3 (350-454), CHS (455-456)) (121-456)], (135-213')-disulfuro con la cadena ligera kappa *Mus musculus* (1'-213') [V-KAPPA (*Mus musculus* IGKV4-59*01 (100%) -IGKJ5*01 (100%)) CDR-IMGT [5.3.9] (27-31.49-51.88-96) (1'-106') -*Mus musculus* IGKC1*01 (100%) (107'-213')];
dímero (229-229":232-232":235-235":238-238")-tetrakisdisulfuro, producido en una línea celular de mieloma murino SP2/0, forma glicosilada alfa, sustituída en N^6 de un promedio de 1,6 residuos de lisilo con grupos de 4-[(1*RS*)-1-{[L-metionil-cadena A de toxina de ricina (Met-RTA, no glicosilada, producida por *Escherichia coli*)-S^{260}-il]sulfanil}etil]benzoilo

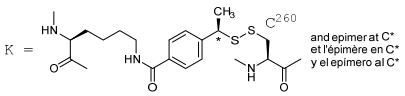
Heavy chain / Chaîne lourde / Cadena pesada
```
QVQLQQSGAE LARPGASVKM SCKASGYTFT SYTMHWVKQR PGQGLEWIGY  50
INPSSGYTNY IQRFKDKATL TADKSSSTAY MQVSSLTSED SAVYYCARGS 100
RYDYYGMDYW GQGTSVTVSS AKTTPPSVYP LAPGCGDTTG SSVTLGCLVK 150
GYFPESVTVT WNSGSLSSSV HTFPALLQSG LYTMSSSVTV PSSTWPSQTV 200
TCSVAHPASS TTVDKKLEPS GPISTINPCP PCKECHKCPA PNLEGGPSVF 250
IFPPNIKDVL MISLTPKVTC VVVDVSEDDP DVQISWFVNN VEVHTAQTQT 300
HREDYNSTIR VVSTLPIQHQ DWMSGKEFKC KVNNKDLPSP IERTISKIKG 350
LVRAPQVYIL PPPAEQLSRK DVSLTCLVVG FNPGDISVEW TSNGHTEENY 400
KDTAPVLDSD GSYFIYSKLN MKTSKWEKTD SFSCNVRHEG LKNYYLKKTI 450
SRSPGK                                                  456
```

Light chain / Chaîne légère / Cadena ligera
```
QIVLTQSPAI MSASPGEKVT MTCSASSSVS YMHWYQQKSG TSPKRWIYDT  50
SKLASGVPAR FSGSGSGTSY SLTISSMEAE DAATYYCQQW SSNPLTFGAG 100
TKLELKRADA APTVSIFPPS SEQLTSGGAS VVCFLNNFYP KDINVKWKID 150
GSERQNGVLN SWTDQDSKDS TYSMSSTLTL TKDEYERHNS YTCEATHKTS 200
TSPIVKSFNR NEC                                         213
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Met-Ricin A chain / Met-chaîne A de la Ricine / Met-cadena A de la Ricina
```
MIFPKQYPII NFTTAGATVQ SYTNFIRAVR GRLTTGADVR HDIPVLPNRV 50
GLPINQRFIL VELSNHAELS VTLALDVTNA YVVGYRAGNS AYFFHPDNQE 100
DAEAITHLFT DVQNRYTFAF GGNYDRLEQL AGNLRENIEL GNGPLEEAIS 150
ALYYYSTGGT QLPTLARSFI ICIQMISEAA RFQYIEGEMR TRIRYNRRSA 200
PDPSVITLEN SWGRLSTAIQ ESNQGAFASP IQLQRRNGSK FSVYDVSILI 250
PIIALMVYRC APPPSSQF                                    268
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 147-202 270-330 376-434
22"-96" 147"-202" 270"-330' 376'-434"
Intra-L (C23-C104) 23'-87' 133'-193'
23'"-87'" 133'"-193'"
Inter-H-L (CH1 11-CL 126) 135-213' 135"-213'"
Inter-H-H (h 12, h 15, h 18, h 21) 229-229" 232-232" 235-235" 238-238"
Met-RTA: C172 = Cys-SH,
C260 = Cys-S-S-CH(CH3)-p-C6H4-CO-[N6-Lys(H,L)]

Conjugation sites / Sites de conjugaison / Posiciones de coniugación
major: K74 K141' K206'
K74" K141'" K206'"
minor: K326 K329 K349 K442 K447 K18' K52' K168'
K326" K329" K349" K442" K447" K18'" K52'" K168'"



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

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
306, 306"
Fucosylated complex bi-antennary SP2/0-type glycans / glycanes de type SP2/0 bi-antennaires complexes fucosylés / glicanos de tipo SP2/0 biantenarios complejos fucosilados.

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
456, 456"

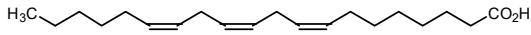
daleutonum

daleuton (8*Z*,11*Z*,14*Z*)-icosa-8,11,14-trienoic acid

daleuton acide (8*Z*,11*Z*,14*Z*)-icosa-8,11,14-triénoïque

daleutón ácido (8*Z*,11*Z*,14*Z*)-icosa-8,11,14-trienoico

$C_{20}H_{34}O_2$



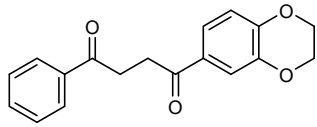
dalosirvatum

dalosirvat 1-(2,3-dihydro-1,4-benzodioxin-6-yl)-4-phenylbutane-1,4-dione

dalosirvat 1-(2,3-dihydro-1,4-benzodioxin-6-yl)-4-phénylbutane-1,4-dione

dalosirvat 1-(2,3-dihidro-1,4-benzodioxin-6-il)-4-fenilbutano-1,4-diona

$C_{18}H_{16}O_4$



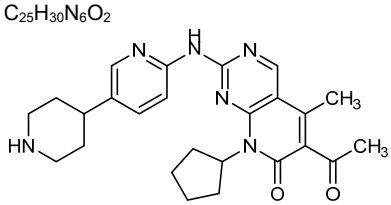
dalpiciclibum

dalpiciclib 6-acetyl-8-cyclopentyl-5-methyl-2-{[5-(piperidin-4-yl)pyridin-2-yl]amino}pyrido[2,3-*d*]pyrimidin-7(8*H*)-one

dalpiciclib 6-acétyl-8-cyclopentyl-5-méthyl-2-{[5-(pipéridin-4-yl)pyridin-2-yl]amino}pyrido[2,3-*d*]pyrimidin-7(8*H*)-one

dalpiciclib 6-acetil-8-ciclopentil-5-metil-2-{[5-(piperidin-4-il)piridin-2-il]amino}pirido[2,3-*d*]pirimidin-7(8*H*)-ona

$C_{25}H_{30}N_6O_2$

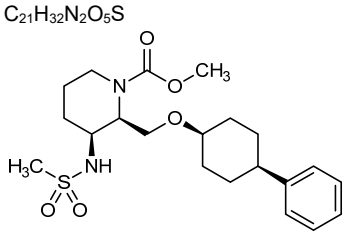


danavorextonum

danavorexton methyl (2*R*,3*S*)-3-(methanesulfonamido)-2-{[(*cis*-4-phenylcyclohexyl)oxy]methyl}piperidine-1-carboxylate

danavorexton (2*R*,3*S*)-3-(méthanesulfonamido)-2-{[(*cis*-4-phénylcyclohexyl)oxy]méthyl}pipéridine-1-carboxylate de méthyle

danavorextón (2*R*,3*S*)-2-{[(*cis*-4-fenilciclohexil)oxi]metil}-3-(metanosulfonamido)piperidina-1-carboxilato de metilo



dapiglutidum

dapiglutide — human glucagon like peptide-2 (GLP-2) analogue; $N^{6.16}$-[*N*-(17-carboxyheptadecanoyl)-L-γ-glutamyl]-[A^{2}>Aib (2-methylalanine), D^{3}>E, S^{7}>T, D^{8}>S, M^{10}>L, N^{11}>A, N^{16}>K, L^{17}>Q, N^{24}>A, T^{29}>H]human glucagon-like peptide 2 (GLP-2)

dapiglutide — analogue du peptide 2 semblable au glucagon (GLP-2) humain; $N^{6.16}$-[*N*-(17-carboxyheptadécanoyl)-L-γ-glutamyl]-[A^{2}>Aib (2-méthylalanine), D^{3}>E, S^{7}>T, D^{8}>S, M^{10}>L, N^{11}>A, N^{16}>K, L^{17}>Q, N^{24}>A, T^{29}>H]peptide 2 semblable au glucagon humain (GLP-2)

dapiglutida — análogo del péptido 2 semejante al glucagón (GLP-2) humano; $N^{6.16}$-[*N*-(17-carboxiheptadecanoil)-L-γ-glutamil]-[A^{2}>Aib (2-metilalanina), D^{3}>E, S^{7}>T, D^{8}>S, M^{10}>L, N^{11}>A, N^{16}>K, L^{17}>Q, N^{24}>A, T^{29}>H]]péptido 2 semejante al glucagón humano (GLP-2)

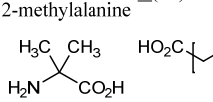
$C_{192}H_{302}N_{46}O_{57}$

Sequence / Séquence / Secuencia

HXEGSFTSEL ATILDKQAAR DFIAWLIQHK ITD 33

Modified residues / Résidus modifiés / Restos modificados

X (2) 2-methylalanine



K(16) N^{6}-[17-carboxyheptadecanoyl-γ-Glu]-Lys

daplusiranum

daplusiran — *all-P-ambo-O*-[(2*R*,3*S*)-2-(hydroxymethyl)oxolan-3-yl] hydrogen 5'-*O*-({[(2*R*,3*S*)-3-({[(*cis*-4-{(3*S*,8*S*)-17-[(2-acetamido-2-deoxy-β-D-galactopyranosyl)oxy]-3,8-bis[(2-{2-[(2-acetamido-2-deoxy-β-D-galactopyranosyl)oxy]ethoxy}ethyl)carbamoyl]-6,11-dioxo-15-oxa-2,7,12-triazaheptadecan-1-oyl}cyclohexyl)oxy]hydroxyphosphorothioyl}oxy)oxolan-2-yl]methoxy}hydroxyphosphorothioyl)-2'-*O*-methylguanylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-*O*-methylguanylyl-(3'→5')-2'-*O*-methylguanylyl-(3'→5')-2'-*O*-methyladenylyl-(3'→5')-2'-*O*-methylcytidylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-deoxy-2'-fluorocytidylyl-(3'→5')-2'-deoxy-2'-fluorouridylyl-(3'→5')-2'-deoxy-2'-fluorocytidylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-*O*-methylcytidylyl-(3'→5')-2'-*O*-methyladenylyl-(3'→5')-2'-*O*-methyladenylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-*O*-methylcytidylyl-(3'→5')-2'-*O*-methyl-*P*-thio-3'-uridylate duplex with *all-P-ambo*-2'-*O*-methyl-*P*-thioadenylyl-(3'→5')-2'-deoxy-2'-fluoro-*P*-thioguanylyl-(3'→5')-2'-*O*-methyl-*P*-thioadenylyl-(3'→5')-2'-deoxy-2'-fluoroadenylyl-(3'→5')-2'-*O*- methyladenylyl-

(3'→5')-2'-deoxy-2'-fluoroadenylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-deoxy-2'-fluorouridylyl-(3'→5')-2'-*O*-methylguanylyl-(3'→5')-2'-deoxy-2'-fluoroadenylyl-(3'→5')-2'-*O*-methylguanylyl-(3'→5')-2'-deoxy-2'-fluoroadenylyl-(3'→5')-2'-*O*-methylguanylyl-(3'→5')-2'-deoxy-2'-fluoroadenylyl-(3'→5')-2'-*O*-methyladenylyl-(3'→5')-2'-deoxy-2'-fluoroguanylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-deoxy-2'-fluorocytidylyl-(3'→5')-2'-*O*-methylcytidylyl-(3'→5')-2'-*O*-methyl-*P*-thioadenylyl-(3'→5')-2'-*O*-methylcytidine

daplusiran

tout-P-ambo-5'-*O*-({[(2*R*,3*S*)-3-({[(*cis*-4-{(3*S*,8*S*)-17-[(2-acétamido-2-désoxy-β-D-galactopyranosyl)oxy]-3,8-bis[(2-{2-[(2-acétamido-2-désoxy-β-D-galactopyranosyl)oxy]éthoxy}éthyl)carbamoyl]-6,11-dioxo-15-oxa-2,7,12-triazaheptadécan-1-oyl}cyclohexyl)oxy]hydroxyphosphorothioyl}oxy)oxolan-2-yl]méthoxy}hydroxyphosphorothioyl)-2'-*O*-méthylguanylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-*O*-méthylguanylyl-(3'→5')-2'-*O*-méthylguanylyl-(3'→5')-2'-*O*-méthyladénylyl-(3'→5')-2'-*O*-méthylcytidylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-désoxy-2'-fluorocytidylyl-(3'→5')-2'-désoxy-2'-fluorouridylyl-(3'→5')-2'-désoxy-2'-fluorocytidylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-*O*-méthylcytidylyl-(3'→5')-2'-*O*-méthyladénylyl-(3'→5')-2'-*O*-méthyladénylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-*O*-méthylcytidylyl-(3'→5')-hydrogéno-2'-*O*-méthyl-*P*-thio-3'-uridylate de *O*-[(2*R*,3*S*)-2-(hydroxyméthyl)oxolan-3-yle]
duplex avec *tout-P-ambo*-2'-*O*-méthyl-*P*-thioadénylyl-(3'→5')-2'-désoxy-2'-fluoro-*P*-thioguanylyl-(3'→5')-2'-*O*-méthyl-*P*-thioadénylyl-(3'→5')-2'-désoxy-2'-fluoroadénylyl-(3'→5')-2'-*O*-méthyladénylyl-(3'→5')-2'-désoxy-2'-fluoroadénylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-désoxy-2'-fluorouridylyl-(3'→5')-2'-*O*-méthylguanylyl-(3'→5')-2'-désoxy-2'-fluoroadénylyl-(3'→5')-2'-*O*-méthylguanylyl-(3'→5')-2'-désoxy-2'-fluoroadénylyl-(3'→5')-2'-*O*-méthylguanylyl-(3'→5')-2'-désoxy-2'-fluoroadénylyl-(3'→5')-2'-*O*-méthyladénylyl-(3'→5')-2'-désoxy-2'-fluoroguanylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-désoxy-2'-fluorocytidylyl-(3'→5')-2'-*O*-méthylcytidylyl-(3'→5')-2'-*O*-méthyl-*P*-thioadénylyl-(3'→5')-2'-*O*-méthylcytidine

daplusirán

todo-P-ambo-5'-*O*-({[(2*R*,3*S*)-3-({[(*cis*-4-{(3*S*,8*S*)-17-[(2-acetamido-2-desoxi-β-D-galactopiranosil)oxi]-3,8-bis[(2-{2-[(2-acetamido-2-desoxi-β-D-galactopiranosil)oxi]etoxi}etil)carbamoil]-6,11-dioxo-15-oxa-2,7,12-triazaheptadecan-1-oil}ciclohexil)oxi]hidroxifosforotioil}oxi)oxolan-2-il]metoxi}hidroxifosforotioil)-2'-*O*-metilguanilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metilguanilil-(3'→5')-2'-*O*-metilguanilil-(3'→5')-2'-*O*-metiladenilil-(3'→5')-2'-*O*-metilcitidilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-desoxi-2'-fluorocitidilil-(3'→5')-2'-desoxi-2'-fluorouridilil-(3'→5')-2'-desoxi-2'-fluorocitidilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metilcitidilil-(3'→5')-2'-*O*-metiladenilil-(3'→5')-2'-*O*-metiladenilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metilcitidilil-(3'→5')-hidrógeno-2'-*O*-metil-*P*-tio-3'-uridilato de *O*-[(2*R*,3*S*)-2-(hidroximetil)oxolan-3-ilo]
duplex con *todo-P-ambo*-2'-*O*-metil-*P*-tioadenilil-(3'→5')-2'-desoxi-2'-fluoro-*P*-tioguanilil-(3'→5')-2'-*O*-metil-*P*-tioadenilil-(3'→5')-2'-desoxi-2'-fluoroadenilil-(3'→5')-2'-*O*-metiladenilil-(3'→5')-2'-desoxi-2'-fluoroadenilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-desoxi-2'-fluorouridilil-(3'→5')-2'-*O*-metilguanilil-(3'→5')-2'-desoxi-2'-fluoroadenilil-(3'→5')-2'-*O*-metilguanilil-(3'→5')-2'-desoxi-2'-fluoroadenilil-(3'→5')-2'-*O*-metilguanilil-(3'→5')-2'-desoxi-2'-fluoroadenilil-(3'→5')-2'-*O*-metiladenilil-(3'→5')-2'-desoxi-2'-fluoroguanilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-desoxi-2'-fluorocitidilil-(3'→5')-2'-*O*-metilcitidilil-(3'→5')-2'-*O*-metil-*P*-tioadenilil-(3'→5')-2'-*O*-metilcitidina

$C_{492}H_{650}F_{12}N_{163}O_{310}P_{43}S_7$

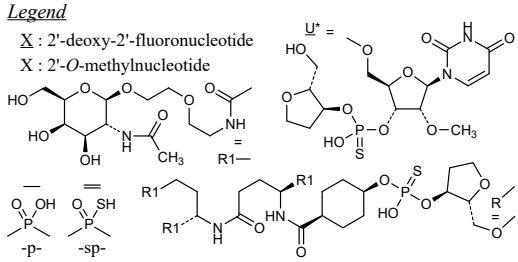
(3'-5') R=G-U-G-G-A-C-U-U-C-U-C-U-C-A-A-U-U-U-U-C-U*

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

Legend

X : 2'-deoxy-2'-fluoronucleotide

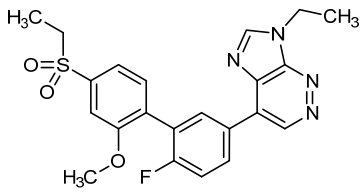
X : 2'-*O*-methylnucleotide



darigabatum

darigabat	4-[4'-(ethanesulfonyl)-6-fluoro-2'-methoxy[1,1'-biphenyl]-3-yl]-7-ethyl-7*H*-imidazo[4,5-*c*]pyridazine
darigabat	4-[4'-(éthanesulfonyl)-6-fluoro-2'-méthoxy[1,1'-biphényl]-3-yl]-7-éthyl-7*H*-imidazo[4,5-*c*]pyridazine
darigabat	4-[4'-(etanosulfonil)-6-fluoro-2'-metoxi[1,1'-bifenil]-3-il]-7-etil-7*H*-imidazo[4,5-*c*]piridazina

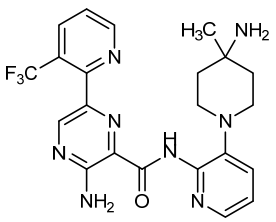
$C_{22}H_{21}FN_4O_3S$



darovasertibum

darovasertib	3-amino-*N*-[3-(4-amino-4-methylpiperidin-1-yl)pyridin-2-yl]-6-[3-(trifluoromethyl)pyridin-2-yl]pyrazine-2-carboxamide
darovasertib	3-amino-*N*-[3-(4-amino-4-méthylpipéridin-1-yl)pyridin-2-yl]-6-[3-(trifluorométhyl)pyridin-2-yl]pyrazine-2-carboxamide
darovasertib	3-amino-*N*-[3-(4-amino-4-metilpiperidin-1-il)piridin-2-il]-6-[3-(trifluorometil)piridin-2-il]pirazina-2-carboxamida

$C_{22}H_{23}F_3N_8O$



daxdilimabum #

daxdilimab	immunoglobulin G1-lambda, anti-[*Homo sapiens* LILRA4 (leukocyte immunoglobulin like receptor A4, ILT7, CD85g)], *Homo sapiens* monoclonal antibody; gamma1 heavy chain *Homo sapiens* (1-452) [VH (*Homo sapiens* IGHV1-18*01 (98.0%) -(IGHD) -IGHJ2*01 (92.9%)) CDR-IMGT [8.8.15] (26-33.51-58.97-111) (1-122) -*Homo sapiens* IGHG1*03 (100%) G1m3, nG1m1 (CH1 R120 (219) (123-220), hinge 1-15 (221-235), CH2 (236-345), CH3 E12 (361), M14 (363) (346-450), CHS (451-452)) (123-452)], (225-215')-disulfide with lambda light chain *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV2-14*01 (98.0%) -IGLJ2*01 (90.9%)) CDR-IMGT [9.3.10] (26-34.52-54.91-100) (1'-110') -*Homo sapiens* IGLC2*01 (100%) (111'-216')]; dimer (231-231'':234-234'')-bisdisulfide, produced in a Chinese hamster ovary (CHO)-derived cell line, glycoform alfa
daxdilimab	immunoglobuline G1-lambda, anti-[*Homo sapiens* LILRA4 (récepteur A4 immunoglobuline-like des leucocytes, ILT7, CD85g)], anticorps monoclonal *Homo sapiens*; chaîne lourde gamma1 *Homo sapiens* (1-452) [VH (*Homo sapiens* IGHV1-18*01 (98.0%) -(IGHD) -IGHJ2*01 (92.9%)) CDR-IMGT [8.8.15] (26-33.51-58.97-111) (1-122) -*Homo sapiens* IGHG1*03 (100%) G1m3, nG1m1 (CH1 R120 (219) (123-220), charnière 1-15 (221-235), CH2 (236-345), CH3 E12 (361), M14 (363) (346-450), CHS (451-452)) (123-452)], (225-215')-disulfure avec la chaîne légère lambda *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV2-14*01 (98.0%) -IGLJ2*01 (90.9%)) CDR-IMGT [9.3.10] (26-34.52-54.91-100) (1'-110') -*Homo sapiens* IGLC2*01 (100%) (111'-216')]; dimère (231-231'':234-234'')-bisdisulfure, produite dans une lignée cellulaire dérivée des cellules ovariennes de hamster chinois (CHO), glycoforme alfa
daxdilimab	inmunoglobulina G1-lambda, anti-[*Homo sapiens* LILRA4 (receptor A4 inmunoglobulina-like de los leucocitos, ILT7, CD85g)], anticuerpo monoclonal *Homo sapiens*; cadena pesada gamma1 *Homo sapiens* (1-452) [VH (*Homo sapiens* IGHV1-18*01 (98.0%) -(IGHD) -IGHJ2*01 (92.9%)) CDR-IMGT [8.8.15] (26-33.51-58.97-111) (1-122) -*Homo sapiens* IGHG1*03 (100%) G1m3, nG1m1 (CH1 R120 (219) (123-220), bisagra 1-15 (221-235), CH2 (236-345), CH3 E12 (361), M14 (363) (346-450), CHS (451-452)) (123-452)], (225-215')-disulfuro con la cadena ligera lambda *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV2-14*01 (98.0%) -IGLJ2*01 (90.9%)) CDR-IMGT [9.3.10] (26-34.52-54.91-100) (1'-110') -*Homo sapiens* IGLC2*01 (100%) (111'-216')]; dímero (231-231'':234-234'')-bisdisulfuro, producido en una línea celular derivada de las células ováricas de hámster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

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QVQLQQSGAE VKKPGASVKV SCKASGYTFT SYGISWVRQA PGQGLEWMGW  50
ISAYNGNTNY AQKLQGRVTM TIDTSTSTAY MELRSLRSDD TAVYYCARNG 100
LWGWDSDAFD IWGRGTLVTV SSASTKGPSV FPLAPSSKST SGGTAALGCL 150
VKDYFPEPVT VSWNSGALTS GVHTFPAVLQ SSGLYSLSSV VTVPSSSLGT 200
QTYICNVNHK PSNTKVDKRV EPKSCDKTHT CPPCPAPELL GGPSVFLFPP 250
KPKDTLMISR TPEVTCVVVD VSHEDPEVKF NWYVDGVEVH NAKTKPREEQ 300
YNSTYRVVSV LTVLHQDWLN GKEYKCKVSN KALPAPIEKT ISKAKGQPRE 350
PQVYTLPPSR EEMTKNQVSL TCLVKGFYPS DIAVEWESNG QPENNYKTTP 400
PVLDSDGSFF LYSKLTVDKS RWQQGNVFSC SVMHEALHNH YTQKSLSLSP 450
GK                                                      452
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Light chain / Chaîne légère / Cadena ligera

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QSALTQPASV SGSPGQSITI SCTGTSSDVG GYNYVSWYQQ HPGKAPKLMI  50
YDVSNRPSGV SNRFSGSKSG NTASLTISGL QAEDEADYYC SSYTSSSTVV 100
FGGGTKVTVL GQPKAAPSVT LFPPSSEELQ ANKATLVCLI SDFYPGAVTV 150
AWKADSSPVK AGVETTTPSK QSNNKYAASS YLSLTPEQWK SHRSYSCQVT 200
HEGSTVEKTV APTECS                                       216
```

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) 22'-90' 138'-197'
22'"-90'" 138'"-197'"
Inter-H-L (h 5-CL 126) 225-215' 225"-215'"
Inter-H-H (h 11, h 14) 231-231" 234-234"

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

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

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
452, 452"

dazodalibepum #

dazodalibep

engineered binding protein (1-85) anti-(human CD40 ligand) derived from the human tenascin third fibronectin type III domain (785-869), fused via the peptidyl linker ^{86}GGGGGGGGGGGGGGG^{100} to engineered binding protein (101-190) anti-(human CD40 ligand) derived from the human tenascin third fibronectin type III domain (780-869), fused via the peptidyl linker ^{191}GGGGGGGGGG^{200} to human albumin (201-785), variant (C^{34}>S^{234}), produced in *Escherichia coli*; [tenascin (785-869)-peptide (1-85) (containing a third fibronectin type III domain), engineered for binding to the CD40 ligand (CD40L)]-[G_{15} linker (86-100)]-[tenascin (780-869)-peptide (101-190) (containing a third fibronectin type III domain), engineered for binding to the CD40 ligand (CD40L)]-[G_{10} linker (91-100)]-[(C^{34}>S)-human serum albumin (HSA)] fusion protein, produced in *Escherichia coli*

dazodalibep

protéine de liaison mise au point (1-85) anti-(ligand de CD40 humain) dérivée du troisième domaine de la fibronectine de type III de la ténascine humaine, fusionnée via un peptide liant ^{86}GGGGGGGGGGGGGGG^{100} à la protéine de liaison mise au point (101-190) anti-(ligand de CD40 humain) dérivée du troisième domaine de la fibronectine de type III de la ténascine humaine, fusionnée via un peptide liant ^{191}GGGGGGGGGG^{200} à l'albumine humaine (201-785), variant (C^{34}>S^{234}), produite par *Escherichia coli*;
protéine de fusion de [ténascine (785-869)-peptide (1-85) (contenant un troisième domaine de fibronectine de type III), conçu pour se lier au ligand de CD40 (CD40L)]-[peptide G_{15} de liaison (86-100)]-[ténascine (780-869)-peptide (101-190) (contenant un troisième domaine de fibronectine de type III), conçu pour se lier au ligand de CD40 (CD40L)]-[peptide G_{10} de liaison (91-100)]-[(C^{34}>S)-albumine sérique humaine (ASH)], produite par *Escherichia coli*

dazodalibep

proteína de unión diseñada (1-85) anti-(ligando CD40 humano) derivada de un tercer dominio de fibronectina tipo III de tenascina humana (785-869), fusionada a través de un conector ^{86}GGGGGGGGGGGGGGG^{100} a la proteína de unión diseñada (101-190) anti-(ligando CD40 humano) derivado de un tercer dominio de fibronectina tipo III de tenascina humana (780-869), fusionado a través de un conector peptidil ^{191}GGGGGGGGGG^{200} a la albúmina humana (201-785), variante (C^{34}>S^{234}), producida en *Escherichia coli*;
proteína de fusión de [tenascina (785-869)-péptido (1-85) (que contiene un tercer dominio de fibronectina tipo III), diseñado para unirse al ligando de CD40 (CD40L)]-[péptido conector G_{15} (86-100)]-[tenascina (780-869)-péptido (101-190) (que contiene un tercer dominio de fibronectina tipo III), diseñado para unirse al ligando de CD40 (CD40L)]-[péptido conector G_{10} (91-100)]-[(C^{34}>S)-albúmina sérica humana (ASH)], producida por *Escherichia coli*

Sequence / Séquence / Secuencia

```
SQIEVKDVTD TTALITWSDD FGEYVWCELT YGIKDVPGDR TTIDLWYHHA   50
HYSIGNLKPD TEYEVSLICR SGDMSSNPAK ETFTTGGGGG GGGGGGGGGG  100
RLDAPSQIEV KDVTDTTALI TWSDDFGEYV WCELTYGIKD VPGDRTTIDL  150
WYHHAHYSIG NLKPDTEYEV SLICRSGDMS SNPAKETFTT GGGGGGGGGG  200
DAHKSEVAHR FKDLGEENFK ALVLIAFAQY LQQSPFEDHV KLVNEVTEFA  250
KTCVADESAE NCDKSLHTLF GDKLCTVATL RETYGEMADC CAKQEPERNE  300
CFLQHKDDNP NLPRLVRPEV DVMCTAFHDN EETFLKKYLY EIARRHPYFY  350
APELLFFAKR YKAAFTECCQ AADKAACLLP KLDELRDEGK ASSAKQRLKC  400
ASLQKFGERA FKAWAVARLS QRFPKAEFAE VSKLVTDLTK VHTECCHGDL  450
LECADDRADL AKYICENQDS ISSKLKECCE KPLLEKSHCI AEVENDEMPA  500
DLPSLAADFV ESKDVCKNYA EAKDVFLGMF LYEYARRHPD YSVVLLLRLA  550
KTYETTLEKC CAAADPHECY AKVFDEFKPL VEEPQNLIKQ NCELFEQLGE  600
YKFQNALLVR YTKKVPQVST PTLVEVSRNL GKVGSKCCKH PEAKRMPCAE  650
DYLSVVLNQL CVLHEKTPVS DRVTKCCTES LVNRRPCFSA LEVDETYVPK  700
EFNAETFTFH ADICTLSEKE RQIKKQTALV ELVKHKPKAT KEQLKAVMDD  750
FAAFVEKCCK ADDKETCFAE EGKKLVAASQ AALGL                  785
```

Mutations / Mutations / Mutaciones
$F^{18,123}$>S, $K^{19,124}$>D, $P^{20,125}$>D, $L^{21,126}$>F, $A^{22,127}$>G, $I^{24,129}$>Y, $D^{25,130}$>V, $G^{26,131}$>W, $I^{27,132}$>C, $T^{46,151}$>W, $E^{47,152}$>Y, $D^{48,153}$>H, $E^{49,154}$>H, $N^{50,155}$>A, $Q^{51,156}$>H, $S^{69,174}$>C, $R^{71,176}$>S, C^{234}>S

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
27-69, 132-174, 253-262, 275-290, 291-301, 324-368, 369-377, 400-445, 446-453, 465-478, 479-489, 516-560, 561-569, 592-637, 638-648, 661-676, 677-687, 714-758, 759-767

Glycosylation sites / Sites de glycosylation / Posiciones de glicosilación
none / aucune / ninguna

depemokimabum #
depemokimab

immunoglobulin G1-kappa, anti-[*Homo sapiens* IL5 (interleukin 5, IL-5)], humanized monoclonal antibody;
gamma1 heavy chain humanized (1-449) [VH humanized (*Homo sapiens* IGHV2-70*19 (75.8%) -(IGHD) -IGHJ4*01 (85.7%)) CDR-IMGT [8.7.13] (26-33.51-57.96-108) (1-119) -*Homo sapiens* IGHG1*03 G1m3, nG1m1, G1v21 CH2 Y15.1, T16, E18 (CH1 R120 (216) (120-217), hinge 1-15 (218-232), CH2 M15.1>Y (254), S16>T (256), T18>E (258) (233-342), CH3 E12 (358), M14 (360) (343-447), CHS (448-449)) (120-449)], (222-220')-disulfide with kappa light chain humanized (1'-220') [V-KAPPA (*Homo sapiens* IGKV4-1*01 (91.1%) -IGKJ2*02 (90.9%)) 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')]; dimer (228-228":231-231")-bisdisulfide, produced in Chinese hamster ovary (CHO)-K1 cell line lacking the glutamine synthetase (GS) gene, glycoform alfa

dépémokimab

immunoglobuline G1-kappa, anti-[*Homo sapiens* IL5 (interleukine 5, IL-5)], anticorps monoclonal humanisé;
chaîne lourde gamma1 humanisée (1-449) [VH humanisé (*Homo sapiens* IGHV2-70*19 (75.8%) -(IGHD) -IGHJ4*01 (85.7%)) CDR-IMGT [8.7.13] (26-33.51-57.96-108) (1-119) -*Homo sapiens* IGHG1*03 G1m3, nG1m1, G1v21 CH2 Y15.1, T16, E18 (CH1 R120 (216) (120-217), charnière 1-15 (218-232), CH2 M15.1>Y (254), S16>T (256), T18>E (258) (233-342), CH3 E12 (358), M14 (360) (343-447), CHS (448-449)) (120-449)], (222-220')-disulfure avec la chaîne légère kappa humanisée (1'-220') [V-KAPPA humanisé (*Homo sapiens* IGKV4-1*01 (91.1%) -IGKJ2*02 (90.9%)) 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')];
dimère (228-228":231-231")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) lignée cellulaire CHO-K1 ne présentant pas le gène de la glutamine synthétase, glycoforme alfa

depemokimab

inmunoglobulina G1-kappa, anti-[*Homo sapiens* IL5 (interleukina 5, IL-5)], anticuerpo monoclonal humanizado;
cadena pesada gamma1 humanizada (1-449) [VH humanizado (*Homo sapiens* IGHV2-70*19 (75.8%) -(IGHD) -IGHJ4*01 (85.7%)) CDR-IMGT [8.7.13] (26-33.51-57.96-108) (1-119) -*Homo sapiens* IGHG1*03 G1m3, nG1m1, G1v21 CH2 Y15.1, T16, E18 (CH1 R120 (216) (120-217), bisagra 1-15 (218-232), CH2 M15.1>Y (254), S16>T (256), T18>E (258) (233-342), CH3 E12 (358), M14 (360) (343-447), CHS (448-449)) (120-449)], (222-220')-disulfuro con la cadena ligera kappa humanizada (1'-220') [V-KAPPA humanizado (*Homo sapiens* IGKV4-1*01 (91.1%) -IGKJ2*02 (90.9%)) 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 (228-228":231-231")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular CHO-K1 en ausencia del gen glutamina sintetasa (GS), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVTLRESGPA LVKPTQTLTL TCTVSGFSLT GSSVHWVRQP PGKGLEWLGV  50
IWASGGTDYN SALMSRLSIS KDTSRNQVVL TMTNMDPVDT ATYYCARDPP 100
SGLLRLDYWG RGTLVTVSSA STKGPSVFPL APSSKSTSGG TAALGCLVKD 150
YFPEPVTVSW NSGALTSGVH TFPAVLQSSG LYSLSSVVTV PSSSLGTQTY 200
ICNVNHKPSN TKVDKRVEPK SCDKTHTCPP CPAPELLGGP SVFLFPPKPK 250
DTLYITREPE VTCVVVDVSH EDPEVKFNWY VDGVEVHNAK TKPREEQYNS 300
TYRVVSVLTV LHQDWLNGKE YKCKVSNKAL PAPIEKTISK AKGQPREPQV 350
YTLPPSREEM TKNQVSLTCL VKGFYPSDIA VEWESNGQPE NNYKTTPPVL 400
DSDGSFFLYS KLTVDKSRWQ QGNVFSCSVM HEALHNHYTQ KSLSLSPGK  449
```

Light chain / Chaîne légère / Cadena ligera

```
DIVMTQSPDS LAVSLGERAT INCKSSQSLL NSGNQKNYLA WYQQKPGQPP  50
KLLIYGASTR ESGVPDRFSG SGSGTDFTLT ISSLQAEDVA VYYCQNVHSF 100
PFTFGGGTKL 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) 22-95 146-202 263-323 369-427
22"-95" 146"-202" 263"-323" 369"-427"
Intra-L (C23-C104) 23'-94' 140'-200'
23'"-94'" 140'"-200'"
Inter-H-L (h 5-CL 126) 222-220' 222"-220'"
Inter-H-H (h 11, h 14) 228-228" 231-231"

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

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

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
449, 449"

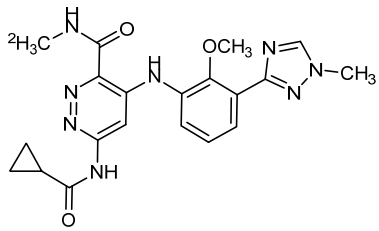
deucravacitinibum

deucravacitinib — 6-(cyclopropanecarboxamido)-4-[2-methoxy-3-(1-methyl-1*H*-1,2,4-triazol-3-yl)anilino]-*N*-($^2H_3$)methylpyridazine-3-carboxamide

deucravacitinib — 6-(ciclopropanocarboxamido)-4-[2-méthoxy-3-(1-méthyl-1*H*-1,2,4-triazol-3-yl)anilino]-*N*-($^2H_3$)méthylpyridazine-3-carboxamide

deucravacitinib — 6-(ciclopropanocarboxamido)-*N*-($^2H_3$)metil-4-[3-(1-metil-1*H*-1,2,4-triazol-3-il)-2-metoxianilino]piridazina-3-carboxamida

$C_{20}H_{19}{}^2H_3N_8O_3$



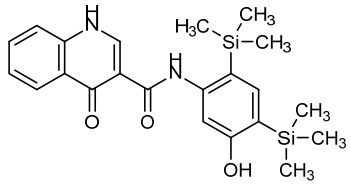
dirocaftorum

dirocaftor — *N*-[5-hydroxy-2,4-bis(trimethylsilyl)phenyl]-4-oxo-1,4-dihydroquinoline-3-carboxamide

dirocaftor — *N*-[5-hydroxy-2,4-bis(triméthylsilyl)phényl]-4-oxo-1,4-dihydroquinoléine-3-carboxamide

dirocaftor — *N*-[5-hidroxi-2,4-bis(trimetilsilil)fenil]-4-oxo-1,4-dihidroquinoleína-3-carboxamida

$C_{22}H_{28}N_2O_3Si_2$



divozilimabum #

divozilimab — immunoglobulin G1-kappa, anti-[*Homo sapiens* MS4A1 (membrane-spanning 4-domains subfamily A member 1, CD20)], monoclonal antibody;
gamma1 heavy chain (1-451) [VH (*Homo sapiens* IGHV1-46*01 (86.7%) -(IGHD) -IGHJ1*01 (86.7%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -*Homo sapiens* IGHG1*03 (100%) G1m3, nG1m1 (CH1 R120 (218) (122-219), hinge 1-15 (220-234), CH2 (235-344), CH3 E12 (360), M14 (362) (345-449), CHS (450-451)) (122-451)], (224-213')-disulfide with kappa light chain (1'-213') [V-KAPPA (*Mus musculus* IGKV4-72*01 (85.3%) -IGKJ1*01 (90.9%)/*Homo sapiens* IGKV3D-11*02 (73.3%) -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 (230-230'':233-233'')-bisdisulfide, produced in a Chinese hamster ovary (CHO)-S cell line, glycoform alfa

divozilimab

immunoglobuline G1-kappa, anti-[*Homo sapiens* MS4A1 (membre 1 de la sous-famille A à 4 domaines transmembranaires, CD20)], anticorps monoclonal;
chaîne lourde gamma1 (1-451) [VH (*Homo sapiens* IGHV1-46*01 (86.7%) -(IGHD) -IGHJ1*01 (86.7%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -*Homo sapiens* IGHG1*03 (100%) G1m3, nG1m1 (CH1 R120 (218) (122-219), charnière 1-15 (220-234), CH2 (235-344), CH3 E12 (360), M14 (362) (345-449), CHS (450-451)) (122-451)], (224-213')-disulfure avec la chaîne légère kappa (1'-213') [V-KAPPA (*Mus musculus* IGKV4-72*01 (85.3%) -IGKJ1*01 (90.9%)/*Homo sapiens* IGKV3D-11*02 (73.3%) -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 (230-230":233-233")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) lignée cellulaire CHO-S, glycoforme alfa

divozilimab

inmunoglobulina G1-kappa, anti-[*Homo sapiens* MS4A1 (miembro 1 de la subfamilia A con 4 dominios transmembranarios, CD20)], anticuerpo monoclonal;
cadena pesada gamma1 (1-451) [VH (*Homo sapiens* IGHV1-46*01 (86.7%) -(IGHD) -IGHJ1*01 (86.7%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -*Homo sapiens* IGHG1*03 (100%) G1m3, nG1m1 (CH1 R120 (218) (122-219), bisagra 1-15 (220-234), CH2 (235-344), CH3 E12 (360), M14 (362) (345-449), CHS (450-451)) (122-451)], (224-213')-disulfuro con la cadena ligera kappa (1'-213') [V-KAPPA (*Mus musculus* IGKV4-72*01 (85.3%) -IGKJ1*01 (90.9%)/*Homo sapiens* IGKV3D-11*02 (73.3%) -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 (230-230":233-233")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular CHO-S, forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVQPGAE VVKPGASVKV SCKASGYTFT SYNMHWVRQA PGRGLEWMGA  50
IYPGNGDTSY NQKFKGRVTM TRDKSTSTVY MELSSLRSED TAVYYCARST 100
YYGGDWYFNV WGQGTLVTVS SASTKGPSVF PLAPSSKSTS GGTAALGCLV 150
KDYFPEPVTV SWNSGALTSG VHTFPAVLQS SGLYSLSSVV TVPSSSLGTQ 200
TYICNVNHKP SNTKVDKRVE PKSCDKTHTC PPCPAPELLG GPSVFLFPPK 250
PKDTLMISRT PEVTCVVVDV SHEDPEVKFN WYVDGVEVHN AKTKPREEQY 300
NSTYRVVSVL TVLHQDWLNG KEYKCKVSNK ALPAPIEKTI SKAKGQPREP 350
QVYTLPPSRE EMTKNQVSLT CLVKGFYPSD IAVEWESNGQ PENNYKTTPP 400
VLDSDGSFFL YSKLTVDKSR WQQGNVFSCS VMHEALHNHY TQKSLSLSPG 450
K                                                       451
```

Light chain / Chaîne légère / Cadena ligera

```
QIVLSQSPAI LSASPGERVT LTCRASSSVS YIHWFQQKPG KAPKPLIYAT  50
SNLASGVPSR FSGSGSGTDF SLTISRVEPE DFAVYYCQQW TSNPPTFGGG 100
TKVEIKRTVA APSVFIFPPS DEQLKSGTAS VVCLLNNFYP REAKVQWKVD 150
NALQSGNSQE SVTEQDSKDS TYSLSSTLTL SKADYEKHKV YACEVTHQGL 200
SSPVTKSFNR GEC                                          213
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 148-204 265-325 371-429
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, h 14) 230-230" 233-233"

N-terminal glutaminyl cyclization to pyroglutamyl (pE, 5-oxoprolyl)
L VL Q1:
1', 1'"

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.

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
451, 451"

ebronucimabum #

ebronucimab

immunoglobulin G1-lambda2, anti-[*Homo sapiens* PCSK9 (proprotein convertase subtilisin/kexin type 9, neural apoptosis-regulated convertase 1, NARC1, NARC-1, proprotein convertase 9, PC9)], *Homo sapiens* monoclonal antibody;
gamma1 heavy chain *Homo sapiens* (1-453) [VH (*Homo sapiens* IGHV3-21*01 (91.8%) -(IGHD) - IGHJ3*01 (100%)) CDR-IMGT [8.8.16] (26-33.51-58.97-112) (1-123)-*Homo sapiens* IGHG1*01 (100%), G1m17,1 (CH1 K120 (220) (124-221), hinge 1-15 (222-236), CH2 (237-346), CH3 D12 (362), L14 (364) (347-451), CHS (452-453)) (124-453)], (226-216')-disulfide with lambda2 light chain *Homo sapiens* (1'-217') [V-LAMBDA (*Homo sapiens* IGLV2-11*01 (81.6%) -IGLJ1*01 (90.9%)) CDR-IMGT [9.3.11] (26-34.52-54.91-101) (1'-111') -*Homo sapiens* IGLC2*01 (100%) (112'-217')];
dimer (232-232":235-235")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

ébronucimab

immunoglobuline G1-lambda2, anti-[*Homo sapiens* PCSK9 (proprotéine convertase subtilisine/kexine type 9, convertase 1 régulée par l'apoptose neuronale, NARC1, NARC-1, proprotéine convertase 9, PC9)], anticorps monoclonal *Homo sapiens*;
chaîne lourde gamma1 *Homo sapiens* (1-453) [VH (*Homo sapiens* IGHV3-21*01 (91.8%) -(IGHD) - IGHJ3*01 (100%)) CDR-IMGT [8.8.16] (26-33.51-58.97-112) (1-123) -*Homo sapiens* IGHG1*01 (100%), G1m17,1 (CH1 K120 (220) (124-221), charnière 1-15 (222-236), CH2 (237-346), CH3 D12 (362), L14 (364) (347-451), CHS (452-453)) (124-453)], (226-216')-disulfure avec la chaîne légère lambda2 *Homo sapiens* (1'-217') [V-LAMBDA (*Homo sapiens* IGLV2-11*01 (81.6%) -IGLJ1*01 (90.9%)) CDR-IMGT [9.3.11] (26-34.52-54.91-101) (1'-111') -*Homo sapiens* IGLC2*01 (100%) (112'-217')];
dimère (232-232":235-235")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

ebronucimab

inmunoglobulina G1-lambda2, anti-[*Homo sapiens* PCSK9 (proproteína convertasa subtilisina/kexina tipo 9, convertasa 1 regulada por la apoptosis neuronal, NARC1, NARC-1, proproteína convertasa 9, PC9)], anticuerpo monoclonal *Homo sapiens*;
cadena pesada gamma1 *Homo sapiens* (1-453) [VH (*Homo sapiens* IGHV3-21*01 (91.8%) -(IGHD) - IGHJ3*01 (100%)) CDR-IMGT [8.8.16] (26-33.51-58.97-112) (1-123) -*Homo sapiens* IGHG1*01 (100%), G1m17,1 (CH1 K120 (220) (124-221), bisagra 1-15 (222-236), CH2 (237-346), CH3 D12 (362), L14 (364) (347-451), CHS (452-453)) (124-453)], (226-216')-disulfuro con la cadena ligera lambda2 *Homo sapiens* (1'-217') [V-LAMBDA (*Homo sapiens* IGLV2-11*01 (81.6%) -IGLJ1*01 (90.9%)) CDR-IMGT [9.3.11] (26-34.52-54.91-101) (1'-111') -*Homo sapiens* IGLC2*01 (100%) (112'-217')];
dímero (232-232":235-235")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVESGGG LVQPGRSLRL SCAASGFTFS SYSMNWVRQA PGKGLEWVSG  50
ISSSSSYISY ADSVQGRFTI SRDNGKNSLY LQMNSLRAED TALYFCAREY 100
DFWSAYYDAF DVWGQGTMVT VSSASTKGPS VFPLAPSSKS TSGGTAALGC 150
LVKDYFPEPV TVSWNSGALT SGVHTFPAVL QSSGLYSLSS VVTVPSSSLG 200
TQTYICNVNH KPSNTKVDKK VEPKSCDKTH TCPPCPAPEL LGGPSVFLFP 250
PKPKDTLMIS RTPEVTCVVV DVSHEDPEVK FNWYVDGVEV HNAKTKPREE 300
QYNSTYRVVS VLTVLHQDWL NGKEYKCKVS NKALPAPIEK TISKAKGQPR 350
EPQVYTLPPS RDELTKNQVS LTCLVKGFYP SDIAVEWESN GQPENNYKTT 400
PPVLDSDGSF FLYSKLTVDK SRWQQGNVFS CSVMHEALHN HYTQKSLSLS 450
PGK                                                     453
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Light chain / Chaîne légère / Cadena ligera

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QSELTQPRSV SGSPGQSVTI SCTGTSRNIG GGNDVHWYQQ HPGKAPKLLI  50
SGVIERSSGV PDRFSGSKSG NTASLTISGL QAEDEADYYC QSFDGSLSGS 100
VFGTGTDVTV LGQPKAAPSV TLFPPSSEEL QANKATLVCL ISDFYPGAVT 150
VAWKADSSPV KAGVETTTPS KQSNNKYAAS SYLSLTPEQW KSHRSYSCQV 200
THEGSTVEKT VAPTECS                                      217
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Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 150-206 267-327 373-431
22"-96" 150"-206" 267"-327" 373"-431"
Intra-L (C23-C104) 22'-90' 139'-198'
22'"-90'" 139'"-198'"
Inter-H-L (h 5-CL 126) 226-216' 226"-216"
Inter-H-H (h 11, h 14) 232-232" 235-235"

N-terminal glutaminyl cyclization to pyroglutamyl (pE, 5-oxoprolyl)
L VL Q1:
1', 1'"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
303, 303"
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 / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
453, 453"

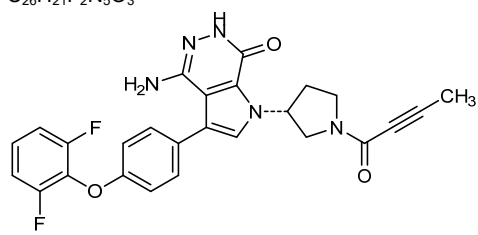
edralbrutinibum

edralbrutinib — 4-amino-1-[(3*R*)-1-(but-2-ynoyl)pyrrolidin-3-yl]-3-[4-(2,6-difluorophenoxy)phenyl]-1,6-dihydro-7*H*-pyrrolo[2,3-*d*]pyridazin-7-one

édralbrutinib — 4-amino-1-[(3*R*)-1-(but-2-ynoyl)pyrrolidin-3-yl]-3-[4-(2,6-difluorophénoxy)phényl]-1,6-dihydro-7*H*-pyrrolo[2,3-*d*]pyridazin-7-one

edralbrutinib — 4-amino-1-[(3*R*)-1-(but-2-inoil)pirrolidin-3-il]-3-[4-(2,6-difluorofenoxi)fenil]-1,6-dihidro-7*H*-pirrolo[2,3-*d*]piridazin-7-ona

$C_{26}H_{21}F_2N_5O_3$



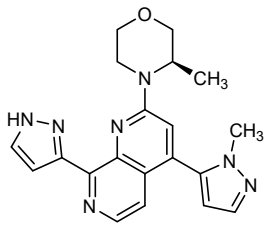
elimusertibum

elimusertib — 2-[(3*R*)-3-methylmorpholin-4-yl]-4-(1-methyl-1*H*-pyrazol-5-yl)-8-(1*H*-pyrazol-3-yl)-1,7-naphthyridine

élimusertib — 2-[(3*R*)-3-méthylmorpholin-4-yl]-4-(1-méthyl-1*H*-pyrazol-5-yl)-8-(1*H*-pyrazol-3-yl)-1,7-naphtyridine

elimusertib 2-[(3*R*)-3-metilmorfolin-4-il]-4-(1-metil-1*H*-pirazol-5-il)-8-(1*H*-pirazol-3-il)-1,7-naftiridina

$C_{20}H_{21}N_7O$



eluvixtamabum #

eluvixtamab immunoglobulin scFv-scFv, anti-[*Homo sapiens* CD33 (sialic acid binding Ig-like lectin 3, SIGLEC3, SIGLEC-3, gp67, p67)] and anti-[*Homo sapiens* CD3E (CD3 epsilon)], monoclonal antibody single chain, bispecific;
IG scFv-scFv single chain, anti-CD33 and anti-CD3E (1-511) [scFv-VH-V-kappa anti-CD33 (1-250) [VH (*Homo sapiens* IGHV1-18*01 (82.7%) -(IGHD) -IGHJ4*01 (93.3%)) CDR-IMGT [8.8.15] (26-33.51-58.97-111) (1-122)-15-mer tris(tetraglycyl-seryl) linker (123-137) -V-KAPPA (*Homo sapiens* IGKV4-1*01 (83.2%) -IGKJ5*01 (100%)) CDR-IMGT [12.3.9] (164-175.193-195.232-240) (138-250)] -6-mer seryl-tetraglycyl-seryl linker (251-256) -scFv-VH-V-lambda anti-CD3E (257-505) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD)-IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (282-289.307-316.355-370) (257-381) -15-mer tris(tetraglycyl-seryl) linker (382-396) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (422-430.448-450.487-495) (397-505)] -hexahistidine (506-511)], non-glycosylated, produced in Chinese hamster ovary (CHO) cells

éluvixtamab immunoglobuline scFv-scFv, anti-[*Homo sapiens* CD33 (lectine 3 de type Ig-like liant l'acide sialique, SIGLEC3, SIGLEC-3, gp67, p67)] et anti-[*Homo sapiens* CD3E (CD3 epsilon)], anticorps monoclonal à chaîne unique, bispécifique;
IG scFv-scFv à chaîne unique, anti-CD33 et anti-CD3E (1-511) [scFv-VH-V-kappa anti-CD33 (1-250) [VH (*Homo sapiens* IGHV1-18*01 (82.7%) -(IGHD) -IGHJ4*01 (93.3%)) CDR-IMGT [8.8.15] (26-33.51-58.97-111) (1-122)-15-mer tris(tétraglycyl-séryl) linker (123-137) -V-KAPPA (*Homo sapiens* IGKV4-1*01 (83.2%) -IGKJ5*01 (100%)) CDR-IMGT [12.3.9] (164-175.193-195.232-240) (138-250)] -6-mer séryl-tétraglycyl-séryl linker (251-256) -scFv-VH-V-lambda anti-CD3E (257-505) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD)-IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (282-289.307-316.355-370) (257-381) -15-mer tris(tétraglycyl-séryl) linker (382-396) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%) CDR-IMGT [9.3.9] (422-430.448-450.487-495) (397-505)] -hexahistidine (506-511)], non-glycosylé, produit dans des cellules ovariennes de hamster chinois (CHO)

eluvixtamab inmunoglobulina scFv-scFv, anti-[*Homo sapiens* CD33 (lectina 3 de tipo Ig-like aglutinando el ácido siálico, SIGLEC3, SIGLEC-3, gp67, p67)] y anti-[*Homo sapiens* CD3E (CD3 épsilon)], anticuerpo monoclonal con cadena única, biespecífico;

IG scFv-scFv con cadena única, anti-CD33 y anti-CD3E (1-511) [scFv-VH-V-kappa anti-CD33 (1-250) [VH (*Homo sapiens* IGHV1-18*01 (82.7%) -(IGHD) -IGHJ4*01 (93.3%)) CDR-IMGT [8.8.15] (26-33.51-58.97-111) (1-122)-15-mer tris(tetraglicil-seril) linker (123-137) -V-KAPPA (*Homo sapiens* IGKV4-1*01 (83.2%) -IGKJ5*01 (100%)) CDR-IMGT [12.3.9] (164-175.193-195.232-240) (138-250)] -6-mer seril-tetraglicil-seril linker (251-256) -scFv-VH-V-lambda anti-CD3E (257-505) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD)-IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (282-289.307-316.355-370) (257-381) -15-mer tris(tetraglicil-seril) linker (382-396) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%) CDR-IMGT [9.3.9] (422-430.448-450.487-495) (397-505)] -hexahistidina (506-511)], no glicosilado, producido en las células ováricas de hamster chino (CHO)

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Heavy chain / Chaîne lourde / Cadena pesada
QVQLVQSGAE VKKPGESVKV SCKASGYTFT NYGMNWVKQA PGQGLEWMGW  50
INTYTGEPTY ADKFQGRVTM TTDTSTSTAY MEIRNLGGDD TAVYYCARWS 100
WSDGYYVYFD YWGQGTSVTV SSGGGGSGGG GSGGGGSDIV MTQSPDSLTV 150
SLGERTTINC KSSQSVLDSS TNKNSLAWYQ QKPGQPPKLL LSWASTRESG 200
IPDRFSGSGS GTDFTLTIDS PQPEDSATYY CQQSAHFPIT FGQGTRLEIK 250
SGGGGSEVQL VESGGGLVQP GGSLKLSCAA SGFTFNKYAM NWVRQAPGKG 300
LEWVARIRSK YNNYATYYAD SVKDRFTISR DDSKNTAYLQ MNNLKTEDTA 350
VYYCVRHGNF GNSYISYWAY WGQGTLVTVS SGGGGSGGGG SGGGGSQTVV 400
TQEPSLTVSP GGTVTLTCGS STGAVTSGNY PNWVQQKPGQ APRGLIGGTK 450
FLAPGTPARF SGSLLGGKAA LTLSGVQPED EAEYYCVLWY SNRWVFGGGT 500
KLTVLHHHHH H                                            511
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Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-V (C23 C104) 22-96 160-231 278-354 418-486

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

No N-glycosylation sites / pas de sites de N-glycosylation / ningùn posición de N-glycosilación
Aglycosylated

emerfetamabum #
emerfetamab

immunoglobulin scFv-scFv-scFc, anti-[*Homo sapiens* CD33 (sialic acid binding Ig-like lectin 3, SIGLEC3, SIGLEC-3, gp67, p67)] and anti-[*Homo sapiens* CD3E (CD3 epsilon, Leu-4)], monoclonal antibody single chain (scFv)2-scFc, bispecific;
IG scFv-scFv-scFc single chain, anti-CD33 and anti-CD3E (1-993) [scFv-VH-V-kappa anti-CD33 (1-250) [VH (*Homo sapiens* IGHV1-18*01 G49>C (44) (81.6%) -(IGHD) -IGHJ4*01 (93.3%)) CDR-IMGT [8.8.15] (26-33.51-58.97-111) (1-122) -15-mer tris(tetraglycyl-seryl) linker (123-137) -V-KAPPA (*Homo sapiens* IGKV4-1*01 (83.2%) -IGKJ5*01 Q120>C (243) (91.7%)) CDR-IMGT [12.3.9] (164-175.193-195.232-240) (138-250)] -6-mer seryl-tetraglycyl-seryl linker (251-256) -scFv-VH-V-lambda anti-CD3E (257-505) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (282-289.307-316.355-370) (257-381) -15-mer tris(tetraglycyl-seryl) linker (382-396) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (422-430.448-450.487-495) (397-505)] -4-mer tetraglycyl linker (506-509) -scFc (h-CH2-CH3)-(h-CH2-CH3) (510-993) [*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (hinge 6-15 (510-519), CH2 R83>C (581), N84.4>G (586), V85>C (591) (520-629), CH3 E12 (645), M14 (647) (630-734), CHS (735-736)) (510-736) -30-mer hexakis(tetraglycyl-seryl) linker (737-766) -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (hinge 6-15 (767-776), CH2 R83>C (838), N84.4>G (843), V85>C (848) (777-886), CH3 E12 (902), M14 (904) (887-991), CHS (992-993)) (767-993)]], non-glycosylated, produced in Chinese hamster ovary (CHO) cells

émerfétamab	immunoglobuline scFv-scFv-scFc, anti-[*Homo sapiens* CD33 (lectine 3 de type Ig-like liant l'acide sialique, SIGLEC3, SIGLEC-3, gp67, p67)], et anti-[*Homo sapiens* CD3E (CD3 epsilon, Leu-4)], anticorps monoclonal à chaîne unique (scFv)2-scFc, bispécifique; IG scFv-scFv-scFc chaîne unique, anti-CD33 et anti-CD3E (1-993) [scFv-VH-V-kappa anti-CD33 (1-250) [VH (*Homo sapiens* IGHV1-18*01 G49>C (44) (81.6%) -(IGHD) -IGHJ4*01 (93.3%)) CDR-IMGT [8.8.15] (26-33.51-58.97-111) (1-122) -15-mer-tris(tétraglycyl-séryl) linker (123-137) -V-KAPPA (*Homo sapiens* IGKV4-1*01 (83.2%) -IGKJ5*01 Q120>C (243) (91.7%)) CDR-IMGT [12.3.9] (164-175.193-195.232-240) (138-250)] -6-mer séryl-tétraglycyl-séryl linker (251-256) -scFv-VH-V-lambda anti-CD3E (257-505) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (282-289.307-316.355-370) (257-381) -15-mer tris(tétraglycyl-séryl) linker (382-396) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (422-430.448-450.487-495) (397-505)] -4-mer-tétraglycyl linker (506-509) -scFc (h-CH2-CH3)-(h-CH2-CH3) (510-993) [*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (charnière 6-15 (510-519), CH2 R83>C (581), N84.4>G (586), V85>C (591) (520-629), CH3 E12 (645), M14 (647) (630-734), CHS (735-736)) (510-736) -30-mer hexakis(tétraglycyl-séryl) linker (737-766) -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (charnière 6-15 (767-776), CH2 R83>C (838), N84.4>G (843), V85>C (848) (777-886), CH3 E12 (902), M14 (904) (887-991), CHS (992-993)) (767-993)]], non-glycosylé, produit dans des cellules ovariennes de hamster chinois (CHO)
emerfetamab	inmunoglobulina scFv-scFv-scFc, anti-[*Homo sapiens* CD33 (lectina 3 de tipo Ig-like aglutinando el ácido siálico, SIGLEC3, SIGLEC-3, gp67, p67)], y anti-[*Homo sapiens* CD3E (CD3 épsilon, Leu-4)], anticuerpo monoclonal con cadena única (scFv)2-scFc, biespecífico; IG scFv-scFv-scFc cadena única, anti-CD33 y anti-CD3E (1-993) [scFv-VH-V-kappa anti-CD33 (1-250) [VH (*Homo sapiens* IGHV1-18*01 G49>C (44) (81.6%) -(IGHD) -IGHJ4*01 (93.3%)) CDR-IMGT [8.8.15] (26-33.51-58.97-111) (1-122) -15-mer-tris(tetraglicil-seril) linker (123-137) -V-KAPPA (*Homo sapiens* IGKV4-1*01 (83.2%) -IGKJ5*01 Q120>C (243) (91.7%)) CDR-IMGT [12.3.9] (164-175.193-195.232-240) (138-250)] -6-mer seril-tetraglicil-seril linker (251-256) -scFv-VH-V-lambda anti-CD3E (257-505) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (282-289.307-316.355-370) (257-381) -15-mer tris(tetraglicil-seril) linker (382-396) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (422-430.448-450.487-495) (397-505)] -4-mer-tetraglicil linker (506-509) -scFc (h-CH2-CH3)-(h-CH2-CH3) (510-993) [*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (bisagra 6-15 (510-519), CH2 R83>C (581), N84.4>G (586), V85>C (591) (520-629), CH3 E12 (645), M14 (647) (630-734), CHS (735-736)) (510-736) -30-mer hexakis(tetraglicil-seril) linker (737-766) -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (bisagra 6-15 (767-776), CH2 R83>C (838), N84.4>G (843), V85>C (848) (777-886), CH3 E12 (902), M14 (904) (887-991), CHS (992-993)) (767-993)]], no glicosilado, producido en las células ováricas de hamster chino (CHO)

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGESVKV SCKASGYTFT NYGMNWVKQA PGQCLEWMGW  50
INTYTGEPTY ADKFQGRVTM TTDTSTSTAY MEIRNLGGDD TAVYYCARWS 100
WSDGYYVYFD YWGQGTSVTV SSGGGGSGGG GSGGGGSDIV MTQSPDSLTV 150
SLGERTTINC KSSQSVLDSS TNKNSLAWYQ QKPGQPPKLL LSWASTRESG 200
IPDRFSGSGS GTDFTLTIDS PQPEDSATYY CQQSAHFPIT FGCGTRLEIK 250
SGGGGSEVQL VESGGGLVQP GGSLKLSCAA SGFTFNKYAM NWVRQAPGKG 300
LEWVARIRSK YNNYATYYAD SVKDRFTISR DDSKNTAYLQ MNNLKTEDTA 350
VYYCVRHGNF GNSYISYWAY WGQGTLVTVS SGGGGSGGGG SGGGGSQTVV 400
TQEPSLTVSP GGTVTLTCGS STGAVTSGNY PNWVQQKPGQ APRGLIGGTK 450
FLAPGTPARF SGSLLGGKAA LTLSGVQPED EAEYYCVLWY SNRWVFGGGT 500
KLTVLGGGGD KTHTCPPCPA PELLGGPSVF LFPPKPKDTL MISRTPEVTC 550
VVVDVSHEDP EVKFNWYVDG VEVHNAKTKP CEEQYGSTYR CVSVLTVLHQ 600
DWLNGKEYKC KVSNKALPAP IEKTISKAKG QPREPQVYTL PPSREEMTKN 650
QVSLTCLVKG FYPSDIAVEW ESNGQPENNY KTTPPVLDSD GSFFLYSKLT 700
VDKSRWQQGN VFSCSVMHEA LHNHYTQKSL SLSPGKGGGG SGGGGSGGGG 750
SGGGGSGGGG SGGGGSDKTH TCPPCPAPEL LGGPSVFLFP PKPKDTLMIS 800
RTPEVTCVVV DVSHEDPEVK FNWYVDGVEV HNAKTKPCEE QYGSTYRCVS 850
VLTVLHQDWL NGKEYKCKVS NKALPAPIEK TISKAKGQPR EPQVYTLPPS 900
REEMTKNQVS LTCLVKGFYP SDIAVEWESN GQPENNYKTT PPVLDSDGSF 950
FLYSKLTVDK SRWQQGNVFS CSVMHEALHN HYTQKSLSLS PGK        993
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Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro

Intra-V (C23 C104)	22-96	160-231	278-354	418-486	
Intra-C (C23-C104)	550-610	656-714	807-867	913-971	
Intra-CH2 (C83-C85)	581-591	838-848			
Inter-VH-VL (C49-C120)	44-243				
Inter-h11 (h 11 - h 11)	515-772				
Inter-h14 (h 14 - h 14)	518-775				

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

No N-glycosylation sites / pas de sites de N-glycosylation / ningún posición de N-glicosilación
CH2 N84.4>G:
586, 843
Aglycosylated

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
CHS K2:
993

enibarcimabum

enibarcimab	immunoglobulin G1-kappa, anti-[*Homo sapiens* ADM (adrenomedullin)], monoclonal antibody; gamma1 heavy chain (1-448) [VH (*Homo sapiens* IGHV1-69*01 (86.5%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (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)], (221-219')-disulfide with kappa light chain (1'-219') [V-KAPPA (*Mus musculus* IGKV1-117*01 (88.0%) -IGKJ2*01 (100%)/*Homo sapiens* IGKV2-30*01 (88.0%) -IGKJ2*01 (91.7%)) CDR-IMGT [11.3.9] (27-37.55-57.94-102) (1'-112') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (158), V101 (196) (113'-219')]; dimer (227-227'':230-230'')-bisdisulfide, produced in Chinese hamster ovary (CHO)-DG44 cell line, glycoform alfa
énibarcimab	immunoglobuline G1-kappa, anti-[*Homo sapiens* ADM (adrénomédulline)], anticorps monoclonal; chaîne lourde gamma1 (1-448) [VH (*Homo sapiens* IGHV1-69*01 (86.5%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (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)], (221-219')-disulfure avec la chaîne légère kappa (1'-219') [V-KAPPA (*Mus musculus* IGKV1-117*01 (88.0%) -IGKJ2*01 (100%)/*Homo sapiens* IGKV2-30*01 (88.0%) -IGKJ2*01 (91.7%)) CDR-IMGT [11.3.9] (27-37.55-57.94-102) (1'-112') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (158), V101 (196) (113'-219')]; dimère (227-227'':230-230'')-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) lignée cellulaire CHO-DG44, glycoforme alfa

enibarcimab

inmunoglobulina G1-kappa, anti-[*Homo sapiens* ADM (adrenomedulina)], anticuerpo monoclonal;
cadena pesada gamma1 (1-448) [VH (*Homo sapiens* IGHV1-69*01 (86.5%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (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)], (221-219')-disulfuro con la cadena ligera kappa (1'-219') [V-KAPPA (*Mus musculus* IGKV1-117*01 (88.0%) -IGKJ2*01 (100%)/*Homo sapiens* IGKV2-30*01 (88.0%) -IGKJ2*01 (91.7%)) CDR-IMGT [11.3.9] (27-37.55-57.94-102) (1'-112') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (158), V101 (196) (113'-219')];
dímero (227-227":230-230")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular CHO-DG44, forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGSSVKV SCKASGYTFS RYWIEWVRQA PGQGLEWIGE  50
ILPGSGSTNY NQKFQGRVTI TADTSTSTAY MELSSLRSED TAVYYCTEGY 100
EYDGFDYWGQ GTTVTVSSAS 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
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Light chain / Chaîne légère / Cadena ligera

```
DVVLTQSPLS LPVTLGQPAS ISCRSSQSIV YSNGNTYLEW YLQRPGQSPR  50
LLIYRVSNRF SGVPDRFSGS GSGTDFTLKI SRVEAEDVGV YYCFQGSHIP 100
YTFGGGTKLE 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) 22-96 145-201 262-322 368-426
22"-96" 145"-201" 262"-322" 368"-426"
Intra-L (C23-C104) 23'-93' 139'-199'
23'"-93'" 139'"-199'"
Inter-H-L (h 5-CL 126) 221-219' 221"-219'"
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.

enomimeranum #

enomimeran

Messenger RNA encoding melanoma-associated antigen 3 (MAGE-A3).
Messenger RNA (mRNA), 5'-capped, encoding codon-optimised melanoma-associated antigen 3 (MAGE-A3, cancer/testis antigen 1.3) expressed as a fusion protein comprising a secretory signal peptide, MAGE-A3, P2P16 tetanus toxoid-derived helper epitopes and a major histocompatibility complex (MHC) class I transmembrane and cytoplasmic domain (MITD), connected by three glycine/serine-rich (GS) linker peptides, flanked by 5' and 3' untranslated regions and a 3' poly(A) tail.

énomiméran

ARN messager codant pour l'antigène 3 associé au mélanome (MAGE-A3).

	Un ARN messager (ARNm), protégé en 5', codant pour l'antigène 3 associé au mélanome (MAGE-A3, antigène 1.3 du cancer testiculaire) , avec des codons optimisés, exprimé sous la forme d'une protéine de fusion comprenant un peptide signal de sécrétion, MAGE-A3, les épitopes auxiliaires P2P16 dérivés de l'anatoxine tétanique et un domaine transmembranaire et cytoplasmique (MITD) du complexe majeur d'histocompatibilité (CMH) de classe I, reliés par trois peptides de liaison riches en glycine/sérine (GS), flanqués de régions non traduites en 5' et 3' et d'une queue poly(A) en 3'.
enomimerán	ARN mensajero que codifica para el antígeno asociado a melanoma 3 (MAGE-A3). ARN mensajero (ARNm), protegido en 5', que codifica para el antígeno asociado a melanoma 3 (MAGE-A3, antígeno de cáncer/testículo 1.3), con codones optimizados, expresado como una proteína de fusión que consta de un péptido señal de secreción, MAGE-A3, los epítopos auxiliares P2P16 derivados del toxoide tetánico y un dominio citoplásmico y transmembrana del complejo principal de histocompatibilidad (MHC) de clase I, conectados mediante tres péptidos de enlace ricos en glicina/serina (GS), flanqueado por las regiones 5' y 3' no traducidas y una cola poly(A) en 3'.

entacingenum turiparvovecum #

entacingene turiparvovec	A replication-defective adeno-associated viral vector encoding cone photoreceptor cyclic nucleotide-gated channel β3 (CNGB3). A recombinant non-replicating adeno-associated viral vector serotype 8 (rAAV8), encoding codon-optimised human cone photoreceptor cyclic nucleotide gated channel β3 (CNGB3), under the control of the human cone arrestin (hCAR) promoter and an SV40 poly(A) sequence, flanked by AAV2 inverted terminal repeats (ITR).
entacingène turiparvovec	Un vecteur adénoviral à réplication défectueuse codant pour le canal du photorécepteur conique β3 (CNGB3), dépendant des nucléotides cycliques. Un vecteur adénoviral recombinant non réplicatif de sérotype 8 (rAAV8), codant pour le canal du photorécepteur du cône humain β3 (CNGB3), dépendant des nucléotides cycliques, avec des codons optimisés, sous le contrôle du promoteur hCAR (arrestine du cône humain) et d'une séquence poly(A) SV40, flanquée de répétitions terminales inversées (ITR) AAV2.
entacingén turiparvovec	Un vector de virus adeno-asociado, deficiente de replicación, que codifica para el canal β3 regulado por nucleótidos cíclicos (CNGB3) del fotorreceptor de los conos. Un vector de virus adeno-asociado recombinante serotipo 8 (rAAV8), deficiente de replicación, que codifica para el canal β3 regulado por nucleótidos cíclicos (CNGB3) del fotorreceptor de los conos, con codones optimizados, bajo el control del promotor de la arrestina de cono humana (hCAR) y una secuencia poly(A) de SV40, flanqueado por las repeticiones invertidas terminales (ITR) del AAV2.

eplontersenum

eplontersen

all-P-ambo-5'-*O*-(28-[(2-acetamido-2-deoxy-β-D-galactopyranosyl)oxy]-16,16-bis{[3-({6-[(2-acetamido-2-deoxy-β-D-galactopyranosyl)oxy]hexyl}amino)-3-oxopropoxy]methyl}-1-hydroxy-1,10,14,21-tetraoxo-2,18-dioxa-9,15,22-triaza-1λ^5-phosphaoctacosan-1-yl)-2'-*O*-(2-methoxyethyl)-5-methyl-*P*-thiouridylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-5-methylcytidylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-5-methyluridylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-5-methyluridylyl-(3'→5')-2'-*O*-(2-methoxyethyl)guanylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-2'-deoxy-5-methyl-*P*-thiocytidylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-deoxy-*P*-thioguanylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-2'-deoxy-*P*-thioadenylyl-(3'→5')-2'-*O*-(2-methoxyethyl)adenylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-5-methyluridylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-5-methyl-*P*-thiocytidylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-5-methyl-*P*-thiocytidylyl-(3'→5')-2'-*O*-(2-methoxyethyl)-5-methylcytidine

éplontersen

tout-P-ambo-5'-*O*-(28-[(2-acétamido-2-désoxy-β-D-galactopyranosyl)oxy]-16,16-bis{[3-({6-[(2-acétamido-2-désoxy-β-D-galactopyranosyl)oxy]hexyl}-amino)-3-oxopropoxy]méthyl}-1-hydroxy-1,10,14,21-tétraoxo-2,18-dioxa-9,15,22-triaza-1λ^5-phosphaoctacosan-1-yl)-2'-*O*-(2-méthoxyéthyl)-5-méthyl-*P*-thiouridylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-5-méthylcytidylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-5-méthyluridylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-5-méthyluridylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)guanylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-2'-désoxy-5-méthyl-*P*-thiocytidylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-*P*-thiothymidylyl-(3'→5')-2'-désoxy-*P*-thioguanylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-2'-désoxy-*P*-thioadénylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)adénylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-5-méthyluridylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-5-méthyl-*P*-thiocytidylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-5-méthyl-*P*-thiocytidylyl-(3'→5')-2'-*O*-(2-méthoxyéthyl)-5-méthylcytidine

eplontersén

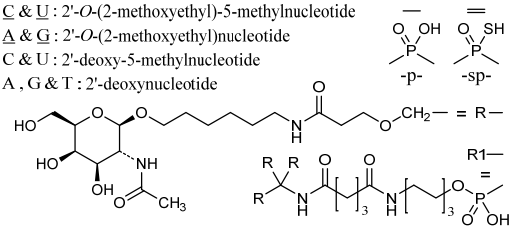
todo-P-ambo-5'-*O*-(28-[(2-acetamido-2-desoxi-β-D-galactopiranosil)oxi]-16,16-bis{[3-({6-[(2-acetamido-2-desoxi-β-D-galactopiranosil)oxi]hexil}amino)-3-oxopropoxi]metil}-1-hidroxi-1,10,14,21-tetraoxo-2,18-dioxa-9,15,22-triaza-1λ^5-fosfaoctacosan-1-il)-2'-*O*-(2-metoxietil)-5-metil-*P*-tiouridilil-(3'→5')-2'-*O*-(2-metoxietil)-5-metilcitidilil-(3'→5')-2'-*O*-(2-metoxietil)-5-metiluridilil-(3'→5')-2'-*O*-(2-metoxietil)-5-metiluridilil-(3'→5')-2'-*O*-(2-metoxietil)guanilil-(3'→5')-2'-desoxi-*P*-tioguanilil-(3'→5')-*P*-tiotimidilil-(3'→5')-*P*-tiotimidilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-2'-desoxi-5-metil-*P*-tiocitidilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-*P*-tiotimidilil-(3'→5')-2'-desoxi-*P*-tioguanilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-2'-desoxi-*P*-tioadenilil-(3'→5')-2'-*O*-(2-metoxietil)adenilil-(3'→5')-2'-*O*-(2-metoxietil)-5-metiluridilil-(3'→5')-2'-*O*-(2-metoxietil)-5-metil-*P*-tiocitidilil-(3'→5')-2'-*O*-(2-metoxietil)-5-metil-*P*-tiocitidilil-(3'→5')-2'-*O*-(2-metoxietil)-5-metilcitidina

$C_{296}H_{437}N_{77}O_{156}P_{20}S_{13}$

(3'-5') R1-U=C-U-U-G-d(G=T=T=A=C=A=T=G=A=A=)A-U-C=C=C

Legend:

C & U : 2'-*O*-(2-methoxyethyl)-5-methylnucleotide
A & G : 2'-*O*-(2-methoxyethyl)nucleotide
C & U : 2'-deoxy-5-methylnucleotide
A , G & T : 2'-deoxynucleotide



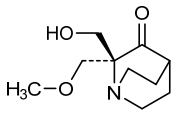
eprenetapoptum

eprenetapopt — *rac*-(2*R*)-2-(hydroxymethyl)-2-(methoxymethyl)-1-azabicyclo[2.2.2]octan-3-one

éprénétapopt — *rac*-(2*R*)-2-(hydroxyméthyl)-2-(méthoxyméthyl)-1-azabicyclo[2.2.2]octan-3-one

eprenetapopt — *rac*-(2*R*)-2-(hidroximetil)-2-(metoximetil)-1-azabiciclo[2.2.2]octan-3-ona

$C_{10}H_{17}NO_3$



and enantiomer
et énantiomère
y enantiómero

etevritamabum #

etevritamab — immunoglobulin scFv-scFv, anti-[*Homo sapiens* EGFR (epidermal growth factor receptor, receptor tyrosine-protein kinase erbB-1, ERBB1, HER1, HER-1, ERBB) variant III (EGFRvIII)] and anti-[*Homo sapiens* CD3E (CD3 epsilon, Leu-4)], monoclonal antibody single chain, bispecific;
IG scFv-scFv single chain (1-512) [scFv-VH-V-kappa anti-EGFRvIII(1-251) [VH (*Homo sapiens* IGHV3-33*01 G49>C (44) (93.9%) -IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.17] (26-33.51-58.97-113) (1-124) -15-mer tris(tetraglycyl-seryl) linker (125-139) -V-KAPPA (*Homo sapiens* IGKV2-24*01 (92.0%) -IGKJ1*01 Q120>C (244) (90.9%)) CDR-IMGT [11.3.9] (166-176.194-196.233-241) (140-251)] -6-mer seryl-tetraglycyl-seryl linker (252-257) -scFv-VH-V-lambda anti-CD3E (258-506) [VH (*Mus musculus* IGHV10-1*02 (91.9%)-(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87.0%)-(IGHD) -IGHJ5*01 (100%)) [8.10.16] (258-382) - 15-mer tris(tetraglycyl-seryl) linker (383-397) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%) CDR-IMGT [9.3.9] (423-431.449-451.488-496) (398-506)] -hexahistidine (507-512)], non-glycosylated, produced in Chinese hamster ovary (CHO) cells

étévritamab

immunoglobuline scFv-scFv, anti-[*Homo sapiens* EGFR (récepteur du facteur de croissance épidermique, récepteur tyrosine-protéine kinase erb-1, ERBB1, HER1, HER-1, ERBB) variant III (EGFRvIII)] et anti-[*Homo sapiens* CD3E (CD3 epsilon, Leu-4)], anticorps monoclonal à chaîne unique, bispécifique;
IG scFv-scFv chaîne unique (1-512) [scFv-VH-V-kappa anti-EGFRvIII(1-251) [VH (*Homo sapiens* IGHV3-33*01 G49>C (44) (93.9%) -IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.17] (26-33.51-58.97-113) (1-124) -15-mer tris(tétraglycyl-séryl) linker (125-139) – V-KAPPA (*Homo sapiens* IGKV2-24*01 (92.0%) -IGKJ1*01 Q120>C (244) (90.9%)) CDR-IMGT [11.3.9] (166-176.194-196.233-241) (140-251)] -6-mer séryl-tétraglycyl-séryl linker (252-257) -scFv-VH-V-lambda anti-CD3E (258-506) [VH (*Mus musculus* IGHV10-1*02 (91.9%)-(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87.0%)-(IGHD) -IGHJ5*01 (100%)) [8.10.16] (258-382) -15-mer tris(tétraglycyl-séryl) linker (383-397) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%) CDR-IMGT [9.3.9] (423-431.449-451.488-496) (398-506)] -hexahistidine (507-512)], non-glycosylé, produit dans des cellules ovariennes de hamsters chinois (CHO)

etevritamab

inmunoglobulina scFv-scFv, anti-[*Homo sapiens* EGFR (receptor del factor de crecimiento epidérmico, receptor tirosina-proteína kinasa erb-1, ERBB1, HER1, HER-1, ERBB) variante III (EGFRvIII)] y anti-[*Homo sapiens* CD3E (CD3 epsilon, Leu-4)], anticuerpo monoclonal de cadena única, biespecífico;
IG scFv-scFv cadena única (1-512) [scFv-VH-V-kappa anti-EGFRvIII(1-251) [VH (*Homo sapiens* IGHV3-33*01 G49>C (44) (93.9%) -IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.17] (26-33.51-58.97-113) (1-124) -15-mer tris(tetraglicil-seril) linker (125-139) – V-KAPPA (*Homo sapiens* IGKV2-24*01 (92.0%) -IGKJ1*01 Q120>C (244) (90.9%)) CDR-IMGT [11.3.9] (166-176.194-196.233-241) (140-251)] -6-mer seril-tetraglicil-seril linker (252-257) -scFv-VH-V-lambda anti-CD3E (258-506) [VH (*Mus musculus* IGHV10-1*02 (91.9%)-(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87.0%)-(IGHD) -IGHJ5*01 (100%)) [8.10.16] (258-382) -15-mer tris(tetraglicil-seril) linker (383-397) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%) CDR-IMGT [9.3.9] (423-431.449-451.488-496) (398-506)] -hexahistidina (507-512)], no glicosilado, producido en las células ováricas de hámster chino (CHO)

Sequence / Séquence / Secuencia

```
QVQLVESGGG VVQSGRSLRL SCAASGFTFR NYGMHWVRQA PGKCLEWVAV  50
IWYDGSDKYY ADSVRGRFTI SRDNSKNTLY LQMNSLRAED TAVYYCARDG 100
YDILTGNPRD FDYWGQGTLV TVSSGGGGSG GGGSGGGGSD TVMTQTPLSS 150
HVTLGQPASI SCRSSQSLVH SDGNTYLSWL QQRPGQPPRL LIYRISRRFS 200
GVPDRFSGSG AGTDFTLEIS RVEAEDVGVY YCMQSTHVPR TFGCGTKVEI 250
KSGGGGSEVQ LVESGGGLVQ PGGSLKLSCA ASGFTFNKYA MNWVRQAPGK 300
GLEWVARIRS KYNNYATYYA DSVKDRFTIS RDDSKNTAYL QMNNLKTEDT 350
AVYYCVRHGN FGNSYISYWA YWGQGTLVTV SSGGGGSGGG GSGGGGSQTV 400
VTQEPSLTVS PGGTVTLTCG SSTGAVTSGN YPNWVQQKPG QAPRGLIGGT 450
KFLAPGTPAR FSGSLLGGKA ALTLSGVQPE DEAEYYCVLW YSNRWVFGGG 500
TKLTVLHHHH HH                                          512
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-chain (C23 C104):V 22-96 162-232 279-355 419-487
(C49-C120) V 44-244

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

No N-glycosylation sites / pas de sites de N-glycosylation / ningùm posición de N-glycosilación
Aglycosylated

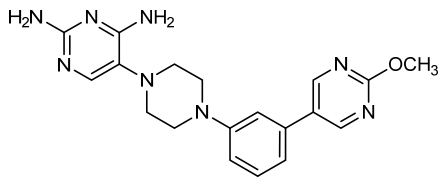
fanotaprimum

fanotaprim — 5-{4-[3-(2-methoxypyrimidin-5-yl)phenyl]piperazin-1-yl}pyrimidine-2,4-diamine

fanotaprim — 5-{4-[3-(2-méthoxypyrimidin-5-yl)phényl]pipérazin-1-yl}pyrimidine-2,4-diamine

fanotaprim — 5-{4-[3-(2-metoxipirimidin-5-il)fenil]piperazin-1-il}pirimidina-2,4-diamina

$C_{19}H_{22}N_8O$



favezelimabum #

favezelimab — immunoglobulin G4-kappa, anti-[*Homo sapiens* LAG3 (lymphocyte activating 3, lymphocyte-activation 3, CD223)], humanized monoclonal antibody;
gamma4 heavy chain humanized (1-446) [VH (*Homo sapiens* IGHV1-58*01 (85.6%) -(IGHD) -IGHJ1*01 (91.7%)) [8.8.12] (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 humanized (1'-218') [V-KAPPA (*Homo sapiens* IGKV2D-29*01 (82.0%) -IGKJ4*01 (100%))[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

favézélimab — immunoglobuline G4-kappa, anti-[*Homo sapiens* LAG3 (activateur 3 des lymphocytes, lymphocyte-activation 3, CD223)], anticorps monoclonal humanisé;
chaîne lourde gamma4 humanisée (1-446) [VH (*Homo sapiens* IGHV1-58*01 (85.6%) -(IGHD) -IGHJ1*01 (91.7%)) [8.8.12] (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 humanisée (1'-218') [V-KAPPA (*Homo sapiens* IGKV2D-29*01 (82.0%) -IGKJ4*01 (100%)) [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 hamsters chinois (CHO), glycoforme alfa

favezelimab

inmunoglobulina G4-kappa, anti-[*Homo sapiens* LAG3 (activador 3 de los linfocitos, linfocito-activación 3, CD223)], anticuerpo monoclonal humanizado; cadena pesada gamma4 humanizada (1-446) [VH (*Homo sapiens* IGHV1-58*01 (85.6%) -(IGHD) - IGHJ1*01 (91.7%)) [8.8.12] (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 humanizada (1'-218') [V-KAPPA (*Homo sapiens* IGKV2D-29*01 (82.0%) -IGKJ4*01 (100%)) [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 en las células ováricas de hamsters chinos (CHO), glicoforma alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QMQLVQSGPE VKKPGTSVKV SCKASGYTFT DYNVDWVRQA RGQRLEWIGD  50
INPNDGGTIY AQKFQERVTI TVDKSTSTAY MELSSLRSED TAVYYCARNY 100
RWFGAMDHWG QGTTVTVSSA STKGPSVFPL APCSRSTSES TAALGCLVKD 150
YFPEPVTVSW NSGALTSGVH TFPAVLQSSG LYSLSSVVTV PSSSLGTKTY 200
TCNVDHKPSN TKVDKRVESK YGPPCPPCPA PEFLGGPSVF LFPPKPKDTL 250
MISRTPEVTC VVVDVSQEDP EVQFNWYVDG VEVHNAKTKP REEQFNSTYR 300
VVSVLTVLHQ DWLNGKEYKC KVSNKGLPSS IEKTISKAKG QPREPQVYTL 350
PPSQEEMTKN QVSLTCLVKG FYPSDIAVEW ESNGQPENNY KTTPPVLDSD 400
GSFFLYSRLT VDKSRWQEGN VFSCSVMHEA LHNHYTQKSL SLSLGK     446
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Light chain / Chaîne légère / Cadena ligera

```
DIVMTQTPLS LSVTPGQPAS ISCKASQSLD YEGDSDMNWY LQKPGQPPQL  50
LIYGASNLES GVPDRFSGSG SGTDFTLKIS RVEAEDVGVY YCQQSTEDPR 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 disulfu

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 11, h 14) 225-225" 228-228"

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

H CH2 N84.4:
296, 296"

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

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

firazorextonum

firazorexton

N-{(2*S*,3*S*)-1-(2-hydroxy-2-methylpropanoyl)-2-[(2,3',5'-trifluoro[1,1'-biphenyl]-3-yl)methyl]pyrrolidin-3-yl}methanesulfonamide

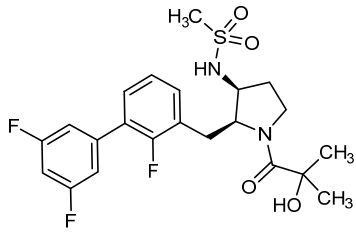
firazorexton

N-{(2*S*,3*S*)-1-(2-hydroxy-2-méthylpropanoyl)-2-[(2,3',5'-trifluoro[1,1'-biphényl]-3-yl)méthyl]pyrrolidin-3-yl}méthanesulfonamide

firazorextón

N-{(2*S*,3*S*)-1-(2-hidroxi-2-metilpropanoil)-2-[(2,3',5'-trifluoro[1,1'-bifenil]-3-il)metil]pirrolidin-3-il}metanosulfonamida

$C_{22}H_{25}F_3N_2O_4S$



flotufolastatum (^{18}F)

flotufolastat (^{18}F)

N^2-(*N*-{(4*S*)-4-carboxy-4-[4,7,10-tris(carboxymethyl)-1,4,7,10-tetraaza-cyclododecan-1-yl]butanoyl}-3-[4-(di-*tert*-butyl(^{18}F)fluorosilyl)benzamido]-D-alanyl)-*N*^{6}-[4-(*N*^{2}-{*N*-[(L-glutamic acid-*N*-yl)carbonyl]-L-γ-glutamyl}-D-ornithin-*N*^{5}-yl)-4-oxobutanoyl]-D-lysine

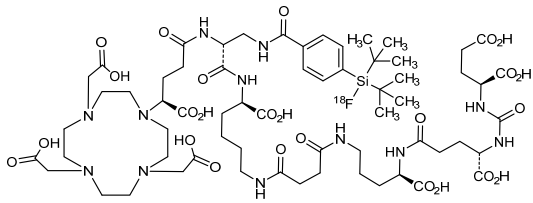
flotufolastat (^{18}F)

N^2-(*N*-{(4*S*)-4-carboxy-4-[4,7,10-tris(carboxyméthyl)-1,4,7,10-tétraaza-cyclododécan-1-yl]butanoyl}-3-[4-(di-*tert*-butyl(^{18}F)fluorosilyl)benzamido]-D-alanyl)-*N*^{6}-[4-(*N*^{2}-{*N*-[(acide L-glutamique-*N*-yl)carbonyl]-L-γ-glutamyl}-D-ornithin-*N*^{5}-yl)-4-oxobutanoyl]-D-lysine

flotufolastat (^{18}F)

N^2-(*N*-{(4*S*)-4-carboxi-4-[4,7,10-tris(carboximetil)-1,4,7,10-tetraazaciclo-dodecan-1-il]butanoil}-3-[4-(di-*terc*-butil(^{18}F)fluorosilil)benzamido]-D-alanil)-*N*^{6}-[4-(*N*^{2}-{*N*-[(ácido L-glutámico-*N*-il)carbonil]-L-γ-glutamil}-D-ornitin-*N*^{5}-il)-4-oxobutanoil]-D-lisina

$C_{63}H_{99}{}^{18}FN_{12}O_{25}Si$



flubentylosinum

flubentylosin

[(4*R*,5*S*,6*S*,7*R*,9*R*,11*E*,13*E*,15*R*,16*R*)-15-{[(6-deoxy-2,3-di-*O*-methyl-β-D-allopyranosyl)oxy]methyl}-6-{[3,6-dideoxy-4-*O*-{2,6-dideoxy-4-*O*-[(4-fluorophenyl)methyl]-3-*C*-methyl-α-L-*ribo*-hexopyranosyl}-3-(dimethylamino)-β-D-glucopyranosyl]oxy}-16-ethyl-4-hydroxy-5,9,13-trimethyl-2,10-dioxo-1-oxacyclohexadeca-11,13-dien-7-yl]acetaldehyde;
4^B-*O*-(4-fluorobenzyl)tylosin

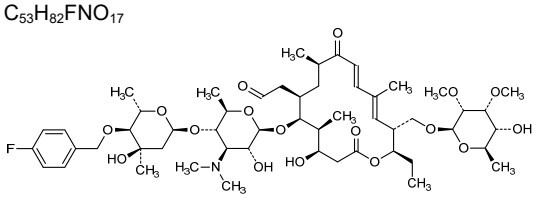
flubentylosine

[(4*R*,5*S*,6*S*,7*R*,9*R*,11*E*,13*E*,15*R*,16*R*)-15-{[(6-désoxy-2,3-di-*O*-méthyl-β-D-allopyranosyl)oxy]méthyl}-6-{[3,6-didésoxy-4-*O*-{2,6-didésoxy-4-*O*-[(4-fluorophényl)méthyl]-3-*C*-méthyl-α-L-*ribo*-hexopyranosyl}-3-(diméthylamino)-β-D-glucopyranosyl]oxy}-16-éthyl-4-hydroxy-5,9,13-triméthyl-2,10-dioxo-1-oxacyclohexadéca-11,13-dién-7-yl]acetaldehyde;
4^B-*O*-(4-fluorobenzyl)tylosine

flubentilosina

[(4*R*,5*S*,6*S*,7*R*,9*R*,11*E*,13*E*,15*R*,16*R*)-15-{[(6-desoxi-2,3-di-*O*-metil-β-D-alopiranosil)oxi]metil}-6-{[3,6-didesoxi-4-*O*-{2,6-didesoxi-4-*O*-[(4-fluorofenil)metil]-3-*C*-metil-α-L-*ribo*-hexopiranosil}-3-(dimetilamino)-β-D-glucopiranosil]oxi}-16-etil-4-hidroxi-5,9,13-trimetil-2,10-dioxo-1-oxaciclohexadeca-11,13-dien-7-il]acetaldehído; 4^B-*O*-(4-fluorobencil)tilosina

$C_{53}H_{82}FNO_{17}$



fordadistrogenum movaparvovecum #

fordadistrogene movaparvovec

A replication-defective adeno-associated viral vector encoding a codon-optimised mini-dystrophin (DMD).
A recombinant replication-defective adeno-associated viral vector serotype 9 (rAAV9), encoding a codon-optimised mini-dystrophin (DMD) gene comprising the N-terminus, hinge regions H1, H3 and H4, spectrin-like repeats R1, R2 and R22-24, and the C-terminal cysteine-rich region, under the control of a human muscle-specific synthetic enhancer/promoter and a synthetic poly(A) sequence, flanked by AAV2 inverted terminal repeats (ITR).

fordadistrogène movaparvovec

Un vecteur adénoviral à réplication défectueuse et codant pour une mini-dystrophine (DMD) avec des codons optimisés.
Un vecteur adénoviral recombinant de sérotype 9 (rAAV9) à réplication défectueuse, codant pour un gène de mini-dystrophine (DMD) avec des codons optimisés, comprenant l'extrémité N-terminale, les régions charnières H1, H3 et H4, les répétitions de type spectrine R1, R2 et R22-24, et la région C-terminale riche en cystéines, sous le contrôle d'un promoteur/amplificateur synthétique spécifique du muscle humain et d'une séquence synthétique poly(A), flanquée de répétitions terminales inversées (ITR) de l'AAV2.

fordadistrogén movaparvovec

Un vector de virus adeno-asociado, deficiente de replicación, que codifica para una mini-distrofina (DMD) con los codones optimizados.
Un vector de virus adeno-asociado recombinante de serotipo 9 (rAAV9), deficiente de replicación, que codifica para un gen de mini-distrofina (DMD) con los codones optimizados que contiene el extremo N-terminal, las regiones bisagra H1, H3 y H4, las repeticiones de tipo espectrina R1, R2 y R22-24, y la región C-terminal rica en cisteínas, bajo el control de un promotor/amplificador (enhancer) sintético específico de músculo humano y una secuencia poly(A) sintética, flanqueado por las repeticiones terminales invertidas (ITR) del AAV2.

gallium (^{68}Ga) gozetotidum

gallium (^{68}Ga) gozetotide

{*N*-[(*N*^{6}-{6-[3-(3-{[{2-[{[5-(2-carboxyethyl)-2-hydroxy-κ*O*-phenyl]methyl}(carboxy-κ*O*-methyl)amino-κ*N*]ethyl}(carboxy-κ*O*-methyl)amino-κ*N*]methyl}-4-hydroxy-κ*O*-phenyl)propanamido]hexanoyl}-L-lysin-*N*^{2}-yl)carbonyl]-L-glutamato(3−)}(^{68}Ga)gallium

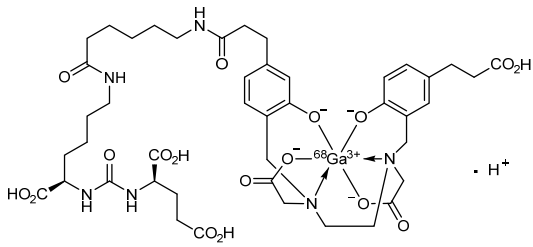
gallium (^{68}Ga) gozétotide

{*N*-[(*N*^{6}-{6-[3-(3-{[{2-[{[5-(2-carboxyéthyl)-2-hydroxy-κ*O*-phényl]méthyl}(carboxy-κ*O*-méthyl)amino-κ*N*]éthyl}(carboxy-κ*O*-méthyl)amino-κ*N*]méthyl}-4-hydroxy-κ*O*-phényl)propanamido]hexanoyl}-L-lysin-*N*^{2}-yl)carbonyl]-L-glutamato(3−)}(^{68}Ga)gallium

galio (^{68}Ga) gozetótida

{*N*-[(*N*^{6}-{6-[3-(3-{[{2-[{[5-(2-carboxietil)-2-hidroxi-κ*O*-fenil]metil}(carboxi-κ*O*-metil)amino-κ*N*]etil}(carboxi-κ*O*-metil)amino-κ*N*]metil}-4-hidroxi-κ*O*-fenil)propanamido]hexanoil}-L-lisin-*N*^{2}-il)carbonil]-L-glutamato(3−)}(^{68}Ga)galio

$C_{44}H_{59}{}^{68}GaN_6O_{17}$



garivulimabum #

garivulimab

immunoglobulin G1-kappa, anti-[*Homo sapiens* CD274 (programmed death ligand 1, PDL1, PD-L1, B7 homolog 1, B7H1)], humanized monoclonal antibody; gamma1 heavy chain humanized (1-446) [VH humanized (*Homo sapiens* IGHV3-NL1*01 (84.7%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.7.11] (26-33.51-57.96-106) (1-117) -*Homo sapiens* IGHG1*01 G1m17,1, G1v4 CH2 A114 (CH1 K120 (214) (118-215), hinge 1-15 (216-230) -CH2 V1.2>A (234), P114>A (329) (231-339), CH3 D12 (355), L14 (357) (340-444), CHS (445-446)) (118-446)], (220-215')-disulfide with kappa light chain humanized (1'-215') [V-KAPPA humanized (*Homo sapiens* IGKV1-5*03 (84.0%) -IGKJ2*01 (91.7%)) CDR-IMGT [6.3.10] (27-32.50-52.89-98) (1'-108') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (154), V101 (192) (109'-215')]; dimer (226-226":229-229")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

garivulimab

immunoglobuline G1-kappa, anti-[*Homo sapiens* CD274 (ligand 1 de mort programmée, PDL1, PD-L1, homologue 1 de B7, B7H1)], anticorps monoclonal humanisé;

chaîne lourde gamma1 humanisée (1-446) [VH humanisé (*Homo sapiens* IGHV3-NL1*01 (84.7%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.7.11] (26-33.51-57.96-106) (1-117) -*Homo sapiens* IGHG1*01 G1m17,1, G1v4 CH2 A114 (CH1 K120 (214) (118-215), charnière 1-15 (216-230) -CH2 V1.2>A (234), P114>A (329) (231-339), CH3 D12 (355), L14 (357) (340-444), CHS (445-446)) (118-446)], (220-215')-disulfure avec la chaîne légère kappa humanisée (1'-215') [V-KAPPA humanisé (*Homo sapiens* IGKV1-5*03 (84.0%) -IGKJ2*01 (91.7%)) CDR-IMGT [6.3.10] (27-32.50-52.89-98) (1'-108') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (154), V101 (192) (109'-215')]; dimère (226-226":229-229")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

garivulimab

inmunoglobulina G1-kappa, anti-[*Homo sapiens* CD274 (ligando 1 de muerte programada, PDL1, PD-L1, homólogo 1 de B7, B7H1)], anticuerpo monoclonal humanizado; cadena pesada gamma1 humanizada (1-446) [VH humanizado (*Homo sapiens* IGHV3-NL1*01 (84.7%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.7.11] (26-33.51-57.96-106) (1-117) -*Homo sapiens* IGHG1*01 G1m17,1, G1v4 CH2 A114 (CH1 K120 (214) (118-215), bisagra 1-15 (216-230) -CH2 V1.2>A (234), P114>A (329) (231-339), CH3 D12 (355), L14 (357) (340-444), CHS (445-446)) (118-446)], (220-215')-disulfuro con la cadena ligera kappa humanizada (1'-215') [V-KAPPA humanizado (*Homo sapiens* IGKV1-5*03 (84.0%) -IGKJ2*01 (91.7%)) CDR-IMGT [6.3.10] (27-32.50-52.89-98) (1'-108') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (154), V101 (192) (109'-215')]; dímero (226-226":229-229")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVESGGG LVQPGGSLRL SCAVSGFSLT SYGVHWVRQA PGKGLEWVAV  50
IWAGGSTNYA DSVKGRFTIS KDTSKNTVYL QMNSLRAEDT AVYYCAKPYG 100
TSAMDYWGQG TLVTVSSAST KGPSVFPLAP SSKSTSGGTA ALGCLVKDYF 150
PEPVTVSWNS GALTSGVHTF PAVLQSSGLY SLSSVVTVPS SSLGTQTYIC 200
NVNHKPSNTK VDKKVEPKSC DKTHTCPPCP APPAAGPSVF LFPPKPKDTL 250
MISRTPEVTC VVVDVSHEDP EVKFNWYVDG VEVHNAKTKP REEQYNSTYR 300
VVSVLTVLHQ DWLNGKEYKC KVSNKALAAP IEKTISKAKG QPREPQVYTL 350
PPSRDELTKN QVSLTCLVKG FYPSDIAVEW ESNGQPENNY KTTPPVLDSD 400
GSFFLYSKLT VDKSRWQQGN VFSCSVMHEA LHNHYTQKSL SLSPGK     446
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Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS LSASVGDRVT ITCKASQDVG IVVAWYQQKP GKAPKLLIYW  50
ASIRHTGVPS RFSGSGSGTE FTLTISSLQP DDFATYYCQQ YSNYPLYTFG 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) 22-95 144-200 260-320 366-424
22"-95" 144"-200" 260"-320" 366"-424"
Intra-L (C23-C104) 23'-88' 135'-195'
23'"-88'" 135'"-195'"
Inter-H-L (h 5-CL 126) 220-215' 220"-215'"
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:
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 / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
446, 446"

garveleucelum

garveleucel	Allogeneic T cell-enriched leukocyte preparation, devoid of alloreactive T cells. The cells are derived from peripheral blood mononuclear cells (PBMCs) collected by apheresis from a haploidentical stem cell donor. The cells are lymphocyte enriched, and during processing patient and donor cells are co-cultured *ex vivo* in an MLR (mixed lymphocyte reaction) to stimulate activation of host alloreactive T-cells and subsequent depletion of these cells using a proprietary rhodamine-based photodynamic treatment. In this process, monocytes are largely eliminated from the cell mixture. The cells are primarily T cells (average ~90%) consisting of both CD4+ T-helper cells and CD8+ T-cytotoxic cells (mean CD4:CD8 ratio of 2.1), and other leucocytes (average ~10%, with B-cells (~ 6-7%) and NK cells (~ 2-3%).
garvéleucel	Préparation de leucocytes enrichis en cellules T allogéniques, dépourvus de cellules T alloréactives. Les cellules sont dérivées de cellules mononucléaires du sang périphérique (PBMC) prélevées par aphérèse chez un donneur de cellules souches partiellement compatible pour les antigènes HLA. Les cellules sont enrichies en lymphocytes et, pendant le traitement, les cellules du patient et du donneur sont co-cultivées *ex vivo* selon une RML (réaction lymphocytaire mixte) pour stimuler l'activation des cellules T allo-réactives de l'hôte et l'épuisement ultérieur de ces cellules grâce à un traitement photodynamique exclusif à base de rhodamine. Dans ce processus, les monocytes sont largement éliminés du mélange de cellules. Les cellules sont principalement des cellules T (en moyenne ~90%) composées à la fois de cellules T auxiliaires CD4+ et de cellules T cytotoxiques CD8+ (rapport moyen CD4:CD8 de 2.1), et d'autres leucocytes (en moyenne ~10%, avec des cellules B (~6-7%) et des cellules NK (~ 2-3%).
garveleucel	Preparación de leucocitos enriquecidos en células T alogénicos, desprovistos de células T aloreactivas. Las células se obtienen a partir de células mononucleares de sangre periférica (PBMCs) recogidas por aféresis de un donante de células madre haploidéntico. Las células se enriquecen en linfocitos, y durante el procesamiento, las células del paciente y del donante se co-cultivan *ex vivo* en una MLR (reacción mixta de linfocitos) para estimular la activación de células T aloreactivas frente al huésped y la subsiguiente depleción de estas células usando un tratamiento fotodinámico basado en la rodamina. En este proceso, los monocitos en su mayoría se eliminan de la mezcla celular. Las células son principalmente células T (~90% como media) y consisten en células T colaboradoras CD4+ y células T citotóxicas CD8+ (ratio medio CD4:CD8 de 2.1), y otros leucocitos (media ~10%, con células B (~6-7%) y células NK (~2-3%).

gavocabtagenum autoleucelum #

gavocabtagene autoleucel	Autologous T cells transduced *ex vivo* with a self-inactivating lentiviral vector encoding an anti-mesothelin (MSLN) chimeric antigen receptor Autologous T cells transduced *ex vivo* with a non-replicating, self-inactivating (SIN) lentiviral vector, encoding an anti-mesothelin (MSLN) single-domain antibody (sdAb) based chimeric antigen receptor with a leader sequence derived from granulocyte-macrophage colony-stimulating factor receptor alpha (GMCSFR-alpha), fused to the CD3ε subunit of the T-cell receptor (TCR) via an A3(G4S)3LE flexible linker, which is incorporated into the endogenous TCR complex upon expression. The transgene is under control of elongation factor-1 alpha (EF-1α) promoter and woodchuck hepatitis virus post-transcriptional regulatory element. The vector genome also contains a packaging signal, a partial *gag* sequence, a Rev Response Element (RRE), a central polypurine tract (cPPT) and a 3' polypurine tract (3'PPT).
gavocabtagène autoleucel	Cellules T autologues transduites *ex vivo* avec un vecteur lentiviral non réplicatif codant pour un récepteur chimérique anti-mésothéline (MSLN). Cellules T autologues transduites *ex vivo* avec un vecteur lentiviral non réplicatif et auto-inactivable (SIN), codant pour un récepteur antigénique chimérique basé sur les anticorps anti-mésothéline (MSLN) à domaine unique (sdAb). Il comprend une séquence leader dérivée du récepteur alpha du facteur de stimulation des colonies de granulocytes-macrophages (GMCSFR-alpha), fusionné à la sous-unité CD3ε du récepteur des cellules T (TCR) via un polypeptide lieur flexible nommé A3(G4)3LE, qui est incorporé dans le complexe TCR endogène lors de l'expression. Le transgène est sous le contrôle du promoteur du facteur d'élongation 1 alpha (EF-1α) ainsi que de l'élément régulateur post-transcriptionnel du virus de l'hépatite de la marmotte. Le génome du vecteur contient aussi un signal de conditionnement des gènes, une séquence *gag* partielle, un élément de réponse Rev (RRE), une région centrale avec tractus polypurin (cPPT) et un tractus polypurin 3' (3'PPT).
gavocabtagén autoleucel	Células T autólogas transducidas *ex vivo* con un vector lentiviral auto-inactivante que codifica para un receptor de antígenos quimérico anti-mesotelina (MSLN). Células T autólogas transducidas *ex vivo* con vector lentiviral auto-inactivante, no replicativo, que codifica para un receptor de antígenos quimérico basado en un anticuerpo de domino único (sdAb) anti-mesotelina (MSLN) con una secuencia líder derivada del receptor alfa del factor estimulador de colonias de granulocitos-macrófagos (GMCSFR-alfa), fusionado a la subunidad CD3ε del receptor de la célula T (TCR) mediante un conector (linker) flexible A3(G4S)3LE, que se incorpora en el complejo TCR endógeno al expresarse. El transgen está bajo el control del promotor del factor de elongación 1 alfa (EF-1α) y elemento regulador post-transcripcional del virus de la hepatitis de la marmota. El genoma del vector también contiene una señal empaquetadora, un secuencia *gag* parcial, un elemento de respuesta Rev (RRE), un segmento central de polipurinas (cPPT) y un segmento 3' de polipurinas (3'PPT).

geptanolimabum #

geptanolimab

immunoglobulin G4-kappa, anti-[*Homo sapiens* PDCD1 (programmed cell death 1, PD-1, PD1, CD279)], monoclonal antibody;
gamma4 heavy chain (1-440) [VH (*Homo sapiens*IGHV7-4-1*02 (85.7%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.7] (26-33.51-58.97-103) (1-114)-*Homo sapiens* IGHG4*01, G4v5 h P10 (CH1 (115-212), hinge 1-12 S10>P (222) (213-224), CH2 (225-334), CH3 (335-439), CHS K>del (440) (115-440)], (28-217')-disulfide with kappa light chain (1'-217') [V-KAPPA (*Mus musculus* IGKV3-5*01 (89.9%) -IGKJ1*01 (90.9%)/*Homo sapiens* IGKV3D-11*02 (64.9%) -IGKJ2*01 (100%)) CDR-IMGT [10.3.8] (27-36.54-56.93-100) (1'-110') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (156), V101 (194) (111'-217')];
dimer (220-220":223-223")-bisdisulfide, produced in Chinese hamster ovary (CHO)-S cell line, glycoform alfa

geptanolimab

immunoglobuline G4-kappa, anti-[*Homo sapiens* PDCD1 (protéine 1 de mort cellulaire programmée, PD-1, PD1, CD279)], anticorps monoclonal;
chaîne lourde gamma4 (1-440) [VH (*Homo sapiens* IGHV7-4-1*02 (85.7%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.7] (26-33.51-58.97-103) (1-114) -*Homo sapiens* IGHG4*01, G4v5 h P10 (CH1 (115-212), charnière 1-12 S10>P (222) (213-224), CH2 (225-334), CH3 (335-439), CHS K>del (440) (115-440)], (128-217')-disulfure avec la chaîne légère kappa (1'-217') [V-KAPPA (*Mus musculus* IGKV3-5*01 (89.9%) -IGKJ1*01 (90.9%)/*Homo sapiens* IGKV3D-11*02 (64.9%) -IGKJ2*01 (100%)) CDR-IMGT [10.3.8] (27-36.54-56.93-100) (1'-110') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (156), V101 (194) (111'-217')];
dimère (220-220":223-223")-bisdisulfure, produit dans des cellules ovariennes de hamsters chinois (CHO) lignée cellulaire CHO-S, glycoforme alfa

geptanolimab

inmunoglobulina G4-kappa, anti-[*Homo sapiens* PDCD1 (proteína 1 de muerte celular programada, PD-1, PD1, CD279)], anticuerpo monoclonal;
cadena pesada gamma4 (1-440) [VH (*Homo sapiens* IGHV7-4-1*02 (85.7%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.7] (26-33.51-58.97-103) (1-114) -*Homo sapiens* IGHG4*01, G4v5 h P10 (CH1 (115-212), bisagra 1-12 S10>P (222) (213-224), CH2 (225-334), CH3 (335-439), CHS K>del (440) (115-440)], (128-217')-disulfuro con la cadena ligera kappa (1'-217') [V-KAPPA (*Mus musculus* IGKV3-5*01 (89.9%) -IGKJ1*01 (90.9%)/*Homo sapiens* IGKV3D-11*02 (64.9%) -IGKJ2*01 (100%)) CDR-IMGT [10.3.8] (27-36.54-56.93-100) (1'-110') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (156), V101 (194) (111'-217')];
dímero (220-220":223-223")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular CHO-S, forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QIQLVQSGSE LKKPGASVKV SCKASGYTFT NFGMNWVRQA PGQGLKWMGW  50
ISGYTREPTY AADFKGRFVI SLDTSVSTAY LQISSLKAED TAVYYCARDV 100
FDYWGQGTLV TVSSASTKGP SVFPLAPCSR STSESTAALG CLVKDYFPEP 150
VTVSWNSGAL TSGVHTFPAV LQSSGLYSLS SVVTVPSSSL GTKTYTCNVD 200
HKPSNTKVDK RVESKYGPPC PPCPAPEFLG GPSVFLFPPK PKDTLMISRT 250
PEVTCVVVDV SQEDPEVQFN WYVDGVEVHN AKTKPREEQF NSTYRVVSVL 300
TVLHQDWLNG KEYKCKVSNK GLPSSIEKTI SKAKGQPREP QVYTLPPSQE 350
EMTKNQVSLT CLVKGFYPSD IAVEWESNGQ PENNYKTTPP VLDSDGSFFL 400
YSRLTVDKSR WQEGNVFSCS VMHEALHNHY TQKSLSLSLG            440
```

Light chain / Chaîne légère / Cadena ligera

```
DIVLTQSPAS LAVSPGQRAT ITCRASESVD NYGYSFMNWF QQKPGQPPKL  50
LIYRASNLES GVPARFSGSG SRTDFTLTIN PVEADDTANY YCQQSNADPT 100
FGQGTKLEIK RTVAAPSVFI FPPSDEQLKS GTASVVCLLN NFYPREAKVQ 150
WKVDNALQSG NSQESVTEQD SKDSTYSLSS TLTLSKADYE KHKVYACEVT 200
HQGLSSPVTK SFNRGEC                                     217
```

Post-translational modifications

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

Intra-H (C23-C104) 22-96 141-197 255-315 361-419
22"-96" 141"-197" 255"-315" 361"-419"
Intra-L (C23-C104) 23'-92' 137'-197'
23'"-92'" 137'"-197'"
Inter-H-L (h 10-CL 126) 128-217' 128"-217'"
Inter-H-H (h 8, h 11) 220-220" 223-223"

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:
291, 291"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados.

gindameranum #

gindameran

Messenger RNA encoding cancer/testis antigen 1 (New York oesophageal squamous cell carcinoma antigen-1).
Messenger RNA (mRNA), 5'-capped, encoding codon-optimised New York esophageal squamous cell carcinoma antigen-1 (NY-ESO-1; cancer/testis antigen 1, CTAG1A) expressed as a fusion protein comprising a secretory signal peptide, NY-ESO-1, P2P16 tetanus toxoid-derived helper epitopes and a major histocompatibility complex (MHC) class I transmembrane and cytoplasmic domain (MITD), connected by three glycine/serine-rich (GS) linker peptides, flanked by 5' and 3' untranslated regions and a 3' poly(A) tail.

gindaméran

ARN messager codant pour l'antigène 1 du cancer testiculaire (antigène 1 du carcinome squameux de l'œsophage, dit de New York).
ARN messager (ARNm), protégé en 5', codant pour l'antigène 1 du carcinome squameux de l'œsophage, dit de New York (NY-ESO-1; antigène 1 du cancer testiculaire, CTAG1A), avec des codons optimisés, exprimé sous la forme d'une protéine de fusion comprenant un peptide signal de sécrétion, NY-ESO-1, les épitopes auxiliaires P2P16 dérivés de l'anatoxine tétanique et un domaine transmembranaire et cytoplasmique (MITD) du complexe majeur d'histocompatibilité (CMH) de classe I, reliés par trois peptides de liaison riches en glycine/sérine (GS), flanqués de régions non traduites en 5' et 3' et d'une queue poly(A) en 3'.

gindamerán	ARN mensajero que codifica para el antígeno 1 de cáncer/testículo (antígeno 1 de carcinoma escamoso del esófago Nueva York). ARN mensajero (ARNm), protegido en 5', que codifica para el antígeno 1 de carcinoma escamoso del esófago Nueva York (NY-ESO-1; antígeno cáncer/testículo 1, CTAG1A) con codones optimizados, que se expresa como una proteína de fusión que consta de un péptido señal de secreción, NY-ESO-1, los epítopos auxiliares P2P16 derivados del toxoide tetánico y un dominio citoplásmico y transmembrana del complejo principal de histocompatibilidad (MHC) de clase I (MITD), conectados mediante tres péptidos de enlace ricos en glicina/serina (GS), flanqueado por las regiones 5' y 3' no traducidas y una cola poly(A) en 3'.
grisnilimabum #	
grisnilimab	immunoglobulin G2A-lambda, anti-[CD7 (CD7 antigen (p41),GP40, LEU-9, TP41, Tp40)], *Mus musculus* monoclonal antibody; gamma2a heavy chain *Mus musculus* (1-453) [VH (*Mus musculus* IGHV9-3-1*01 (98%) -(IGHD) -IGHJ2*01 (93.3%)) CDR-IMGT [8.8.16] (26-33.51-58.97-112) (1-123) -*Mus musculus* IGHG2A*01 (100%) (CH1 (124-220), hinge 1-16 (221-236), CH2 (237-346), CH3 (347-451), CHS (452-453)) (124-453)], (138-214')-disulfide with lambda light chain *Mus musculus* (1'-215') [V-LAMBDA (*Mus musculus* IGLV1*01 (98%) -IGLJ1*01 (100%)) CDR-IMGT [9.3.9] (26-34.52-54.91-99) (1'-109') -*Mus musculus* IGLC1*01 (100%) (110'-215')]; dimer (230-230":233-233":235-235")-trisdisulfide, produced in SP2/0-derived mouse myeloma cells, glycoform alfa
grisnilimab	immunoglobuline G2A-lambda, anti-[CD7 (CD7 antigène (p41), GP40, LEU-9, TP41, Tp40)], anticorps monoclonal *Mus musculus*; chaîne lourde gamma2a *Mus musculus* (1-453) [VH (*Mus musculus* IGHV9-3-1*01 (98%) -(IGHD) -IGHJ2*01 (93.3%)) CDR-IMGT [8.8.16] (26-33.51-58.97-112) (1-123) -*Mus musculus* IGHG2A*01 (100%) (CH1 (124-220), charnière 1-16 (221-236), CH2 (237-346), CH3 (347-451), CHS (452-453)) (124-453)], (138-214')-disulfure avec la chaîne légère lambda *Mus musculus* (1'-215') [V-LAMBDA (*Mus musculus* IGLV1*01 (98%) -IGLJ1*01 (100%)) CDR-IMGT [9.3.9] (26-34.52-54.91-99) (1'-109') -*Mus musculus* IGLC1*01 (100%) (110'-215')]; dimère (230-230":233-233":235-235")-trisdisulfure, produit par une ligne cellulaire derivée de myélome murin SP2/0, glycoforme alfa
grisnilimab	inmunoglobulina G2A-lambda, anti-[CD7 (CD7 antígeno (p41), GP40, LEU-9, TP41, Tp40)], anticuerpo monoclonal *Mus musculus*;

cadena pesada gamma2a *Mus musculus* (1-453) [VH (*Mus musculus* IGHV9-3-1*01 (98%) -(IGHD) -IGHJ2*01 (93.3%)) CDR-IMGT [8.8.16] (26-33.51-58.97-112) (1-123) -*Mus musculus* IGHG2A*01 (100%) (CH1 (124-220), bisagra 1-16 (221-236), CH2 (237-346), CH3 (347-451), CHS (452-453)) (124-453)], (138-214')-disulfuro con la cadena ligera lambda *Mus musculus* (1'-215') [V-LAMBDA (*Mus musculus* IGLV1*01 (98%) -IGLJ1*01 (100%)) CDR-IMGT [9.3.9] (26-34.52-54.91-99) (1'-109') -*Mus musculus* IGLC1*01 (100%) (110'-215')];
dímero (230-230":233-233":235-235")-trisdisulfuro, producido en una línea celular de mieloma murino SP2/0, forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QIQLVQSGPE LKKPGETVKI SCKASGYTFT NYGMNWVKQA PGKGLMWLGW  50
INTYTGEPTY ADDFKGRFAF SLETSASTAY LQINNLKNED TATYFCARWA 100
YFYGSSPYFF DYWGQGTTLT VSSAKTTAPS VYPLAPVCGD TTGSSVTLGC 150
LVKGYFPEPV TLTWNSGSLS SGVHTFPAVL QSDLYTLSSS VTVTSSTWPS 200
QSITCNVAHP ASSTKVDKKI EPRGPTIKPC PPCKCPAPNL LGGPSVFIFP 250
PKIKDVLMIS LSPIVTCVVV DVSEDDPDVQ ISWFVNNVEV HTAQTQTHRE 300
DYNSTLRVVS ALPIQHQDWM SGKEFKCKVN NKDLPAPIER TISKPKGSVR 350
APQVYVLPPP EEEMTKKQVT LTCMVTDFMP EDIYVEWTNN GKTELNYKNT 400
EPVLDSDGSY FMYSKLRVEK KNWVERNSYS CSVVHEGLHN HHTTKSFSRT 450
PGK                                                     453
```

Light chain / Chaîne légère / Cadena ligera

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QAVVTQESAL TTSPGETVTL TCRSSTGAVT TSNYANWVQE KPDHLFTGLI  50
GGTNNRAPGV PARFSGSLIG DKAALTITGA QTEDEAIYFC ALWCSNHLVF 100
GGGTKLTVLG QPKSSPSVTL FPPSSEELET NKATLVCTIT DFYPGVVTVD 150
WKVDGTPVTQ GMETTQPSKQ SNNKYMASSY LTLTARAWER HSSYSCQVTH 200
EGHTVEKSLS RADCS                                        215
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 150-205 267-327 373-431
22"-96" 150"-205" 267"-327" 373"-431"
Intra-L (C23-C104) 22'-90' 137'-196'
22'"-90'" 137'"-196'"
Inter-H-L (CH1 11-CL 126) 138-214' 138"-214'"
Inter-H-H (h 12, h 15, h 18) 230-230" 233-233" 235-235"

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

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
303, 303"
Fucosylated complex bi-antennary SP2/0-type glycans / glycanes de type SP2/0 bi-antennaires complexes fucosylés / glicanos de tipo SP2/0 biantenarios complejos fucosilados

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
453, 453"

grisnilimabum setaritoxum #
grisnilimab setaritox

immunoglobulin G2A-lambda, anti-[CD7 (CD7 antigen (p41),GP40, LEU-9, TP41, Tp40)], *Mus musculus* monoclonal antibody conjugated to ricin toxin A (RTA); gamma2a heavy chain *Mus musculus* (1-453) [VH (*Mus musculus* IGHV9-3-1*01 (98%) -(IGHD) -IGHJ2*01 (93.3%)) CDR-IMGT [8.8.16] (26-33.51-58.97-112) (1-123) -*Mus musculus* IGHG2A*01 (100%) (CH1 (124-220), hinge 1-16 (221-236), CH2 (237-346), CH3 (347-451), CHS (452-453)) (124-453)], (138-214')-disulfide

	with lambda light chain *Mus musculus* (1'-215') [V-LAMBDA (*Mus musculus* IGLV1*01 (98%) - IGLJ1*01 (100%)) CDR-IMGT [9.3.9] (26-34.52-54.91-99) (1'-109') -*Mus musculus* IGLC1*01 (100%) (110'-215')]; dimer (230-230":233-233":235-235")-trisdisulfide, produced in SP2/0-derived mouse myeloma cells, glycoform alfa, substituted at N^6 of an average of 1.6 lysyl residues with 4-[(1*RS*)-1-{[L-methionyl-ricin toxin A-chain (Met-RTA, non-glycosylated, produced in *Escherichia coli*)-S^{260}-yl]sulfanyl}ethyl]benzoyl groups
grisnilimab sétaritox	immunoglobuline G2A-lambda, anti-[CD7 (CD7 antigène (p41), GP40, LEU-9, TP41, Tp40)], anticorps monoclonal *Mus musculus* conjugué à la toxine A de la ricine (RTA); chaîne lourde gamma2a *Mus musculus* (1-453) [VH (*Mus musculus* IGHV9-3-1*01 (98%) -(IGHD) - IGHJ2*01 (93.3%)) CDR-IMGT [8.8.16] (26-33.51-58.97-112) (1-123) -*Mus musculus* IGHG2A*01 (100%) (CH1 (124-220), charnière 1-16 (221-236), CH2 (237-346), CH3 (347-451), CHS (452-453)) (124-453)], (138-214')-disulfure avec la chaîne légère lambda *Mus musculus* (1'-215') [V-LAMBDA (*Mus musculus* IGLV1*01 (98%) -IGLJ1*01 (100%)) CDR-IMGT [9.3.9] (26-34.52-54.91-99) (1'-109') -*Mus musculus* IGLC1*01 (100%) (110'-215')]; dimère (230-230":233-233":235-235")-trisdisulfure, produit par une lignée cellulaire dérivée de myélome murin SP2/0, glycoforme alfa, substitué en N^6 sur un moyenne de 1.6 résidus lysyl par des groupes 4-[(1*RS*)-1-{[L-méthionyl-chaîne A de la toxine de ricine (Met-RTA, non-glycosylée, produite par *Escherichia coli*)-S^{260}-yl]sulfanyl}éthyl]benzoyle
grisnilimab setaritox	inmunoglobulina G2A-lambda, anti-[CD7 (CD7 antígeno (p41), GP40, LEU-9, TP41, Tp40)], anticuerpo monoclonal *Mus musculus* conjugado con la toxina A de la ricina (RTA); cadena pesada gamma2a *Mus musculus* (1-453) [VH (*Mus musculus* IGHV9-3-1*01 (98%) -(IGHD) - IGHJ2*01 (93.3%)) CDR-IMGT [8.8.16] (26-33.51-58.97-112) (1-123) -*Mus musculus* IGHG2A*01 (100%) (CH1 (124-220), bisagra 1-16 (221-236), CH2 (237-346), CH3 (347-451), CHS (452-453)) (124-453)], (138-214')-disulfuro con la cadena ligera lambda *Mus musculus* (1'-215') [V-LAMBDA (*Mus musculus* IGLV1*01 (98%) -IGLJ1*01 (100%)) CDR-IMGT [9.3.9] (26-34.52-54.91-99) (1'-109') -*Mus musculus* IGLC1*01 (100%) (110'-215')]; dímero (230-230":233-233":235-235")-trisdisulfuro, producido en una línea celular de mieloma murino SP2/0, forma glicosilada alfa, sustituída en N^6 de un promedio de 1,6 residuos de lisilo con grupos de 4-[(1*RS*)-1-{[L-metionil-cadena A de toxina de ricina (Met-RTA, no glicosilada, producida por *Escherichia coli*)-S^{260}-il]sulfanil}etil]benzoilo

Heavy chain / Chaîne lourde / Cadena pesada

```
QIQLVQSGPE LKKPGETVKI SCKASGYTFT NYGMNWVKQA PGKGLMWLGW  50
INTYTGEPTY ADDFKGRFAF SLETSASTAY LQINNLKNED TATYFCARWA 100
YFYGSSPYFF DYWGQGTTLT VSSAKTTAPS VYPLAPVCGD TTGSSVTLGC 150
LVKGYFPEPV TLTWNSGSLS SGVHTFPAVL QSDLYTLSSS VTVTSSTWPS 200
QSITCNVAHP ASSTKVDKKI EPRGPTIKPC PPCKCPAPNL LGGPSVFIFP 250
PKIKDVLMIS LSPIVTCVVV DVSEDDPDVQ ISWFVNNVEV HTAQTQTHRE 300
DYNSTLRVVS ALPIQHQDWM SGKEFKCKVN NKDLPAPIER TISKPKGSVR 350
APQVYVLPPP EEEMTKKQVT LTCMVTDFMP EDIYVEWTNN GKTELNYKNT 400
EPVLDSDGSY FMYSKLRVEK KNWVERNSYS CSVVHEGLHN HHTTKSFSRT 450
PGK                                                     453
```

Light chain / Chaîne légère / Cadena ligera

```
QAVVTQESAL TTSPGETVTL TCRSSTGAVT TSNYANWVQE KPDHLFTGLI  50
GGTNNRAPGV PARFSGSLIG DKAALTITGA QTEDEAIYFC ALWCSNHLVF 100
GGGTKLTVLG QPKSSPSVTL FPPSSEELET NKATLVCTIT DFYPGVVTVD 150
WKVDGTPVTQ GMETTQPSKQ SNNKYMASSY LTLTARAWER HSSYSCQVTH 200
EGHTVEKSLS RADCS                                        215
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Met-Ricin A chain / Met-chaîne A de la Ricine / Met-cadena A de la Ricina

```
MIFPKQYPII NFTTAGATVQ SYTNFIRAVR GRLTTGADVR HDIPVLPNRV 50
GLPINQRFIL VELSNHAELS VTLALDVTNA YVVGYRAGNS AYFFHPDNQE 100
DAEAITHLFT DVQNRYTFAF GGNYDRLEQL AGNLRENIEL GNGPLEEAIS 150
ALYYYSTGGT QLPTLARSFI ICIQMISEAA RFQYIEGEMR TRIRYNRRSA 200
PDPSVITLEN SWGRLSTAIQ ESNQGAFASP IQLQRRNGSK FSVYDVSILI 250
PIIALMVYRC APPPSSQF                                     268
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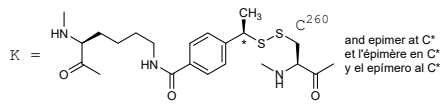
Post-translational modifications

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

Intra-H (C23-C104) 22-96 150-205 267-327 373-431
22"-96" 150"-205" 267"-327" 373"-431"
Intra-L (C23-C104) 22'-90' 137'-196'
22'"-90'" 137'"-196'"
Inter-H-L (CH1 11-CL 126) 138-214' 138"-214'"
Inter-H-H (h 12, h 15, h 18) 230-230" 233-233" 235-235"
heterogeneous patterns involving 94' and 94'" e.g.:
96-94' 138-94' 150-94' 94'-137'
96"-94'" 138"-94'" 150"-94'" 94'"-137'"
Met-RTA: C172 = Cys-SH, C260 = Cys-S-S-CH(CH3)-p-C6H4-CO-[N6-Lys(H,L)]

Conjugation sites / Sites de conjugaison / Posiciones de coniugación

major: K87 K228 K72' K113'
K87" K228" K72'" K113'"
minor: K43 K215 K323 K332 K398 K421 K132'
K43" K215" K323" K332" K398" K421" K132'"



N-terminal glutaminyl cyclization to pyroglutamyl (pE, 5-oxoprolyl)

H VH Q1:
1, 1"
L VL Q1:
1', 1'"

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

H CH2 N84.4:
303, 303"
Fucosylated complex bi-antennary SP2/0-type glycans / glycanes de type SP2/0 bi-antennaires complexes fucosylés / glicanos de tipo SP2/0 biantenarios complejos fucosilados.

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal

H CHS K2:
453, 453"

hepcidinum

hepcidin — hepcidin (human) (hepatical bactericidal protein, hepcidin-25, liver-expressed antimicrobial peptide 1, LEAP-1, hepatic antimicrobial peptide, HAMP, ferroportin regulator protein): *S*^{7},*S*^{23}:*S*^{10},*S*^{13}:*S*^{11},*S*^{19}:*S*^{14},*S*^{22}-tetracyclo(L-α-aspartyl-L-threonyl-L-histidyl-L-phenylalanyl-L-prolyl-L-isoleucyl-L-cysteinyl-L-isoleucyl-L-phenylalanyl-L-cysteinyl-L-cysteinylglycyl-L-cysteinyl-L-cysteinyl-L-histidyl-L-arginyl-L-seryl-L-lysyl-L-cysteinylglycyl-L-methionyl-L-cysteinyl-L-cysteinyl-L-lysyl-L-threonine)

hepcidine — hepcidine (humaine) (protéine bactéricide hépatique, hepcidine-25, peptide antimicrobien exprimé par le foie 1, LEAP-1, peptide antimicrobien hépatique, HAMP, protéine régulatrice de la ferroportine):

S^{7},*S*^{23}:*S*^{10},*S*^{13}:*S*^{11},*S*^{19}:*S*^{14},*S*^{22}-tétracyclo(L-α-aspartyl-L-thréonyl-L-histidyl-L-phénylalanyl-L-prolyl-L-isoleucyl-L-cystéinyl-L-isoleucyl-L-phénylalanyl-L-cystéinyl-L-cystéinylglycyl-L-cystéinyl-L-cystéinyl-L-histidyl-L-arginyl-L-séryl-L-lysyl-L-cystéinylglycyl-L-méthionyl-L-cystéinyl-L-cystéinyl-L-lysyl-L-thréonine)

hepcidina

hepcidina (humana) (proteína bactericida hepática, hepcidina-25, péptido antimicrobiano expresado en el hígado 1, LEAP-1, péptido antimicrobiano hepático, HAMP, proteína reguladora de ferroportina): *S*^{7},*S*^{23}:*S*^{10},*S*^{13}:*S*^{11},*S*^{19}:*S*^{14},*S*^{22}-tetraciclo(L-α-aspartil-L-treonil-L-histidil-L-fenilalanil-L-prolil-L-isoleucil-L-cisteinil-L-isoleucil-L-fenilalanil-L-cisteinil-L-cisteinilglicil-L-cisteinil-L-cisteinil-L-histidil-L-arginil-L-seril-L-lisil-L-cisteinilglicil-L-metionil-L-cisteinil-L-cisteinil-L-lisil-L-treonina)

$C_{113}H_{170}N_{34}O_{31}S_9$

Sequence / Séquence / Secuencia
DTHFPICIFC CGCCHRSKCG MCCKT 25

Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
7-23, 10-13, 11-19, 14-22

ibezapolstatum

ibezapolstat

2-{[(3,4-dichlorophenyl)methyl]amino}-7-[2-(morpholin-4-yl)ethyl]-1,7-dihydro-6*H*-purin-6-one

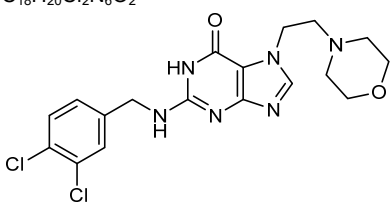
ibézapolstat

2-{[(3,4-dichlorophényl)méthyl]amino}-7-[2-(morpholin-4-yl)éthyl]-1,7-dihydro-6*H*-purin-6-one

ibezapolstat

2-{[(3,4-diclorofenil)metil]amino}-7-[2-(morfolin-4-il)etil]-1,7-dihidro-6*H*-purin-6-ona

$C_{18}H_{20}Cl_2N_6O_2$



icapamespibum

icapamespib

9-{2-[(2,2-dimethylpropyl)amino]ethyl}-8-[(6-iodo-2*H*-1,3-benzodioxol-5-yl)sulfanyl]-9*H*-purin-6-amine

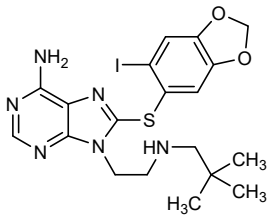
icapamespib

9-{2-[(2,2-diméthylpropyl)amino]éthyl}-8-[(6-iodo-2*H*-1,3-benzodioxol-5-yl)sulfanyl]-9*H*-purin-6-amine

icapamespib

9-{2-[(2,2-dimetilpropil)amino]etil}-8-[(6-iodo-2*H*-1,3-benzodioxol-5-il)sulfanil]-9*H*-purin-6-amina

$C_{19}H_{23}IN_6O_2S$



idactamabum #

idactamab	immunoglobulin G1-kappa, anti-[*Homo sapiens* SLC1A5 (solute carrier family 1 member 5,neutral amino acid transporter, RDRC, M7V1,AAAT, ASCT2)], *Homo sapiens* monoclonal antibody; gamma1 heavy chain *Homo sapiens* (1-452) [VH (*Homo sapiens* IGHV4-34*01 (96.9%) -(IGHD) -IGHJ4*01 (100%)) [8.7.15] (1-121) -*Homo sapiens* IGHG1*03 G1m3, nG1m1 (CH1 R120 (218) (122-219), hinge 1-15 (220-234), CH2 3^4>ins^cysteinyl (244) (235-345), CH3 E12 (361), M14 (363) (346-450), CHS (451-452))(122-452)], (224-214')-disulfide with kappa light chain *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-5*03 (94.7%) -IGKJ1*01 (100%)) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (230-230'':233-233'')-bisdisulfide, produced in a Chinese hamster ovary (CHO) cell line derived from CHO-K1, glycoform alfa
idactamab	immunoglobuline G1-kappa, anti-[*Homo sapiens* SLC1A5 (famille du porteur soluté 1 membre 5, transporteur d'acide aminé neutre, RDRC, M7V1, AAAT, ASCT2)], anticorps monoclonal *Homo sapiens;* chaîne lourde gamma1 *Homo sapiens* (1-452) [VH (*Homo sapiens* IGHV4-34*01 (96.9%) -(IGHD) -IGHJ4*01 (100%)) [8.7.15] (1-121) -*Homo sapiens* IGHG1*03 G1m3, nG1m1 (CH1 R120 (218) (122-219), charnière 1-15 (220-234), CH2 3^4>ins^cysteinyl (244) (235-345), CH3 E12 (361), M14 (363) (346-450), CHS (451-452)) (122-452)], (224-214')-disulfure avec la chaîne légère kappa *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-5*03 (94.7%) -IGKJ1*01 (100%)) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (230-230'':233-233'')-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) dérivant de la lignée cellulaire CHO-K1, glycoforme alfa
idactamab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* SLC1A5 (familia del portador de soluto 1 miembro 5, transportador de ácido amino neutral, RDRC, M7V1, AAAT, ASCT2)], anticuerpo monoclonal *Homo sapiens*; cadena pesada gamma1 *Homo sapiens* (1-452) [VH (*Homo sapiens* IGHV4-34*01 (96.9%) -(IGHD) -IGHJ4*01 (100%)) [8.7.15] (1-121) -*Homo sapiens* IGHG1*03 G1m3, nG1m1 (CH1 R120 (218) (122-219), bisagra 1-15 (220-234), CH2 3^4>ins^cisteinil (244) (235-345), CH3 E12 (361), M14 (363) (346-450), CHS (451-452)) (122-452)], (224-214')-disulfuro con la cadena ligera kappa *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-5*03 (94.7%) -IGKJ1*01 (100%)) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (230-230'':233-233'')-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular derivada de CHO-K1, forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLQQWGAG LLKPSETLSL TCAVYGGSFS GYYWSWIRQP PGKGLEWIGE  50
IHHSGGANYN PSLKSRVTIS VDTSKNQFSL KLSSVTAADT AVYYCARGQG 100
KNWHYDYFDY WGQGTLVTVS SASTKGPSVF PLAPSSKSTS GGTAALGCLV 150
KDYFPEPVTV SWNSGALTSG VHTFPAVLQS SGLYSLSSVV TVPSSSLGTQ 200
TYICNVNHKP SNTKVDKRVE PKSCDKTHTC PPCPAPELLG GPSCVFLFPP 250
KPKDTLMISR TPEVTCVVVD VSHEDPEVKF NWYVDGVEVH NAKTKPREEQ 300
YNSTYRVVSV LTVLHQDWLN GKEYKCKVSN KALPAPIEKT ISKAKGQPRE 350
PQVYTLPPSR EEMTKNQVSL TCLVKGFYPS DIAVEWESNG QPENNYKTTP 400
PVLDSDGSFF LYSKLTVDKS RWQQGNVFSC SVMHEALHNH YTQKSLSLSP 450
GK                                                      452
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Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPST LSASVGDRVT ITCRASQSIR SWLAWYQQKP GKAPKLLIYK  50
ASILKIGVPS RFSGSGSGTE FTLTISSLQP DDFATYYCQQ YYSYSRTFGQ 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
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Post-translational modifications

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

Intra-H (C23-C104) 22-95 148-204 266-326 372-430
22"-95" 148"-204" 266"-326" 372"-430"

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

Inter-H-L (h 5-CL 126) 224-214' 224"-214'"

Inter-H-H (h 11, h 14) 230-230" 233-233"

Cysteinyl inserted for conjugation capped by a cysteinyl
H CH2 C3^4):
244, 244"

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"

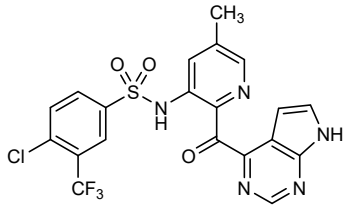
ilacirnonum

ilacirnon — 4-chloro-*N*-[5-methyl-2-(7*H*-pyrrolo[2,3-*d*]pyrimidine-4-carbonyl)pyridin-3-yl]-3-(trifluoromethyl)benzene-1-sulfonamide

ilacirnon — 4-chloro-*N*-[5-méthyl-2-(7*H*-pyrrolo[2,3-*d*]pyrimidine-4-carbonyl)pyridin-3-yl]-3-(trifluorométhyl)benzène-1-sulfonamide

ilacirnón — 4-cloro-*N*-[5-metil-2-(7*H*-pirrolo[2,3-*d*]pirimidina-4-carbonil)piridin-3-il]-3-(trifluorometil)benceno-1-sulfonamida

$C_{20}H_{13}ClF_3N_5O_3S$



insulinum icodecum

insulin icodec — human insulin A-chain (1-21) variant (Y>E^{14}), human insulin B-chain (1-29) variant (Y>H^{16}, F>H^{25}) conjugated at K^{29B} at its N^6 to (22*S*)-22,42-dicarboxy-10,19,24-trioxo-3,6,12,15-tetraoxa-9,18,23-triazadotetracontan-1-oyl; $N^{6.29B}$-[(22*S*)-22,42-dicarboxy-10,19,24-trioxo-3,6,12,15-tetraoxa-9,18,23-triazadotetracontan-1-oyl]-[Tyr14^A>Glu, Tyr16^B>His, Phe25^B>His]-des-Thr30^B-human insulin

insuline icodec

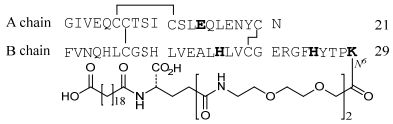
chaîne A de l'insuline humaine (1-21) variant (Y>E^{14}), chaîne B de l'insuline humaine (1-29) variant (Y>H^{16}, F>H^{25}), conjuguée en K^{29B} par son *N*^{6} à (22*S*)-22,42-dicarboxy-10,19,24-trioxo-3,6,12,15-tétraoxa-9,18,23-triazadotétracontan-1-oyle; *N*$^{6.29B}$-[(22*S*)-22,42-dicarboxy-10,19,24-trioxo-3,6,12,15-tétraoxa-9,18,23-triazadotétracontan-1-oyl]-[Tyr14^{A}>Glu, Tyr16^{B}>His, Phé25^{B}>His]-des-Thr30^{B}-insuline humaine

insulina icodec

insulina humana cadena-A (1-21) variante (Y>E^{14}), insulina humana cadena-B (1-29) variante (Y>H^{16}, F>H^{25}) conjugada con K^{29B} con su *N*^{6} al (22*S*)-22,42-dicarboxi-10,19,24-trioxo-3,6,12,15-tetraoxa-9,18,23-triazadotetracontan-1-oilo; *N*$^{6.29B}$-[(22*S*)-22,42-dicarboxi-10,19,24-trioxo-3,6,12,15-tetraoxa-9,18,23-triazadotetracontan-1-oil]-[Tir14^{A}>Glu, Tir16^{B}>His, Fen25^{B}>His]-des-Tre30^{B}-insulina humana

$C_{280}H_{435}N_{71}O_{87}S_6$

Sequences / Séquences / Secuencias



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

Intra-chain 6^{A}-11^{A}

Inter-chain 7^{A}-7^{B}, 20^{A}-19^{B}

Modifications / Modifications / Modificaciones

$Lys29^{B}$ conjugated at N^{6}

inupadenantum

inupadenant

(+)-5-amino-3-{2-[4-(2,4-difluoro-5-{2-[(*S*)-methanesulfinyl]ethoxy}phenyl)piperazin-1-yl]ethyl}-8-(furan-2-yl)[1,3]thiazolo[5,4-*e*][1,2,4]triazolo[1,5-*c*]pyrimidin-2(3*H*)-one

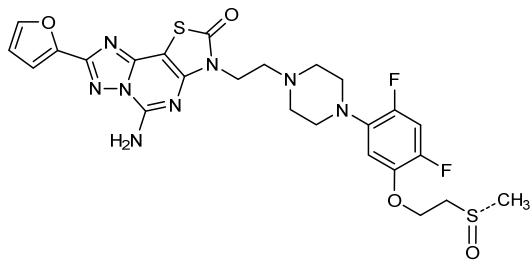
inupadénant

(+)-5-amino-3-{2-[4-(2,4-difluoro-5-{2-[(*S*)-méthanesulfinyl]éthoxy}phényl)pipérazin-1-yl]éthyl}-8-(furan-2-yl)[1,3]thiazolo[5,4-*e*][1,2,4]triazolo[1,5-*c*]pyrimidin-2(3*H*)-one

inupadenant

(+)-5-amino-3-{2-[4-(2,4-difluoro-5-{2-[(*S*)-metanosulfinil]etoxi}fenil)piperazin-1-il]etil}-8-(furan-2-il)[1,3]tiazolo[5,4-*e*][1,2,4]triazolo[1,5-*c*]pirimidin-2(3*H*)-ona

$C_{25}H_{26}F_2N_8O_4S_2$



invimestrocelum

invimestrocel	Allogeneic human multipotent adult progenitor cells (MAPC) derived from bone marrow and isolated by density gradient centrifugation. The cells are expanded *ex vivo* on fibronectin-coated surfaces under low-oxygen conditions and in the presence of growth media for the creation of a master cell bank (passage 4), a working cell bank (passage 6) and active substance (passage 9). The cells are adherent, secrete proangiogenic factors (including VEGF, IL-8 and CXCL5) and of mesenchymal progenitor lineage (*in vitro* differentiation to endothelial, hepatic and neuronal lineages). The cells express CD49c and CD90 (≥ 95% of the cells), and lack expression of CD45 and HLA II (< 5%). Additional markers include >90% CD13, CD44, CD73, CD105 and <5% CD34. The cells have also been shown to induce T cell suppression.
invimestrocel	Cellules humaines adultes progénitrices multipotentes qui sont allogéniques (MAPC), dérivées de la moelle osseuse et isolées par centrifugation à gradient de densité. Les cellules sont amplifiées *ex vivo* sur des surfaces recouvertes de fibronectine dans des conditions de faible teneur en oxygène et en présence de milieux de croissance pour la création d'une banque de cellules primaires (passage 4) et d'une banque de cellules de travail (passage 6) et d'une substance active produit fini (passage 9). Les cellules sont adhérentes, sécrètent des facteurs pro-angiogéniques (notamment le VEGF, l'IL-8 et la CXCL5) et sont de la lignée progénitrice mésenchymateuse (différenciation *in vitro* en lignées endothéliales, hépatiques et neuronales). Les cellules expriment CD49c et CD90 (≥ 95% des cellules), et sont négatives pour CD45 et HLA II (< 5%). Les marqueurs supplémentaires comprennent > 90 % de CD13, CD44, CD73, CD105 et < 5 % de CD34. Il a également été démontré que les cellules induisent la suppression des lymphocytes T.
invimestrocel	Células progenitoras adultas multipotentes humanas alogénicas (MAPC) derivadas de médula ósea y aisladas mediante centrifugación en gradiente de densidad. Las células se expanden *ex vivo* en superficies cubiertas de fibronectina en condiciones de oxígeno bajo y en presencia de medio de crecimiento para la creación de un banco de células maestro (pase 4) y un banco de células de trabajo (pase 6) y el principio activo (pase 9). Las células son adherentes, secretan factores proangiogénicos (incluyendo VEGF, IL-8 y CXCL5) y son de la línea progenitora mesenquimal (diferenciación *in vitro* a las líneas endotelial, hepática y neuronal). Las células expresan CD49c (≥ 95% de las células), y carecen de expresión de CD45 y HLA II (<5%). Otros marcadores adicionales incluyen >90% de CD13, CD44, CD73, CD105 y <5% de CD34. Se ha demostrado también que las células inducen supresión de linfocitos T.

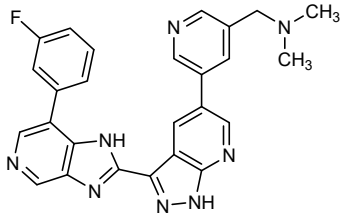
ipivivintum

ipivivint — 1-(5-{3-[7-(3-fluorophenyl)-1*H*-imidazo[4,5-*c*]pyridin-2-yl]-1*H*-pyrazolo[3,4-*b*]pyridin-5-yl}pyridin-3-yl)-*N*,*N*-dimethylmethanamine

ipivivint — 1-(5-{3-[7-(3-fluorophényl)-1*H*-imidazo[4,5-*c*]pyridin-2-yl]-1*H*-pyrazolo[3,4-*b*]pyridin-5-yl}pyridin-3-yl)-*N*,*N*-diméthylméthanamine

ipivivint — 1-(5-{3-[7-(3-fluorofenil)-1*H*-imidazo[4,5-*c*]piridin-2-il]-1*H*-pirazolo[3,4-*b*]piridin-5-il}piridin-3-il)-*N*,*N*-dimetilmetanamina

$C_{26}H_{21}FN_8$



izuralimabum #

izuralimab — immunoglobulin half-IG G1-kappa/scFv-h-CH2-CH3, anti-[*Homo sapiens* ICOS (inductible T-cell costimulatory, activation-inducible lymphocyte immunomediatory molecule, AILIM, CD278)] and anti-[*Homo sapiens* PDCD1 (programmed cell death 1, PD-1, PD1, CD279)], monoclonal antibody, bispecific; gamma1 heavy chain anti-ICOS (1-454) [VH (*Homo sapiens* IGHV1-2*02 (99%) -(IGHD) -IGHJ3*02 (100%)) CDR-IMGT [8.8.18] (26-33.51-58.97-114) (1-125) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 N114>D (216) R120>K (222) (126-223), hinge 1-15 (224-238), CH2 E1.4,L1.3>P (241), L1.2>V (242), G1.1>A (243), S29>K (274), Q84.2>E (302) (239-347), CH3 E12 (363), M14 (365), L24>D (375), K26>S (377), N44>D (391), Q97>E (425), N100>D (428), M107>L (435), N114>S (441) (348-452), CHS (453-454)) (126-454)], (228-214')-disulfide with kappa light chain anti-ICOS (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-12*01 (96.8%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')];
IG scFv-h-CH2-CH3 single chain, anti-PDCD1 (1''-480'') [scFv-V-kappa-VH anti-PDCD1 (1''-249'')[V-KAPPA (*Homo sapiens* IGKV3-15*01 (80.0%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1''-107'') -20-mer tetrakis(glycyl-lysyl-prolyl-glycyl-seryl) linker (108''-127'') -VH (*Mus musculus* IGHV6-6*02 (87.0%) -(IGHD) -IGHJ1*03 (86.7%)/*Homo sapiens* IGHV3-15*07 (81.8%) -(IGHD) -IGHJ2*01 (93.3%)) CDR-IMGT [8.10.13] (153-160.178-187.226-238) (128''-249'')] -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (250''-480'') [hinge 1-15 C5>S (254) (250-264) -CH2 E1.4,L1.3>P (267), L1.2>V (268), G1.1>A (269), S29>K (300) (265-373),CH3 E12 (389), E13>Q (390), M14 (391), S20>K (397), M107>L (461), N114>S (467) (374-478), CHS (479-480)]];
dimer (234-260'':237-263'')-bisdisulfide, produced in Chinese hamster ovary (CHO)-S cell line, glycoform alfa

izuralimab	immunoglobuline demi-IG G1-kappa/scFv-h-CH2-CH3, anti-[*Homo sapiens* ICOS (costimulateur inductible du lymphocyte T, molécule immunomédiateur lymphocytaire inductible par activation, AILIM, CD278)] et anti-[*Homo sapiens* PDCD1 (protéine 1 de mort cellulaire programmée, PD-1, PD1, CD279)], anticorps monoclonal, bispécifique; chaîne lourde gamma1 anti-ICOS (1-454) [VH (*Homo sapiens* IGHV1-2*02 (99%) -(IGHD) -IGHJ3*02 (100%)) CDR-IMGT [8.8.18] (26-33.51-58.97-114) (1-125) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 N114>D (216) R120>K (222) (126-223), charnière 1-15 (224-238), CH2 E1.4,L1.3>P (241), L1.2>V (242), G1.1>A (243), S29>K (274), Q84.2>E (302) (239-347), CH3 E12 (363), M14 (365), L24>D (375), K26>S (377), N44>D (391), Q97>E (425), N100>D (428), M107>L (435), N114>S (441) (348-452), CHS (453-454)) (126-454)], (228-214')-disulfure avec la chaîne légère kappa anti-ICOS (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-12*01 (96.8%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')]; IG scFv-h-CH2-CH3 chaîne unique, anti-PDCD1 (1"-480") [scFv V-kappa-VH anti-PDCD1 (1"-249") [V-KAPPA (*Homo sapiens* IGKV3-15*01 (80.0%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1"-107") -20-mer tétrakis(glycyl-lysyl-prolyl-glycyl-séryl) linker (126"-145") -VH (*Mus musculus* IGHV6-6*02 (87.0%) -(IGHD) -IGHJ1*03 (86.7%)/*Homo sapiens* IGHV3-15*07 (81.8%) -(IGHD) -IGHJ2*01 (93.3%)) CDR-IMGT [8.10.13] (153-160.178-187.226-238) (128"-249")] -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (250"-480") [charnière 1-15 C5>S (254) (250-264) -CH2 E1.4,L1.3>P (267), L1.2>V (268), G1.1>A (269), S29>K (300) (265-373), CH3 E12 (389), E13>Q (390), M14 (391), S20>K (397), M107>L (461), N114>S (467) (374-478), CHS (479-480)]]; dimère (234-260":237-263")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) lignée cellulaire CHO-S, glycoforme alfa
izuralimab	inmunoglobulina demi-IG G1-kappa/scFv-h-CH2-CH3, anti-[*Homo sapiens* ICOS (coestimulador inducible del linfocito T, molécula inmunomediadora linfocitaria inducible por activación, AILIM, CD278)] y anti-[*Homo sapiens* PDCD1 (proteína 1 de muerte celular programada, PD-1, PD1, CD279)], anticuerpo monoclonal, biespecífico; cadena pesada gamma1 anti-ICOS (1-454) [VH (*Homo sapiens* IGHV1-2*02 (99%) -(IGHD) -IGHJ3*02 (100%)) CDR-IMGT [8.8.18] (26-33.51-58.97-114) (1-125) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 N114>D (216) R120>K (222) (126-223), bisagra 1-15 (224-238), CH2 E1.4,L1.3>P (241), L1.2>V (242), G1.1>A (243), S29>K (274), Q84.2>E (302) (239-347), CH3 E12 (363), M14 (365), L24>D (375), K26>S (377), N44>D (391), Q97>E (425), N100>D (428), M107>L (435), N114>S (441) (348-452), CHS (453-454)) (126-454)], (228-214')-disulfuro con la cadena ligera kappa anti-ICOS (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-12*01 (96.8%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')]; IG scFv-h-CH2-CH3 cadena única, anti-PDCD1 (1"-480") [scFv V-kappa-VH anti-PDCD1 (1"-249") [V-KAPPA (*Homo sapiens* IGKV3-15*01 (80.0%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1"-107") -20-mer tetrakis(glicil-lisil-prolil-glicil-seril) linker (126"-145") -VH (*Mus musculus* IGHV6-6*02 (87.0%) -(IGHD) -IGHJ1*03 (86.7%)/*Homo sapiens* IGHV3-15*07 (81.8%) -(IGHD) -IGHJ2*01 (93.3%)) CDR-IMGT [8.10.13] (153-160.178-187.226-238) (128"-249")] -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (250"-480") [bisagra 1-15 C5>S (254) (250-264) -CH2 E1.4,L1.3>P (267), L1.2>V (268), G1.1>A (269), S29>K (300) (265-373), CH3 E12 (389), E13>Q (390), M14 (391), S20>K (397), M107>L (461), N114>S (467) (374-478), CHS (479-480)]]; dímero (234-260":237-263")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular CHO-S, forma glicosilada alfa

1.Heavy chain / Chaîne lourde / Cadena pesada (anti-ICOS)

```
QVQLVQSGAE VKKPGASVKV SCKASGYTFT GYYMHWVRQA PGQGLEWMGW  50
INPHSGGTNY AQKFQGRVTM TRDTSISTAY MELSRLRSDD TAVYYCARTY 100
YYDSSGYYHD AFDIWGQGTM VTVSSASTKG PSVFPLAPSS KSTSGGTAAL 150
GCLVKDYFPE PVTVSWNSGA LTSGVHTFPA VLQSSGLYSL SSVVTVPSSS 200
LGTQTYICNV NHKPSDTKVD KKVEPKSCDK THTCPPCPAP PVAGPSVFLF 250
PPKPKDTLMI SRTPEVTCVV VDVKHEDPEV KFNWYVDGVE VHNAKTKPRE 300
EEYNSTYRVV SVLTVLHQDW LNGKEYKCKV SNKALPAPIE KTISKAKGQP 350
REPQVYTLPP SREEMTKNQV SLTCDVSGFY PSDIAVEWES DGQPENNYKT 400
TPPVLDSDGS FFLYSKLTVD KSRWEQGDVF SCSVLHEALH SHYTQKSLSL 450
SPGK                                                    454
```

2. Light chain / Chaîne légère / Cadena ligera (anti-ICOS)

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

3. Chain / Chaîne / Cadena IG scFv-h-CH2-CH3 (anti-PDCD1)

```
EIVLTQSPAT LSASPGERVT LTCRASQSVG NDVAWYQQKP GQAPRLLINY  50
ASHRYTGVPD RFTGSGYGTE FTLTISSVQS EDFGVYYCQQ DFSSPRTFGG 100
GTKVEIKGKP GSGKPGSGKP GSGKPGSEVQ LVESGGGLVK PGGSLRLSCV 150
ASGFTFSNYW MNWVRQAPGK GLEWVAEIRL YSNNYATHYA ESVKGRFTIS 200
RDDSKSTLYL QMNNLKTEDT GVYYCTRYYG NYGGYFDVWG RGTLVTVSSE 250
PKSSDKTHTC PPCPAPPVAG PSVFLFPPKP KDTLMISRTP EVTCVVVDVK 300
HEDPEVKFNW YVDGVEVHNA KTKPREEQYN STYRVVSVLT VLHQDWLNGK 350
EYKCKVSNKA LPAPIEKTIS KAKGQPREPQ VYTLPPSREQ MTKNQVKLTC 400
LVKGFYPSDI AVEWESNGQP ENNYKTTPPV LDSDGSFFLY SKLTVDKSRW 450
QQGNVFSCSV LHEALHSHYT QKSLSLSPGK                       480
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 152-208 268-328 374-432
Intra-L (C23-C104) 23'-88' 134'-194'
Intra-chain 3 23"-88" 149"-225" 294"-354" 400"-458"
Inter-H-L (h 5-CL 126) 228-214'
Inter-H-chain 3 (h 11, h 14) 234-260" 237-263"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
304, 330"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados.

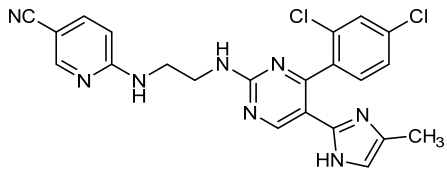
laduviglusibum

laduviglusib — 6-[(2-{[4-(2,4-dichlorophenyl)-5-(4-methyl-1*H*-imidazol-2-yl)pyrimidin-2-yl]amino}ethyl)amino]pyridine-3-carbonitrile

laduviglusib — 6-[(2-{[4-(2,4-dichlorophényl)-5-(4-méthyl-1*H*-imidazol-2-yl)pyrimidin-2-yl]amino}éthyl)amino]pyridine-3-carbonitrile

laduviglusib — 6-[(2-{[4-(2,4-diclorofenil)-5-(4-metil-1*H*-imidazol-2-il)pirimidin-2-il]amino}etil)amino]piridina-3-carbonitrilo

$C_{22}H_{18}Cl_2N_8$



lazucirnonum

lazucirnon — (4^2*R*)-1^4-chloro-*N*,*N*,1^3,7^6-tetramethyl-4^5,5-dioxo-6-aza-7(2)-pyridina-3(1,4)-piperidina-4(1,2)-pyrrolidina-1(1)-benzenaheptaphane-7^4-carboxamide

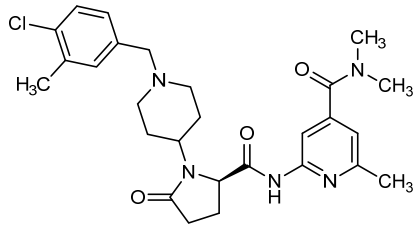
lazucirnon

(4^2*R*)-1^4-chloro-*N*,*N*,1^3,7^6-tétraméthyl-4^5,5-dioxo-6-aza-7(2)-pyridina-3(1,4)-pipéridina-4(1,2)-pyrrolidina-1(1)-benzénaheptaphane-7^4-carboxamide

lazucirnón

(4^2*R*)-1^4-cloro-*N*,*N*,1^3,7^6-tetrametil-4^5,5-dioxo-6-aza-7(2)-piridina-3(1,4)-piperidina-4(1,2)-pirrolidina-1(1)-bencenaheptafano-7^4-carboxamida

$C_{27}H_{34}ClN_5O_3$



lerodalcibepum #

lerodalcibep

engineered binding protein (1-96) anti-(human proprotein convertase subtilisin/kexin type 9), derived from human tenth fibronectin type III domain, fused via peptidyl linker (^{97}GSGSGS^{102}) to human serum albumin (103-687), variant (C^{34}>A^{136}), produced in Chinese hamster ovary (CHO) cells;
human fibronectin tenth type III domain variant anti-[human PCSK9 (pro-protein convertase subtilisin/kexin type 9, neural apoptosis-regulated convertase 1, NARC-1, proprotein convertase 9, PC9)] (1-96) fused via a $(GS)_3$ peptide linker (97-102) with [Cys^{34}>Ala (136)]-human serum albumin (HSA) (103-687), produced in Chinese hamster ovary (CHO) cells, non-glycosylated

lérodalcibep

protéine de liaison mise au point (1-96) anti-(proprotéine convertase subtilisine/kexine type 9), dérivée du dixième domaine de la fibronectine humaine de type III, fusionnée via un peptide de liaison (^{97}GSGSGS^{102}) à l'albumine sérique humaine (103-687), variant (C^{34}>A^{136}), produit dans des cellules ovariennes de hamster chinois (CHO);
peptide variant du dixième domaine de la fibronectine humaine de type III anti-[PCSK9 humain (proprotéine convertase subtilisine/kexine type 9, convertase 1 régulée par l'apoptose neuronale, NARC-1, proprotéine convertase 9, PC9)] (1-96) fusionné via un peptide $(GS)_3$ (97-102) à la [Cys^{34}>Ala (136)]-albumine sérique humaine (ASH) (103-687), produit dans des cellules ovariennes de hamsters chinois (CHO), non-glycosylé

lerodalcibep

proteína de unión diseñada (1-96) anti-(proproteína convertasa humana subtilisina/kexina tipo 9), derivada del décimo dominio de la fibronectina humana del tipo III, fusionada a través de un conector peptidil (^{97}GSGSGS^{102}) a la albúmina sérica humana (103-687), variante (C^{34}>A^{136}), producido en células ováricas de hámster Chino (CHO);

variante del décimo dominio de la fibronectina humana del tipo III anti-[PCSK9 humano (proproteína convertasa subtilisina/kexina tipo 9, convertasa 1 regulada por la apoptosa neuronal, NARC-1, proproteína convertasa 9, PC9)] fusionada mediante un péptido $(GS)_3$ (97-102) a la [Cis^{34}>Ala (136)]-albúmina sérica humana (ASH) (103-687), producido en células ováricas de hámster Chino (CHO), no glicosilado

Sequence / Séquence / Secuencia

```
VSDVPRDLEV VAATPTSLLI SWDAPAEGYG YYRITYGETG GNSPVQEFTV   50
PVSKGTATIS GLKPGVDYTI TVYAVEFDFP GAGYYHRPIS INYRTEGSGS  100
GSDAHKSEVA HRFKDLGEEN FKALVLIAFA QYLQQAPFED HVKLVNEVTE  150
FAKTCVADES AENCDKSLHT LFGDKLCTVA TLRETYGEMA DCCAKQEPER  200
NECFLQHKDD NPNLPRLVRP EVDVMCTAFH DNEETFLKKY LYEIARRHPY  250
FYAPELLFFA KRYKAAFTEC CQAADKAACL LPKLDELRDE GKASSAKQRL  300
KCASLQKFGE RAFKAWAVAR LSQRFPKAEF AEVSKLVTDL TKVHTECCHG  350
DLLECADDRA DLAKYICENQ DSISSKLKEC CEKPLLEKSH CIAEVENDEM  400
PADLPSLAAD FVESKDVCKN YAEAKDVFLG MFLYEYARRH PDYSVVLLLR  450
LAKTYETTLE KCCAAADPHE CYAKVFDEFK PLVEEPQNLI KQNCELFEQL  500
GEYKFQNALL VRYTKKVPQV STPTLVEVSR NLGKVGSKCC KHPEAKRMPC  550
AEDYLSVVLN QLCVLHEKTP VSDRVTKCCT ESLVNRRPCF SALEVDETYV  600
PKEFNAETFT FHADICTLSE KERQIKKQTA LVELVKHKPK ATKEQLKAVM  650
DDFAAFVEKC CKADDKETCF AEEGKKLVAA SQAALGL                687
```

Mutation / Mutation / Mutación

C^{136}>**A**

Post-translational modifications

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

155-164, 177-192, 193-203, 226-270, 271-279, 302-347, 348-355, 367-380, 381-391, 418-462, 463-471, 494-539, 540-550, 563-578, 579-589, 616-660, 661-669

Glycosylation sites / Sites de glycosylation / Posiciones de glicosilación

none / aucune / ninguna

letaplimabum #

letaplimab

immunoglobulin G4-kappa, anti-[*Homo sapiens* CD47 (integrin associated protein, IAP, MER6, OA3)], *Homo sapiens* monoclonal antibody;
gamma4 heavy chain *Homo sapiens* (1-441) [VH (*Homo sapiens* IGHV4-59*01 (100%) -(IGHD) -IGHJ1*01 (100%)) CDR-IMGT [8.7.9] (26-33.51-57.96-104) (1-115)-*Homo sapiens* IGHG4*01, G4v4 CH2 A1.3, A1.2 (CH1 (116-213), hinge 1-12 S10>P (223) (214-225), CH2 F1.3>A (229), L1.2>A (230) (226-335), CH3 (336-440), CHS K>del (441) (116-441)], (129-214')-disulfide with kappa light chain *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-12*01 (96.8%) -IGKJ4*01 (91.7%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (221-221":224-224")-bisdisulfide, produced in Chinese hamster ovary (CHO)-S cell line, glycoform alfa

létaplimab

immunoglobuline G4-kappa, anti-[*Homo sapiens* CD47 (protéine associée à l'intégrine, IAP, MER6, OA3)], anticorps monoclonal *Homo sapiens*;

chaîne lourde gamma4 *Homo sapiens*(1-441) [VH (*Homo sapiens* IGHV4-59*01 (100%) -(IGHD) - IGHJ1*01 (100%)) CDR-IMGT [8.7.9] (26-33.51-57.96-104) (1-115) -*Homo sapiens* IGHG4*01, G4v4 CH2 A1.3, A1.2 (CH1 (116-213), charnière 1-12 S10>P (223) (214-225), CH2 F1.3>A (229), L1.2>A (230) (226-335), CH3 (336-440), CHS K>del (441) (116-441)], (129-214')-disulfure avec la chaîne légère kappa *Homo sapiens*(1'-214') [V-KAPPA (*Homo sapiens* IGKV1-12*01 (96.8%) -IGKJ4*01 (91.7%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (221-221":224-224")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) lignée cellulaire CHO-S, glycoforme alfa

letaplimab

inmunoglobulina G4-kappa, anti-[*Homo sapiens* CD47 (proteína asociada a la integrina, IAP, MER6, OA3)], anticuerpo monoclonal *Homo sapiens;*
cadena pesada gamma4 *Homo sapiens*(1-441) [VH (*Homo sapiens* IGHV4-59*01 (100%) -(IGHD) - IGHJ1*01 (100%)) CDR-IMGT [8.7.9] (26-33.51-57.96-104) (1-115) -*Homo sapiens* IGHG4*01, G4v4 CH2 A1.3, A1.2 (CH1 (116-213), bisagra 1-12 S10>P (223) (214-225), CH2 F1.3>A (229), L1.2>A (230) (226-335), CH3 (336-440), CHS K>del (441) (116-441)], (129-214')-disulfuro con la cadena ligera kappa *Homo sapiens*(1'-214') [V-KAPPA (*Homo sapiens* IGKV1-12*01 (96.8%) -IGKJ4*01 (91.7%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (221-221":224-224")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular CHO-S, forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLQESGPG LVKPSETLSL TCTVSGGSIS SYYWSWIRQP PGKGLEWIGY  50
IYYSGSTNYN PSLKSRVTIS VDTSKNQFSL KLSSVTAADT AVYYCARGKT 100
GSAAWGQGTL VTVSSASTKG PSVFPLAPCS RSTSESTAAL GCLVKDYFPE 150
PVTVSWNSGA LTSGVHTFPA VLQSSGLYSL SSVVTVPSSS LGTKTYTCNV 200
DHKPSNTKVD KRVESKYGPP CPPCPAPEAA GGPSVFLFPP KPKDTLMISR 250
TPEVTCVVVD VSQEDPEVQF NWYVDGVEVH NAKTKPREEQ FNSTYRVVSV 300
LTVLHQDWLN GKEYKCKVSN KGLPSSIEKT ISKAKGQPRE PQVYTLPPSQ 350
EEMTKNQVSL TCLVKGFYPS DIAVEWESNG QPENNYKTTP PVLDSDGSFF 400
LYSRLTVDKS RWQEGNVFSC SVMHEALHNH YTQKSLSLSL G          441
```

Light chain / Chaîne légère / Cadena ligera

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

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-95 142-198 256-316 362-420
22"-95" 142"-198" 256"-316" 362"-420"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (CH1 10-CL 126) 129-214' 129"-214'"
Inter-H-H (h 8, h 11) 221-221" 224-224"

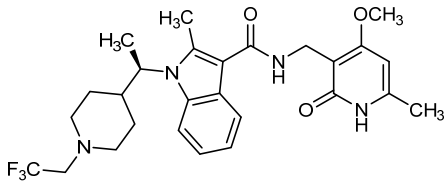
N-terminal glutaminyl cyclization to pyroglutamyl (pE, 5-oxoprolyl)
L VH Q1:
1, 1"

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.

lirametostatum

lirametostat	*N*-[(4-methoxy-6-methyl-2-oxo-1,2-dihydropyridin-3-yl)methyl]-2-methyl-1-{(1*R*)-1-[1-(2,2,2-trifluoroethyl)piperidin-4-yl]ethyl}-1*H*-indole-3-carboxamide
liramétostat	*N*-[(4-méthoxy-6-méthyl-2-oxo-1,2-dihydropyridin-3-yl)méthyl]-2-méthyl-1-{(1*R*)-1-[1-(2,2,2-trifluoroéthyl)pipéridin-4-yl]éthyl}-1*H*-indole-3-carboxamide
lirametostat	2-metil-*N*-[(6-metil-4-metoxi-2-oxo-1,2-dihidropiridin-3-il)metil]-1-{(1*R*)-1-[1-(2,2,2-trifluoroetil)piperidin-4-il]etil}-1*H*-indol-3-carboxamida

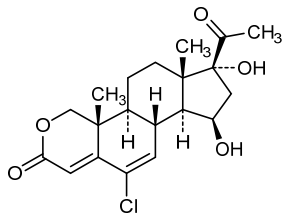
$C_{27}H_{33}F_3N_4O_3$



ludateronum

ludaterone	6-chloro-15β,17-dihydroxy-2-oxapregna-4,6-diene-3,20-dione
ludatérone	6-chloro-15β,17-dihydroxy-2-oxaprégna-4,6-diène-3,20-dione
ludaterona	6-cloro-15β,17-dihidroxi-2-oxapregna-4,6-dieno-3,20-diona

$C_{20}H_{25}ClO_5$



lutetium (^{177}Lu) vipivotidum tetraxetanum

lutetium (^{177}Lu) vipivotide tetraxetan	{*N*-[(N^6-{3-(naphthalen-2-yl)-*N*-[*trans*-4-({2-[4,7,10-tris(carboxy-κ$^3O^4$,O^7,O^{10}-methyl)-1,4,7,10-tetraazacyclododecan-1-yl-κ$^4N^1$,N^4,N^7,N^{10}]acetamido-κ*O*}methyl)cyclohexane-1-carbonyl]-L-alanyl}-L-lysin-N^2-yl)carbonyl]-L-glutamato(3−)}(^{177}Lu)lutetium

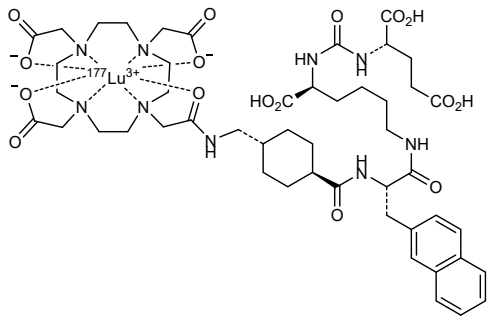
lutécium (^{177}Lu) vipivotide tétraxetan

{*N*-[(*N*^{6}-{3-(naphtalén-2-yl)-*N*-[*trans*-4-({2-[4,7,10-tris(carboxy-κ^3*O*^{4},*O*^{7},*O*^{10}-méthyl)-1,4,7,10-tétraazacyclododécan-1-yl-κ^4*N*^{1},*N*^{4},*N*^{7},*N*^{10}]acétamido-κ*O*}méthyl)cyclohexane-1-carbonyl]-L-alanyl}-L-lysin-*N*^{2}-yl)carbonyl]-L-glutamato(3−)}(^{177}Lu)lutecium

lutecio (^{177}Lu) vipivotida tetraxetán

{*N*-[(*N*^{6}-{3-(naftalen-2-il)-*N*-[*trans*-4-({2-[4,7,10-tris(carboxi-κ^3*O*^{4},*O*^{7},*O*^{10}-metil)-1,4,7,10-tetraazaciclododecan-1-il-κ^4*N*^{1},*N*^{4},*N*^{7},*N*^{10}]acetamido-κ*O*}metil)ciclohexano-1-carbonil]-L-alanil}-L-lisin-*N*^{2}-il)carbonil]-L-glutamato(3−)}(^{177}Lu)lutecio

$C_{49}H_{68}{}^{177}LuN_9O_{16}$



melrilimabum #

melrilimab

immunoglobulin G2-kappa, anti-[*Homo sapiens* IL1RL1 (interleukin 1 receptor like 1, DER4, FIT-1, growth stimulation expressed 2 gene, ST2, IL33R)], *Homo sapiens* monoclonal antibody;
gamma2 heavy chain *Homo sapiens* (1-449) [VH (*Homo sapiens* IGHV3-23*01 (91.8%) -(IGHD) -IGHJ4*01(92.9%)) CDR-IMGT [8.8.16] (26-33.51-58.97-112) (1-123) -*Homo sapiens* IGHG2*02v G2m23>G2m.., G2v3 CH2 A1.2, A1, S2, A30, L92, S115, S116 (CH1 T92 (195) (124-221), hinge 1-12 (222-233), CH2 V1.2>A (237), G1>A (239), P2>S (240), H30>A (270), M45.1>V (284), V92>L (311), A115>S (332), P116>S (333) (234-342), CH3 (343-447), CHS (448-449)) (124-449)], (137-214')-disulfide with kappa light chain *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV3D-11*02 (95.6%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')];
dimer (225-225":226-226":229-229":232-232")-tetrakisdisulfide, produced in Chinese hamster ovary (CHO)-K1SV cell line lacking the Glutamine Synthetase (GS) gene, glycoform alfa

melrilimab

immunoglobuline G2-kappa, anti-[*Homo sapiens* IL1RL1 (récepteur like 1 de l'interleukine 1, DER4, FIT1, gène 2 exprimé lors de la stimulation de la croissance, ST2, IL33R)], anticorps monoclonal *Homo sapiens*;

chaîne lourde gamma2 *Homo sapiens* (1-449) [VH (*Homo sapiens* IGHV3-23*01 (91.8%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.16] (26-33.51-58.97-112) (1-123) -*Homo sapiens* IGHG2*02v G2m23>G2m.., G2v3 CH2 A1.2, A1, S2, A30, L92, S115, S116 (CH1 T92 (195) (124-221), charnière 1-12 (222-233), CH2 V1.2>A (237), G1>A (239), P2>S (240), H30>A (270), M45.1>V (284), V92>L (311), A115>S (332), P116>S (333) (234-342), CH3 (343-447), CHS (448-449)) (124-449)], (137-214')-disulfure avec la chaîne légère kappa *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV3D-11*02 (95.6%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (225-225":226-226":229-229":232-232")-tétrakisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) lignée cellulaire CHO-K1SV ne présentant pas le gène de la glutamine synthétase, glycoforme alfa

melrilimab

inmunoglobulina G2-kappa, anti-[*Homo sapiens* IL1RL1 (receptor like 1 de la interleukina 1, DER4, FIT1, gen 2 expresado durante la estimulación del crecimiento, ST2, IL33R)], anticuerpo monoclonal *Homo sapiens*; cadena pesada gamma2 *Homo sapiens* (1-449) [VH (*Homo sapiens* IGHV3-23*01 (91.8%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.16] (26-33.51-58.97-112) (1-123) -*Homo sapiens* IGHG2*02v G2m23>G2m.., G2v3 CH2 A1.2, A1, S2, A30, L92, S115, S116 (CH1 T92 (195) (124-221), bisagra 1-12 (222-233), CH2 V1.2>A (237), G1>A (239), P2>S (240), H30>A (270), M45.1>V (284), V92>L (311), A115>S (332), P116>S (333) (234-342), CH3 (343-447), CHS (448-449)) (124-449)], (137-214')-disulfuro con la cadena ligera kappa *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV3D-11*02 (95.6%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (225-225":226-226":229-229":232-232")-tetrakisdisulfuro, producido en las células ováricas de hámsters chinos (CHO) línea celular CHO-K1SV en ausencia del gen Glutamina Sintetasa (GS)forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLLESGGG LVQPGGSLRL SCAASGFTFS IYDMIWVRQA PGKGLEWVSS  50
IRGEGGGTYY ADSVKGRFTI SRDNSKNTLY LQMNSLRAED TAVYYCARDP 100
WSTEGSFFVL DYWGQGTLVT VSSASTKGPS VFPLAPCSRS TSESTAALGC 150
LVKDYFPEPV TVSWNSGALT SGVHTFPAVL QSSGLYSLSS VVTVTSSNFG 200
TQTYTCNVDH KPSNTKVDKT VERKCCVECP PCPAPPAAAS SVFLFPPKPK 250
DTLMISRTPE VTCVVVDVSA EDPEVQFNWY VDGVEVHNAK TKPREEQFNS 300
TFRVVSVLTV LHQDWLNGKE YKCKVSNKGL PSSIEKTISK TKGQPREPQV 350
YTLPPSREEM TKNQVSLTCL VKGFYPSDIA VEWESNGQPE NNYKTTPPML 400
DSDGSFFLYS KLTVDKSRWQ QGNVFSCSVM HEALHNHYTQ KSLSLSPGK  449
```

Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPAT LSLSPGERAT LSCRASQSVD DDLAWYQQKP GQAPRLLIYD  50
ASNRATGIPA RFSGSGSGTD FTLTISSLEP EDFAVYYCQQ YITAPLTFGQ 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

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

```
Intra-H (C23-C104)   22-96     150-206  263-323  369-427
                    22"-96"  150"-206"  263"-323"  369"-427"
Intra-L (C23-C104)   23'-88'    134'-194'
                    23'"-88'"  134'"-194'"
Inter-H-L (CH1 10-CL 126)*    137-214'  137"-214'"
Inter-H-H (h 4, h 5, h 8, h 11)*  225-225"  226-226"  229-229"  232-232"
```

*In addition to the isoform A, isoform A/B characterized by an inter-H-H (h 4 - CH1 10) 225-137'" and an inter-H-L (h 4- CL 126) 225"-214'", instead of the inter-H-H (h 4 - h 4) 225-225" and of one of the two inter-H-L (CH1 10-CL 126) 137"-214'"; isoform B characterized by an inter-H-H (h 5 - CH1 10) 226-137 and an inter-H-L (h 5- CL 126) 226"-214', instead of the inter-H-H (h 5 - h 5) 226-226" and of the inter-H-L (CH1 10-CL 126) 137-214'.
* En plus de l'isoforme A, isoforme A/B caractérisée par un inter-H-H (h 4 - CH1 10) 225-137" et un inter-H-L (h 4- CL 126) 225"-214'", au lieu de l'inter-H-H (h 4 - h 4) 225-225" et de l'un des deux inter-H-L (CH1 10-CL 126) 137"-214'"; isoforme B caractérisée par un inter-H-H (h 5 - CH1 10) 226-137 et un inter-H-L (h 5- CL 126) 226"-214', au lieu de l'inter-H-H (h 5 - h 5) 226-226" et de l'inter-H-L (CH1 10-CL 126) 137-214'.
* Además de la isoforma A, isoforma A/B caracterizado por un inter-H-H (h 4 - CH1 10) 225-137'" y un inter-H-L (h 4- CL 126) 225"-214'", enlugar del inter-H-H (h 4 - h 4) 225-225" y uno de los dos inter-H-L (CH1 10-CL 126) 137"-214'"; isoforma B caracterizado por un inter-H-H (h 5 - CH1 10) 226-137 y un inter-H-L (h 5- CL 126) 226"-214', en lugar del inter-H-H (h 5 - h 5) 226-226" y del inter-H-L (CH1 10-CL 126) 137-214'.

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

```
H CH2 N84.4:
299, 299'"
```

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

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal

```
H CHS K2:
449, 449'"
```

milvexianum

milvexian

(5*R*,9*S*)-9-{4-[5-chloro-2-(4-chloro-1*H*-1,2,3-triazol-1-yl)phenyl]-6-oxopyrimidin-1(6*H*)-yl}-2^2-(difluoromethyl)-5-methyl-2^2*H*-3-aza-1(4,2)-pyridina-2(3,4)-pyrazolacyclononaphan-4-one

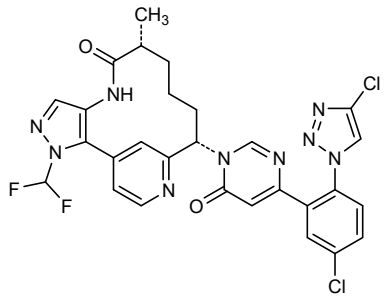
milvexian

(5*R*,9*S*)-9-{4-[5-chloro-2-(4-chloro-1*H*-1,2,3-triazol-1-yl)phényl]-6-oxopyrimidin-1(6*H*)-yl}-2^2-(difluorométhyl)-5-méthyl-2^2*H*-3-aza-1(4,2)-pyridina-2(3,4)-pyrazolacyclononaphan-4-one

milvexián

(5*R*,9*S*)-9-{4-[5-cloro-2-(4-cloro-1*H*-1,2,3-triazol-1-il)fenil]-6-oxopirimidin-1(6*H*)-il}-2^2-(difluorometil)-5-metil-2^2*H*-3-aza-1(4,2)-piridina-2(3,4)-pirazolaciclononafan-4-ona

$C_{28}H_{23}Cl_2F_2N_9O_2$



mipasetamabum #

mipasetamab

immunoglobulin G1-kappa, anti-[*Homo sapiens* AXL (AXL receptor tyrosine kinase, tyrosine-protein kinase receptor UFO)], humanized monoclonal antibody; gamma1 heavy chain humanized (1-451) [VH humanized (*Homo sapiens* IGHV3-30*03 (92.9%) -(IGHD) -IGHJ4*01 (92.3%)) CDR-IMGT [8.8.15] (26-33.51-58.97-111) (1-122) -*Homo sapiens* IGHG1*03, G1m3>G1m17, nG1m1 (CH1 R>K 120 (219) (123-220), hinge 1-15 (221-235), CH2 (236-345), CH3 E12 (361), M14 (363) (346-450), CHS K>del (451)) (123-451)], (225-215')-disulfide with kappa light chain humanized (1'-215') [V-KAPPA humanized (*Homo sapiens* IGKV3-11*01 (84.4%) -IGKJ4*01 (90.9%)) 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 (231-231''':234-234'')-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

mipasétamab

immunoglobuline G1-kappa, anti-[*Homo sapiens* AXL (récepteur tyrosine kinase AXL, récepteur tyrosine-protéine kinase UFO)], anticorps monoclonal humanisé;

chaîne lourde gamma1 humanisée (1-451) [VH humanisé (*Homo sapiens* IGHV3-30*03 (92.9%) -(IGHD) -IGHJ4*01 (92.3%)) CDR-IMGT [8.8.15] (26-33.51-58.97-111) (1-122) -*Homo sapiens* IGHG1*03, G1m3>G1m17, nG1m1 (CH1 R>K 120 (219) (123-220), charnière 1-15 (221-235), CH2 (236-345), CH3 E12 (361), M14 (363) (346-450), CHS K>del (451)) (123-451)], (225-215')-disulfure avec la chaîne légère kappa humanisée (1'-215') [V-KAPPA humanisé (*Homo sapiens* IGKV3-11*01 (84.4%) -IGKJ4*01 (90.9%)) 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')]; dimère (231-231":234-234")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

mipasetamab

inmunoglobulina G1-kappa, anti-[*Homo sapiens* AXL (receptor tirosina kinasa AXL, receptor tirosina-proteína kinasa UFO)], anticuerpo monoclonal humanizado; cadena pesada gamma1 humanizada (1-451) [VH humanizado (*Homo sapiens* IGHV3-30*03 (92.9%) -(IGHD) -IGHJ4*01 (92.3%)) CDR-IMGT [8.8.15] (26-33.51-58.97-111) (1-122) -*Homo sapiens* IGHG1*03, G1m3>G1m17, nG1m1 (CH1 R>K 120 (219) (123-220), bisagra 1-15 (221-235), CH2 (236-345), CH3 E12 (361), M14 (363) (346-450), CHS K>del (451)) (123-451)], (225-215')-disulfuro con la cadena ligera kappa humanizada (1'-215') [V-KAPPA humanizado (*Homo sapiens* IGKV3-11*01 (84.4%) -IGKJ4*01 (90.9%)) 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')]; dímero (231-231":234-234")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVESGGG VVQPGRSLRL SCAASGFTFS SYGMSWVRQA PGKGLEWVAT  50
ISSGGSYTYY PDSVKGRFTI SRDNSKNTLY LQMNSLRAED TAVYYCARHP 100
IYYTYDDTMD YWGQGTTVTV SSASTKGPSV FPLAPSSKST SGGTAALGCL 150
VKDYFPEPVT VSWNSGALTS GVHTFPAVLQ SSGLYSLSSV VTVPSSSLGT 200
QTYICNVNHK PSNTKVDKKV EPKSCDKTHT CPPCPAPELL GGPSVFLFPP 250
KPKDTLMISR TPEVTCVVVD VSHEDPEVKF NWYVDGVEVH NAKTKPREEQ 300
YNSTYRVVSV LTVLHQDWLN GKEYKCKVSN KALPAPIEKT ISKAKGQPRE 350
PQVYTLPPSR EEMTKNQVSL TCLVKGFYPS DIAVEWESNG QPENNYKTTP 400
PVLDSDGSFF LYSKLTVDKS RWQQGNVFSC SVMHEALHNH YTQKSLSLSP 450
G                                                       451
```

Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPGT LSLSPGERAT LSCSASSSVS SGNFHWYQQK PGLAPRLLIY  50
RTSNLASGIP ARFSGSGSGT DFTLTISSLE PEDFAVYYCQ QWSGYPWTFG 100
GGTKLEIKRT 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) 22-96 149-205 266-326 372-430
22"-96" 149"-205" 266"-326" 372"-430"
Intra-L (C23-C104) 23'-89' 135'-195'
23'"-89"' 135'"-195'"
Inter-H-L (h 5-CL 126) 225-215' 225"-215'"
Inter-H-H (h 11, h 14) 231-231" 234-234"

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 [glycoengineered GalNAcN3 (*N*-azidoacetyl-D-galactosamine)]:
302, 302"-bis[*N*-[*O*-2-(acetylamino)-6-azido-2,6-dideoxy- β-D-galactopyranosyl-(1->4)-*O*-[6-deoxy-α-L-galactopyranosyl-(1->6)]-2-(acetylamino)-2-deoxy- β-D-glucopyranosyl]-L-asparagine]

mipasetamabum uzoptirinum #

mipasetamab uzoptirine	immunoglobulin G1-kappa, anti-[*Homo sapiens* AXL (AXL receptor tyrosine kinase, tyrosine-protein kinase receptor UFO)], humanized monoclonal antibody conjugated to the pyrrolobenzodiazepine (PBD) dimer, SG3199; gamma1 heavy chain humanized (1-451) [VH humanized (*Homo sapiens* IGHV3-30*03 (92.9%) -(IGHD) -IGHJ4*01 (92.3%)) CDR-IMGT [8.8.15] (26-33.51-58.97-111) (1-122) -*Homo sapiens* IGHG1*03 nG1m1 (CH1 R120>K (219) (123-220), hinge 1-15 (221-235), CH2 (236-345), CH3 E12 (361), M14 (363) (346-450), CHS K>del (451)) (123-451)], (225-215')-disulfide with kappa light chain humanized (1'-215') [V-KAPPA (*Homo sapiens* IGKV3-11*01 (84.4%) -IGKJ4*01 (90.9%)) 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 (231-231":234-234")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa; conjugated on the two glycoengineered N84.4, via a spacer and a cleavable valine-alanine linker, to the cytotoxic pyrrolobenzodiazepine (PBD) dimer, SG3199
mipasétamab uzoptirine	immunoglobuline G1-kappa, anti-[*Homo sapiens* AXL (récepteur tyrosine kinase AXL, récepteur tyrosine-protéine kinase UFO)], anticorps monoclonal humanisé conjugué au dimère de pyrrolobenzodiazépine (PBD), SG3199; chaîne lourde gamma1 humanisée (1-451) [VH (*Homo sapiens* IGHV3-30*03 (92.9%) -(IGHD) -IGHJ4*01 (92.3%)) CDR-IMGT [8.8.15] (26-33.51-58.97-111) (1-122) -*Homo sapiens* IGHG1*03 nG1m1 (CH1 R120>K (219) (123-220), charnière 1-15 (221-235), CH2 (236-345), CH3 E12 (361), M14 (363) (346-450), CHS K>del (451)) (123-451)], (225-215')-disulfure avec la chaîne légère kappa humanisée (1'-215') [V-KAPPA (*Homo sapiens* IGKV3-11*01 (84.4%) -IGKJ4*01 (90.9%)) 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')]; dimère (231-231":234-234")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa; conjugué sur les deux N84.4 glycomodifiés, via un espaceur et un linker clivable valine-alanine, au dimère pyrrolobenzodiazépine (PBD) cytotoxique, SG3199
mipasetamab uzoptirina	inmunoglobulina G1-kappa, anti-[*Homo sapiens* AXL (receptor tirosina kinasa AXL, receptor tirosina-proteína kinasa UFO)], anticuerpo monoclonal humanizado conjugado con el dímero de pirrolobenzodiazepina (PBD), SG3199; cadena pesada gamma1 humanizada (1-451) [VH (*Homo sapiens* IGHV3-30*03 (92.9%) -(IGHD) -IGHJ4*01 (92.3%)) CDR-IMGT [8.8.15] (26-33.51-58.97-111) (1-122) -*Homo sapiens* IGHG1*03 nG1m1 (CH1 R120>K (219) (123-220), bisagra 1-15 (221-235), CH2 (236-345), CH3 E12 (361), M14 (363) (346-450), CHS K>del (451)) (123-451)], (225-215')-disulfuro con la cadena ligera kappa humanizada (1'-215') [V-KAPPA (*Homo sapiens* IGKV3-11*01 (84.4%) -IGKJ4*01 (90.9%)) 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')];

dímero (231-231":234-234")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa; conjugado sobre los dos N84.4 glicomodificados, mediante un espaciador y un conector escindible valina-alanina, al dímero pirrolobenzodiazepina (PBD) citotóxico, SG3199

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVESGGG VVQPGRSLRL SCAASGFTFS SYGMSWVRQA PGKGLEWVAT  50
ISSGGSYTYY PDSVKGRFTI SRDNSKNTLY LQMNSLRAED TAVYYCARHP 100
IYYTYDDTMD YWGQGTTVTV SSASTKGPSV FPLAPSSKST SGGTAALGCL 150
VKDYFPEPVT VSWNSGALTS GVHTFPAVLQ SSGLYSLSSV VTVPSSSLGT 200
QTYICNVNHK PSNTKVDKKV EPKSCDKTHT CPPCPAPELL GGPSVFLFPP 250
KPKDTLMISR TPEVTCVVVD VSHEDPEVKF NWYVDGVEVH NAKTKPREEQ 300
YNSTYRVVSV LTVLHQDWLN GKEYKCKVSN KALPAPIEKT ISKAKGQPRE 350
PQVYTLPPSR EEMTKNQVSL TCLVKGFYPS DIAVEWESNG QPENNYKTTP 400
PVLDSDGSFF LYSKLTVDKS RWQQGNVFSC SVMHEALHNH YTQKSLSLSP 450
G                                                       451
```

Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPGT LSLSPGERAT LSCSASSSVS SGNFHWYQQK PGLAPRLLIY  50
RTSNLASGIP ARFSGSGSGT DFTLTISSLE PEDFAVYYCQ QWSGYPWTFG 100
GGTKLEIKRT 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

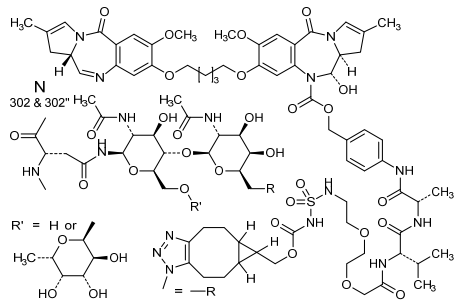
Intra-H (C23-C104) 22-96 149-205 266-326 372-430
22"-96" 149"-205" 266"-326" 372"-430"
Intra-L (C23-C104) 23'-89' 135'-195'
23'"-89'" 135'"-195'"
Inter-H-L (h 5-CL 126) 225-215' 225"-215'"
Inter-H-H (h 11, h 14) 231-231" 234-234"

N-terminal glutaminyl cyclization to pyroglutamyl (pE, 5-oxoprolyl)

H VH Q1:
1, 1"

Chemically modified N-glycosylation sites / Sites de N-glycosylation chimiquement modifiés / Posiciones de N-glicosilación modificadas químicamente

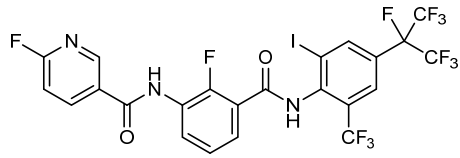
H CH2 N84.4:
302, 302"



modoflanerum

modoflaner	6-fluoro-*N*-(2-fluoro-3-{[4-(heptafluoropropan-2-yl)-2-iodo-6-(trifluoromethyl)phenyl]carbamoyl}phenyl)pyridine-3-carboxamide
modoflaner	6-fluoro-*N*-(2-fluoro-3-{[4-(heptafluoropropan-2-yl)-2-iodo-6-(trifluorométhyl)phényl]carbamoyl}phényl)pyridine-3-carboxamide
modoflaner	6-fluoro-*N*-(2-fluoro-3-{[4-(heptafluoropropan-2-il)-2-iodo-6-(trifluorometil)fenil]carbamoil}fenil)piridina-3-carboxamida

$C_{23}H_{10}F_{12}IN_3O_2$



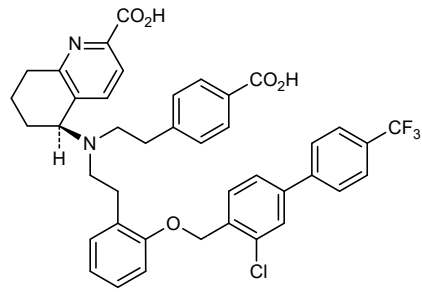
mosliciguatum

mosliciguat — (9^5*S*)-8-[2-(4-carboxyphenyl)ethyl]-2^3-chloro-1^4-(trifluoromethyl)-9^{5,6,7,8}-tetrahydro-4-oxa-8-aza-9(5)-quinolina-1(1),2(1,4),5(1,2)-tribenzenanonaphane-9^2-carboxylic acid

mosliciguat — acide (9^5*S*)-8-[2-(4-carboxyphényl)éthyl]-2^3-chloro-1^4-(trifluorométhyl)-9^{5,6,7,8}-tétrahydro-4-oxa-8-aza-9(5)-quinoléina-1(1),2(1,4),5(1,2)-tribenzénanonaphane-9^2-carboxylique

mosliciguat — ácido (9^5*S*)-8-[2-(4-carboxifenil)etil]-2^3-cloro-1^4-(trifluorometil)-9^{5,6,7,8}-tetrahidro-4-oxa-8-aza-9(5)-quinoleína-1(1),2(1,4),5(1,2)-tribencenanonafano-9^2-carboxílico

$C_{41}H_{36}ClF_3N_2O_5$



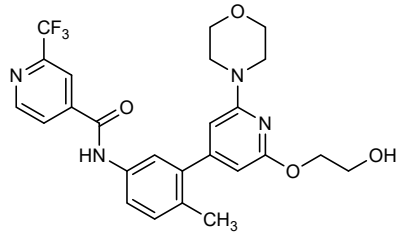
naporafenibum

naporafenib — *N*-{3-[2-(2-hydroxyethoxy)-6-(morpholin-4-yl)pyridin-4-yl]-4-methylphenyl}-2-(trifluoromethyl)pyridine-4-carboxamide

naporafénib — *N*-{3-[2-(2-hydroxyéthoxy)-6-(morpholin-4-yl)pyridin-4-yl]-4-méthylphényl}-2-(trifluorométhyl)pyridine-4-carboxamide

naporafenib — *N*-{3-[2-(2-hidroxietoxi)-6-(morfolin-4-il)piridin-4-il]-4-metilfenil}-2-(trifluorometil)piridina-4-carboxamida

$C_{25}H_{25}F_3N_4O_4$



nedosiranum

nedosiran

all-P-ambo-2'-*O*-methyl-*P*-thioadenylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-deoxy-2'-fluoroguanylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-deoxy-2'-fluorouridylyl-(3'→5')-2'-*O*-methylguanylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-deoxy-2'-fluorocytidylyl-(3'→5')-2'-deoxy-2'-fluorocytidylyl-(3'→5')-2'-deoxy-2'-fluorouridylyl-(3'→5')-2'-deoxy-2'-fluorouridylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-deoxy-2'-fluorouridylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-deoxy-2'-fluoroadenylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-deoxy-2'-fluorocytidylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-*O*-methylguanylyl-(3'→5')-2'-*O*-methyladenylyl-(3'→5')-2'-*O*-methylguanylyl-(3'→5')-2'-*O*-methylcytidylyl-(3'→5')-2'-*O*-methyladenylyl-(3'→5')-2'-*O*-methylguanylyl-(3'→5')-2'-*O*-methylcytidylyl-(3'→5')-2'-*O*-methylcytidylyl-(3'→5')-2'-*O*-{[2-(2-{5-[(2-acetamido-2-deoxy-β-D-galactopyranosyl)oxy]pentanamido}ethoxy)ethoxy]methyl}guanylyl-(3'→5')-2'-*O*-{[2-(2-{5-[(2-acetamido-2-deoxy-β-D-galactopyranosyl)oxy]pentanamido}ethoxy)ethoxy]methyl}adenylyl-(3'→5')-2'-*O*-{[2-(2-{5-[(2-acetamido-2-deoxy-β-D-galactopyranosyl)oxy]pentanamido}ethoxy)ethoxy]methyl}adenylyl-(3'→5')-2'-*O*-{[2-(2-{5-[(2-acetamido-2-deoxy-β-D-galactopyranosyl)oxy]pentanamido}ethoxy)ethoxy]methyl}adenylyl-(3'→5')-2'-*O*-methylguanylyl-(3'→5')-2'-*O*-methylguanylyl-(3'→5')-2'-*O*-methylcytidylyl-(3'→5')-2'-*O*-methyluridylyl-(3'→5')-2'-*O*-methylguanylyl-(3'→5')-2'-*O*-methylcytidine
duplex with *all-P-ambo*-2'-*O*-methyl-*P*-thioguanylyl-(5'→3')-2'-*O*-methyl-*P*-thioguanylyl-(5'→3')-2'-*O*-methyluridylyl-(5'→3')-2'-*O*-methyladenylyl-(5'→3')-2'-deoxy-2'-fluorocytidylyl-(5'→3')-2'-*O*-methyladenylyl-(5'→3')-2'-deoxy-2'-fluoroadenylyl-(5'→3')-2'-*O*-methylcytidylyl-(5'→3')-2'-deoxy-2'-fluoroadenylyl-(5'→3')-2'-*O*-methylguanylyl-(5'→3')-2'-*O*-methylguanylyl-(5'→3')-2'-*O*-methyladenylyl-(5'→3')-2'-deoxy-2'-fluoroadenylyl-(5'→3')-2'-deoxy-2'-fluoroadenylyl-(5'→3')-2'-*O*-methyladenylyl-(5'→3')-2'-deoxy-2'-fluoroadenylyl-(5'→3')-2'-*O*-methyluridylyl-(5'→3')-2'-deoxy-2'-fluoroadenylyl-(5'→3')-2'-deoxy-2'-fluoro-*P*-thioguanylyl-(5'→3')-2'-deoxy-2'-fluoro-*P*-thioadenylyl-(5'→3')-2'-deoxy-2'-fluoro-*P*-thiocytidylyl-(5'→3')-methyl hydrogen 2'-*O*-methyl-5'-oxa-*O*-5'-carba-5'-uridylate

nédosiran

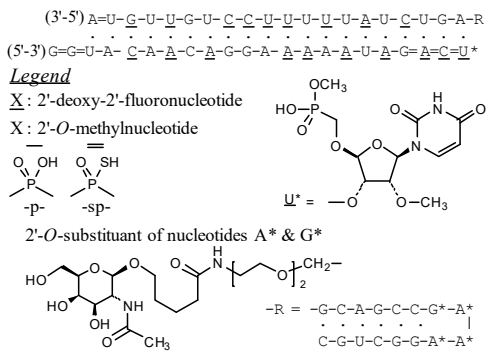
tout-P-ambo-2'-*O*-méthyl-*P*-thioadénylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-désoxy-2'-fluoroguanylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-désoxy-2'-fluorouridylyl-(3'→5')-2'-*O*-méthylguanylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-désoxy-2'-fluorocytidylyl-(3'→5')-2'-désoxy-2'-fluorocytidylyl-(3'→5')-2'-désoxy-2'-fluorouridylyl-(3'→5')-2'-désoxy-2'-fluorouridylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-désoxy-2'-fluorouridylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-désoxy-2'-fluoroadénylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-désoxy-2'-fluorocytidylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-*O*-méthylguanylyl-(3'→5')-2'-*O*-méthyladénylyl-(3'→5')-2'-*O*-méthylguanylyl-(3'→5')-2'-*O*-méthylcytidylyl-(3'→5')-2'-*O*-méthyladénylyl-(3'→5')-2'-*O*-méthylguanylyl-(3'→5')-2'-*O*-méthylcytidylyl-(3'→5')-2'-*O*-méthylcytidylyl-(3'→5')-2'-*O*-{[2-(2-{5-[(2-acétamido-2-désoxy-β-D-galactopyranosyl)oxy]pentanamido}éthoxy)éthoxy]méthyl}guanylyl-(3'→5')-2'-*O*-{[2-(2-{5-[(2-acétamido-2-désoxy-β-D-galactopyranosyl)oxy]pentanamido}éthoxy)éthoxy]méthyl}adénylyl-(3'→5')-2'-*O*-{[2-(2-{5-[(2-acétamido-2-désoxy-β-D-galactopyranosyl)oxy]pentanamido}éthoxy)éthoxy]méthyl}adénylyl-(3'→5')-2'-*O*-{[2-(2-{5-[(2-acétamido-2-désoxy-β-D-galactopyranosyl)oxy]pentanamido}éthoxy)éthoxy]méthyl}adénylyl-(3'→5')-2'-*O*-méthylguanylyl-(3'→5')-2'-*O*-méthylguanylyl-(3'→5')-2'-*O*-méthylcytidylyl-(3'→5')-2'-*O*-méthyluridylyl-(3'→5')-2'-*O*-méthylguanylyl-(3'→5')-2'-*O*-méthylcytidine

duplex avec acide *tout-P-ambo*-2'-*O*-méthyl-*P*-thioguanylyl-(5'→3')-2'-*O*-méthyl-*P*-thioguanylyl-(5'→3')-2'-*O*-méthyluridylyl-(5'→3')-2'-*O*-méthyl-adénylyl-(5'→3')-2'-désoxy-2'-fluorocytidylyl-(5'→3')-2'-*O*-méthyladénylyl-(5'→3')-2'-désoxy-2'-fluoroadénylyl-(5'→3')-2'-*O*-méthylcytidylyl-(5'→3')-2'-désoxy-2'-fluoroadénylyl-(5'→3')-2'-*O*-méthylguanylyl-(5'→3')-2'-*O*-méthylguanylyl-(5'→3')-2'-*O*-méthyladénylyl-(5'→3')-2'-désoxy-2'-fluoroadénylyl-(5'→3')-2'-désoxy-2'-fluoroadénylyl-(5'→3')-2'-*O*-méthyladénylyl-(5'→3')-2'-désoxy-2'-fluoroadénylyl-(5'→3')-2'-*O*-méthyluridylyl-(5'→3')-2'-désoxy-2'-fluoroadénylyl-(5'→3')-2'-désoxy-2'-fluoro-*P*-thioguanylyl-(5'→3')-2'-désoxy-2'-fluoro-*P*-thioadénylyl-(5'→3')-2'-désoxy-2'-fluoro-*P*-thiocytidylyl-(5'→3')-hydrogéno-2'-*O*-méthyl-5'-oxa-*O*-5'-carba-5'-uridylate de méthyle

nedosirán

todo-P-ambo-2'-*O*-metil-*P*-tioadenilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-desoxi-2'-fluoroguanilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-desoxi-2'-fluorouridilil-(3'→5')-2'-*O*-metilguanilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-desoxi-2'-fluorocitidilil-(3'→5')-2'-desoxi-2'-fluorocitidilil-(3'→5')-2'-desoxi-2'-fluorouridilil-(3'→5')-2'-desoxi-2'-fluorouridilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-desoxi-2'-fluorouridilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-des-oxi-2'-fluoroadenilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-desoxi-2'-fluoro-citidilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metilguanilil-(3'→5')-2'-*O*-metiladenilil-(3'→5')-2'-*O*-metilguanilil-(3'→5')-2'-*O*-metilcitidilil-(3'→5')-2'-*O*-metiladenilil-(3'→5')-2'-*O*-metilguanilil-(3'→5')-2'-*O*-metilcitidilil-(3'→5')-2'-*O*-metilcitidilil-(3'→5')-2'-*O*-{[2-(2-{5-[(2-acetamido-2-desoxi-β-D-galactopiranosil)oxi]-pentanamido}etoxi)etoxi]metil}guanilil-(3'→5')-2'-*O*-{[2-(2-{5-[(2-acetamido-2-desoxi-β-D-galactopiranosil)oxi]pentanamido}etoxi)etoxi]metil}adenilil-(3'→5')-2'-*O*-{[2-(2-{5-[(2-acetamido-2-desoxi-β-D-galactopiranosil)oxi]pentanamido}etoxi)etoxi]metil}adenilil-(3'→5')-2'-*O*-{[2-(2-{5-[(2-acetamido-2-desoxi-β-D-galactopiranosil)oxi]pentanamido}etoxi)etoxi]metil}adenilil-(3'→5')-2'-*O*-metilguanilil-(3'→5')-2'-*O*-metilguanilil-(3'→5')-2'-*O*-metilcitidilil-(3'→5')-2'-*O*-metiluridilil-(3'→5')-2'-*O*-metilguanilil-(3'→5')-2'-*O*-metilcitidina
dúplex con *todo-P-ambo*-2'-*O*-metil-*P*-tioguanilil-(5'→3')-2'-*O*-metil-*P*-tioguanilil-(5'→3')-2'-*O*-metiluridilil-(5'→3')-2'-*O*-metiladenilil-(5'→3')-2'-desoxi-2'-fluorocitidilil-(5'→3')-2'-*O*-metiladenilil-(5'→3')-2'-desoxi-2'-fluoroadenilil-(5'→3')-2'-*O*-metilcitidilil-(5'→3')-2'-desoxi-2'-fluoroadenilil-(5'→3')-2'-*O*-metilguanilil-(5'→3')-2'-*O*-metilguanilil-(5'→3')-2'-*O*-metiladenilil-(5'→3')-2'-desoxi-2'-fluoroadenilil-(5'→3')-2'-desoxi-2'-fluoroadenilil-(5'→3')-2'-*O*-metiladenilil-(5'→3')-2'-desoxi-2'-fluoroadenilil-(5'→3')-2'-*O*-metiluridilil-(5'→3')-2'-desoxi-2'-fluoroadenilil-(5'→3')-2'-desoxi-2'-fluoro-*P*-tioguanilil-(5'→3')-2'-desoxi-2'-fluoro-*P*-tioadenilil-(5'→3')-2'-desoxi-2'-fluoro-*P*-tiocitidilil-(5'→3')-hidrógeno-2'-*O*-metil-5'-oxa-*O*-5'-carba-5'-uridilato de metilo

$C_{662}H_{865}F_{19}N_{231}O_{413}P_{57}S_6$



nemvaleukinum alfa #

nemvaleukin alfa

human interleukin 2 fragment (1-59), variant (Cys^{125}>Ser^{51}), fused via peptidyl linker (^{60}GG^{61}) to human interleukin 2 fragment (62-132), fused via peptidyl linker (^{133}GSGGGS^{138}) to human interleukin 2 receptor α-chain fragment (139-303), produced in Chinese hamster ovary (CHO) cells, glycosylated; human interleukin 2 (IL-2) (75-133)-peptide [$Cys^{125(51)}$>Ser]-mutant (1-59), fused via a G_2 peptide linker (60-61) to human interleukin 2 (IL-2) (4-74)-peptide (62-132) and via a GSG_3S peptide linker (133-138) to human interleukin 2 receptor α-chain (IL2R subunit alpha, IL2Rα, IL2RA) (1-165)-peptide (139-303), produced in Chinese hamster ovary (CHO) cells, glycoform alfa

nemvaleukine alfa

fragment de l'interleukine 2 humaine (1-59), variant (Cys^{125}>Ser^{51}), fusionné via un peptide liant (^{60}GG^{61}) à un fragment de l'interleukine 2 humaine (62-132), fusionné via un peptide liant (^{133}GSGGGS^{138}) au fragment de la chaîne α du récepteur de l'interleukine 2 (139-303), produit dans des cellules ovariennes de hamsters chinois (CHO), glycosylé; peptide 75-133 d'interleukine 2 humaine (IL-2) mutante [$Cys^{125(51)}$>Ser] (1-59), fusionnée via un peptide G_2 (60-61) au peptide 4-74 d'inter-leukine humaine 2 (IL-2) (62-132) et via un peptide GSG_3S (133-138) au peptide 1-165 de la chaîne α du récepteur de l'interleukine 2 humaine (sous-unité alpha de IL2R, IL2Rα, IL2RA) (139-303), produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

nemvaleukina alfa

fragmento de interleukina 2 humana (1-59), variante (Cis^{125}>Ser^{51}), fusionado a través de un conector peptidil (^{60}GG^{61}) al fragmento de interleukina 2 humana (62-132), fusionado a través de un conector peptidil (^{133}GSGGGS^{138}) al fragmento humano de la cadena α del receptor de interleukina 2 (139-303), producido en células ováricas de hámster Chino (CHO), glicosilado;
péptido 75-133 de la interleukina 2 humana (IL-2) mutante [$Cis^{125(51)}$>Ser] (1-59), fusionado a través de un péptido G_2 (60-61) al péptido 4-74 de la interleukina 2 humana (IL-2) (62-132) y a través de un péptido GSG_3S (133-138) al péptido 1-165 de la cadena α del receptor de interleukina 2 humano (subunidad alfa de IL2R, IL2Rα, IL2RA) (139-303), producido en células ováricas de hámster Chino (CHO), glicosilada alfa

Sequence / Séquence / Secuencia

```
SKNFHLRPRD LISNINVIVL ELKGSETTFM CEYADETATI VEFLNRWITF   50
SQSIISTLTG GSSSTKKTQL QLEHLLLDLQ MILNGINNYK NPKLTRMLTF  100
KFYMPKKATE LKHLQCLEEE LKPLEEVLNL AQGSGGGSEL CDDDPPEIPH  150
ATFKAMAYKE GTMLNCECKR GFRRIKSGSL YMLCTGNSSH SSWDNQCQCT  200
SSATRNTTKQ VTPQPEEQKE RKTTEMQSPM QPVDQASLPG HCREPPPWEN  250
EATERIYHFV VGQMVYYQCV QGYRALHRGP AESVCKMTHG KTRWTQPQLI  300
CTG                                                     303
```

Mutation / Mutation / Mutación

C^{51}>S

Post-translational modifications

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

31-116, 141-285, 184-242, 269-301, 166-197 or 166-199, 168-199 or 168-197

Glycosylation sites / Sites de glycosylation / Posiciones de glicosilación

N187, N206, T212

obecabtagenum autoleucelum #

obecabtagene autoleucel

Autologous CD4+ and CD8+ T cells transduced *ex vivo* with a self-inactivating lentiviral vector encoding an anti-CD19 chimeric antigen receptor.
Autologous CD4+ and CD8+ T cells, enriched from peripheral blood mononuclear cells (PBMCs) obtained by apheresis transduced *ex vivo* with a non-replicating, self-inactivating (SIN) lentiviral vector, encoding a chimeric antigen receptor (CAR) consisting of an anti-CD19 specific scFv, a CD8α stalk, transmembrane domain and anchor, a 41BB endodomain and a CD3 zeta endodomain, under the control of a human PGK1 promoter and a modified Woodchuck post transcriptional response element. The vector genome also contains a 5' terminal CMV enhancer/promoter, a Ψ packaging signal, a Rev response element (RRE) and a central polypurine tract (cPPT).

obécabtagène autoleucel

Cellules T CD4+ et CD8+ autologues transduites *ex vivo* avec un vecteur lentiviral auto-inactivable codant pour un récepteur chimérique contre l'antigène CD19.
Cellules T CD4+ et CD8+ autologues, enrichies de cellules mononuclées de sang périphérique (PBMC) et obtenues par aphérèse, transduites *ex vivo* avec un vecteur lentiviral non réplicatif et auto-inactivable (SIN), codant pour un récepteur chimérique d'antigène (CAR) consistant en un scFv spécifique de CD19, un fragment extracellulaire, un domaine transmembranaire et la partie d'ancrage de CD8α, un endo-domaine de 41BB et un endo-domaine de CD3 zêta, sous le contrôle d'un promoteur PGK1 humain et d'un élément de réponse post-transcriptionnel Woodchuck modifié. Le génome du vecteur contient également un promoteur/amplificateur CMV placé en position terminale 5', un signal d'empaquetage Ψ, un élément de réponse Rev (RRE) et un segment central de polypurine (cPPT).

obecabtagén autoleucel

Células T CD4+ y CD8+ autólogas transducidas ex vivo con un vector lentiviral auto-inactivante que codifica para un receptor de antígenos quimérico anti-CD19.
Células T CD4+ y CD8+ autólogas, enriquecidas a partir de células mononucleares de sangre periférica (PBMCs) obtenidas por aféresis, transducidas *ex vivo* con un vector lentiviral no replicativo, auto-inactivante (SIN), que codifica para un receptor de antígenos quimérico (CAR) que consta de scFv específico anti-CD19, un tallo CD8α, un dominio transmembranal y de anclaje, un endodominio 41BB y un endodominio CD3 zeta, bajo el control de un promotor PGK1 humano y un elemento de respuesta post transcripcional de marmota modificado. El genoma del vector también contiene un potenciador (enhancer)/promotor de CMV en 5', una señal de empaquetamiento Ψ, un elemento de respuesta Rev (RRE) y un tramo central de polipurinas (cPPT).

obrindatamabum #

obrindatamab

immunoglobulin G1 scFv-h-CH2-CH3(_scFv)_h-CH2-CH3, anti-[*Homo sapiens* CD276 (B7H3, B7-H3, B7RP-2)] and anti-[*Homo sapiens* CD3E (CD3 epsilon)], monoclonal antibody, bispecific; IG scFv-h-CH2-CH3 single chain, anti-CD276 and anti-CD3E (1-504) [scFv-V-kappa-VH anti-CD276 and anti-CD3E (1-240) [V-KAPPA anti-CD276 (*Homo sapiens* IGKV1D-13*01 (85.1%) -IGHJ2*02 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1-107) -8-mer triglycyl-seryl-tetraglycyl linker (108-115) -VH anti-CD3E (*Mus musculus* IGHV10-1*02 (89.9%) -(IGHD) -GHJ3*01 (93.3%)/*Homo sapiens* IGHV3-72*01 (87.0%) -(IGHD) -IGHJ6*01 (90.9%)) CDR-IMGT [8.10.16] (141-148.166-175.214-229) (116-240)] -linker-E-coil (241-277) [6-mer diglycyl-cysteinyl-triglycyl linker (241-246) -28-mer tetrakis(glutamyl-valyl-dialanyl-leucyl-glutamyl-lysyl) E-coil motif (247-274) -3-mer triglycyl linker (275-277)] -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1, G1v14 CH2 A1.3, A1.2, G1v32 CH3 W22 (knob) (278-504) [hinge 6-15 (278-287), CH2 L1.3>A (291), L1.2>A (292) (288-397), CH3 E12 (413), M14 (415), T22>W (423) (398-502), CHS (503-504)]]; (243-243')-disulfide with the IG scFv single chain, anti-CD3E and anti-CD276 (1'-274') [scFv V-lambda-VH anti-CD3E and anti-CD276 (1'-240') [V-LAMBDA anti-CD3 (*Mus musculus* IGLV1*01 (81.2%) -IGLJ1*01 (100%)/*Homo sapiens* IGLV7-46*01 (77.9%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (26-34.52-54.91-99) (1'-109') -9-mer tetraglycyl-seryl-tetraglycyl linker (110'-118') -VH anti-CD276 (*Homo sapiens* IGHV3-48*02 (91.8%) -(IGHD) -IGHJ4*01 (85.7%)) CDR-IMGT [8.8.15] (144-151.169-176.215-229) (119'-240')] -6-mer diglycyl-cysteinyl-triglycyl linker (241'-246') -28-mer tetrakis(lysyl-valyl-dialanyl-leucyl-lysyl-glutamyl) K-coil motif (247'-274')];
(283-6'':286-9'')-bisdisulfide with the IG h-CH2-CH3 chain, IGHG1*03 nG1m1, G1v14 CH2 A1.3, A1.2, IGHG1v33 CH3 S22, A24, V86 (hole) (1''-227'') [hinge 6-15 (1''-10''), CH2 L1.3>A (14), L1.2>A (15) (11''-120''), CH3 E12 (136), M14 (138), T22>S (146), L24>A (148), Y86>V (187), H115>R (215) (121''-225''), CHS (226''-227'')], produced in Chinese hamster ovary (CHO) cells, glycoform alfa

obrindatamab

immunoglobuline G1 scFv-h-CH2-CH3(_scFv)_h-CH2-CH3, anti-[*Homo sapiens* CD276 (B7H3, B7-H3, B7RP-2)] et anti-[*Homo sapiens* CD3E (CD3 epsilon)], anticorps monoclonal, bispécifique; IG scFv-h-CH2-CH3 chaîne unique, anti-CD276 et anti-CD3E (1-504) [scFv-V-kappa-VH anti-CD276 et anti-CD3E (1-240) [V-KAPPA anti-CD276 (*Homo sapiens* IGKV1D-13*01 (85.1%) -IGHJ2*02 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1-107) -8-mer triglycyl-séryl-tétraglycyl linker (108-115) -VH anti-CD3E (*Mus musculus* IGHV10-1*02 (89.9%) -(IGHD) -GHJ3*01 (93.3%)/*Homo sapiens* IGHV3-72*01 (87.0%) -(IGHD) -IGHJ6*01 (90.9%)) CDR-IMGT [8.10.16] (141-148.166-175.214-229) (116-240)] -linker-E-coil (241-277) [-6-mer diglycyl-cystéinyl-triglycyl linker (241-246) -28-mer tétrakis(glutamyl-valyl-dialanyl-leucyl-glutamyl-lysyl) E-coil motif (247-274) -3-mer triglycyl linker (275-277)] -*Homo sapiens* IGHG1*03 h-CH2-CH3 nG1m1, G1v14 CH2 A1.3, A1.2, G1v32 CH3 W22 (knob) (278-504) [charnière 6-15 (278-287), CH2 L1.3>A (291), L1.2>A (292) (288-397), CH3 E12 (413), M14 (415), T22>W (423) (398-502), CHS (503-504)]; (243-243')-disulfure avec la chaîne unique IG scFv, anti-CD3E et

	anti-CD276 (1'-274') [scFv V-lambda-VH anti-CD3E et anti-CD276 (1'-240') [V-LAMBDA anti-CD3 (*Mus musculus* IGLV1*01 (81.2%) -IGLJ1*01 (100%)/*Homo sapiens* IGLV7-46*01 (77.9%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (26-34.52-54.91-99) (1'-109') -9-mer tétraglycyl-séryl-tétraglycyl linker (110'-118') -VH anti-CD276 (*Homo sapiens* IGHV3-48*02 (91.8%) -(IGHD) -IGHJ4*01 (85.7%)) CDR-IMGT [8.8.15] (144-151.169-176.215-229) (119'-240') -6-mer diglycyl-cystéinyl-triglycyl linker (241'-246') -28-mer tétrakis(lysyl-valyl-dialanyl-leucyl-lysyl-glutamyl) K-coil motif (247'-274')]; (283-6":286-9")-bisdisulfure avec la chaîne IG h-CH2-CH3, IGHG1*03 nG1m1, G1v14 CH2 A1.3, A1.2, IGHG1v33 CH3 S22, A24, V86 (hole) (1"-227") [charnière 6-15 (1"-10"), CH2 L1.3>A (14), L1.2>A (15) (11"-120"), CH3 E12 (136), M14 (138), T22>S (146), L24>A (148), Y86>V (187), H115>R (215) (121"-225"), CHS (226"-227")], produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa
obrindatamab	inmunoglobulina G1 scFv-h-CH2-CH3(_scFv)_h-CH2-CH3, anti-[*Homo sapiens* CD276 (B7H3, B7-H3, B7RP-2)] y anti-[*Homo sapiens* CD3E (CD3 épsilon)], anticuerpo monoclonal, biespecífico; IG scFv-h-CH2-CH3 cadena única, anti-CD276 y anti-CD3E (1-504) [scFv-V-kappa-VH anti-CD276 y anti-CD3E (1-240) [V-KAPPA anti-CD276 (*Homo sapiens* IGKV1D-13*01 (85.1%) -IGHJ2*02 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1-107) -8-mer triglicil-seril-tetraglicil linker (108-115) -VH anti-CD3E (*Mus musculus* IGHV10-1*02 (89.9%) -(IGHD) -GHJ3*01 (93.3%)/*Homo sapiens* IGHV3-72*01 (87.0%) -(IGHD) -IGHJ6*01 (90.9%)) CDR-IMGT [8.10.16] (141-148.166-175.214-229) (116-240)] -linker-E-coil (241-277) [-6-mer diglicil-cisteinil-triglicil linker (241-246) -28-mer tetrakis(glutamil-valil-dialanil-leucil-glutamil-lisil) E-coli motif (247-274) -3-mer triglicil linker (275-277)] -*Homo sapiens* IGHG1*03 h-CH2-CH3 nG1m1, G1v14 CH2 A1.3, A1.2, G1v32 CH3 W22 (knob) (278-504) [bisagra 6-15 (278-287), CH2 L1.3>A (291), L1.2>A (292) (288-397), CH3 E12 (413), M14 (415), T22>W (423) (398-502), CHS (503-504)]; (243-243')-disulfuro con la cadena única IG scFv, anti-CD3E y anti-CD276 (1'-274') [scFv V-lambda-VH anti-CD3E y anti-CD276 (1'-240') [V-LAMBDA anti-CD3 (*Mus musculus* IGLV1*01 (81.2%) -IGLJ1*01 (100%)/*Homo sapiens* IGLV7-46*01 (77.9%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (26-34.52-54.91-99) (1'-109') -9-mer tetraglicil-seril-tetraglicil linker (110'-118') -VH anti-CD276 (*Homo sapiens* IGHV3-48*02 (91.8%) -(IGHD) -IGHJ4*01 (85.7%)) CDR-IMGT [8.8.15] (144-151.169-176.215-229) (119'-240') -6-mer diglicil-cisteinil-triglicil linker (241'-246') -28-mer tetrakis(lisil-valil-dialanil-leucil-lisil-glutamil) K-coli motif (247'-274')]; (283-6":286-9")-bisdisulfuro con la cadena IG h-CH2-CH3, IGHG1*03 nG1m1, G1v14 CH2 A1.3, A1.2, IGHG1v33 CH3 S22, A24, V86 (hole) (1"-227") [bisagra 6-15 (1"-10"), CH2 L1.3>A (14), L1.2>A (15) (11"-120"), CH3 E12 (136), M14 (138), T22>S (146), L24>A (148), Y86>V (187), H115>R (215) (121"-225"), CHS (226"-227")], producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa

1. Chain / Chaîne / Cadena: IG scFv h-CH2-CH3 (V-kappa anti-CD276, VH anti-CD3E)

```
DIQLTQSPSF LSASVGDRVT ITCKASQNVD TNVAWYQQKP GKAPKALIYS  50
ASYRYSGVPS RFSGSGSGTD FTLTISSLQP EDFATYYCQQ YNNYPFTFGQ 100
GTKLEIKGGG SGGGGEVQLV ESGGGLVQPG GSLRLSCAAS GFTFSTYAMN 150
WVRQAPGKGL EWVGRIRSKY NNYATYYADS VKDRFTISRD DSKNSLYLQM 200
NSLKTEDTAV YYCVRHGNFG NSYVSWFAYW GQGTLVTVSS GGCGGGEVAA 250
LEKEVAALEK EVAALEKEVA ALEKGGGDKT HTCPPCPAPE AAGGPSVFLF 300
PPKPKDTLMI SRTPEVTCVV VDVSHEDPEV KFNWYVDGVE VHNAKTKPRE 350
EQYNSTYRVV SVLTVLHQDW LNGKEYKCKV SNKALPAPIE KTISKAKGQP 400
REPQVYTLPP SREEMTKNQV SLWCLVKGFY PSDIAVEWES NGQPENNYKT 450
TPPVLDSDGS FFLYSKLTVD KSRWQQGNVF SCSVMHEALH NHYTQKSLSL 500
SPGK                                                    504
```

2. Chain / Chaîne / Cadena: IG scFv (V-lambda anti-CD3E, VH anti-CD276)

```
QAVVTQEPSL TVSPGGTVTL TCRSSTGAVT TSNYANWVQQ KPGQAPRGLI  50
GGTNKRAPWT PARFSGSLLG GKAALTITGA QAEDEADYYC ALWYSNLWVF 100
GGGTKLTVLG GGGSGGGGEV QLVESGGGLV QPGGSLRLSC AASGFTFSSF 150
GMHWVRQAPG KGLEWVAYIS SDSSAIYYAD TVKGRFTISR DNAKNSLYLQ 200
MNSLRDEDTA VYYCGRGREN IYYGSRLDYW GQGTTVTVSS GGCGGGKVAA 250
LKEKVAALKE KVAALKEKVA ALKE                              274
```

3. Chain / Chaîne / Cadena: IG h-CH2-CH3

```
DKTHTCPPCP APEAAGGPSV FLFPPKPKDT LMISRTPEVT CVVVDVSHED  50
PEVKFNWYVD GVEVHNAKTK PREEQYNSTY RVVSVLTVLH QDWLNGKEYK 100
CKVSNKALPA PIEKTISKAK GQPREPQVYT LPPSREEMTK NQVSLSCAVK 150
GFYPSDIAVE WESNGQPENN YKTTPPVLDS DGSFFLVSKL TVDKSRWQQG 200
NVFSCSVMHE ALHNRYTQKS LSLSPGK                           227
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-chain 1 (C23-C104) 23-88 137-213 318-378 424-482
Intra-chain 2 (C23-C104) 22'-90' 140'-214'
Intra-chain 3 (C23-C104) 41"-101" 147"-205"
Inter-chains 1 - 2 243-243'
Inter-chains 1 - 3 (h 11 -h 11) 283-6"
(h 14 -h 14) 286-9"

N-terminal glutamine cyclization to pyroglutamate (pE, 5-oxoproline)
V-lambda Q1:
1'

Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados.
N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
CH2 N84.4:
354, 77"

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
CHS K2:
504, 227"

ociperlimabum #

ociperlimab — immunoglobulin G1-kappa, anti-[*Homo sapiens* TIGIT (T-cell immunoreceptor with Ig domain and ITIM, V-set Ig member 9, VSIG9, V-set and transmembrane member 3, VSTM3)], humanized monoclonal antibody; gamma1 heavy chain humanized (1-449) [VH (*Homo sapiens* IGHV3-66*01 (88.8%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.12] (26-33.51-58.97-108) (1-119) -*Homo sapiens* IGHG1*01 nG1m1, G1m17 (CH1 K120 (216) (120-217), hinge 1-15 (218-232), CH2 (233-342), CH3 E12 (358), M14 (360) (343-447), CHS (448-449)) (120-449)], (222-214')-disulfide with kappa light chain humanized (1'-214') [V-KAPPA (*Homo sapiens* IGKV3-15*01 (87.4%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')];
dimer (228-228":231-231")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

ociperlimab — immunoglobuline G1-kappa, anti-[*Homo sapiens* TIGIT (immunorécepteur des lymphocytes T avec domaine Ig et ITIM, membre 9 de l'Ig V-set, VSIG9, membre 3 de l'Ig V-set et région transmembrane, VSTM3)], anticorps monoclonal humanisé;

chaîne lourde gamma1 humanisée (1-449) [VH (*Homo sapiens* IGHV3-66*01 (88.8%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.12] (26-33.51-58.97-108) (1-119) -*Homo sapiens* IGHG1*01 nG1m1, G1m17 (CH1 K120 (216) (120-217), charnière 1-15 (218-232), CH2 (233-342), CH3 E12 (358), M14 (360) (343-447), CHS (448-449)) (120-449)], (222-214')-disulfure avec la chaîne légère kappa humanisée (1'-214') [V-KAPPA (*Homo sapiens* IGKV3-15*01 (87.4%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')];
dimère (228-228":231-231")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

ociperlimab

inmunoglobulina G1-kappa, anti-[*Homo sapiens* TIGIT (inmunoreceptor de los linfocitos T con dominio Ig y ITIM, miembro 9 de la Ig V-set, VSIG9, miembro 3 de la Ig V-set y región transmembrana, VSTM3)], anticuerpo monoclonal humanizado;
cadena pesada gamma1 humanizada (1-449) [VH (*Homo sapiens* IGHV3-66*01 (88.8%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.12] (26-33.51-58.97-108) (1-119) -*Homo sapiens* IGHG1*01 nG1m1, G1m17 (CH1 K120 (216) (120-217), bisagra 1-15 (218-232), CH2 (233-342), CH3 E12 (358), M14 (360) (343-447), CHS (448-449)) (120-449)], (222-214')-disulfuro con la cadena ligera kappa humanizada (1'-214') [V-KAPPA (*Homo sapiens* IGKV3-15*01 (87.4%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')];
dímero (228-228":231-231")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVESGGG LVQPGGSLRL SCAASGFTFS DYYMYWVRQA PGKGLEWVAY  50
ITKGGGSTYY PDSVKGRFTI SRDNAKNTLY LQMNSLRAED TAVYYCARQT 100
NYDFTMDYWG QGTLVTVSSA STKGPSVFPL APSSKSTSGG TAALGCLVKD 150
YFPEPVTVSW NSGALTSGVH TFPAVLQSSG LYSLSSVVTV PSSSLGTQTY 200
ICNVNHKPSN TKVDKKVEPK SCDKTHTCPP CPAPELLGGP SVFLFPPKPK 250
DTLMISRTPE VTCVVVDVSH EDPEVKFNWY VDGVEVHNAK TKPREEQYNS 300
TYRVVSVLTV LHQDWLNGKE YKCKVSNKAL PAPIEKTISK AKGQPREPQV 350
YTLPPSREEM TKNQVSLTCL VKGFYPSDIA VEWESNGQPE NNYKTTPPVL 400
DSDGSFFLYS KLTVDKSRWQ QGNVFSCSVM HEALHNHYTQ KSLSLSPGK  449
```

Light chain / Chaîne légère / Cadena ligera

```
EIVMTQSPAT LSVSPGERAT LSCKASQDVG TSVAWYQQKP GQAPRLLIYW  50
ASARHTGIPA RFSGSGSGTE FTLTISSLQS EDFAVYYCQQ YSSYPLTFGG 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

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

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

C-terminal lysine clipping:
H CHS K2:
449, 449"

omodenbamabum #

omodenbamab	immunoglobulin G3-kappa, anti-[*Staphylococcus aureus* SpA (Staphylococcal protein A)], *Homo sapiens* monoclonal antibody; gamma3 heavy chain *Homo sapiens* (1-502) [VH (*Homo sapiens* IGHV3-23*04 (90.8%) -(IGHD) -IGHJ5*01 (93.3%)) CDR-IMGT [8.8.18] (26-33.51-58.97-114) (1-125) -*Homo sapiens* IGHG3*01, G3m5* (G3m5,10,11,13,14,26,27) (CH1 (126-223), hinge 1-42 (224-285), CH2 (286-395), CH3 S44 (439), M84 (452), Q98 (474), I101 (477), R115 (490), F116 (491) (396-500), CHS (501-502)) (126-502)], (139-214')-disulfide with kappa light chain *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-39*01 (90.5%) -IGKJ5*01 (91.7%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (236-236'':239-239'':245-245'':251-251'':254-254'':260-260'':266-266'':269-269'':275-275'':281-281'':284-284'')-undecakisdisulfide, produced in Chinese hamster ovary (CHO)-K1SV cells, glycoform alfa
omodenbamab	immunoglobuline G3-kappa, anti-[*Staphylococcus aureus* SpA (protéine A de Staphylocoque)], anticorps monoclonal *Homo sapiens*; chaîne lourde gamma3 *Homo sapiens* (1-502) [VH (*Homo sapiens* IGHV3-23*04 (90.8%) -(IGHD) -IGHJ5*01 (93.3%)) CDR-IMGT [8.8.18] (26-33.51-58.97-114) (1-125) -*Homo sapiens* IGHG3*01, G3m5* (G3m5,10,11,13,14,26,27) (CH1 (126-223), charnière 1-42 (224-285), CH2 (286-395), CH3 S44 (439), M84 (452), Q98 (474), I101 (477), R115 (490), F116 (491) (396-500), CHS (501-502)) (126-502)], (139-214')-disulfure avec la chaîne légère kappa *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-39*01 (90.5%) -IGKJ5*01 (91.7%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (236-236'':239-239'':245-245'':251-251'':254-254'':260-260'':266-266'':269-269'':275-275'':281-281'':284-284'')-undecakisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO)-K1SV, glycoforme alfa
omodenbamab	inmunoglobulina G3-kappa, anti-[*Staphylococcus aureus* SpA (proteína A de Estafilococo)], anticuerpo monoclonal *Homo sapiens*; cadena pesada gamma3 *Homo sapiens* (1-502) [VH (*Homo sapiens* IGHV3-23*04 (90.8%) -(IGHD) -IGHJ5*01 (93.3%)) CDR-IMGT [8.8.18] (26-33.51-58.97-114) (1-125) -*Homo sapiens* IGHG3*01, G3m5* (G3m5,10,11,13,14,26,27) (CH1 (126-223), bisagra 1-42 (224-285), CH2 (286-395), CH3 S44 (439), M84 (452), Q98 (474), I101 (477), R115 (490), F116 (491) (396-500), CHS (501-502)) (126-502)], (139-214')-disulfuro con la cadena ligera kappa *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-39*01 (90.5%) -IGKJ5*01 (91.7%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (236-236'':239-239'':245-245'':251-251'':254-254'':260-260'':266-266'':269-269'':275-275'':281-281'':284-284'')-undecakisdisulfuro, producido en las células ováricas de hámster chino (CHO)-K1SV, forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVESGGG LVQPGGSLRL SCAASGFTFS TYGMSWVRQA PGKGLEWVSS  50
ITGSGRSTFY ADSVKGRFTI SRDNSTNTLS LQMNSLRAED TAVYYCARSP 100
ADIVTGYYPW WFDLWGQGTL VTVSSASTKG PSVFPLAPCS RSTSGGTAAL 150
GCLVKDYFPE PVTVSWNSGA LTSGVHTFPA VLQSSGLYSL SSVVTVPSSS 200
LGTQTYTCNV NHKPSNTKVD KRVELKTPLG DTTHTCPRCP EPKSCDTPPP 250
CPRCPEPKSC DTPPPCPRCP EPKSCDTPPP CPRCPAPELL GGPSVFLFPP 300
KPKDTLMISR TPEVTCVVVD VSHEDPEVQF KWYVDGVEVH NAKTKPREEQ 350
YNSTFRVVSV LTVLHQDWLN GKEYKCKVSN KALPAPIEKT ISKTKGQPRE 400
PQVYTLPPSR EEMTKNQVSL TCLVKGFYPS DIAVEWESSG QPENNYNTTP 450
PMLDSDGSFF LYSKLTVDKS RWQQGNIFSC SVMHEALHNR FTQKSLSLSP 500
GK                                                      502
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Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS LSASIGDRVT ITCRASQSIN TYLNWYQQKP GKAPRLLIAG  50
ASSLQSGVPS RFSGSGSGTD FTLTISSLQP EDFATYYCQQ ANSFPLTFGQ 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) 22-96 152-208 316-376 422-480
22"-96" 152"-208" 316"-376" 422"-480"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (CH1 10-CL 126) 139-214' 139"-214'"
Inter-H-H (h1 13, h1 16, 236-236" 239-239"
h2 5, h2 11, h2 14 245-245" 251-251" 254-254"
h3 5, h3 11, h3 14, 260-260" 266-266" 269-269"
h4 5, h4 11, h4 14) 275-275" 281-281" 284-284"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
352, 352"
Fucosylated complex bi-antennary CHO-type glycans / glycanes de type CHO bi-antennaires complexes fucosylés / glicanos de tipo CHO biantenarios complejos fucosilados.

O-glycosylation sites / Sites de O-glycosylation / Posiciones de O-glicosilación
h2 S7 h3 S7 h4 S7
247, 247" 262, 262" 277, 277"
Sialylated glycans regularly present / glycanes sialylés régulièrement présents / glicanos sialilados regularmente presentes

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
502, 502"

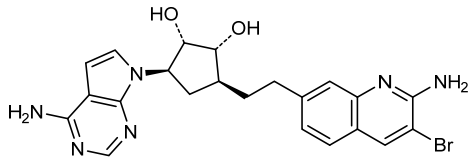
onametostatum

onametostat — (1*S*,2*R*,3*S*,5*R*)-3-[2-(2-amino-3-bromoquinolin-7-yl)ethyl]-5-(4-amino-7*H*-pyrrolo[2,3-*d*]pyrimidin-7-yl)cyclopentane-1,2-diol

onamétostat — (1*S*,2*R*,3*S*,5*R*)-3-[2-(2-amino-3-bromoquinoléin-7-yl)éthyl]-5-(4-amino-7*H*-pyrrolo[2,3-*d*]pyrimidin-7-yl)cyclopentane-1,2-diol

onametostat — (1*S*,2*R*,3*S*,5*R*)-3-[2-(2-amino-3-bromoquinolein-7-il)etil]-5-(4-amino-7*H*-pirrolo[2,3-*d*]pirimidin-7-il)ciclopentano-1,2-diol

$C_{22}H_{23}BrN_6O_2$



ontasameranum #

ontasameran — Messenger RNA encoding transmembrane phosphatase with tensin homology (TPTE).

	Messenger RNA (mRNA), 5'-capped, encoding codon-optimised transmembrane phosphatase with tensin homology (TPTE; cancer/testis antigen 44) expressed as a fusion protein comprising a secretory signal peptide, TPTE, P2P16 tetanus toxoid-derived helper epitopes and a major histocompatibility complex (MHC) class I transmembrane and cytoplasmic domain (MITD), connected by three glycine/serine-rich (GS) linker peptides, flanked by 5' and 3' untranslated regions and a 3' poly(A) tail.
ontasaméran	ARN messager codant pour la phosphatase transmembranaire homologue à la tensine (TPTE). Un ARN messager (ARNm), protégé en 5', codant pour la phosphatase transmembranaire homologue à la tensine (TPTE ; antigène 44 du cancer testiculaire), avec des codons optimisés, exprimé sous la forme d'une protéine de fusion comprenant un peptide signal de sécrétion, TPTE, les épitopes auxiliaires P2P16 dérivés de l'anatoxine tétanique et un domaine transmembranaire et cytoplasmique (MITD) du complexe majeur d'histocompatibilité (CMH) de classe I, reliés par trois peptides de liaison riches en glycine/sérine (GS), flanqués de régions non traduites en 5' et 3' et d'une queue poly(A) en 3'.
ontasamerán	ARN mensajero que codifica para la fosfatasa transmembranal con homología con la tensina (TPTE). ARN mensajero (ARNm), protegido en 5', que codifica para la fosfatasa transmembranal con homología con la tensina (TPTE; antígeno de cáncer/testículo 44), con codones optimizados, expresada como una proteína de fusión que consta de un péptido señal de secreción, TPTE, los epítopos auxiliares P2P16 derivados del toxoide tetánico y un dominio citoplásmico y transmembrana del complejo principal de histocompatibilidad (MHC) de clase I, conectados mediante tres péptidos de enlace ricos en glicina/serina (GS), flanqueado por las regiones 5' y 3' no traducidas y una cola poly(A) en 3'.
oplunofuspum # oplunofusp	*Actinomyces viscosus* L-methionyl sialidase (exo-α-sialidase) catalytic domain fragment (239-631, 2-394 in the current sequence), fused to human amphiregulin heparin binding domain fragment (25-45, 395-415 in the current sequence) anti-(binding to human heparin and cell surface glycosaminoglycans), produced in *Escherichia coli*; L-methionyl (1)-sialidase (exo-α-sialidase, EC:3.2.1.18) (*Actinomyces viscosus*) (239-631)-peptide (containing the sialidase domain) (2-394), fused to human amphiregulin (25-45)-peptide (binding to human heparin and glycosaminoglycans) (395-415), produced in *Escherichia coli*
oplunofusp	L-méthionyl, fragment du domaine catalytique (239-631, 2-394 dans la séquence actuelle) de la sialidase d'*Actinomyces viscosus* (exo-α-sialidase), fusionné à un fragment du domaine liant l'héparine de l'amphiréguline humaine (25-45, 395-415 dans la séquence actuelle) anti-(liant aux glycosaminoglycanes de surface cellulaire et à l'héparine, humains), produit dans *Escherichia coli;*

L-méthionyl (1)-peptide 239-631 de sialidase (exo-α-sialidase, EC:3.2.1.18) (*Actinomyces viscosus*) (contenant le domaine sialidase) (2-394), fusionné au peptide 25-45 de l'amphiréguline humaine (se liant aux glycosaminoglycanes et à l'héparine) (395-415), produit dans *Escherichia coli*

oplunofusp

L-metionil sialidasa(exo-α-sialidasa) *Actinomyces viscosus* fragmento con dominio catalítico (239-631, 2-394 en la secuencia actual), fusionado al fragmento del dominio de unión a la heparina de la anfiregulina humana (25-45, 395-415 en la secuencia actual) anti-(unión a la heparina humana y a los glicosaminoglicanos de superficie celular, humanos), producido in *Escherichia coli*;
L-metionil (1)-péptido 239-631 de sialidasa (exo-α-sialidasa, EC:3.2.1.18) (*Actinomyces viscosus*) (que contiene el dominio de sialidasa) (2-394), fusionado al péptido 25-45 de anfiregulina humana (se une a glicosaminoglicanos y heparina) (395-415), producido en *Escherichia coli*

Sequence / Séquence / Secuencia

```
MGDHPQATPA PAPDASTELP ASMSQAQHLA ANTATDNYRI PAITTAPNGD   50
LLISYDERPK DNGNGGSDAP NPNHIVQRRS TDGGKTWSAP TYIHQGTETG  100
KKVGYSDPSY VVDHQTGTIF NFHVKSYDQG WGGSRGGTDP ENRGIIQAEV  150
STSTDNGWTW THRTITADIT KDKPWTARFA ASGQGIQIQH GPHAGRLVQQ  200
YTIRTAGGAV QAVSVYSDDH GKTWQAGTPI GTGMDENKVV ELSDGSLMLN  250
SRASDGSGFR KVAHSTDGGQ TWSEPVSDKN LPDSVDNAQI IRAFPNAAPD  300
DPRAKVLLLS HSPNPRPWSR DRGTISMSCD DGASWTTSKV FHEPFVGYTT  350
IAVQSDGSIG LLSEDAHNGA DYGGIWYRNF TMNWLGEQCG QKPAKRKKKG  400
GKNGKNRRNR KKKNP                                        415
```

Post-translational modifications
Disulfide bridge location / Position du pont disulfure / Posición del puente disulfuro
329-389

Glycosylation sites / Sites de glycosylation / Posiciones de glicosilación
none / aucune / ninguna

pacanalotamabum #
pacanalotamab

immunoglobulin scFv-scFv, anti-[*Homo sapiens* TNFRSF17 (TNF receptor superfamily member 17, tumor necrosis factor receptor superfamily, member 17, B cell maturation antigen, BCMA, BCM, TNFRSF13A, CD269)] and anti-[*Homo sapiens* CD3E (CD3 epsilon)], monoclonal antibody single chain, bispecific;
IG scFv-scFv single chain, anti-TNFRSF17 and anti-CD3E (1-504) [scFv-VH-V-kappa anti-TNFRSF17 (1-243) [VH (*Homo sapiens* IGHV1-46*01 (85.7%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -15-mer tris(tetraglycyl-seryl) linker (122-136) -V-KAPPA (*Homo sapiens* IGKV1-33*01 (91.6%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (163-168.186-188.225-233) (137-243)] -6-mer seryl-tetraglycyl-seryl linker (244-249) -scFv-VH-V-lambda anti-CD3E (250-498) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (275-282.300-309.348-363) (250-374) -15-mer tris(tetraglycyl-seryl) linker (375-389) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%) CDR-IMGT [9.3.9 (415-423.441-443.480-488) (390-498)] -hexahistidine (499-504)], non-glycosylated, produced in Chinese hamster ovary (CHO) cells

pacanalotamab

immunoglobuline scFv-scFv, anti-[*Homo sapiens* TNFRSF17 (membre 17 de la superfamille des récepteurs du TNF, membre 17 de la superfamille des récepteurs du facteur de nécrose tumorale, antigène de maturation de cellule B, BCMA, BCM, TNFRSF13A, CD269)] et anti-[*Homo sapiens* CD3E (CD3 epsilon)], anticorps monoclonal à chaîne unique, bispécifique; IG scFv-scFv chaîne unique, anti-TNFRSF17 et anti-CD3E (1-504) [scFv-VH-V-kappa anti-TNFRSF17 (1-243) [VH (*Homo sapiens* IGHV1-46*01 (85.7%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121)-15-mer tris(tétraglycyl-séryl) linker (122-136) -V-KAPPA (*Homo sapiens* IGKV1-33*01 (91.6%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (163-168.186-188.225-233) (137-243)] -6-mer séryl-tétraglycyl-séryl linker (244-249) -scFv-V-lambda anti-CD3E (250-498) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD)-IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (275-282.300-309.348-363) (250-374) -15-mer tris(tétraglycyl-séryl) linker (375-389) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%) CDR-IMGT [9.3.9] (415-423.441-443.480-488) (390-498)] -hexahistidine (499-504)], non-glycosylé, produit dans des cellules ovariennes de hamster chinois (CHO)

pacanalotamab

inmunoglobulina scFv-scFv, anti-[*Homo sapiens* TNFRSF17 (miembro 17 de la superfamilia de los receptores del TNF, miembro 17 de la superfamilia de los receptores del factor de necrosis tumoral, antígeno de maduración de célula B, BCMA, BCM, TNFRSF13A, CD269)] y anti-[*Homo sapiens* CD3E (CD3 épsilon)], anticuerpo monoclonal con cadena única, biespecífico; IG scFv-scFv cadena única, anti-TNFRSF17 y anti-CD3E (1-504) [scFv-VH-V-kappa anti-TNFRSF17 (1-243) [VH (*Homo sapiens* IGHV1-46*01 (85.7%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121)-15-mer tris(tetraglicil-seril) linker (122-136) -V-KAPPA (*Homo sapiens* IGKV1-33*01 (91.6%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (163-168.186-188.225-233) (137-243)] -6-mer seril-tetraglicil-seril linker (244-249) -scFv-V-lambda anti-CD3E (250-498) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD)-IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (275-282.300-309.348-363) (250-374) -15-mer tris(tetraglicil-seril) linker (375-389) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%) CDR-IMGT [9.3.9] (415-423.441-443.480-488) (390-498)] -hexahistidina (499-504)], no glicosilado, producido en las células ováricas de hamster chino (CHO)

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGASVKV SCKASGYTFT NHIIHWVRQA PGQGLEWMGY  50
INPYPGYHAY NEKFQGRATM TSDTSTSTVY MELSSLRSED TAVYYCARDG 100
YYRDTDVLDY WGQGTLVTVS SGGGGSGGGG SGGGGSDIQM TQSPSSLSAS 150
VGDRVTITCQ ASQDISNYLN WYQQKPGKAP KLLIYYTSRL HTGVPSRFSG 200
SGSGTDFTFT ISSLEPEDIA TYYCQQGNTL PWTFGQGTKV EIKSGGGGSE 250
VQLVESGGGL VQPGGSLKLS CAASGFTFNK YAMNWVRQAP GKGLEWVARI 300
RSKYNNYATY YADSVKDRFT ISRDDSKNTA YLQMNNLKTE DTAVYYCVRH 350
GNFGNSYISY WAYWGQGTLV TVSSGGGGSG GGGSGGGGSQ TVVTQEPSLT 400
VSPGGTVTLT CGSSTGAVTS GNYPNWVQQK PGQAPRGLIG GTKFLAPGTP 450
ARFSGSLLGG KAALTLSGVQ PEDEAEYYCV LWYSNRWVFG GGTKLTVLHH 500
HHHH                                                    504
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-V (C23 C104) 22-96 159-224 271-347 411-479

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

No N-glycosylation sites / pas de sites de N-glycosylation / ningún posición de N-glicosilación
Aglycosylated

pariglasgenum brecaparvovecum #

pariglasgene brecaparvovec	A non-replicating adeno-associated viral vector encoding codon-optimized human glucose-6-phosphatase (G6PC). A recombinant non-replicating adeno-associated viral vector serotype 8 (rAAV8), encoding codon-optimized human glucose-6-phosphatase (G6PC) under the control of the native human G6PC promoter/enhancer and an SV40 polyadenylation sequence, containing a chimeric intron in the 5' UTR between the promoter/enhancer and the transgene, flanked by AAV2 inverted terminal repeats (ITR).
pariglasgène brécaparvovec	Un vecteur adéno-viral non-réplicatif codant pour la glucose-6-phosphatase (G6PC) humaine avec des codons optimisés. Un vecteur recombinant adéno-viral non-réplicatif de sérotype 8 (rAAV8), codant pour la glucose-6-phosphatase (G6PC) humaine avec des codons optimisés, sous le contrôle du promoteur/activateur de la G6PC humaine native et d'une séquence de polyadénylation du SV40, contenant un intron chimérique dans l'UTR 5' entre le promoteur/activateur et le transgène, flanqué de répétitions terminales inversées (ITR) AAV2.
pariglasgén brecaparvovec	Un vector viral adeno-asociado, no replicativo, que codifica para la glucosa-6-fosfatasa (G6PC) humana, con codones optimizados. Un vector viral adeno-asociado recombinante de serotipo 8 (rAAV8) no replicativo, que codifica para la glucosa-6-fosfatasa (G6PC) humana, con codones optimizados, bajo el control del promotor/potenciador (enhancer) nativo de la G6PC humana y una secuencia de poliadenilación del SV40, conteniendo un intron quimérico en la región 5' UTR entre el promotor/potenciador y el transgén, flanqueado por repeticiones invertidas terminales (ITR) del AAV2.

pavurutamabum #

pavurutamab	immunoglobulin scFv-scFv-scFc, anti-[*Homo sapiens* TNFRSF17 (TNF receptor superfamily member 17, tumor necrosis factor receptor superfamily, member 17, B cell maturation antigen, BCMA, BCM, TNFRSF13A, CD269)] and anti-[*Homo sapiens* CD3E (CD3 epsilon, Leu-4)], monoclonal antibody single chain (scFv)2-scFc, bispecific; IG single chain scFv-scFv-scFc, anti-TNFRS17 and anti-CD3E (1-986) [scFv-VH-V-kappa anti-TNFRSF17 (1-243) [VH (*Homo sapiens* IGHV1-46*01 G49>C (44) (84.7%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -15-mer tris(tetraglycyl-seryl) linker (122-136)-V-KAPPA (*Homo sapiens* IGKV1-33*01 (91.6%) -IGKJ1*01 Q120>C (236) (91.7%)) CDR-IMGT [6.3.9] (163-168.186-188.225-233) (137-243)] -6 mer seryl-tetraglycyl-seryl linker (244-249) -scFv-VH-V-lambda anti-CD3E (250-498) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (275-282.300-309.348-363) (250-374) -15-mer tris(tetraglycyl-seryl) linker (375-389) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (415-423.441-443.480-488) (390-498)] -4-mer tetraglycyl linker

	(499-502) -scFc (h-CH2-CH3)-(h-CH2-CH3) (503-986) [*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (hinge 6-15 (503-512), CH2 R83>C (574), N84.4>G (579), V85>C (584) (513-622), CH3 E12 (638), M14 (640) (623-727), CHS (728-729)) (503-729) -30-mer hexakis(tetraglycyl-seryl) linker (730-759) -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (hinge 6-15 (760-769), CH2 R83>C (831), N84.4>G (836), V85>C (841) (770-879), CH3 E12 (895), M14 (897) (880-984), CHS (985-986)) (760-986)], non-glycosylated, produced in Chinese hamster ovary (CHO) cells
pavurutamab	immunoglobuline scFv-scFv-scFc, anti-[*Homo sapiens* TNFRSF17 (membre 17 de la superfamille des récepteurs du TNF, membre 17 de la superfamille des récepteurs du facteur de nécrose tumorale, antigène de maturation de cellule B, BCMA, BCM, TNFRSF13A, CD269)] et anti-[*Homo sapiens* CD3E (CD3 epsilon, Leu-4)], anticorps monoclonal à chaîne unique (scFv)2-scFc, bispécifique; IG à chaîne unique scFv-scFv-scFc, anti-TNFRSF17 et anti-CD3E (1-986) [scFv-VH-V-kappa anti-TNFRSF17 (1-243) [VH (*Homo sapiens* IGHV1-46*01 G49>C (44) (84.7%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -15-mer tris(tétraglycyl-séryl) linker (122-136)-V-KAPPA (*Homo sapiens* IGKV1-33*01 (91.6%) -IGKJ1*01 Q120>C (236) (91.7%)) CDR-IMGT [6.3.9] (163-168.186-188.225-233) (137-243)] -6-mer séryl-tétraglycyl-séryl linker (244-249) -scFv-VH-V-lambda anti-CD3E (250-498) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (275-282.300-309.348-363) (250-374) -15-mer tris(tétraglycyl-séryl) linker (375-389) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (415-423.441-443.480-488) (390-498)] -4-mer tétraglycyl linker (499-502) -scFc (h-CH2-CH3)-(h-CH2-CH3) (503-986) [*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (503-729) (charnière 6-15 (503-512), CH2 R83>C (574), N84.4>G (579), V85>C (584) (513-622), CH3 E12 (638), M14 (640) (623-727), CHS (728-729)) -30-mer hexakis(tétraglycyl-séryl) linker (730-759) -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (charnière 6-15 (760-769), CH2 R83>C (831), N84.4>G (836), V85>C (841) (770-879), CH3 E12 (895), M14 (897) (880-984), CHS (985-986)) (760-986]], non-glycosylé, produit dans des cellules ovariennes de hamster chinois (CHO)
pavurutamab	inmunoglobulina scFv-scFv-scFc, anti-[*Homo sapiens* TNFRSF17 (miembro 17 de la superfamilia de los receptores del TNF, miembro 17 de la superfamilia de los receptores del factor de necrosis tumoral, antígeno de maduración de célula B, BCMA, BCM, TNFRSF13A, CD269)] y anti-[*Homo sapiens* CD3E (CD3 épsilon, Leu-4)], anticuerpo monoclonal con cadena única (scFv)2-scFc, biespecífico;

IG con cadena única scFv-scFv-scFc, anti-TNFRSF17 y anti-CD3E (1-986) [scFv-VH-V-kappa anti-TNFRSF17 (1-243) [VH (*Homo sapiens* IGHV1-46*01 G49>C (44) (84.7%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -15-mer tris(tetraglicil-seril) linker (122-136)-V-KAPPA (*Homo sapiens* IGKV1-33*01 (91.6%) -IGKJ1*01 Q120>C (236) (91.7%)) CDR-IMGT [6.3.9] (163-168.186-188.225-233) (137-243)] -6-mer seril-tetraglicil-seril linker (244-249) -scFv-VH-V-lambda anti-CD3E (250-498) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (275-282.300-309.348-363) (250-374) -15-mer tris(tetraglicil-seril) linker (375-389) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (415-423.441-443.480-488) (390-498)] -4-mer tetraglicil linker (499-502) -scFc (h-CH2-CH3)-(h-CH2-CH3) (503-986) [*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (503-729) (bisagra 6-15 (503-512), CH2 R83>C (574), N84.4>G (579), V85>C (584) (513-622), CH3 E12 (638), M14 (640) (623-727), CHS (728-729)) -30-mer hexakis(tetraglicil-seril) linker (730-759) -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (bisagra 6-15 (760-769), CH2 R83>C (831), N84.4>G (836), V85>C (841) (770-879), CH3 E12 (895), M14 (897) (880-984), CHS (985-986)) (760-986]], no glicosilado, producido en las células ováricas de hamster chino (CHO)

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGASVKV SCKASGYTFT NHIIHWVRQA PGQCLEWMGY   50
INPYPGYHAY NEKFQGRATM TSDTSTSTVY MELSSLRSED TAVYYCARDG  100
YYRDTDVLDY WGQGTLVTVS SGGGGSGGGG SGGGGSDIQM TQSPSSLSAS  150
VGDRVTITCQ ASQDISNYLN WYQQKPGKAP KLLIYYTSRL HTGVPSRFSG  200
SGSGTDFTFT ISSLEPEDIA TYYCQQGNTL PWTFGCGTKV EIKSGGGGSE  250
VQLVESGGGL VQPGGSLKLS CAASGFTFNK YAMNWVRQAP GKGLEWVARI  300
RSKYNNYATY YADSVKDRFT ISRDDSKNTA YLQMNNLKTE DTAVYYCVRH  350
GNFGNSYISY WAYWGQGTLV TVSSGGGGSG GGGSGGGGSQ TVVTQEPSLT  400
VSPGGTVTLT CGSSTGAVTS GNYPNWVQQK PGQAPRGLIG GTKFLAPGTP  450
ARFSGSLLGG KAALTLSGVQ PEDEAEYYCV LWYSNRWVFG GGTKLTVLGG  500
GGDKTHTCPP CPAPELLGGP SVFLFPPKPK DTLMISRTPE VTCVVVDVSH  550
EDPEVKFNWY VDGVEVHNAK TKPCEEQYGS TYRCVSVLTV LHQDWLNGKE  600
YKCKVSNKAL PAPIEKTISK AKGQPREPQV YTLPPSREEM TKNQVSLTCL  650
VKGFYPSDIA VEWESNGQPE NNYKTTPPVL DSDGSFFLYS KLTVDKSRWQ  700
QGNVFSCSVM HEALHNHYTQ KSLSLSPGKG GGGSGGGGSG GGGSGGGGSG  750
GGGSGGGGSD KTHTCPPCPA PELLGGPSVF LFPPKPKDTL MISRTPEVTC  800
VVVDVSHEDP EVKFNWYVDG VEVHNAKTKP CEEQYGSTYR CVSVLTVLHQ  850
DWLNGKEYKC KVSNKALPAP IEKTISKAKG QPREPQVYTL PPSREEMTKN  900
QVSLTCLVKG FYPSDIAVEW ESNGQPENNY KTTPPVLDSD GSFFLYSKLT  950
VDKSRWQQGN VFSCSVMHEA LHNHYTQKSL SLSPGK               986
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Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-V (C23 C104) 22-96 159-224 271-347 411-479
Intra-C (C23-C104) 543-603 649-707 800-860 906-964
Intra-CH2 (C83-C85) 574-584 831-841
Inter VH-VL (C49-C120) 44-236
Inter h11 (h 11-h 11) 508-765
Inter h14 (h 14-h 14) 511-768

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

No N-glycosylation sites / pas de sites de N-glycosylation / ningún posición de N-glicosilación
H CH2 N84.4>G:
579, 836
Aglycosylated

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
CHS K2:
986

pegtibatinasum #

pegtibatinase

human cystathionine β-synthase fragment (2-413, M[1] cleaved) mutant (C[15]>S), homodimer, produced in *Escherichia coli*, pegylated at *N*[6] of lysine residues with an average of five 5-[α-methylpoly(oxyethylene)-ω-oxy]-5-oxopentanoyl groups per protein monomer;
des-Met[1]-[Cys[15]>Ser] human cystathionine β-synthase (CBS, beta-thionase, serine sulfhydrase, EC:4.2.1.22) (2-413)-peptide, non-covalent dimer, produced in *Escherichia coli*, substituted with approximately five 5-[α-methylpoly(oxyethylene)-ω-oxy]-5-oxopentanoyl groups (20 kDa each) per protein monomer at *N*[6] of lysine residues

pegtibatinase

fragment de la cystathionine β-synthase humaine (2-413, M[1] supprimée) mutant (C[15]>S), homodimère, produit dans *Escherichia coli*, pégylé en *N*[6] des résidus lysine avec une moyenne de cinq groupes 5-[α-méthylpoly(oxyéthylène)-ω-oxy]-5-oxopentanoyle par monomère de protéine;
peptide 2-413 de des-Mét[1]-[Cys[15]>Sér] cystathionine β-synthase humaine (CBS, bêta-thionase, sérine sulfhydrase, EC: 4.2.1.22), dimère non covalent, produit dans *Escherichia coli*, substitué par environ cinq groupes 5-[α-méthylpoly(oxyéthylène)-ω-oxy]-5-oxopentanoyle (~20 kDa chacun) par monomère de protéine au *N*[6] des résidus de lysine

pegtibatinasa

fragmento de la cistationina β-sintasa humana (2-413, M[1] escindido) mutante (C[15]>S), homodímero, producido en *Escherichia coli*, pegilada en *N*[6] residuos de lisina con una medida de cinco grupos 5-[α-metilpoli(oxietileno)-ω-oxi]-5-oxopentanoilo por monómero de proteína;
péptido 2-413 de des-Met[1]-[Cis[15]>Ser] cistationina β-sintasa humana (CBS, beta-tionasa, serina sulfhidrasa, EC: 4.2.1.22), dímero no covalente, producido en *Escherichia coli*, sustituido con aproximadamente cinco grupos 5-[α-metilpoli(oxietilen)-ω-oxi]-5-oxopentanoilo (~20 kDa cada uno) por proteína monomérica en *N*[6] de residuos de lisina

Sequence / Séquence / Secuencia

```
-PSETPQAEV GPTGSPHRSG PHSAKGSLEK GSPEDKEAKE PLWIRPDAPS   50
RCTWQLGRPA SESPHHHTAP AKSPKILPDI LKKIGDTPMV RINKIGKKFG  100
LKCELLAKCE FFNAGGSVKD RISLRMIEDA ERDGTLKPGD TIIEPTSGNT  150
GIGLALAAAV RGYRCIIVMP EKMSSEKVDV LRALGAEIVR TPTNARFDSP  200
ESHVGVAWRL KNEIPNSHIL DQYRNASNPL AHYDTTADEI LQQCDGKLDM  250
LVASVGTGGT ITGIARKLKE KCPGCRIIGV DPEGSILAEP EELNQTEQTT  300
YEVEGIGYDF IPTVLDRTVV DKWFKSNDEE AFTFARMLIA QEGLLCGGSA  350
GSTVAVAVKA AQELQEGQRC VVILPDSVRN YMTKFLSDRW MLQKGFLKEE  400
DLTEKKPWWW HLR                                          415
```

Mutation / Mutation / Mutación

C[15]>S

Post-translational modifications

Removal of Met[1] / Suppression de Met[1] / Eliminación de Met[1]

Disulfide bridges location / Position des ponts disulfure / Posición del puentes disulfuro

272-275, 272'-275' (and further variable potential bridges)

Glycosylation sites / Sites de glycosylation / Posiciones de glicosilación

none / aucune / ninguna

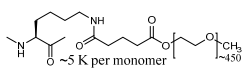
Cofactor binding sites / Sites de liaison des cofacteurs / Sitios de unión de cofactores

N^{6}-pyridoxylidene 5'-phosphate / 5'-phosphate de N^{6}-pyridoxylidène / 5'-fosfato de N^{6}-piridoxilideno K119, K119'

heme B (protoheme IX) / hème b (protohème IX) / hemo B (protohemo IX)

Cys52-S -Fe(II)- N^{1}-His65, Cys52'-S -Fe(II)- N^{1}-His65'

Chemical modification / Modification chimique / Modificación química



pegulicianinum

pegulicianine

N-[6-(1-{2-[3,6-bis(2,3-dihydro-1*H*-indol-1-yl)xanthylium-9-yl]benzene-1-sulfonyl}piperidine-4-carboxamido)hexanoyl]glycylglycyl-L-arginyl-N^6-(6-{2-[(1*E*,3*E*,5*Z*)-5-(1-ethyl-3,3-dimethyl-5-sulfonato-1,3-dihydro-2*H*-indol-2-ylidene)penta-1,3-dien-1-yl]-3,3-dimethyl-5-sulfonato-3*H*-indol-1-ium-1-yl}hexanoyl)-L-lysyl-[2-(2-aminoethoxy)ethoxy]acetyl-*S*-[(3*RS*)-1-{6-[α-methylpoly(oxyethylene)-ω-amino]-6-oxohexyl}-2,5-dioxopyrrolidin-3-yl]-L-cysteinamide

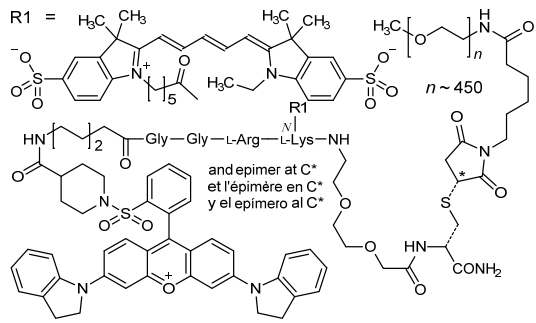
pégulicianine

N-[6-(1-{2-[3,6-bis(2,3-dihydro-1*H*-indol-1-yl)xanthylium-9-yl]benzène-1-sulfonyl}pipéridine-4-carboxamido)hexanoyl]glycylglycyl-L-arginyl-N^6-(6-{2-[(1*E*,3*E*,5*Z*)-5-(1-éthyl-3,3-diméthyl-5-sulfonato-1,3-dihydro-2*H*-indol-2-ylidene)penta-1,3-dién-1-yl]-3,3-diméthyl-5-sulfonato-3*H*-indol-1-ium-1-yl}hexanoyl)-L-lysyl-[2-(2-aminoéthoxy)éthoxy]acétyl-*S*-[(3*RS*)-1-{6-[α-méthylpoly(oxyethylène)-ω-amino]-6-oxohexyl}-2,5-dioxopyrrolidin-3-yl]-L-cystéinamide

pegulicianina

N-[6-(1-{2-[3,6-bis(2,3-dihidro-1*H*-indol-1-il)xantilio-9-il]benceno-1-sulfonil}piperidina-4-carboxamido)hexanoil]glicilglicil-L-arginil-N^6-(6-{2-[(1*E*,3*E*,5*Z*)-5-(1-etil-3,3-dimetil-5-sulfonato-1,3-dihidro-2*H*-indol-2-ilideno)penta-1,3-dien-1-il]-3,3-dimetil-5-sulfonato-3*H*-indol-1-io-1-il}hexanoil)-L-lisil-[2-(2-aminoetoxi)etoxi]acetil-*S*-[(3*RS*)-1-{6-[α-metilpoli(oxietileno)-ω-amino]-6-oxohexil}-2,5-dioxopirrolidin-3-il]-L-cisteinamida

$C_{116}H_{147}N_{19}O_{23}S_4(C_2H_4O)_n$



pelabresibum

pelabresib

2-[(4*S*)-6-(4-chlorophenyl)-1-methyl-4*H*-[1,2]oxazolo[5,4-*d*][2]benzazepin-4-yl]acetamide

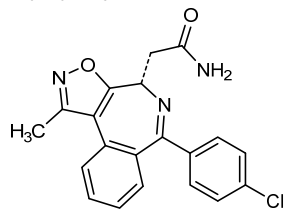
pélabrésib

2-[(4*S*)-6-(4-chlorophényl)-1-méthyl-4*H*-[1,2]oxazolo[5,4-*d*][2]benzazépin-4-yl]acetamide

pelabresib

2-[(4*S*)-6-(4-clorofenil)-1-metil-4*H*-[1,2]oxazolo[5,4-*d*][2]benzazepin-4-il]acetamida

$C_{20}H_{16}ClN_3O_2$



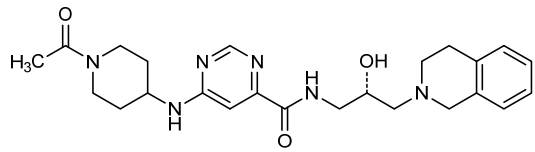
pemrametostatum

pemrametostat — 6-[(1-acetylpiperidin-4-yl)amino]-*N*-[(2*S*)-3-(3,4-dihydroisoquinolin-2(1*H*)-yl)-2-hydroxypropyl]pyrimidine-4-carboxamide

pemramétostat — 6-[(1-acétylpipéridin-4-yl)amino]-*N*-[(2*S*)-3-(3,4-dihydroisoquinoléin-2(1*H*)-yl)-2-hydroxypropyl]pyrimidine-4-carboxamide

pemrametostat — 6-[(1-acetilpiperidin-4-il)amino]-*N*-[(2*S*)-3-(3,4-dihidroisoquinolein-2(1*H*)-il)-2-hidroxipropil]pirimidina-4-carboxamida

$C_{24}H_{32}N_6O_3$



penpulimabum #

penpulimab — immunoglobulin G1-kappa, anti-[*Homo sapiens* PDCD1 (programmed cell death 1, PD-1, PD1, CD279)], monoclonal antibody;
gamma1 heavy chain (1-448) [VH (*Homo sapiens* IGHV3-23*04 (88.7%) -(IGHD) -IGHJ6*01 (90.9%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (1-118) - *Homo sapiens* IGHG1*01 G1m17,1, G1v14 CH2 A1.3, A1.2 (CH1 K120 (215) (119-216), hinge 1-15 (217-231), CH2 L1.3>A (235), L1.2>A (236), G1>A (238) (232-341), CH3 D12 (357), L14 (359) (342-446), CHS (447-448)) (119-448)], (221-214')-disulfide with kappa light chain (1'-214') [V-KAPPA (*Mus musculus* IGKV14-111*01 (86.3%) -IGKJ5*01 (100%)/*Homo sapiens* IGKV1-16*01 (80%) -IGKJ2*01 (81.8%) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')];
dimer (227-227'':230-230'')-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

penpulimab — immunoglobuline G1-kappa, anti-[*Homo sapiens* PDCD1 (protéine 1 de mort cellulaire programmée, PD-1, PD1, CD279)], anticorps monoclonal;

chaîne lourde gamma1 (1-448) [VH (*Homo sapiens* IGHV3-23*04 (88.7%) -(IGHD) -IGHJ6*01 (90.9%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (1-118) -*Homo sapiens* IGHG1*01 G1m17,1, G1v14 CH2 A1.3, A1.2 (CH1 K120 (215) (119-216), charnière 1-15 (217-231), CH2 L1.3>A (235), L1.2>A (236), G1>A (238) (232-341), CH3 D12 (357), L14 (359) (342-446), CHS (447-448)) (119-448)], (221-214')-disulfure avec la chaîne légère kappa (1'-214') [V-KAPPA (*Mus musculus* IGKV14-111*01 (86.3%) -IGKJ5*01 (100%)/*Homo sapiens* IGKV1-16*01 (80%) -IGKJ2*01 (81.8%) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')];
dimère (227-227'':230-230'')-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

penpulimab

inmunoglobulina G1-kappa, anti-[*Homo sapiens* PDCD1 (proteína 1 de muerte celular programada, PD-1, PD1, CD279)], anticuerpo monoclonal;
cadena pesada gamma1 (1-448) [VH (*Homo sapiens* IGHV3-23*04 (88.7%) -(IGHD) -IGHJ6*01 (90.9%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (1-118) -*Homo sapiens* IGHG1*01 G1m17,1, G1v14 CH2 A1.3, A1.2 (CH1 K120 (215) (119-216), bisagra 1-15 (217-231), CH2 L1.3>A (235), L1.2>A (236), G1>A (238) (232-341), CH3 D12 (357), L14 (359) (342-446), CHS (447-448)) (119-448)], (221-214')-disulfuro con la cadena ligera kappa (1'-214') [V-KAPPA (*Mus musculus* IGKV14-111*01 (86.3%) -IGKJ5*01 (100%)/*Homo sapiens* IGKV1-16*01 (80%) -IGKJ2*01 (81.8%) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')];
dímero (227-227'':230-230'')-bisdisulfuro, producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa



Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVESGGG LVQPGGSLRL SCAASGFAFS SYDMSWVRQA PGKGLDWVAT 050
ISGGGRYTYY PDSVKGRFTI SRDNSKNNLY LQMNSLRAED TALYYCANRY 100
GEAWFAYWGQ GTLVTVSSAS TKGPSVFPLA PSSKSTSGGT AALGCLVKDY 150
FPEPVTVSWN SGALTSGVHT FPAVLQSSGL YSLSSVVTVP SSSLGTQTYI 200
CNVNHKPSNT KVDKKVEPKS CDKTHTCPPC PAPEAAGAPS 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
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Light chain / Chaîne légère / Cadena ligera

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DIQMTQSPSS MSASVGDRVT FTCRASQDIN TYLSWFQQKP GKSPKTLIYR 050
ANRLVSGVPS RFSGSGSGQD YTLTISSLQP EDMATYYCLQ YDEFPLTFGA 100
GTKLELKRTV 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) 22-96 145-201 262-322 368-426
22"-96" 145"-201" 262"-322" 368"-426"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (h 5-CL 126) 221-214' 221"-214'"
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 / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
448, 448"

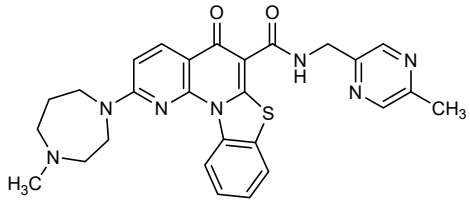
pidnarulexum

pidnarulex — 2-(4-methyl-1,4-diazepan-1-yl)-*N*-[(5-methylpyrazin-2-yl)methyl]-5-oxo-5*H*-[1,3]benzothiazolo[3,2-*a*][1,8]naphthyridine-6-carboxamide

pidnarulex — 2-(4-méthyl-1,4-diazépan-1-yl)-*N*-[(5-méthylpyrazin-2-yl)méthyl]-5-oxo-5*H*-[1,3]benzothiazolo[3,2-*a*][1,8]naphtyridine-6-carboxamide

pidnarulex — 2-(4-metil-1,4-diazepan-1-il)-*N*-[(5-metilpirazin-2-il)metil]-5-oxo-5*H*-[1,3]benzotiazolo[3,2-*a*][1,8]naftiridina-6-carboxamida

$C_{27}H_{27}N_7O_2S$



pimivalimabum #

pimivalimab — immunoglobulin G4-kappa, anti-[*Homo sapiens* PDCD1 (programmed cell death 1, PD-1, PD1, CD279)], *Homo sapiens* monoclonal antibody; gamma4 heavy chain *Homo sapiens* (1-445) [VH (*Homo sapiens* IGHV1-46*01 (96.9%) -(IGHD) - IGHJ5*02 (100%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (1-118)-*Homo sapiens* IGHG4*01 (CH1 (119-216), hinge 1-12 S10>P (226) (217-228), CH2 (229-338), CH3 (339-443), CHS (444-445)) (119-445)], (132-214')-disulfide with kappa light chain *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-5*01 (97.9%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (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

pimivalimab — immunoglobuline G4-kappa, anti-[*Homo sapiens* PDCD1 (protéine 1 de mort cellulaire programmée, PD-1, PD1, CD279)], anticorps monoclonal *Homo sapiens*;
chaîne lourde gamma4 *Homo sapiens* (1-445) [VH (*Homo sapiens* IGHV1-46*01 (96.9%) -(IGHD) - IGHJ5*02 (100%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (1-118) -*Homo sapiens* IGHG4*01 (CH1 (119-216), charnière 1-12 S10>P (226) (217-228), CH2 (229-338), CH3 (339-443), CHS (444-445)) (119-445)], (132-214')-disulfure avec la chaîne légère kappa *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-5*01 (97.9%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (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

pimivalimab

inmunoglobulina G4-kappa, anti-[*Homo sapiens* PDCD1 (proteína 1 de muerte celular programada, PD-1, PD1, CD279)], anticuerpo monoclonal *Homo sapiens*; cadena pesada gamma4 *Homo sapiens* (1-445) [VH (*Homo sapiens* IGHV1-46*01 (96.9%) -(IGHD) -IGHJ5*02 (100%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (1-118) -*Homo sapiens* IGHG4*01 (CH1 (119-216), bisagra 1-12 S10>P (226) (217-228), CH2 (229-338), CH3 (339-443), CHS (444-445)) (119-445)], (132-214')-disulfuro con la cadena ligera kappa *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-5*01 (97.9%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (224-224":227-227")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGASVKV SCKASGYTFP SYYMHWVRQA PGQGLEWMGI  50
INPEGGSTAY AQKFQGRVTM TRDTSTSTVY MELSSLRSED TAVYYCARGG 100
TYYDYTYWGQ GTLVTVSSAS 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 LSLGK      445
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Light chain / Chaîne légère / Cadena ligera

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DIQMTQSPST LSASVGDRVT ITCRASQSIS SWLAWYQQKP GKAPKLLIYE  50
ASSLESGVPS RFSGSGSGTE FTLTISSLQP DDFATYYCQQ YNSFPPTFGG 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 145-201 259-319 365-423
22"-96" 145"-201" 259"-319" 365"-423"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194"
Inter-H-L (h 10-CL 126) 132-214' 132"-214'"
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.

C-terminal lysine clipping:
H CHS K2:
445, 445"

pirepematum

pirepemat

(3*S*)-3-(2,3-difluorophenyl)-3-methoxypyrrolidine

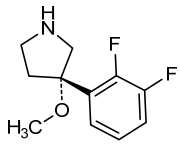
pirépémat

(3*S*)-3-(2,3-difluorophényl)-3-méthoxypyrrolidine

pirepemat

(3*S*)-3-(2,3-difluorofenil)-3-metoxipirrolidina

$C_{11}H_{13}F_2NO$



pomulmeranum #

pomulmeran	Messenger RNA encoding cystic fibrosis transmembrane conductance regulator (CFTR). Messenger RNA (mRNA), 5' capped, encoding codon-optimised human cystic fibrosis transmembrane conductance regulator (CFTR; channel conductance-controlling ATPase, cAMP-dependent chloride channel, ATP-binding cassette sub-family C member 7, ABCC7), flanked by 5' and 3' untranslated regions and a 3' poly(A) tail (200-1000 A).
pomulméran	ARN messager codant pour le régulateur de conductance transmembranaire de la mucoviscidose (CFTR). ARN messager (ARNm), protégé en 5', codant pour le régulateur de conductance transmembranaire de la mucoviscidose humaine avec des codons optimisés (CFTR ; canal ATPase contrôlant la conductance, canal chlorure dépendant de l'AMPc, sous-famille C membre 7, ABCC7), flanqué de régions 5' et 3' non traduites et d'une queue 3' poly(A) (200-1000 A).
pomulmerán	RNA mensajero que codifica para el regulador de la conductancia transmembrana de la fibrosis quística (CFTR). RNA mensajero (RNAm), protegido en 5', que codifica para el regulador de la conductancia transmembrana de la fibrosis quística (CFTR; canal ATPasa controlador de la conductancia, canal de cloro dependiente de AMPc, subfamilia C miembro 7 del casete de unión a ATP, ABCC7) con los codones optimizados, flanqueado por regiones 5' y 3' no traducidas y una cola poly(A) (200-1000 A) en 3'.

posoleucelum

posoleucel	Allogeneic human leukocyte antigen (HLA)-matched virus-specific T cells reactive to cytomegalovirus (CMV), EBV, BK virus, adenovirus and human herpesvirus-6 (HHV-6). The cells are derived from peripheral blood mononuclear cells (PBMCs) from donors seropositive for all five of these viruses. The cells are expanded and co-cultured with 15-mer peptides overlapping by 11 amino acids spanning antigenic proteins from polyomaviruses BK and JC (VP1 and large T), from adenovirus (hexon and penton), from cytomegalovirus (IE1 and pp65), from Epstein-Barr virus (LMP2, EBNA1, BZLF1), and from human herpesvirus-6 (U90, U11 and U14). The cells have specific anti-virus reactivity for each virus above a pre-specified potency threshold, and predominantly express CD3 (generally >95%) with a mixture of CD4+ (average 60%) and CD8+ (average 34%) subsets, including both central (CD45RA-/62L+/CCR7+) and effector (CD45RA-/62L-/CCR7-) memory markers.
posoleucel	Lymphocytes T allogéniques, compatibles pour les antigènes leucocytaires humains (HLA) et spécifiques pour le cytomégalovirus (CMV), l'EBV, le virus BK, l'adénovirus et le virus herpès humain 6 (HHV-6). Les cellules sont dérivées de cellules mononucléaires du sang périphérique (PBMC) provenant de donneurs séropositifs pour ces cinq virus. Les cellules sont amplifiées et cultivées avec des peptides de 15 résidus se chevauchant par 11 acides aminés couvrant les protéines antigéniques du polyomavirus BK et JC (VP1 et grand T), de l'adénovirus (hexon et penton), du cytomégalovirus (IE1 et pp65), du virus d'Epstein-Barr (LMP2, EBNA1, BZLF1), et du virus herpès humain 6 (U90, U11 et U14).

Les cellules ont une réactivité antivirus spécifique pour chacun des virus au-delà d'un seuil prédéfini, et expriment principalement CD3 (généralement >95%) avec un mélange de sous-populations de CD4+ (60% en moyenne) et de CD8+ (34% en moyenne), comprenant des marqueurs des mémoires centrale (CD45RA-/62L+/CCR7+) et effectrice (CD45RA-/62L-/CCR7-).

posoleucel

Células T alogénicas específicas de virus con compatibilidad para el antígeno leucocitario humano (HLA) reactivas frente a citomegalovirus (CMV), EBV, virus BK, adenovirus y herpesvirus humano 6 (HHV-6). Las células se obtienen a partir de células mononucleares de sangre periférica (PBMCs) de donantes seropositivos para estos cinco virus.
Las células tienen una reactividad antivirus específica para cada de estos virus por encima de un umbral de potencia preestablecido, y se expanden y co-cultivan con péptidos de 15 residuos que solapan en 11 amino ácidos cubriendo proteínas antigénicas de poliomavirus BK y JC (VP1 y T grande), de adenovirus (hexón y pentón), de citomegalovirus (IE1 y pp65), de virus de Epstein-Barr (LMP2, EBNA1, BZLF1), y de herpesvirus humano 6 (U90, U11 and U14).
Las células expresan predominantemente CD3 (generalmente >95%) con una mezcla de subtipos CD4+ (60% como media) y CD8+ (34% como media), incluyendo marcadores de memoria central (CD45RA-/62L+/CCR7+) y efectora (CD45RA-/62L-/CCR7-).

radgocitabinum

radgocitabine

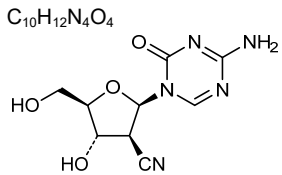
4-amino-1-(2-cyano-2-deoxy-β-D-arabinofuranosyl)pyrimidin-2(1*H*)-one;
2'-cyano-2'-deoxy-D-*arabino*-cytidine

radgocitabine

4-amino-1-(2-cyano-2-désoxy-β-D-arabinofuranosyl)pyrimidin-2(1*H*)-one;
2'-cyano-2'-désoxy-D-*arabino*-cytidine

radgocitabina

4-amino-1-(2-ciano-2-desoxi-β-D-arabinofuranosil)pirimidin-2(1*H*)-ona;
2'-ciano-2'-desoxi-D-*arabino*-citidina



rebonuputemcelum

rebonuputemcel

Allogenic human adult nucleus pulposus cells.
The cells are derived from the central region of intervertebral discs and isolated from the tissue using mechanical and enzymatic (collagenase) procedures. Isolated cells are expanded in culture involving

	adherent and non- adherent conditions until clusters of cells, 100-200 µm in diameter, are generated. Cells comprising the cell substance are dissociated out of these clusters and stored frozen. Cells (on average >95%) express the surface markers CD73, CD90, CD44 and HLA-ABC, and release proteoglycan, collagen and anti-inflammatory cytokines. Cells (on average <3%) lack expression of CD24 (classically associated with native nucleus pulposus cells), CD34, CD45, CD271, Stro-1 or HLA-DR/DP/DQ.
rébonuputemcel	Cellules allogènes du noyau pulpeux humain adulte. Les cellules sont dérivées de la région centrale des disques intervertébraux et isolées du tissu à l'aide de procédures mécaniques et enzymatiques (collagénase). Les cellules isolées sont multipliées en culture dans des conditions adhérentes et non adhérentes jusqu'à ce que des groupes de cellules, de 100 à 200 µm de diamètre, soient générés. Les cellules composant la substance cellulaire sont dissociées de ces amas et conservées congelées. Les cellules (en moyenne> 95%) expriment les marqueurs de surface CD73, CD90, CD44 et HLA-ABC, et libèrent du protéoglycane, du collagène et des cytokines anti-inflammatoires. Les cellules (en moyenne <3%) manquent d'expression de CD24 (classiquement associé aux cellules pulpeuses du noyau natif), CD34, CD45, CD271, Stro-1 ou HLA-DR/DP/DQ.
rebonuputemcel	Células alogénicas del núcleo pulposo adulto humano. Las células son derivadas de la región central de los discos intervertebrales y se aíslan del tejido usando procedimientos mecánicos y enzimáticos (colagenasa). Las células aisladas se expanden en cultivo en condiciones adherentes y no adherentes hasta que se generan grumos de células de 100-200 mm de diámetro. Las células que componen el principio activo se disocian de estos grumos y se almacenan congeladas. >95% de las células expresan los marcadores de superficie CD73, CD90, CD44 y HLA-ABC, y liberan proteoglicano, colágeno y citoquinas anti-inflamatorias. <3% de las células expresan CD24 (asociado clásicamente con células del núcleo pulposo nativo), CD34, CD45, CD271, Stro-1 o HLA-DR/DP/DQ.
recaticimabum # recaticimab	immunoglobulin G1-kappa, anti-[*Homo sapiens* PCSK9 (proprotein convertase subtilisin/kexin type 9, neural apoptosis-regulated convertase 1, NARC1, NARC-1, proprotein convertase 9, PC9)], monoclonal antibody;

	gamma1 heavy chain (1-451) [VH (*Homo sapiens* IGHV1-2*02 (89.8%) -(IGHD) -IGHJ6*01 (100%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -*Homo sapiens* IGHG1*01**,** G1m17,1, G1v21 CH2 Y15.1, T16, E18 (CH1 K120 (218) (122-219), hinge 1-15 (220-234), CH2 M15.1>Y (256), S16>T (258), T18>E (260) (235-344), CH3 D12 (360), L14 (362) (345-449), CHS (450-451)) (122-451)], (224-219')-disulfide with kappa light chain (1'-219') [V-KAPPA (*Mus musculus* IGKV8-21*01 (85%) -IGKJ4*01 (91.7%)/*Homo sapiens* IGKV4-1*01 (76.8%) -IGKJ2*02 (100%)) CDR-IMGT [12.3.8] (27-38.56-58.95-102) (1'-112') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (158), V101 (196) (113-219')]; dimer (230-230":233-233")-bisdisulfide, produced in a Chinese hamster ovary (CHO) cell line (CHOK1SV GS-KO), glycoform alfa
récaticimab	immunoglobuline G1-kappa, anti-[*Homo sapiens* PCSK9 (proprotéine convertase subtilisine/kexine type 9, convertase 1 régulée par l'apoptose neuronale, NARC1, NARC-1, proprotéine convertase 9, PC9)], anticorps monoclonal; chaîne lourde gamma1 (1-451) [VH (*Homo sapiens* IGHV1-2*02 (89.8%) -(IGHD) -IGHJ6*01 (100%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -*Homo sapiens* IGHG1*01**,** G1m17,1, G1v21 CH2 Y15.1, T16, E18 (CH1 K120 (218) (122-219), charnière 1-15 (220-234), CH2 M15.1>Y (256), S16>T (258), T18>E (260) (235-344), CH3 D12 (360), L14 (362) (345-449), CHS (450-451)) (122-451)], (224-219')-disulfure avec la chaîne légère kappa (1'-219') [V-KAPPA (*Mus musculus* IGKV8-21*01 (85%) -IGKJ4*01 (91.7%)/*Homo sapiens* IGKV4-1*01 (76.8%) -IGKJ2*02 (100%)) CDR-IMGT [12.3.8] (27-38.56-58.95-102) (1'-112') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (158), V101 (196) (113-219')]; dimère (230-230":233-233")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) lignée cellulaire CHOK1SV GS-KO, glycoforme alfa
recaticimab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* PCSK9 (proproteína convertasa subtilisina/kexina tipo 9, convertasa 1 regulada por la apoptosis neuronal, NARC1, NARC-1, proproteína convertasa 9, PC9)], anticuerpo monoclonal; cadena pesada gamma1 (1-451) [VH (*Homo sapiens* IGHV1-2*02 (89.8%) -(IGHD) -IGHJ6*01 (100%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -*Homo sapiens* IGHG1*01**,** G1m17,1, G1v21 CH2 Y15.1, T16, E18 (CH1 K120 (218) (122-219), bisagra 1-15 (220-234), CH2 M15.1>Y (256), S16>T (258), T18>E (260) (235-344), CH3 D12 (360), L14 (362) (345-449), CHS (450-451)) (122-451)], (224-219')-disulfuro con la cadena ligera kappa (1'-219') [V-KAPPA (*Mus musculus* IGKV8-21*01 (85%) -IGKJ4*01 (91.7%)/*Homo sapiens* IGKV4-1*01 (76.8%) -IGKJ2*02 (100%)) CDR-IMGT [12.3.8] (27-38.56-58.95-102) (1'-112') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (158), V101 (196) (113-219')]; dímero (230-230":233-233")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular CHOK1SV GS-KO, forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGASVKV SCKASGYTFT DYWMHWVRQA PGQGLEWMGY  50
INPSSGFTKY HQNFKDRVTM TRDTSISTAY MELSRLRSDD TAVYYCARQY 100
DYDEDWYFDV WGQGTTVTVS SASTKGPSVF PLAPSSKSTS GGTAALGCLV 150
KDYFPEPVTV SWNSGALTSG VHTFPAVLQS SGLYSLSSVV TVPSSSLGTQ 200
TYICNVNHKP SNTKVDKKVE PKSCDKTHTC PPCPAPELLG GPSVFLFPPK 250
PKDTLYITRE 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
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Light chain / Chaîne légère / Cadena ligera

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DIVMSQSPSS LSASVGDRVT ITCKSSQSLL NSRTRKNFLA WYQQKPGKSP  50
KLLIYWASTR ESGVPDRFSG SGSGTDFTLT ISSLQPEDFA TYYCKQSFNL 100
FTFGQGTKLE 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) 22-96 148-204 265-325 371-429
22"-96" 148"-204" 265"-325" 371"-429"
Intra-L (C23-C104) 23'-94' 139'-199'
23'"-94'" 139'"-199'"
Inter-H-L (h 5-CL 126) 224-219' 224"-219'"
Inter-H-H (h 11, h 14) 230-230" 233-233"

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:
301, 301"
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 / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
451, 451"

relmacabtagenum autoleucelum #

relmacabtagene autoleucel

Autologous CD4+ and CD8+ enriched T cells transduced *ex vivo* with a self-inactivating lentivirus vector encoding an anti-CD19 chimeric antigen receptor.
Autologous CD4+ and CD8+ T cells, enriched from peripheral blood mononuclear cells (PBMCs) transduced with a non-replicative self-inactivating (SIN) lentiviral vector encoding a chimeric antigen receptor (CAR) consisting of the human CD19-specific scFv, an IgG4 hinge region, CD28 transmembrane domain, CD137 (4-1BB) co-stimulatory domain and CD3 zeta signalling domain, under the control of a hybrid Elongation Factor 1 alpha (EF1α) and Human T cell Leukemia Virus type 1 (HTLV-1) regulatory element promoter and woodchuck hepatitis virus post-transcriptional regulatory element (WPRE). The vector genome also encodes a truncated human epidermal growth factor receptor (EGFRt) that is co-expressed with the CAR and cleaved from it by the T2A self-cleaving peptide. The vector genome also contains a splice donor, a fragment of *gag*, a Rev response element (RRE), a mutated central polypurine tract (cPPT), and a splice acceptor.

relmacabtagène autoleucel

Cellules T autologues enrichies en CD4+ et CD8+ transduites *ex vivo* avec un vecteur lentiviral auto-inactivant codant pour un récepteur chimérique dirigé contre l'antigène CD19.

Cellules T CD4+ et CD8+ autologues, enrichies de cellules mononucléaires du sang périphérique (PBMC), transduites avec un vecteur lentiviral auto-inactivable et non réplicatif (SIN) codant pour un récepteur chimérique (CAR) constitué du scFv spécifique de l'antigène CD19 humain, d'une région charnière IgG4, d'un domaine transmembranaire CD28, du domaine co-stimulateur de CD137 (4-1BB) et du domaine de signalisation CD3 zeta, sous le contrôle d'un hybride du facteur d'allongement 1 alpha (EF1α) et du promoteur de l'élément régulateur du virus de la leucémie humaine à cellules T de type 1 (HTLV-1), ainsi que de l'élément régulateur post-transcriptionnel du virus de l'hépatite de la marmotte (WPRE). Le génome du vecteur code également pour un récepteur tronqué du facteur de croissance épidermique humain (EGFRt) qui est co-exprimé avec le CAR et en est relâché par le peptide T2A auto-coupant. Le génome du vecteur contient également un donneur d'épissage, un fragment de gag, un élément de réponse Rev (RRE), un segment central polypurine muté (cPPT) et un accepteur d'épissage.

relmacabtagén autoleucel

Células T autólogas enriquecidas en CD4+ y CD8+ transducidas *ex vivo* con un lentivirus auto-inactivante que codifica un receptor de antígenos quiméricos anti-CD19.
Las células T autólogas CD4+ y CD8+, enriquecidas a partir de células mononucleares de sangre periférica (PBMCs), transducidas con un vector lentiviral no replicativo y auto-inactivante (SIN) que codifica para un receptor de antígenos quimérico (CAR) consistente en un scFv específico de CD19 humano, una región bisagra IgG4, un dominio transmembrana CD28, un dominio co-estimulador CD137 (4-1BB) y un domino de señalización CD3 zeta, bajo el control de un promotor híbrido del factor de elongación 1 alfa (EF1α) y el elemento regulador del virus de la leucemia de células T de tipo 1 humano (HTLV-1), y elemento regulador post-transcripcional del virus de la hepatitis de la marmota (WPRE). El genoma del vector también codifica para un receptor del factor de crecimiento epidérmico humano truncado (EGFRt) que se coexpresa con el CAR y luego se escinde de él por el péptido de auto escisión T2A. El genoma del vector también contiene un sitio donante de procesamiento (splicing), un fragmento de *gag*, un elemento de respuesta Rev (RRE), un segmento central de polipurinas (cPPT) y un sitio aceptor de procesamiento (splicing).

resiniferatoxinum

resiniferatoxin

[(2*S*,3a*R*,3b*S*,6a*R*,9a*R*,9b*R*,10*R*,11a*R*)-2-benzyl-6a-hydroxy-8,10-dimethyl-7-oxo-11a-(prop-1-en-2-yl)-3a,3b,6,6a,9a,10,11,11a-octahydro-2*H*,7*H*-2,9b-epoxyazuleno[5,4-*e*][1,3]benzodioxol-5-yl]methyl (4-hydroxy-3-methoxyphenyl)acetate

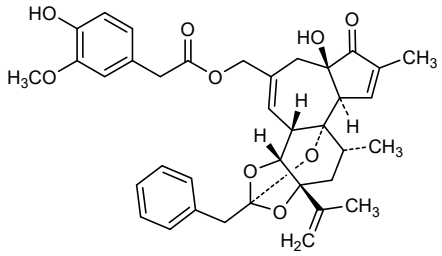
résinifératoxine

(4-hydroxy-3-méthoxyphényl)acétate de [(2*S*,3a*R*,3b*S*,6a*R*,9a*R*,9b*R*,10*R*,11a*R*)-2-benzyl-6a-hydroxy-8,10-diméthyl-7-oxo-11a-(prop-1-én-2-yl)-3a,3b,6,6a,9a,10,11,11a-octahydro-2*H*,7*H*-2,9b-époxyazuléno[5,4-*e*][1,3]benzodioxol-5-yl]méthyle

resiniferatoxina

(4-hidroxi-3-metoxifenil)acetato de [(2*S*,3a*R*,3b*S*,6a*R*,9a*R*,9b*R*,10*R*,11a*R*)-2-bencil-6a-hidroxi-8,10-dimetil-7-oxo-11a-(prop-1-en-2-il)-3a,3b,6,6a,9a,10,11,11a-octahidro-2*H*,7*H*-2,9b-epoxiazuleno[5,4-*e*][1,3]benzodioxol-5-il]metilo

$C_{37}H_{40}O_9$



revakinagenum taroretcelum #

revakinagene taroretcel

Allogeneic human adult retinal pigment epithelial (RPE) cell line stably transfected with a plasmid encoding human ciliary neurotrophic factor (CNTF).
An allogeneic human adult retinal pigment epithelial (RPE) cell line stably transfected with a plasmid encoding human ciliary neurotrophic factor (CNTF) fused in frame to the murine immunoglobulin mu-factor VDJ4C1 signal peptide, under the control of a mouse metallothionein promoter and a human growth hormone polyadenylation signal. The plasmid also contains three eukaryotic expression cassettes for the selectable markers neomycin resistance, mouse DHFR (dihydrofolate reductase) and HSV-TK (thymidine kinase), plus the bacterial components of the pUC18 backbone, including the ampicillin resistance gene (AmpR), origin of replication (ORI) and LacZ gene (alpha fragment of β-galactosidase).

révakinagène taroretcel

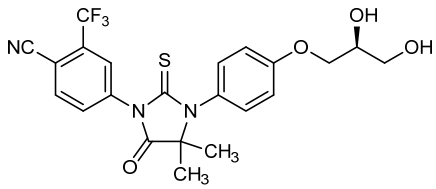
Lignée cellulaire épithéliale allogénique du pigment rétinien humain adulte (EPR) transfectée de façon stable avec un plasmide codant pour le facteur neurotrophique ciliaire humain (CNTF).
Une lignée cellulaire épithéliale allogénique du pigment rétinien humain adulte (RPE) transfectée de manière stable avec un plasmide codant pour le facteur neurotrophique ciliaire humain (CNTF) fusionné dans le cadre de lecture du peptide signal VDJ4C1 du facteur mu d'immunoglobuline murine, sous le contrôle d'un promoteur de la métallothionéine de souris et d'un signal de polyadénylation de l'hormone de croissance humaine. Le plasmide contient également des cassettes d'expression eucaryotes pour trois marqueurs de sélection, à savoir la résistance à la néomycine, la DHFR (réductase du dihydrofolate) et la HSV-TK (kinase de la thymidine) de souris, ainsi que les composants bactériens du plasmide pUC18, dont le gène de résistance à l'ampicilline (AmpR), l'origine de réplication (ORI) et le gène du LacZ (fragment alpha de la β-galactosidase).

revakinagén taroretcel	Línea celular epitelial alogénica de pigmento retiniano adulto (RPE) humano transfectada de forma estable con un plásmido que codifica para el factor neurotrófico ciliar (CNTF) humano. Una línea celular epitelial alogénica de pigmento retiniano adulto (RPE) humano transfectada de forma estable con un plásmido que codifica para el factor neurotrófico ciliar (CNTF) humano fusionado en marco de lectura al péptido señal VDJ4AC1 del factor mu de la inmunoglobulina murina, bajo el control de un promotor de la metalotionina de ratón y una señal de poliadenilación de la hormona de crecimiento humana. El plásmido contiene también tres casetes de expresión eucariotas para los marcadores de selección de resistencia a neomicina, DHFR (dihidrofolato reductasa) de ratón y HSV-TK (timidin quinasa), más los componentes bacterianos del esqueleto de pUC18, incluyendo el gen de resistencia a ampicilina (AmpR), el origin de replicación (ORI) y el gen LacZ (fragmento alfa de la β-galactosidasa).

rezvilutamidum

rezvilutamide	4-(3-{4-[(2*S*)-2,3-dihydroxypropoxy]phenyl}-4,4-dimethyl-5-oxo-2-sulfanylideneimidazolidin-1-yl)-2-(trifluoromethyl)benzonitrile
rezvilutamide	4-(3-{4-[(2*S*)-2,3-dihydroxypropoxy]phényl}-4,4-diméthyl-5-oxo-2-sulfanylidèneimidazolidin-1-yl)-2-(trifluorométhyl)benzonitrile
rezvilutamida	4-(3-{4-[(2*S*)-2,3-dihidroxipropoxi]fenil}-4,4-dimetil-5-oxo-2-sulfanilidenoimidazolidin-1-il)-2-(trifluorometil)benzonitrilo

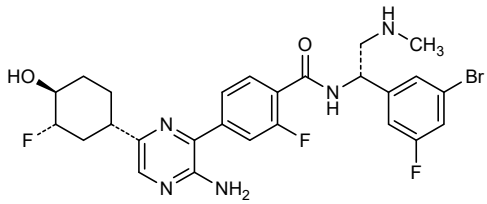
$C_{22}H_{20}F_3N_3O_4S$



rineterkibum

rineterkib	4-{3-amino-6-[(1*S*,3*S*,4*S*)-3-fluoro-4-hydroxycyclohexyl]pyrazin-2-yl}-*N*-[(1*S*)-1-(3-bromo-5-fluorophenyl)-2-(methylamino)ethyl]-2-fluorobenzamide
rinéterkib	4-{3-amino-6-[(1*S*,3*S*,4*S*)-3-fluoro-4-hydroxycyclohexyl]pyrazin-2-yl}-*N*-[(1*S*)-1-(3-bromo-5-fluorophényl)-2-(méthylamino)éthyl]-2-fluorobenzamide
rineterkib	4-{3-amino-6-[(1*S*,3*S*,4*S*)-3-fluoro-4-hidroxiciclohexil]pirazin-2-il}-*N*-[(1*S*)-1-(3-bromo-5-fluorofenil)-2-(metilamino)etil]-2-fluorobenzamida

$C_{26}H_{27}BrF_3N_5O_2$



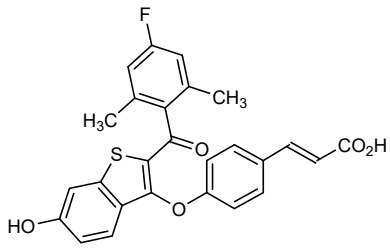
rintodestrantum

rintodestrant — (2*E*)-3-(4-{[2-(4-fluoro-2,6-dimethylbenzoyl)-6-hydroxy-1-benzothiophen-3-yl]oxy}phenyl)prop-2-enoic acid

rintodestrant — acide (2*E*)-3-(4-{[2-(4-fluoro-2,6-diméthylbenzoyl)-6-hydroxy-1-benzothiophén-3-yl]oxy}phényl)prop-2-énoïque

rintodestrant — ácido (2*E*)-3-(4-{[2-(4-fluoro-2,6-dimetilbenzoil)-6-hidroxi-1-benzotiofen-3-il]oxi}fenil)prop-2-enoico

$C_{26}H_{19}FO_5S$



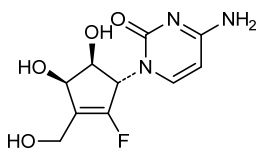
roducitabinum

roducitabine — 4-amino-1-[(1*S*,4*R*,5*S*)-2-fluoro-4,5-dihydroxy-3-(hydroxymethyl)cyclopent-2-en-1-yl]pyrimidin-2(1*H*)-one;
4'a-fluoro-4',4'a-didehydro-4'-*O*-carbacytidine

roducitabine — 4-amino-1-[(1*S*,4*R*,5*S*)-2-fluoro-4,5-dihydroxy-3-(hydroxyméthyl)cyclopent-2-én-1-yl]pyrimidin-2(1*H*)-one;
4'a-fluoro-4',4'a-didéhydro-4'-*O*-carbacytidine

roducitabina — 4-amino-1-[(1*S*,4*R*,5*S*)-2-fluoro-4,5-dihidroxi-3-(hidroximetil)ciclopent-2-en-1-il]pirimidin-2(1*H*)-ona;
4'a-fluoro-4',4'a-didehidro-4'-*O*-carbacitidina

$C_{10}H_{12}FN_3O_4$



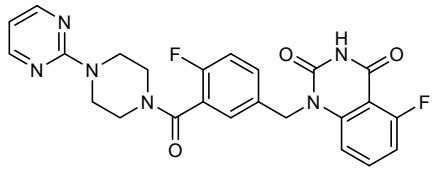
senaparibum

senaparib — 5-fluoro-1-({4-fluoro-3-[4-(pyrimidin-2-yl)piperazine-1-carbonyl]phenyl}methyl)quinazoline-2,4(1*H*,3*H*)-dione

sénaparib — 5-fluoro-1-({4-fluoro-3-[4-(pyrimidin-2-yl)pipérazine-1-carbonyl]phényl}méthyl)quinazoline-2,4(1*H*,3*H*)-dione

senaparib — 5-fluoro-1-({4-fluoro-3-[4-(pirimidin-2-il)piperazina-1-carbonil]fenil}metil)quinazolina-2,4(1*H*,3*H*)-diona

$C_{24}H_{20}F_2N_6O_3$



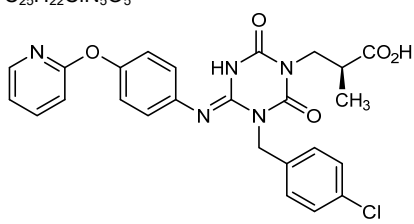
sivopixantum

sivopixant — (2*S*)-3-[(4*E*)-3-[(4-chlorophenyl)methyl]-2,6-dioxo-4-({4-[(pyridin-2-yl)oxy]phenyl}imino)-1,3,5-triazinan-1-yl]-2-methylpropanoic acid

sivopixant — acide (2*S*)-3-[(4*E*)-3-[(4-chlorophényl)méthyl]-2,6-dioxo-4-({4-[(pyridin-2-yl)oxy]phényl}imino)-1,3,5-triazinan-1-yl]-2-méthylpropanoïque

sivopixant — ácido (2*S*)-3-[(4*E*)-3-[(4-clorofenil)metil]-2,6-dioxo-4-({4-[(piridin-2-il)oxi]fenil}imino)-1,3,5-triazinan-1-il)-2-metilpropanoico

$C_{25}H_{22}ClN_5O_5$



sizavaleucelum

sizavaleucel — Allogeneic, HLA-matched CD3+ T-cells, derived from G-CSF mobilized peripheral blood stem cells (PBSC) collected by apheresis. Cells are transplant organ donor-derived, non-cultured and cryopreserved with CD34+ hematopoietic stem cells (HSC) *(firzotemcel (121)(83))* obtained from the same HLA-matched donor. Intended for delivery to a single HLA-matched recipient.

sizavaleucel	Des cellules T CD3+ allogéniques, exprimant des antigènes HLA compatibles, dérivées de cellules souches du sang périphérique (PBSC) mobilisées par le G-CSF et collectées par aphérèse. Les cellules sont dérivées de donneurs d'organes de transplantation, ne sont pas cultivées et sont cryoconservées avec des cellules souches hématopoïétiques (HSC) CD34+ *(firzotemcel (121)(83))* qui proviennent du même donneur compatible pour les antigènes HLA. Destinées à être données à un seul receveur compatible pour les antigènes HLA.
sizavaleucel	Células T CD3+ alogénicas, con HLA compatible, derivadas de células madre de sangre periférica (PBSC) movilizadas con G-CSF y recogidas por aféresis. Las células proceden de donantes de órganos para trasplante, no se cultivan y se criopreservan con células madre hematopoyéticas (HSC) CD34+ *(firzotemcel (121)(83))* obtenidas del mismo donante HLA compatible. Destinadas para administrarse a un sólo receptor HLA compatible.

sotigalimabum #

sotigalimab	immunoglobulin G1-kappa, anti-[*Homo sapiens* CD40 (tumor necrosis factor receptor superfamily member 5, TNFRSF5)], humanized monoclonal antibody; gamma1 heavy chain humanized (1-450) [VH (*Homo sapiens* IGHV3-30*01 (79.8%) -(IGHD) -IGHJ1*01 (90.9%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 G1m17,1 (CH1 K120 (217) (121-218), hinge 1-15 (219-233), CH2 S29>E (270) (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-215')-disulfide with kappa light chain humanized (1'-215') [V-KAPPA (*Homo sapiens* IGKV1-27*01 (91%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.13] (27-32.50-52.89-101) (1'-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)-derived cell line, glycoform alfa
sotigalimab	immunoglobuline G1-kappa, anti-[*Homo sapiens* CD40 (membre 5 de la superfamille des récepteurs du TNF, TNFRSF5)], anticorps monoclonal humanisé; chaîne lourde gamma1 humanisée (1-450) [VH (*Homo sapiens* IGHV3-30*01 (79.8%) -(IGHD) -IGHJ1*01 (90.9%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 G1m17,1 (CH1 K120 (217) (121-218), charnière 1-15 (219-233), CH2 S29>E (270) (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-215')-disulfure avec la chaîne légère kappa humanisée (1'-215') [V-KAPPA (*Homo sapiens* IGKV1-27*01 (91%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.13] (27-32.50-52.89-101) (1'-108') (1'-108') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (154), V101 (192) (109'-215')]; dimère (229-229":232-232")-bisdisulfure, produite dans une lignée cellulaire dérivée des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

sotigalimab

inmunoglobulina G1-kappa, anti-[*Homo sapiens* CD40 (miembro 5 de la superfamilia de los receptores del TNF, TNFRSF5)], anticuerpo monoclonal humanizado; cadena pesada gamma1 humanizada (1-450) [VH (*Homo sapiens* IGHV3-30*01 (79.8%) -(IGHD) - IGHJ1*01 (90.9%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 G1m17,1 (CH1 K120 (217) (121-218), bisagra 1-15 (219-233), CH2 S29>E (270) (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-215')-disulfuro con la cadena ligera kappa humanizada (1'-215') [V-KAPPA (*Homo sapiens* IGKV1-27*01 (91%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.13] (27-32.50-52.89-101) (1'-108') (1'-108') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (154), V101 (192) (109'-215')];
dímero (229-229":232-232")-bisdisulfuro, producido en una línea celular derivada de las células ováricas de hámster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVESGGG VVQPGRSLRL SCAASGFSFS STYVCWVRQA PGKGLEWIAC  50
IYTGDGTNYS ASWAKGRFTI SKDSSKNTVY LQMNSLRAED TAVYFCARPD 100
ITYGFAINFW GPGTLVTVSS ASTKGPSVFP LAPSSKSTSG GTAALGCLVK 150
DYFPEPVTVS WNSGALTSGV HTFPAVLQSS GLYSLSSVVT VPSSSLGTQT 200
YICNVNHKPS NTKVDKKVEP KSCDKTHTCP PCPAPELLGG PSVFLFPPKP 250
KDTLMISRTP EVTCVVVDVE HEDPEVKFNW YVDGVEVHNA KTKPREEQYN 300
STYRVVSVLT VLHQDWLNGK EYKCKVSNKA LPAPIEKTIS KAKGQPREPQ 350
VYTLPPSRDE LTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPV 400
LDSDGSFFLY SKLTVDKSRW QQGNVFSCSV MHEALHNHYT QKSLSLSPGK 450
```

Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS LSASVGDRVT IKCQASQSIS SRLAWYQQKP GKPPKLLIYR  50
ASTLASGVPS RFSGSGSGTD FTLTISSLQP EDVATYYCQC TGYGISWPIG 100
GGTKVEIKRT 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 35-50 147-203 264-324 370-428
22"-96" 35"-50" 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-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 VH N65:
58, 58"
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 / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
450, 450"

sotorasibum

sotorasib

(1*M*)-6-fluoro-7-(2-fluoro-6-hydroxyphenyl)-1-[4-methyl-2-(propan-2-yl)pyridin-3-yl]-4-[(2*S*)-2-methyl-4-(prop-2-enoyl)piperazin-1-yl]pyrido[2,3-*d*]pyrimidin-2(1*H*)-one

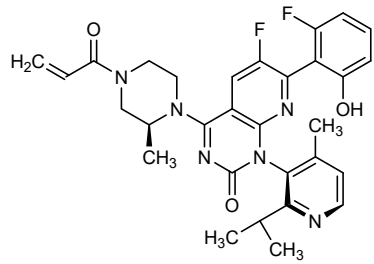
sotorasib

(1*M*)-6-fluoro-7-(2-fluoro-6-hydroxyphényl)-1-[4-méthyl-2-(propan-2-yl)pyridin-3-yl]-4-[(2*S*)-2-méthyl-4-(prop-2-énoyl)pipérazin-1-yl]pyrido[2,3-*d*]pyrimidin-2(1*H*)-one

sotorasib

(1*M*)-6-fluoro-7-(2-fluoro-6-hidroxifenil)-1-[4-metil-2-(propan-2-il)piridin-3-il]-4-[(2*S*)-2-metil-4-(prop-2-enoil)piperazin-1-il]pirido[2,3-*d*]pirimidin-2(1*H*)-ona

$C_{30}H_{30}F_2N_6O_3$



sulanemadlinum

sulanemadlin

C$^{2.11}$,*C*$^{2.4}$-[(4*E*)-undec-4-ene-1,11-diyl](*N*-acetyl-L-leucyl-L-threonyl-L-phenylalanyl-L-alanyl-L-α-glutamyl-L-tyrosyl-L-tryptophyl-L-alanyl-L-glutaminyl-L-leucyl-D-alanyl-L-alanyl-L-alanyl-L-alanyl-L-alanyl-L-alanyl-D-alaninamide)

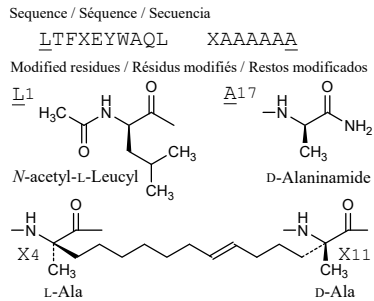
sulanémadline

C$^{2.11}$,*C*$^{2.4}$-[(4*E*)-undéc-4-ène-1,11-diyl](*N*-acétyl-L-leucyl-L-thréonyl-L-phénylalanyl-L-alanyl-L-α-glutamyl-L-tyrosyl-L-tryptophyl-L-alanyl-L-glutaminyl-L-leucyl-D-alanyl-L-alanyl-L-alanyl-L-alanyl-L-alanyl-L-alanyl-D-alaninamide)

sulanemadlina

C$^{2.11}$,*C*$^{2.4}$-[(4*E*)-undec-4-eno-1,11-diil](*N*-acetil-L-leucil-L-treonil-L-fenilalanil-L-alanil-L-α-glutamil-L-tirosil-L-triptofil-L-alanil-L-glutaminil-L-leucil-D-alanil-L-alanil-L-alanil-L-alanil-L-alanil-L-alanil-D-alaninamida)

$C_{95}H_{140}N_{20}O_{23}$



suntinorextonum

suntinorexton

N-[(2*S*,3*S*)-2-[(2,3'-difluoro[1,1'-biphenyl]-3-yl)methyl]-1-(2-hydroxy-2-methylpropanoyl)pyrrolidin-3-yl]ethanesulfonamide

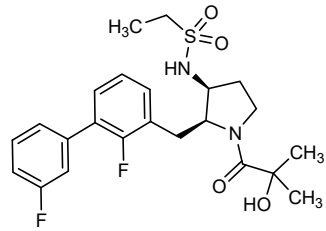
suntinorexton

N-[(2*S*,3*S*)-2-[(2,3'-difluoro[1,1'-biphényl]-3-yl)méthyl]-1-(2-hydroxy-2-méthylpropanoyl)pyrrolidin-3-yl]éthanesulfonamide

suntinorextón

N-[(2*S*,3*S*)-2-[(2,3'-difluoro[1,1'-bifenil]-3-il)metil]-1-(2-hidroxi-2-metilpropanoil)pirrolidin-3-il]etanosulfonamida

$C_{23}H_{28}F_2N_2O_4S$



suratadenoturevum #

suratadenoturev

A replication-competent adenovirus type 5 in which the E1A and E1B genes are under the control of a human telomerase reverse transcriptase (hTERT) and IRES, respectively.
A recombinant replication-competent adenovirus type 5 (Ad-5) in which the E1 gene, including its normal transcriptional regulatory element, has been deleted and replaced by an expression cassette containing an hTERT (human telomerase reverse transcriptase) promoter, the Ad E1A gene, an IRES (internal ribosome entry site) and the Ad E1B gene. E1A expression is controlled by the hTERT promoter; E1B translation is effected by the IRES.

suratadénoturev

Un adénovirus de type 5 réplicatif dans lequel les gènes E1A et E1B sont, respectivement, sous le contrôle de la transcriptase inverse de la télomérase humaine (hTERT) et d'IRES.
Un adénovirus recombinant réplicatif de type 5 (Ad-5) dans lequel le gène E1, y compris son élément normal de régulation de la transcription, a été supprimé et remplacé par une cassette d'expression contenant un promoteur hTERT (transcriptase inverse de la télomérase humaine), le gène Ad E1A, un IRES (site d'entrée interne du ribosome) et le gène Ad E1B. L'expression de E1A est contrôlée par le promoteur hTERT; la traduction de E1B est effectuée par l'IRES.

suratadenoturev

Un adenovirus tipo 5 competente de replicación en el que los genes E1A y E1B están bajo el control de la telomerasa transcriptasa inversa humana (hTERT) e IRES, respectivamente.
Un adenovirus tipo 5 (Ad-5) recombinante competente de replicación en el que el gen E1, incluyendo su elemento de regulación transcripcional normal, ha sido delecionado y reemplazado por un casete de expresión que contiene un promotor de hTERT (telomerasa transcriptasa inversa humana), el gen Ad E1A, un IRES (sitio interno de entrada al ribosoma) y el gen Ad E1B. La expresión de E1A esta controlada por el promotor hTERT; La traducción de E1B se efectúa por el IRES.

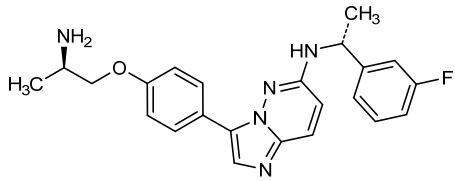
taletrectinibum

taletrectinib — 3-{4-[(2*R*)-2-aminopropoxy]phenyl}-*N*-[(1*R*)-1-(3-fluorophenyl)ethyl]imidazo[1,2-*b*]pyridazin-6-amine

talétrectinib — 3-{4-[(2*R*)-2-aminopropoxy]phényl}-*N*-[(1*R*)-1-(3-fluorophényl)éthyl]imidazo[1,2-*b*]pyridazin-6-amine

taletrectinib — 3-{4-[(2*R*)-2-aminopropoxi]fenil}-*N*-[(1*R*)-1-(3-fluorofenil)etil]imidazo[1,2-*b*]piridazin-6-amina

$C_{23}H_{24}FN_5O$



taniraleucelum

taniraleucel — Allogeneic natural killer (NK) cells derived from CD34+ umbilical cord blood (UCB) hematopoietic stem/progenitor cells.
The cells are expanded and differentiated in the presence of cytokines including thrombopoietin, SCF, Flt3 ligand, IL-7, IL-15 and IL-2 (average population doublings 15) to generate the NK cell population.
Cells (on average >95% of the cells) are CD56+/CD3- and have detectable levels of CD94, NKG2D and CD16.
The cells secrete IFN-γ, perforin and granzyme B, and have cytolytic activity against human tumour cell lines.

taniraleucel — Cellules tueuses naturelles (NK) allogéniques dérivées de cellules souches/progénitrices hématopoïétiques CD34+ du sang de cordon ombilical (UCB).
Les cellules sont amplifiées et différenciées en présence de cytokines, notamment la thrombopoïétine, le SCF, le ligand de Flt3, l'IL-7, l'IL-15 et l'IL-2 (la population double en moyenne 15 fois) pour générer la population de cellules NK.
Les cellules (en moyenne >95% des cellules) sont CD56+/CD3- et ont des niveaux détectables de CD94, NKG2D et CD16. Les cellules sécrètent l'IFN-γ, la perforine et la granzyme B, et ont une activité cytolytique contre les lignées de cellules tumorales humaines.

taniraleucel — Células natural killer (NK) alogénicas derivadas de células madre/progenitoras hematopoyéticas de sangre de cordón umbilical (UCB).
Las células se expanden y diferencian en presencia de citoquinas incluyendo trombopoyetina, SCF, ligando de Flt3, IL-7, IL-15 e IL-2 (la media de duplicaciones de la población es 15 veces) hasta generar la población de células NK. Las células (como media >95% de las células) son CD56+/CD3- y tienen niveles detectables de CD94, NKG2D y CD16. Las células secretan IFN-γ, perforina y granzima B, y tienen actividad citolítica frente a líneas celulares tumorales humanas.

tarlatamabum #

tarlatamab	immunoglobulin scFv-scFv-scFc, anti-[*Homo sapiens* DLL3 (delta-like ligand 3)] and anti-[*Homo sapiens* CD3E (CD3 epsilon, Leu-4)], monoclonal antibody single chain (scFv)2-scFc, bispecific; IG single chain scFv-scFv-scFc, anti-DLL3 and anti-CD3E (1-982) [scFv-VH-V-kappa anti-DLL3 (1-241) [VH (*Homo sapiens* IGHV4-59*01 G49>C (44) (96.9%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.7.12] (26-33.51-57.96-107) (1-118) -15-mer-tris(tetraglycyl-seryl) linker (119-133)-V-KAPPA (*Homo sapiens* IGKV3-20*01 (91.7%) -IGKJ2*01 Q120>C (234) (90.9%)) CDR-IMGT [7.3.9] (160-166.184-186.223-231) (134-241)] -6-mer-seryl-tetraglycyl-seryl linker (242-247) -scFv-VH-V-lambda anti-CD3E (248-496) [VH (*Mus musculus*IGHV10-1*02 (91.9%) -(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87.0%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (273-280.298-307.346-361) (248-372)-15-mer-tris(tetraglycyl-seryl) linker (373-387) – V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (413-421.439-441.478-486) (388-496)] -4-mer-tetraglycyl linker (497-500) - scFc (h-CH2-CH3)-(h-CH2-CH3) (501-982) [*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (hinge 6-15 (501-510), CH2 R83>C (572), N84.4>G (577), V85>C (582) (511-620), CH3 E12 (636), M14 (638) (621-725), CHS>del) (501-725) -30-mer-hexakis(tetraglycyl-seryl) linker (726-755) -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (hinge 6-15 (756-765), CH2 R83>C (827), N84.4>G (832), V85>C (837) (766-875), CH3 E12 (891), M14 (893) (876-980), CHS (981-982)) (756-982)]], non-glycosylated, produced in Chinese hamster ovary (CHO) cells
tarlatamab	immunoglobuline scFv-scFv-scFc, anti-[*Homo sapiens* DLL3 (delta-like ligand 3)] et anti-[*Homo sapiens* CD3E (CD3 epsilon, Leu-4)], anticorps monoclonal à chaîne unique (scFv)2-scFc, bispécifique; IG à chaîne unique scFv-scFv-scFc, anti-DLL3 et anti-CD3E (1-982) [scFv-VH-V-kappa anti-DLL3 (1-241) [VH (*Homo sapiens* IGHV4-59*01 G49>C (44) (96.9%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.7.12] (26-33.51-57.96-107) (1-118) -15-mer-tris(tétraglycyl-séryl) linker (119-133)-V-KAPPA (*Homo sapiens* IGKV3-20*01 (91.7%) -IGKJ2*01 Q120>C (234) (90.9%)) CDR-IMGT [7.3.9] (160-166.184-186.223-231) (134-241)] -6-mer-séryl-tétraglycyl-séryl linker (242-247) -scFv-VH-V-lambda anti-CD3E (248-496) [VH (*Mus musculus*IGHV10-1*02 (91.9%) -(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (273-280.298-307.346-361) (248-372) -15-mer-tris(tétraglycyl-séryl) linker (373-387) – V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (413-421.439-441.478-486) (388-496)] -4-mer-tétraglycyl linker (497-500) - scFc (h-CH2-CH3)-(h-CH2-CH3) (501-982) [*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (charnière 6-15 (501-510), CH2 R83>C (572), N84.4>G (577), V85>C (582) (511-620), CH3 E12 (636), M14 (638) (621-725), CHS>del) (501-725) -30-mer-hexakis(tétraglycyl-séryl) linker (726-755) -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (charnière 6-15 (756-765), CH2 R83>C (827), N84.4>G (832), V85>C (837) (766-875), CH3 E12 (891), M14 (893) (876-980), CHS (981-982)) (756-982)]], non-glycosylé, produit dans des cellules ovariennes de hamster chinois (CHO)

tarlatamab

inmunoglobulina scFv-scFv-scFc, anti-[*Homo sapiens* DLL3 (delta-like ligando 3)] y anti-[*Homo sapiens* CD3E (CD3 épsilon, Leu-4)], anticuerpo monoclonal con cadena única (scFv)2-scFc, biespecífica;
IG con cadena única scFv-scFv-scFc, anti-DLL3 y anti-CD3E (1-982) [scFv-VH-V-kappa anti-DLL3 (1-241) [VH (*Homo sapiens* IGHV4-59*01 G49>C (44) (96.9%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.7.12] (26-33.51-57.96-107) (1-118) -15-mer-tris(tetraglicil-seril) linker (119-133)-V-KAPPA (*Homo sapiens* IGKV3-20*01 (91.7%) -IGKJ2*01 Q120>C (234) (90.9%)) CDR-IMGT [7.3.9] (160-166.184-186.223-231) (134-241)] -6-mer-seril-tetraglicil-seril linker (242-247) - scFv-VH-V-lambda anti-CD3E (248-496) [VH (*Mus musculus* IGHV10-1*02 (91.9%) -(IGHD) -IGHJ3*01 (86.7%)/*Homo sapiens* IGHV3-73*01 (87%) -(IGHD) -IGHJ5*01 (100%)) CDR-IMGT [8.10.16] (273-280.298-307.346-361) (248-372) -15-mer-tris(tetraglicil-seril) linker (373-387) -V-LAMBDA (*Homo sapiens* IGLV7-43*01 (85.1%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.9] (413-421.439-441.478-486) (388-496)] -4-mer-tetraglicil linker (497-500) - scFc (h-CH2-CH3)-(h-CH2-CH3) (501-982) [*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (bisagra 6-15 (501-510), CH2 R83>C (572), N84.4>G (577), V85>C (582) (511-620), CH3 E12 (636), M14 (638) (621-725), CHS>del) (501-725) - 30-mer-hexakis(tetraglicil-seril) linker (726-755) -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (bisagra 6-15 (756-765), CH2 R83>C (827), N84.4>G (832), V85>C (837) (766-875), CH3 E12 (891), M14 (893) (876-980), CHS (981-982)) (756-982)]], no glicosilado, producido en las células ováricas de hámster chino (CHO)

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLQESGPG LVKPSETLSL TCTVSGGSIS SYYWSWIRQP PGKCLEWIGY  50
VYYSGTTNYN PSLKSRVTIS VDTSKNQFSL KLSSVTAADT AVYYCASIAV 100
TGFYFDYWGQ GTLVTVSSGG GGSGGGGSGG GGSEIVLTQS PGTLSLSPGE 150
RVTLSCRASQ RVNNNYLAWY QQRPGQAPRL LIYGASSRAT GIPDRFSGSG 200
SGTDFTLTIS RLEPEDFAVY YCQQYDRSPL TFGCGTKLEI KSGGGGSEVQ 250
LVESGGGLVQ PGGSLKLSCA ASGFTFNKYA MNWVRQAPGK GLEWVARIRS 300
KYNNYATYYA DSVKDRFTIS RDDSKNTAYL QMNNLKTEDT AVYYCVRHGN 350
FGNSYISYWA YWGQGTLVTV SSGGGGSGGG GSGGGGSQTV VTQEPSLTVS 400
PGGTVTLTCG SSTGAVTSGN YPNWVQQKPG QAPRGLIGGT KFLAPGTPAR 450
FSGSLLGGKA ALTLSGVQPE DEAEYYCVLW YSNRWVFGGG TKLTVLGGGG 500
DKTHTCPPCP APELLGGPSV FLFPPKPKDT LMISRTPEVT CVVVDVSHED 550
PEVKFNWYVD GVEVHNAKTK PCEEQYGSTY RCVSVLTVLH QDWLNGKEYK 600
CKVSNKALPA PIEKTISKAK GQPREPQVYT LPPSREEMTK NQVSLTCLVK 650
GFYPSDIAVE WESNGQPENN YKTTPPVLDS DGSFFLYSKL TVDKSRWQQG 700
NVFSCSVMHE ALHNHYTQKS LSLSPGGGGS GGGGSGGGGS GGGGSGGGGS 750
GGGGSDKTHT CPPCPAPELL GGPSVFLFPP KPKDTLMISR TPEVTCVVVD 800
VSHEDPEVKF NWYVDGVEVH NAKTKPCEEQ YGSTYRCVSV LTVLHQDWLN 850
GKEYKCKVSN KALPAPIEKT ISKAKGQPRE PQVYTLPPSR EEMTKNQVSL 900
TCLVKGFYPS DIAVEWESNG QPENNYKTTP PVLDSDGSFF LYSKLTVDKS 950
RWQQGNVFSC SVMHEALHNH YTQKSLSLSP GK                    982
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-V (C23 C104) 22-95 156-222 269-345 409-477
Intra-C (C23-C104) 541-601 647-705 796-856 902-960
Intra-CH2 (C83-C85) 572-582 827-837
Inter-VH-VL (C49-C120) 44-234
Inter-h11 (h 11 - h 11) 506-761
Inter-h14 (h 14 - h 14) 509-764

No N-glycosylation sites / pas de sites de N-glycosylation / ningún posición de N-glicosilación
CH2 N84.4>G:
577, 832
Aglycosylated

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
CHS K2:
982

telpegfilgrastimum #

telpegfilgrastim — human granulocyte colony-stimulating factor (G-CSF, pluripoietin) short isoform, variant (A^1>M), produced in *Escherichia coli*, pegylated with one *N*-{[α-methylpoly(oxyethylene)-ω-oxy]acetyl}-*N*-[α-methylpoly(oxyethylene)-ω-yl]glycyl group at N^2 of M^1 (85-95%) or at N^6 of K^{17} (3-13%) or at N^6 of K^{24}, K^{35} and K^{41} (total not more than 5%);
[1-L-methionine]human granulocyte colony-stimulating factor (G-CSF, pluripoietin) short isoform, produced in *Escherichia coli,* substituted with one *N*-{[α-methylpoly(oxyeth-ylene)-ω-oxy]acetyl}-*N*-[α-methylpoly(oxyethylene)-ω-yl]glycyl group at N^2 of Met^1 (85-95%) or at N^6 of Lys^{17} (3-13 %) or one other lysine residue (total not more than 5%)

telpegfilgrastim — isoforme courte du facteur de stimulation des colonies de granulocytes humain (G-CSF, pluripoiétine), variant (A^1>M), produite dans *Escherichia coli,* pégylé avec un groupe *N*-{[α-méthylpoly(oxyéthylène)-ω-oxy]acétyl}-*N*-[α-méthylpoly(oxyéthylène)-ω-yl]glycyle en N^2 de M^1 (85-95%) ou en
N^6 de K^{17} (3-13%) ou en N^6 de K^{24}, K^{35} et K^{41} (pas plus de 5% au total);
[1-L-méthionine]isoforme courte du facteur de stimulation des colonies de granulocytes humain (G-CSF, pluripoiétine), produite dans *Escherichia coli,* substituée par un groupe *N*-{[α-méthylpoly(oxyéthylène-ω-oxy]acétyl}-*N*-[α-méthylpoly(oxyéthylène)-ω-yl]glycyle en N^2 du $Mét^1$ (85-95 %) ou en N^6 du Lys^{17} (3-13 %) ou d'un autre résidu de lysine (pas plus de 5 % au total)

telpegfilgrastim — factor humano de estimulación de colonias de granulocitos (G-CSF, pluripoyetina) isoforma corta, variante (A^1>M), producido en *Escherichia coli*, pegilado con un grupo *N*-{[α-metilpoli(oxietileno)-ω-oxi]acetil}-*N*-[α-metilpoli(oxietileno)-ω-il]glicilo en N^2 de M^1 (85-95%) o en N^6 de K^{17} (3-13%) o en N^6 de K^{24}, K^{35} y K^{41} (total no más del 5%);
[1-L-metionina]isoforma corta del factor humano de estimulación de colonias de granulocitos (G-CSF, pluripoyetina), producida en *Escherichia coli*, sustituido con un grupo *N*-{[α-metilpoli(oxietileno)-ω-oxi]acetil}-*N*-[α-metilpoli(oxietileno)-ω-il]glicilo en N^2 de la Met^1 (85-95 %) o en N^6 de la Lis^{17} (3-13 %) o un otro residuo de lisina (total no más del 5 %)

$C_{853}H_{1352}N_{224}O_{247}S_9[(C_2H_4O)_{2n}]$ (n ≈ 400-500)

Sequence / Séquence / Secuencia

```
MTPLGPASSL PQSFLLKCLE QVRKIQGDGA ALQEKLCATY KLCHPEELVL   50
LGHSLGIPWA PLSSCPSQAL QLAGCLSQLH SGLFLYQGLL QALEGISPEL  100
GPTLDTLQLD VADFATTIWQ QMEELGMAPA LQPTQGAMPA FASAFQRRAG  150
GVLVASHLQS FLEVSYRVLR HLAQP                             175
```

Mutation / Mutation / Mutación

A^1>**M**

Post-translational modifications

Disulfide bridge location / Position du pont disulfure / Posición del puente disulfuro

37-43, 65-75

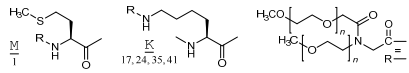
Glycosylation sites / Sites de glycosylation / Posiciones de glicosilación

none / aucune / ninguna

Chemical modification sites / Sites de modification chimique / Posiciones de modificación química

major / principal / mayormente : **M**1, **K**17;

minor / secondaire / inferior : **K**24, **K**35, **K**41



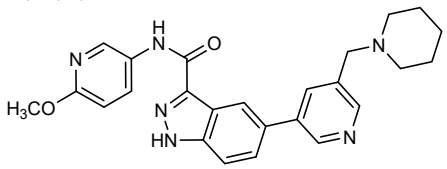
tenvumestrocelum

tenvumestrocel	Allogeneic human mesenchymal stromal cells derived from umbilical cord blood (hUCB-MSCs). The cells are isolated by density-gradient centrifugation and expanded by sub-culturing of the adherent cell population. Cells (on average > 95%) express mesenchymal stromal cell related antigens (CD105 and CD73). The cells are also positive for the CD29 antigen (integrin beta-1), the CD44 antigen (cell adhesion glycoprotein), the CD13 and CD90 antigens, and the HLA-ABC histocompatibility antigen. Cells do not express (on average < 1%) hematopoietic antigens (CD45, CD34 and CD14), histocompatibility antigen (HLA-DR), endothelial cell antigen (CD31), osteoclast antigen (CD51/61), and CD64.
tenvumestrocel	Cellules stromales mésenchymateuses humaines allogéniques dérivées du sang de cordon ombilical (hUCB-MSCs). Les cellules sont isolées par centrifugation à gradient de densité et amplifiées par sous-culture de la population des cellules adhérentes. Les cellules (en moyenne > 95%) expriment des antigènes liés aux cellules stromales mésenchymateuses (CD105 et CD73). Les cellules sont également positives pour l'antigène CD29 (intégrine beta-1), l'antigène CD44 (glycoprotéine d'adhésion cellulaire), les antigènes CD13 et CD90, et l'antigène d'histocompatibilité HLA-ABC. Les cellules n'expriment pas (en moyenne < 1%) les antigènes hématopoïétiques (CD45, CD34 et CD14), l'antigène d'histocompatibilité (HLA-DR), l'antigène des cellules endothéliales (CD31), l'antigène des ostéoclastes (CD51/61), ni l'antigène CD64.
tenvumestrocel	Células estromales mesenquimales humanas alogénicas derivadas de sangre de cordón umbilical (hUCB-MSCs). Las células se aíslan por centrifugación en un gradiente de densidad y se expanden mediante subcultivo de las poblaciones adherentes. Las células (de media >95%) expresan los antígenos relacionados con las células estromales mesenquimales (CD105 y CD73). Las células son también positivas para los antígenos CD29 (integrina beta-1), CD44 (receptor de matriz extracelular), CD13 y CD90, y para el antígeno de histocompatibilidad HLA-ABC. Las células no expresan (de media <1%) antígenos hematopoyéticos (CD45, CD34 y CD14), antígeno de histocomaptiblidad (HLA-DR), antígeno de células endoteliales (CD31), antígeno de osteoclastos (CD51/61), ni CD64.

teplinovivintum

teplinovivint	*N*-(6-methoxypyridin-3-yl)-5-{5-[(piperidin-1-yl)methyl]pyridin-3-yl}-1*H*-indazole-3-carboxamide
téplinovivint	*N*-(6-méthoxypyridin-3-yl)-5-{5-[(pipéridin-1-yl)méthyl]pyridin-3-yl}-1*H*-indazole-3-carboxamide
teplinovivint	*N*-(6-metoxipiridin-3-il)-5-{5-[(piperidin-1-il)metil]piridin-3-il}-1*H*-indazol-3-carboxamida

$C_{25}H_{26}N_6O_2$



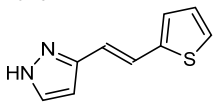
terevalefimum

terevalefim — 3-[(1*E*)-2-(thiophen-2-yl)ethen-1-yl]-1*H*-pyrazole

térévaléfim — 3-[(1*E*)-2-(thiophén-2-yl)éthén-1-yl]-1*H*-pyrazole

terevalefim — 3-[(1*E*)-2-(tiofen-2-il)eten-1-il]-1*H*-pirazol

$C_9H_8N_2S$



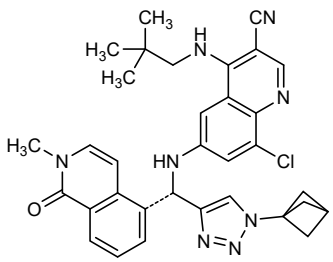
tilpisertibum

tilpisertib — 6-{[(*S*)-[1-(bicyclo[1.1.1]pentan-1-yl)-1*H*-1,2,3-triazol-4-yl](2-methyl-1-oxo-1,2-dihydroisoquinolin-5-yl)methyl]amino}-8-chloro-4-[(2,2-dimethylpropyl)amino]quinoline-3-carbonitrile

tilpisertib — 6-{[(*S*)-[1-(bicyclo[1.1.1]pentan-1-yl)-1*H*-1,2,3-triazol-4-yl](2-méthyl-1-oxo-1,2-dihydroisoquinoléin-5-yl)méthyl]amino}-8-chloro-4-[(2,2-diméthylpropyl)amino]quinoléine-3-carbonitrile

tilpisertib — 6-{[(*S*)-[1-(biciclo[1.1.1]pentan-1-il)-1*H*-1,2,3-triazol-4-il](2-metil-1-oxo-1,2-dihidroisoquinolein-5-il)metil]amino}-8-cloro-4-[(2,2-dimetilpropil)amino]quinoleína-3-carbonitrilo

$C_{33}H_{33}ClN_8O$



tusamitamabum #

tusamitamab — immunoglobulin G1-kappa, anti-[*Homo sapiens* CEACAM5 (carcinoembryonic antigen-related cell adhesion molecule 5, CEA, CD66e)], monoclonal antibody;

	gamma1 heavy chain (1-449) [VH (*Mus musculus* IGHV5-12-1*01 (86.6%) -(IGHD) -IGHJ3*01 (92.9%)/*Homo sapiens* IGHV3-23*01 (77.3%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (217) (121-218), hinge 1-15 (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS K>del (449) (121-449)], (223-214')-disulfide with kappa light chain (1'-214') [V-KAPPA (*Mus musculus* IGKV12-44*01 (87.4%) -IGKJ4*01 (100%)/*Homo sapiens* IGKV1-39*01 (82.1%) -IGKJ2*02 (90.9%)) CDR-IMGT [6.3.9](27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (229-229'':232-232'')-bisdisulfide, produced in Chinese hamster ovary (CHO)-derived cell line, glycoform alfa
tusamitamab	immunoglobuline G1-kappa, anti-[*Homo sapiens* CEACAM5 (molécule d'adhésion cellulaire 5 apparentée à l'antigène carcinoembryonaire, CEA, CD66e)], anticorps monoclonal; chaîne lourde gamma1 (1-449) [VH (*Mus musculus* IGHV5-12-1*01 (86.6%) -(IGHD) -IGHJ3*01 (92.9%)/*Homo sapiens* IGHV3-23*01 (77.3%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (217) (121-218), charnière 1-15 (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS K>del (449) (121-449)], (223-214')-disulfure avec la chaîne légère kappa (1'-214') [V-KAPPA (*Mus musculus* IGKV12-44*01 (87.4%) -IGKJ4*01 (100%)/*Homo sapiens* IGKV1-39*01 (82.1%) -IGKJ2*02 (90.9%)) CDR-IMGT [6.3.9](27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (229-229'':232-232'')-bisdisulfure, produite dans une lignée cellulaire dérivée des cellules ovariennes de hamster chinois (CHO), glycoforme alfa
tusamitamab	inmunoglobulina G1-kappa, anti-[*Homo sapiens* CEACAM5 (molécula de adhesión celular 5 relacionada con el antígeno carcinoembrionario, CEA, CD66e)], anticuerpo monoclonal; cadena pesada gamma1 (1-449) [VH (*Mus musculus* IGHV5-12-1*01 (86.6%) -(IGHD) -IGHJ3*01 (92.9%)/*Homo sapiens* IGHV3-23*01 (77.3%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (217) (121-218), bisagra1-15 (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS K>del (449) (121-449)], (223-214')-disulfuro con la cadena ligera kappa (1'-214') [V-KAPPA (*Mus musculus* IGKV12-44*01 (87.4%) -IGKJ4*01 (100%)/*Homo sapiens* IGKV1-39*01 (82.1%) -IGKJ2*02 (90.9%)) CDR-IMGT [6.3.9](27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (229-229'':232-232'')-bisdisulfuro, producido en una línea celular derivada de las células ováricas de hámster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLQESGPG LVKPGGSLSL SCAASGFVFS SYDMSWVRQT PERGLEWVAY  50
ISSGGGITYA PSTVKGRFTV SRDNAKNTLY LQMNSLTSED TAVYYCAAHY 100
FGSSGPFAYW GQGTLVTVSS ASTKGPSVFP LAPSSKSTSG GTAALGCLVK 150
DYFPEPVTVS WNSGALTSGV HTFPAVLQSS GLYSLSSVVT VPSSSLGTQT 200
YICNVNHKPS NTKVDKKVEP KSCDKTHTCP PCPAPELLGG PSVFLFPPKP 250
KDTLMISRTP EVTCVVVDVS HEDPEVKFNW YVDGVEVHNA KTKPREEQYN 300
STYRVVSVLT VLHQDWLNGK EYKCKVSNKA LPAPIEKTIS KAKGQPREPQ 350
VYTLPPSRDE LTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPV 400
LDSDGSFFLY SKLTVDKSRW QQGNVFSCSV MHEALHNHYT QKSLSLSPG  449
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Light chain / Chaîne légère / Cadena ligera

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DIQMTQSPAS LSASVGDRVT ITCRASENIF SYLAWYQQKP GKSPKLLVYN  50
TRTLAEGVPS RFSGSGSGTD FSLTISSLQP EDFATYYCQH HYGTPPTFGS 100
GTKLEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                         214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 147-203 264-324 370-428
22"-96" 147"-203" 264"-324" 370"-428"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (h 5-CL 126) 223-214' 223"-214'"
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.

tusamitamabum ravtansinum

tusamitamab ravtansine — immunoglobulin G1-kappa, anti-[*Homo sapiens* CEACAM5 (carcinoembryonic antigen-related cell adhesion molecule 5, CEA, CD66e)], monoclonal antibody, conjugated to maytansinoid DM4; gamma1 heavy chain (1-449) [VH (*Mus musculus* IGHV5-12-1*01 (86.6%) -(IGHD) -IGHJ3*01 (92.9%)/*Homo sapiens* IGHV3-23*01 (77.3%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 (100%), G1m17,1 (CH1 K120 (217) (121-218), hinge 1-15 (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS K>del (449) (121-449)], (223-214')-disulfide with kappa light chain (1'-214') [V-KAPPA (*Mus musculus* IGKV12-44*01 (87.4%) -IGKJ4*01 (100%)/*Homo sapiens* IGKV1-39*01 (82.1%) -IGKJ2*02 (90.9%)) CDR-IMGT [6.3.9](27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')];
dimer (229-229":232-232")-bisdisulfide, produced in a Chinese hamster ovary (CHO) cell line derived from CHO-K1SV, glycoform alfa; conjugated, on an average of 3 to 4 lysyl, to maytansinoid DM4 [*N2*'- deacetyl-*N2*'-(4-mercapto-4-methyl-1-oxopentyl)- maytansine] via the reducible SPDB linker [*N*-succinimidyl 4-(2-pyridyldithio)butanoate]
For the *ravtansine* part, please refer to the document "*INN for pharmaceutical substances: Names for radicals, groups and others*"*

tusamitamab ravtansine — immunoglobuline G1-kappa, anti-[*Homo sapiens* CEACAM5 (molécule d'adhésion cellulaire 5 apparentée à l'antigène carcinoembryonaire, CEA, CD66e)], anticorps monoclonal, conjugué au maytansinoïde DM4;
chaîne lourde gamma1 (1-449) [VH (*Mus musculus* IGHV5-12-1*01 (86.6%) -(IGHD) -IGHJ3*01 (92.9%)/*Homo sapiens* IGHV3-23*01 (77.3%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 (100%), G1m17,1 (CH1 K120 (217) (121-218), charnière 1-15 (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS K>del (449) (121-449)], (223-214')-disulfure avec la chaîne légère kappa (1'-214') [V-KAPPA (*Mus musculus* IGKV12-44*01 (87.4%) -IGKJ4*01 (100%)/*Homo sapiens* IGKV1-39*01 (82.1%) -IGKJ2*02 (90.9%)) CDR-IMGT [6.3.9](27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')];

tusamitamab ravtansina

inmunoglobulina G1-kappa, anti-[*Homo sapiens* CEACAM5 (molécula de adhesión celular 5 con el antígeno carcinoembrionario, CEA, CD66e)], anticuerpo monoclonal, conjugado con maitansinoide DM4;
cadena pesada gamma1 (1-449) [VH (*Mus musculus* IGHV5-12-1*01 (86.6%) -(IGHD) -IGHJ3*01 (92.9%)/*Homo sapiens* IGHV3-23*01 (77.3%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 (100%), G1m17,1 (CH1 K120 (217) (121-218), bisagra 1-15 (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS K>del (449) (121-449)], (223-214')-disulfuro con la cadena ligera kappa (1'-214') [V-KAPPA (*Mus musculus* IGKV12-44*01 (87.4%) -IGKJ4*01 (100%)/*Homo sapiens* IGKV1-39*01 (82.1%) -IGKJ2*02 (90.9%)) CDR-IMGT [6.3.9](27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')];
dímero (229-229'':232-232'')-bisdisulfuro, producido en las células ováricas de hámsters chinos (CHO) línea celular derivada de CHO-K1SV, forma glicosilada alfa; conjugado, en 3 a 4 residuos lisil por término medio, con maitansinoide DM4 [*N*2'-deacetil-*N*2'-(4-mercapto-4-metil-1-oxopentil)- maitansina]mediante un conector SPDB reducible [4-(2- piridilditio)butanoato de *N*-succinimidilo]
Para la fracción ravtansina, se ruega referirse al documento "*INN for pharmaceutical substances: Names for radicals, groups and others*"*

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLQESGPG LVKPGGSLSL SCAASGFVFS SYDMSWVRQT PERGLEWVAY  50
ISSGGGITYA PSTVKGRFTV SRDNAKNTLY LQMNSLTSED TAVYYCAAHY 100
FGSSGPFAYW GQGTLVTVSS ASTKGPSVFP LAPSSKSTSG GTAALGCLVK 150
DYFPEPVTVS WNSGALTSGV HTFPAVLQSS GLYSLSSVVT VPSSSLGTQT 200
YICNVNHKPS NTKVDKKVEP KSCDKTHTCP PCPAPELLGG PSVFLFPPKP 250
KDTLMISRTP EVTCVVVDVS HEDPEVKFNW YVDGVEVHNA KTKPREEQYN 300
STYRVVSVLT VLHQDWLNGK EYKCKVSNKA LPAPIEKTIS KAKGQPREPQ 350
VYTLPPSRDE LTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPV 400
LDSDGSFFLY SKLTVDKSRW QQGNVFSCSV MHEALHNHYT QKSLSLSPG  449
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Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPAS LSASVGDRVT ITCRASENIF SYLAWYQQKP GKSPKLLVYN  50
TRTLAEGVPS RFSGSGSGTD FSLTISSLQP EDFATYYCQH HYGTPFTFGS 100
GTKLEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 147-203 264-324 370-428
22"-96" 147"-203" 264"-324" 370"-428"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (h 5-CL 126) 223-214' 223"-214'"
Inter-H-H (h 11, h14) 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.

For the ravtansine part, please refer to the document "INN for pharmaceutical substances: Names for radicals, groups and others"*
Pour la partie ravtansine, veuillez-vous référer au document "INN for pharmaceutical substances: Names for radicals, groups and others"*
Para la fracción ravtansina, se ruega referirse al documento "INN for pharmaceutical substances: Names for radicals, groups and others"*

upifitamabum rilsodotinum

upifitamab rilsodotin

immunoglobulin G1-kappa, anti-[*Homo sapiens* SLC34A2 (solute carrier family 34 sodium phosphate member 2, sodium/phosphate cotransporter 2B, NaPi2b, NaPi3b, NAPI-3B)], monoclonal antibody, conjugated, via a thioether bond, to3 to 5 flexible polymers PHF-BA-EG2-MI-AF-HPA-Ala, each comprising maleimide (MI) bioconjugation linkers and
3 to 4 auristatin F- hydroxypropylamide-L-alanine (AF-HPA-Ala), with a drug ratio of 12:1 to 15:1;

	gamma1 heavy chain (1-449) [VH (*Homo sapiens* IGHV1-46*01 (81.6%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.12] (26-33.51-58.97-108) (1-119) -glycinyl (120) -*Homo sapiens* IGHG1*03 (100%), 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* IGKV1-33*01 (83.2%) -IGKJ2*01 (90.9%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (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; conjugated, via a thioether bond, from 3 to 5 flexible biodegradable polymers, poly(1-hydroxymethylethylene hydroxymethyl-formal) (PHF)-BA-EG2-MI-AF-HPA-Ala, each comprising maleimide (MI) conjugation linkers and 3 to 4 cytotoxic auristatin F- hydroxypropylamide-L-alanine (AF-HPA-Ala), with a drug ratio of 12:1 to 15:1
upifitamab rilsodotine	immunoglobuline G1-kappa, anti-[*Homo sapiens* SLC34A2 (membre 2 de la famille 34 sodium phosphate de transporteurs de solutés, cotransporteur 2B de sodium/phosphate, NaPi2b, NaPi3b, NAPI-3B)], anticorps monoclonal, conjugué, via une liaison thiéther, à 3 à 5 polymères flexibles PHF-BA-EG2-MI-AF-HPA-Ala, comprenant chacun des linkers de bioconjugaison maléimide (MI) et 3 à 4 auristatine F- hydroxypropylamide-alanine (AF-HPA-Ala), dans un rapport produit actif de 12:1 à 15:1; chaîne lourde gamma1 (1-449) [VH (*Homo sapiens* IGHV1-46*01 (81.6%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.12] (26-33.51-58.97-108) (1-119) -glycinyl (120) -*Homo sapiens* IGHG1*03 (100%), 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* IGKV1-33*01 (83.2%) -IGKJ2*01 (90.9%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (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; conjugué, via une liaison thiéther, de 3 à 5 polymères flexibles biodégradables poly(1-hydroxyméthyléthylène hydroxyméthyl-formal) (PHF)-BA-EG2-MI-AF-HPA-Ala, comprenant chacun des linkers de conjugaison maléimide (MI) et 3 à 4 auristatine F- hydroxypropylamide-L-alanine (AF-HPA-Ala) cytotoxiques, dans un rapport produit actif de 12:1 à 15:1
upifitamab rilsodotina	inmunoglobulina G1-kappa, anti-[*Homo sapiens* SLC34A2 (miembro 2 de la familia 34 sodio fosfato de transportadores de solutos, cotransportador 2B de sodio/fosfato, NaPi2b, NaPi3b, NAPI-3B)], anticuerpo monoclonal, conjugado, a través de un enlace tioéter, de 3 a 5 polímeros flexibles PHF-BA-EG2-MI-AF-HPA-Ala, que comprende cada uno de los enlaces de bioconjugación maleimida (MI) y 3 a 4 auristatina F- hidroxipropilamida-L-alanina (AF-HPA-Ala), en una relación de principio activo de 12:1 a 15:1;

cadena pesada gamma1 (1-449) [VH (*Homo sapiens* IGHV1-46*01 (81.6%) -(IGHD) -IGHJ4*01 (92.9%)) CDR-IMGT [8.8.12] (26-33.51-58.97-108) (1-119) -glicinil (120) -*Homo sapiens* IGHG1*03 (100%), 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* IGKV1-33*01 (83.2%) -IGKJ2*01 (90.9%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -arginil (108') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (154), V101 (192) (109'-215')];
dímero (229-229":232-232")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa; conjugado, a través de un enlace tioéter, a 3 a 5 polímeros flexibles biodegradables poli(1-hidroximetiletileno hidroximetil-formal) (PHF)-BA-EG2-MI-AF-HPA-Ala, que comprende cada unos de los enlaces de conjugación maleimida (MI) y
3 a 4 auristatina F- hidroxipropilamida-L-alanina (AF-HPA-Ala) citotóxicos, en una relación de principio activo de 12:1 a 15:1

Heavy chain / Chaîne lourde / Cadena pesada

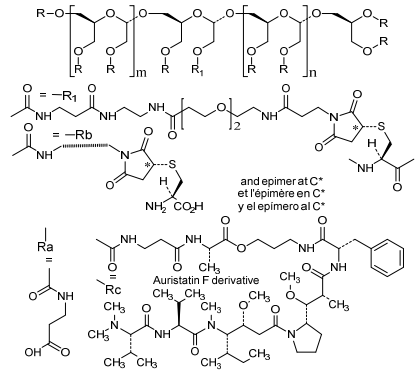
```
QVQLVQSGAE VVKPGASVKM SCKASGYTFT GYNIHWVKQA PGQGLEWIGA  50
IYPGNGDTSY KQKFRGRATL TADTSTSTVY MELSSLRSED SAVYYCARGE 100
TARATFAYWG QGTLVTVSSG ASTKGPSVFP LAPSSKSTSG GTAALGCLVK 150
DYFPEPVTVS WNSGALTSGV HTFPAVLQSS GLYSLSSVVT VPSSSLGTQT 200
YICNVNHKPS NTKVDKRVEP KSCDKTHTCP PCPAPELLGG PSVFLFPPKP 250
KDTLMISRTP 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"
*Two or three of the inter-chain disulfide bridges are not present, 3 to 5 cysteinyl being conjugated each via a thioether bond to one maleimide linker of one flexible polymer comprising 3 to 4 drug units.
*Deux ou trois des ponts disulfures inter-chaînes ne sont pas présents, 3 to 5 cystéinyl étant chacun conjugué via une liaison thioéther à un linker-maléimide d'un polymère flexible comprenant 3 à 4 unités de principe actif.
*Faltan dos o tres puentes disulfuro inter-catenarios, 3 a 5 cisteinil está conjugada a conectores de un polimero flexible que contiene 3 a 4 unidades de principio activo.

Modified residues / résidus modifiés / restos modificados:



m + n ~ 35-75 ; R = H , Ra , Rb or Rc ; ratio H : Ra : Rb : Rc ~ 70 : 20 : 2 : 8

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

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.

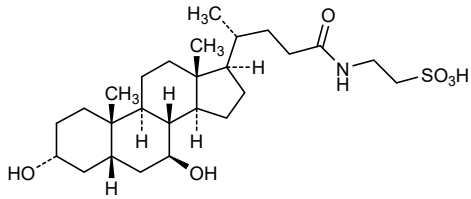
ursodoxicoltaurinum

ursodoxicoltaurine — 2-(3α,7β-dihydroxy-5β-cholan-24-amido)ethane-1-sulfonic acid

ursodoxicoltaurine — acide 2-(3α,7β-dihydroxy-5β-cholan-24-amido)éthane-1-sulfonique

ursodoxicoltaurina — ácido 2-(3α,7β-dihidroxi-5β-colan-24-amido)etano-1-sulfónico

$C_{26}H_{45}NO_6S$



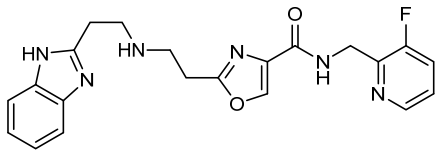
vamifeportum

vamifeport — 2-(2-{[2-(1*H*-benzimidazol-2-yl)ethyl]amino}ethyl)-*N*-[(3-fluoropyridin-2-yl)methyl]-1,3-oxazole-4-carboxamide

vamiféport — 2-(2-{[2-(1*H*-benzimidazol-2-yl)éthyl]amino}éthyl)-*N*-[(3-fluoropyridin-2-yl)méthyl]-1,3-oxazole-4-carboxamide

vamifeport — 2-(2-{[2-(1*H*-benzimidazol-2-il)etil]amino}etil)-*N*-[(3-fluoropiridin-2-il)metil]-1,3-oxazol-4-carboxamida

$C_{21}H_{21}FN_6O_2$



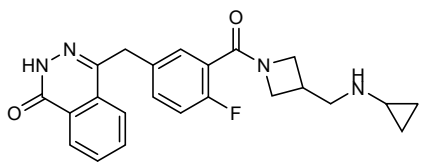
venadaparibum

venadaparib — 3^4-fluoro-7-aza-1(1)-phthalazina-5(1,3)-azetidina-3(1,3)-benzena-8(1)-cyclopropanaoctaphane-1^4(1^3*H*),4-dione

vénadaparib — 3^4-fluoro-7-aza-1(1)-phthalazina-5(1,3)-azétidina-3(1,3)-benzèna-8(1)-cyclopropanaoctaphane-1^4(1^3*H*),4-dione

venadaparib — 3^4-fluoro-7-aza-1(1)-ftalazina-5(1,3)-azetidina-3(1,3)-bencena-8(1)-ciclopropanaoctafano-1^4(1^3*H*),4-diona

$C_{23}H_{23}FN_4O_2$



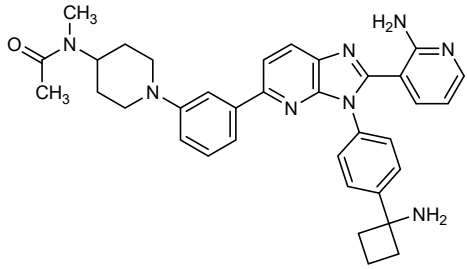
vevorisertibum

vevorisertib — *N*-[1-(3-{3-[4-(1-aminocyclobutyl)phenyl]-2-(2-aminopyridin-3-yl)-3*H*-imidazo[4,5-*b*]pyridin-5-yl}phenyl)piperidin-4-yl]-*N*-methylacetamide

vévorisertib — *N*-[1-(3-{3-[4-(1-aminocyclobutyl)phényl]-2-(2-aminopyridin-3-yl)-3*H*-imidazo[4,5-*b*]pyridin-5-yl}phényl)pipéridin-4-yl]-*N*-méthylacétamide

vevorisertib — *N*-[1-(3-{3-[4-(1-aminociclobutil)fenil]-2-(2-aminopiridin-3-il)-3*H*-imidazo[4,5-*b*]piridin-5-il}fenil)piperidin-4-il]-*N*-metilacetamida

$C_{35}H_{38}N_8O$



vibapapogenum autoleucelum #

vibapapogene autoleucel — Autologous peripheral blood mononuclear cells (PBMCs) expressing human papillomavirus types 16 and 18 antigens.
Autologous peripheral blood mononuclear cells (PBMCs), specifically B lymphocytes and monocytes that are T-cell depleted, transfected *ex vivo* with a non-replicating adenoviral vector that expresses a codon-optimised fusion of tumour-associated antigens (TAAs) E6 and E7 derived from human papillomavirus (HPV) types 16 and 18 (HPV-16/18 E6/E7). The antigen coding region is preceded by a tPA signal sequence and transcription is under the control of the cytomegalovirus (CMV)-tetracycline 10 promoter and the SV40 poly(A) termination sequence. The vector genome is flanked by inverted terminal repeats and contains an encapsidation signal and a K35 knob.

vibapapogène autoleucel — Cellules mononucléaires du sang périphérique autologues exprimant les antigènes de papillomavirus humains de type 16 et 18.
Cellules mononucléaires du sang périphérique autologues, spécifiquement les lymphocytes B et les monocytes qui sont déplétées en lymphocytes T, transfectées *ex vivo* avec une forme non réplicative du vecteur adénoviral exprimant un codon optimisé, fusion des antigènes associés à des tumeurs E6 et E7 dérivés du virus humain du papillome (HPV) types 16 et 18 (HPV-16/18 E6/E7). La région codant l'antigène est précédée d'une séquence signal tPA et la transcription est sous le contrôle du promoteur tétracycline 10 du cytomégalovirus et de la séquence de terminaison poly(A) SV40. Le génome du vecteur est flanqué de répétitions inverses et contient un signal d'encapsidation et un domaine globulaire distal (knob) K35.

vibapapogén autoleucel	Células monucleares de sangre periférica (PBMCs) autólogas que expresan antígenos del papilomavirus humano de tipo 16 y 18. Células monucleares de sangre periférica (PBMCs) autólogas, específicamente linfocitos B y monocitos que están deplecionadas de células T, transfectadas *ex vivo* con un vector adenoviral no replicative que expresa una fusion de los antígenos asociados a tumor (TAAs) E6 y E7 derivados del papillomavirus humano (HPV) de tipo 16 y 18 (HPV-16/18 E6/E7), con codones optimizados. La region codificadora de antigen está precedidad por una secuencia señal tPA y la transcripción está bajo el control del promotor de la tetraciclina 10 del cytomegalovirus (CMV) y la secuencia poly(A) de terminación del SV50. El genoma del vector está flanqueado por repeticiones invertidas terminales y contiene una señal de encapsidación y un dominio globular distal (knob) K35.

vibosameranum #

vibosameran	Messenger RNA encoding tyrosinase. Messenger RNA (mRNA), 5'-capped, encoding codon-optimised tyrosinase (monophenol monooxygenase, tumour rejection antigen AB), expressed as a fusion protein comprising tyrosinase, P2P16 tetanus toxoid-derived helper epitopes and a major histocompatibility complex (MHC) class I transmembrane and cytoplasmic domain, connected by two glycine/serine-rich (GS) linker peptides, flanked by 5' and 3' untranslated regions and a 3' poly(A) tail.
vibosaméran	ARN messager codant pour la tyrosinase. ARN messager (ARNm), protégé en 5', codant pour la tyrosinase (monophénol monooxygénase, antigène de rejet de tumeur AB), avec des codons optimisés, exprimé sous la forme d'une protéine de fusion comprenant la tyrosinase, les épitopes auxiliaires P2P16 dérivés de l'anatoxine tétanique et un domaine transmembranaire et cytoplasmique du complexe majeur d'histocompatibilité (CMH) de classe I, reliés par deux peptides de liaison riches en glycine/sérine (GS), flanqués de régions non traduites en 5' et 3' et d'une queue poly(A) en 3'.
vibosamerán	ARN mensajero que codifica para tirosinasa. ARN mensajero (ARNm), protegido en 5' que codifica para tirosinasa (monofenol monooxigenasa, antígeno de rechazo tumoral AB), con codones optimizados, expresada como una proteína de fusión que consta de la tirosinasa, los epítopos auxiliares P2P16 derivados del toxoide tetánico y un dominio citoplásmico y transmembrana del complejo principal de histocompatibilidad (MHC) de clase I, conectados mediante dos péptidos de enlace ricos en glicina/serina (GS), flanqueado por las regiones 5' y 3' no traducidas y una cola poly(A) en 3'.

vidutolimodum

vidutolimod — immunostimulatory CG-rich palindromic oligodeoxyribonucleotide, flanked by 3'-dG_{10} and 5'-dG_{10} decanucleotides:
deca[2'-deoxyguanylyl-(3'→5')]-2'-deoxyguanylyl-(3'→5')-2'-deoxyadenylyl-(3'→5')-2'-deoxycytidylyl-(3'→5')-2'-deoxyguanylyl-(3'→5')-2'-deoxyadenylyl-(3'→5')-thymidylyl-(3'→5')-2'-deoxycytidylyl-(3'→5')-2'-deoxyguanylyl-(3'→5')-thymidylyl-(3'→5')-2'-deoxycytidylyl-(3'→5')-nona[2'-deoxyguanylyl-(3'→5')]-2'-deoxyguanosine

vidutolimod — oligodésoxyribonucléotide palindromique immunostimulateur riche en CG, flanqué de décanucléotides 3'-dG_{10} et 5'-dG_{10}:
déca[2'-désoxyguanylyl-(3'→5')]-2'-désoxyguanylyl-(3'→5')-2'-désoxyadénylyl-(3'→5')-2'-désoxycytidylyl-(3'→5')-2'-désoxyguanylyl-(3'→5')-2'-désoxyadénylyl-(3'→5')-thymidylyl-(3'→5')-2'-désoxycytidylyl-(3'→5')-2'-désoxyguanylyl-(3'→5')-thymidylyl-(3'→5')-2'-désoxycytidylyl-(3'→5')-nona[2'-désoxyguanylyl-(3'→5')]-2'-désoxyguanosine

vidutolimod — oligodesoxirribonucleótido palindrómico inmunoestimulador rico en CG, flanqueado por decanucleótidos 3'-dG_{10} y 5'-dG_{10}:
deca[2'-desoxiguanilil-(3'→5')]-2'-desoxiguanilil-(3'→5')-2'-desoxiadenilil-(3'→5')-2'-desoxicitidilil-(3'→5')-2'-desoxiguanilil-(3'→5')-2'-desoxiadenilil-(3'→5')-timidilil-(3'→5')-2'-desoxicitidilil-(3'→5')-2'-desoxiguanilil-(3'→5')-timidilil-(3'→5')-2'-desoxicitidilil-(3'→5')-nona[2'-desoxiguanilil-(3'→5')]-2'-desoxiguanosina

$C_{297}H_{363}N_{138}O_{178}P_{29}$

Sequence / Séquence / Secuencia

(3'→5') d(GGGGGGGGGG **GACGATCGTC** GGGGGGGGGG)

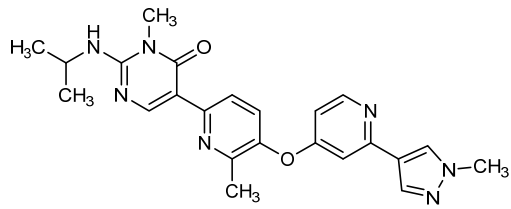
vimseltinibum

vimseltinib — 3-methyl-5-(6-methyl-5-{[2-(1-methyl-1*H*-pyrazol-4-yl)pyridin-4-yl]oxy}pyridin-2-yl)-2-[(propan-2-yl)amino]pyrimidin-4(3*H*)-one

vimseltinib — 3-méthyl-5-(6-méthyl-5-{[2-(1-méthyl-1*H*-pyrazol-4-yl)pyridin-4-yl]oxy}pyridin-2-yl)-2-[(propan-2-yl)amino]pyrimidin-4(3*H*)-one

vimseltinib — 3-metil-5-(6-metil-5-{[2-(1-metil-1*H*-pirazol-4-il)piridin-4-il]oxi}piridin-2-il)-2-[(propan-2-il)amino]pirimidin-4(3*H*)-ona

$C_{23}H_{25}N_7O_2$



vixarelimabum #

vixarelimab	immunoglobulin G4-G1-lambda2, anti-[*Homo sapiens* OSMR (oncostatin M receptor, OSMRB, OSMRbeta)], *Homo sapiens* monoclonal antibody; gamma4-gamma1 heavy chain *Homo sapiens* (1-452) [VH (*Homo sapiens* IGHV1-8*01 (95.9%) -(IGHD) -IGHJ6*01 (95.0%)) CDR-IMGT [8.8.19] (26-33.51-58.97-115) (1-126)-*Homo sapiens* IGHG4*01 CH1-h-CH2, G4v5 h P10, G4v36 CH2 Q84.4 (CH1 (127-224), hinge 1-12 S10>P (234) (225-236), CH2 N84.4>Q (303) (237-346)) -IGHG1*01 CH3-CHS, G1m1 (CH3 D12 (362), L14 (364) (347-451), CHS K>del (452)) (127-452)], (140-215')-disulfide with lambda2 light chain *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV1-44*01 (90.8%) -IGLJ2*01 (100%)) CDR-IMGT [8.3.11] (26-33.51-53.90-100) (1'-110') -*Homo sapiens* IGLC2*01 (100%) (111'-216')]; dimer (232-232":235-235")-bisdisulfide, non-glycosylated, produced in Chinese hamster ovary (CHO)-DG44i cell line
vixarélimab	immunoglobuline G4-G1-lambda2, anti-[*Homo sapiens* OSMR (récepteur de l'oncostatine M, OSMRB, OSMRbeta)], anticorps monoclonal *Homo sapiens*; chaîne lourde gamma4-gamma1 *Homo sapiens*(1-452) [VH (*Homo sapiens* IGHV1-8*01 (95.9%) -(IGHD) -IGHJ6*01 (95.0%)) CDR-IMGT [8.8.19] (26-33.51-58.97-115) (1-126)-*Homo sapiens* IGHG4*01 CH1-h-CH2, G4v5 h P10, G4v36 CH2 Q84.4 (CH1 (127-224), charnière 1-12 S10>P (234) (225-236), CH2 N84.4>Q (303) (237-346)) (127-346) -IGHG1*01 CH3-CHS, G1m1 (CH3 D12 (362), L14 (364) (347-451), CHS K>del (452)) (347-452)], (140-215')-disulfure avec la chaîne légère lambda2 *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV1-44*01 (90.8%) -IGLJ2*01 (100%)) CDR-IMGT [8.3.11] (26-33.51-53.90-100) (1'-110') -*Homo sapiens* IGLC2*01 (100%) (111'-216')]; dimère (232-232":235-235")-bisdisulfure, non-glycosylé, produit dans des cellules ovariennes de hamster chinois (CHO) lignée cellulaire CHO-DG44i
vixarelimab	inmunoglobulina G4-G1-lambda2, anti-[*Homo sapiens* OSMR (receptor de la oncostatina M, OSMRB, OSMRbeta)], anticuerpo monoclonal *Homo sapiens*; cadena pesada gamma4-gamma1 *Homo sapiens*(1-452) [VH (*Homo sapiens* IGHV1-8*01 (95.9%) -(IGHD) -IGHJ6*01 (95.0%)) CDR-IMGT [8.8.19] (26-33.51-58.97-115) (1-126)-*Homo sapiens* IGHG4*01 CH1-h-CH2, G4v5 h P10, G4v36 CH2 Q84.4 (CH1 (127-224), bisagra 1-12 S10>P (234) (225-236), CH2 N84.4>Q (303) (237-346)) (127-346) -IGHG1*01 CH3-CHS, G1m1 (CH3 D12 (362), L14 (364) (347-451), CHS K>del (452)) (347-452)], (140-215')-disulfuro con la cadena ligera lambda2 *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV1-44*01 (90.8%) -IGLJ2*01 (100%)) CDR-IMGT [8.3.11] (26-33.51-53.90-100) (1'-110') -*Homo sapiens* IGLC2*01 (100%) (111'-216')]; dímero (232-232":235-235")-bisdisulfuro, no glicosilado, producido en las células ováricas de hámster chino (CHO) línea celular CHO-DG44i

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGASVKV SCKASGYTFT SYEINWVRQA TGQGLEWMGW  50
MNPNSGYTGY AQKFQGRVTM TRDTSISTAY MEMSSLRSED TAVYYCARDI 100
VAANTDYYFY YGMDVWGQGT TVTVSSASTK GPSVFPLAPC SRSTSESTAA 150
LGCLVKDYFP EPVTVSWNSG ALTSGVHTFP AVLQSSGLYS LSSVVTVPSS 200
SLGTKTYTCN VDHKPSNTKV DKRVESKYGP PCPPCPAPEF LGGPSVFLFP 250
PKPKDTLMIS RTPEVTCVVV DVSQEDPEVQ FNWYVDGVEV HNAKTKPREE 300
QFQSTYRVVS VLTVLHQDWL NGKEYKCKVS NKGLPSSIEK TISKAKGQPR 350
EPQVYTLPPS RDELTKNQVS LTCLVKGFYP SDIAVEWESN GQPENNYKTT 400
PPVLDSDGSF FLYSKLTVDK SRWQQGNVFS CSVMHEALHN HYTQKSLSLS 450
PG                                                      452
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Light chain / Chaîne légère / Cadena ligera

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QSVLTQPPSA SGTPGQRVTI SCSGSNSNIG SNTVNWYHQL PGTAPKLLIY  50
NINKRPSGVP DRFSGSKSGS SASLAISGLQ SEDEADYYCS TWDDSLDGVV 100
FGGGTKLTVL GQPKAAPSVT LFPPSSEELQ ANKATLVCLI SDFYPGAVTV 150
AWKADSSPVK AGVETTTPSK QSNNKYAASS YLSLTPEQWK SHRSYSCQVT 200
HEGSTVEKTV APTECS                                      216
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 153-209 267-327 373-431
22"-96" 153"-209" 267"-327" 373"-431"
Intra-L (C23-C104) 22'-89' 138'-197'
22"'-89"' 138"'-197"'
Inter-H-L (CH1 10-CL 126) 140-215' 140"-215"'
Inter-H-H (h 8, h 11) 232-232" 235-235"

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

No N-glycosylation sites / pas de sites de N-glycosylation / ningùn posición de N-glycosilación
H CH2 N84.4>Q (303)
Aglycosylated

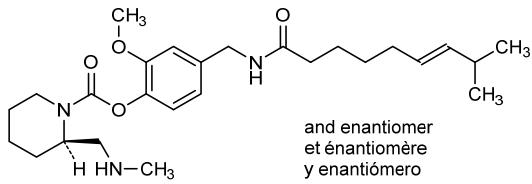
vocacapsaicinum

vocacapsaicin — *rac*-2-methoxy-4-{[(6*E*)-8-methylnon-6-enamido]methyl}phenyl (2*R*)-2-[(methylamino)methyl]piperidine-1-carboxylate

vocacapsaïcine — *rac*-(2*R*)-2-[(méthylamino)méthyl]pipéridine-1-carboxylate de 2-méthoxy-4-{[(6*E*)-8-méthylnon-6-énamido]méthyl}phényle

vocacapsaícina — *rac*-(2*R*)-2-[(metilamino)metil]piperidina-1-carboxilato de 4-{[(6*E*)-8-metilnon-6-enamido]metil}-2-metoxifenilo

$C_{26}H_{41}N_3O_4$



and enantiomer
et énantiomère
y enantiómero

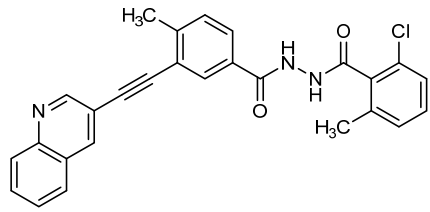
vodobatinibum

vodobatinib — 2-chloro-6-methyl-*N*′-{4-methyl-3-[(quinolin-3-yl)ethynyl]benzoyl}benzohydrazide

vodobatinib — 2-chloro-6-méthyl-*N*′-{4-méthyl-3-[(quinoléin-3-yl)éthynyl]benzoyl}benzohydrazide

vodobatinib — 2-cloro-6-metil-*N*′-{4-metil-3-[(quinolein-3-il)etinil]benzoil}benzohidrazida

$C_{27}H_{20}ClN_3O_2$



vudalimabum #

vudalimab — immunoglobulin half-IG G1-kappa/scFv-h-CH2-CH3, anti-[*Homo sapiens* CTLA4 (cytotoxic T-lymphocyte-associated protein 4, CD152)] and anti-[*Homo sapiens* PDCD1 (programmed cell death 1, PD-1, PD1, CD279)], monoclonal antibody, bispecific;
gamma1 heavy chain anti-CTLA4 (1-447) [VH (*Homo sapiens* IGHV3-48*03 (90.8%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107)(1-118) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 N114>D (209) R120>K (215) (119-216), hinge 1-15 (217-231), CH2 E1.4,L1.3>P (234), L1.2>V (235), G1.1>A (236), S29>K (267), Q84.2>E (295) (232-340), CH3 E12 (356), M14 (358), L24>D (368), K26>S (370), N44>D (384), Q97>E (418), N100>D (421), M107>L (428), N114>S (434) (341-445), CHS (446-447)) (119-447)], (221-215')-disulfide with kappa light chain anti-CTLA4, *Homo sapiens* (1'-215') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (99.0%) -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')];
IG scFv-h-CH2-CH3 single chain, anti-PDCD1 (1''-480'') [scFv V-kappa-VH anti-PDCD1 (1''-249'') [V-KAPPA (*Homo sapiens*IGKV3-15*01 (80.0%)-IGHJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1''-107'') -20-mer tetrakis(glycyl-lysyl-prolyl-glycyl-seryl) linker (108''-127'') -VH (*Mus musculus* IGHV6-6*02 (87.0%) -(IGHD) -IGHJ1*03 (86.7%)/*Homo sapiens* IGHV3-15*07 (81.8%) -(IGHD) -IGHJ2*01 (93.3%)) CDR-IMGT [8.10.13] (153-160.178-187.226-238) (128''-249'')] -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (250''-480'') [hinge 1-15 C5>S (254) (250-264) -CH2 E1.4,L1.3>P (267), L1.2>V (268), G1.1>A (269), S29>K (300) (265-373),CH3 E12 (389), E13>Q (390), M14 (391), S20>K (397), M107>L (461), N114>S (467) (374-478), CHS (479-480)]];
dimer (227-260'':230-263'')-bisdisulfide, produced in Chinese hamster ovary (CHO)-S cell line, glycoform alfa

vudalimab — immunoglobuline demi-IG G1-kappa/scFv-h-CH2-CH3, anti-[*Homo sapiens* CTLA4 (protéine 4 associée aux lymphocytes T cytotoxiques, CD152)] et anti-[*Homo sapiens* PDCD1 (protéine 1 de mort cellulaire programmée, PD-1, PD1, CD279)], anticorps monoclonal, bispécifique;

	chaîne lourde gamma1 anti-CTLA4, (1-447) [VH (*Homo sapiens* IGHV3-48*03 (90.8%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (1-118) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 N114>D (209) R120>K (215) (119-216), charnière 1-15 (217-231), CH2 E1.4,L1.3>P (234), L1.2>V (235), G1.1>A (236), S29>K (267), Q84.2>E (295) (232-340), CH3 E12 (356), M14 (358), L24>D (368), K26>S (370), N44>D (384), Q97>E (418), N100>D (421), M107>L (428), N114>S (434) (341-445), CHS (446-447)) (119-447)], (221-215')-disulfure avec la chaîne légère kappa anti-CTLA4,*Homo sapiens* (1'-215') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (99.0%) -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')]; IG scFv-h-CH2-CH3 chaîne unique, anti-PDCD1 (1''-480'') [scFv V-kappa-VH anti-PDCD1 (1''-249'') [V-KAPPA (*Homo sapiens*IGKV3-15*01 (80.0%)-IGHJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1''-107'') -20-mer tétrakis(glycyl-lysyl-prolyl-glycyl-séryl) linker (108''-127'') -VH (*Mus musculus* IGHV6-6*02 (87.0%) -(IGHD) -IGHJ1*03 (86.7%)/*Homo sapiens* IGHV3-15*07 (81.8%) -(IGHD) -IGHJ2*01 (93.3%)) CDR-IMGT [8.10.13] (153-160.178-187.226-238) (128''-249'')] -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (250''-480'') [charnière 1-15 C5>S (254) (250-264) -CH2 E1.4,L1.3>P (267), L1.2>V (268), G1.1>A (269), S29>K (300) (265-373),CH3 E12 (389), E13>Q (390), M14 (391), S20>K (397), M107>L (461), N114>S (467) (374-478), CHS (479-480)]]; dimère (227-260'':230-263'')-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) lignée cellulaire CHO-S, glycoforme alfa
vudalimab	inmunoglobulina demi-IG G1-kappa/scFv-h-CH2-CH3, anti-[*Homo sapiens* CTLA4 (proteína 4 asociada a los linfocitos T citotóxicos, CD152)] y anti-[*Homo sapiens* PDCD1 (proteína 1 de muerte celular programada, PD-1, PD1, CD279)], anticuerpo monoclonal, biespecífico; cadena pesada gamma1 anti-CTLA4 (1-447) [VH (*Homo sapiens* IGHV3-48*03 (90.8%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.11] (26-33.51-58.97-107) (1-118) -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1 (CH1 N114>D (209) R120>K (215) (119-216), bisagra 1-15 (217-231), CH2 E1.4,L1.3>P (234), L1.2>V (235), G1.1>A (236), S29>K (267), Q84.2>E (295) (232-340), CH3 E12 (356), M14 (358), L24>D (368), K26>S (370), N44>D (384), Q97>E (418), N100>D (421), M107>L (428), N114>S (434) (341-445), CHS (446-447)) (119-447)], (221-215')-disulfuro con la cadena ligera kappa anti-CTLA4,*Homo sapiens* (1'-215') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (99.0%) -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')]; IG scFv-h-CH2-CH3 cadena única, anti-PDCD1 (1''-480'') [scFv V-kappa-VH anti-PDCD1 (1''-249'') [V-KAPPA (*Homo sapiens*IGKV3-15*01 (80.0%)-IGHJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1''-107'') -20-mer tetrakis(glicil-lisil-prolil-glicil-seril) linker (108''-127'') -VH (*Mus musculus* IGHV6-6*02 (87.0%) -(IGHD) -IGHJ1*03 (86.7%)/*Homo sapiens* IGHV3-15*07 (81.8%) -(IGHD) -IGHJ2*01 (93.3%)) CDR-IMGT [8.10.13] (153-160.178-187.226-238) (128''-249'')] -*Homo sapiens* IGHG1*03 h-CH2-CH3, nG1m1 (250''-480'') [bisagra 1-15 C5>S (254) (250-264) -CH2 E1.4,L1.3>P (267), L1.2>V (268), G1.1>A (269), S29>K (300) (265-373),CH3 E12 (389), E13>Q (390), M14 (391), S20>K (397), M107>L (461), N114>S (467) (374-478), CHS (479-480)]]; dímero (227-260'':230-263'')-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular CHO-S, forma glicosilada alfa

1.Heavy chain / Chaîne lourde / Cadena pesada (anti-CTLA4)

```
EVQLVESGGG LVKPGGSLRL SCAASGFTFS SYTMHWVRQA PGKGLEWVSF  50
ISYDGNNKYY ADSVKGRFTI SRDNAKNSLY LQMNSLRAED TAVYYCARTG 100
WLGPFDYWGQ GTLVTVSSAS TKGPSVFPLA PSSKSTSGGT AALGCLVKDY 150
FPEPVTVSWN SGALTSGVHT FPAVLQSSGL YSLSSVVTVP SSSLGTQTYI 200
CNVNHKPSDT KVDKKVEPKS CDKTHTCPPC PAPPVAGPSV FLFPPKPKDT 250
LMISRTPEVT CVVVDVKHED PEVKFNWYVD GVEVHNAKTK PREEEYNSTY 300
RVVSVLTVLH QDWLNGKEYK CKVSNKALPA PIEKTISKAK GQPREPQVYT 350
LPPSREEMTK NQVSLTCDVS GFYPSDIAVE WESDGQPENN YKTTPPVLDS 400
DGSFFLYSKL TVDKSRWEQG DVFSCSVLHE ALHSHYTQKS LSLSPGK    447
```

2. Light chain / Chaîne légère / Cadena ligera (anti-CTLA4)

```
EIVLTQSPGT LSLSPGERAT LSCRASQSVS SSYLAWYQQK PGQAPRLLIY  50
GAFSRATGIP DRFSGSGSGT DFTLTISRLE PEDFAVYYCQ QYGSSPWTFG 100
QGTKVEIKGT VAAPSVFIFP PSDEQLKSGT ASVVCLLNNF YPREAKVQWK 150
VDNALQSGNS QESVTEQDSK DSTYSLSSTL TLSKADYEKH KVYACEVTHQ 200
GLSSPVTKSF NRGEC                                       215
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3. Chain / Chaîne / Cadena IG scFv-h-CH2-CH3 (anti-PDCD1)

```
EIVLTQSPAT LSASPGERVT LTCRASQSVG NDVAWYQQKP GQAPRLLINY  50
ASHRYTGVPD RFTGSGYGTE FTLTISSVQS EDFGVYYCQQ DFSSPRTFGG 100
GTKVEIKGKP GSGKPGSGKP GSGKPGSEVQ LVESGGGLVK PGGSLRLSCV 150
ASGFTFSNYW MNWVRQAPGK GLEWVAEIRL YSNNYATHYA ESVKGRFTIS 200
RDDSKSTLYL QMNNLKTEDT GVYYCTRYYG NYGGYFDVWG RGTLVTVSSE 250
PKSSDKTHTC PPCPAPPVAG PSVFLFPPKP KDTLMISRTP EVTCVVVDVK 300
HEDPEVKFNW YVDGVEVHNA KTKPREEQYN STYRVVSVLT VLHQDWLNGK 350
EYKCKVSNKA LPAPIEKTIS KAKGQPREPQ VYTLPPSREQ MTKNQVKLTC 400
LVKGFYPSDI AVEWESNGQP ENNYKTTPPV LDSDGSFFLY SKLTVDKSRW 450
QQGNVFSCSV LHEALHSHYT QKSLSLSPGK                       480
```

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

Intra-H (C23-C104)	22-96 145-201 261-321 367-425
Intra-L (C23-C104)	23'-89' 135'-195'
Intra-chain 3	23"-88" 149"-225" 294"-354" 400"-458"
Inter-H-L (h 5-CL 126)	221-215'
Inter-H-chain 3 (h 11, h 14)	227-260" 230-263"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
297, 330"
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 / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
447, 480"

zalsenertantum tetraxetanum

zalsenertant tetraxetan

18^4,18^7,18^{10}-tris(carboxymethyl)-4^5-(2,6-dimethoxyphenyl)-7,11,15-trimethyl-3,6,16-trioxo-5^2-(propan-2-yl)-2,7,11,15-tetraaza-18(1)-(1,4,7,10-tetraazacyclododecana)-4(3,1)-pyrazola-1(2)-adamantana-5(1,4)-benzenaoctadecaphane-1^2-carboxylic acid

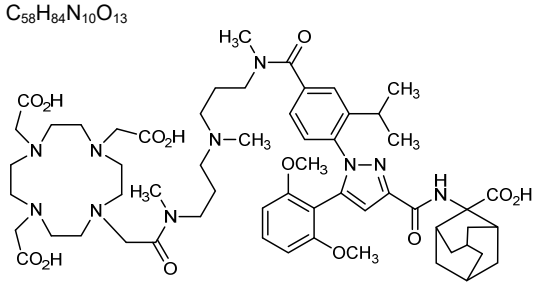
zalsénertant tétraxetan

acide 18^4,18^7,18^{10}-tris(carboxyméthyl)-4^5-(2,6-diméthoxyphényl)-7,11,15-triméthyl-3,6,16-trioxo-5^2-(propan-2-yl)-2,7,11,15-tétraaza-18(1)-(1,4,7,10-tétraazacyclododécana)-4(3,1)-pyrazola-1(2)-adamantana-5(1,4)-benzénaoctadécaphane-1^2-carboxylique

zalsenertant tetraxetán

ácido 18^4,18^7,18^{10}-tris(carboximetil)-4^5-(2,6-dimetoxifenil)-7,11,15-trimetil-3,6,16-trioxo-5^2-(propan-2-il)-2,7,11,15-tetraaza-18(1)-(1,4,7,10-tetraazaciclododecana)-4(3,1)-pirazola-1(2)-adamantana-5(1,4)-bencenaoctadecafano-1^2-carboxílico

$C_{58}H_{84}N_{10}O_{13}$



zanidatamabum zovodotinum #

zanidatamab zovodotin

immunoglobulin half-IG G1-kappa/scFv-h-CH2-CH3, anti-[*Homo sapiens* ERBB2 (epidermal growth factor receptor 2, receptor tyrosine protein kinase erbB-2, EGFR2, HER2, HER-2, p185c-erbB2, NEU, CD340)], humanized monoclonal antibody, biparatopic (targeting two different non-overlapping epitopes on ERBB2, on extracellular domains 2 (ECD2) and 4 (ECD4), respectively), conjugated to auristatin E;
gamma1 heavy chain, anti-ERBB2 extracellular domain 2 (ECD2), humanized (1-449) [VH humanized (*Homo sapiens* IGHV3-66*01 (78.8%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT[8.8.12] (27-34.52-59.98-109) (1-120) -*Homo sapiens* IGHG1*01 G1m17,1 (CH1 K120 (217) (121-218), hinge 1-15 (219-233), CH2 (234-343), CH3 T6>V (353), L7>Y (354), D12 (359), L14 (361), F85.1>A (408), Y86>V (410) (344-448), CHS K2>del (449)) (121-449)], (223- 215')-disulfide with kappa light chain, anti ERBB2 ECD2, humanized (1'-215') [V-KAPPA humanized (*Homo sapiens* IGKV1-16*01 (84.2%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (28-33.51-53.90-98) (1'-108') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (154), V101 (192) (109'-215')];
IG scFv-h-CH2-CH3 single chain, anti-ERBB2 extracellular domain 4 (ECD4), humanized (1"-481") [scFv V-kappa-VH anti-ERBB2 ECD4 (1'-248') [V-KAPPA humanized (*Homo sapiens* IGKV1-39*01 (86.3%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (28-33.51-53.90-98) (1'-108') -20-mer pentakis(diglycyl-seryl-glycyl) linker (109"-128") -VH humanized (*Homo sapiens* IGHV3-66*01 (81.6%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.13] (154-161.179-186.225-237) (129"-248")] -dialanyl linker (249"-250") -*Homo sapiens* IGHG1*01 h-CH2-CH3, G1m1 (251"-481") [hinge 1-15, C5>S (255) (251-265), CH2 (266-375), CH3 T6>V (385), D12 (391), L14 (393), T22>L (401), K79>L (427), T81>W (429) (376-480), CHS K2>del (481)]];
dimer (229-261":232-264")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa, conjugated, on an average of 2 to 3 cysteinyl, to monomethylauristatin E (MMAE), via a cleavable maleimidocaproyl-valyl-citrullinyl-*p*-aminobenzylcarbonyl (mc-val-cit-PABC) type linker

zanidatamab zovodotine

immunoglobuline G1-kappa, anti-[*Homo sapiens* ERBB2 (récepteur 2 du facteur de croissance épidermique, récepteur tyrosine-protéine kinase erbB-2, EGFR2, HER2, HER-2, p185c-erbB2, NEU, CD340)], anticorps monoclonal humanisé, biparatopique (ciblant deux épitopes différents non chevauchants sur ERBB2, respectivement sur les domaines extracellulaires 2 (ECD2) et 4 (ECD4)), conjugué à l'auristatine E;
chaîne lourde gamma1 anti-ERBB2 domaine extracellulaire 2 (ECD2), humanisée (1-449) [VH humanisé (*Homo sapiens* IGHV3-66*01 (78.8%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.12] (27-34.52-59.98-109) (1-120) -*Homo sapiens* IGHG1*01 G1m17,1 (CH1 K120 (217) (121-218), charnière 1-15 (219-233), CH2 (234- 343), CH3 T6>V (353), L7>Y (354), D12 (359), L14 (361), F85.1>A (408), Y86>V (410) (344-448), CHS K2>del (449)) (121-449)], (223-215')-disulfure avec la chaîne légère kappa, anti ERBB2 ECD2, humanisée (1'-215') [V-KAPPA humanisé (*Homo sapiens* IGKV1-16*01 (84.2%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (28-33.51-53.90-98) (1'-108') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (154), V101 (192) (109'-215')];

	IG scFv-h-CH2-CH3 chaîne unique, anti-ERBB2 domaine extracellulaire 4 (ECD4), humanisée (1"-481") [scFv V-kappa-VH anti-ERBB2 ECD4 (1'-248') [V-KAPPA humanisé (*Homo sapiens* IGKV1-39*01 (86.3%) - IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (28-33.51-53.90-98) (1'-108') -20-mer pentakis(diglycyl-seryl-glycyl) linker (109"- 128") -VH humanisé (*Homo sapiens* IGHV3-66*01 (81.6%) -(IGHD) - IGHJ4*01 (100%)) CDR-IMGT [8.8.13] (154-161.179-186.225-237) (129"-248")] -dialanyl linker (249"-250") -*Homo sapiens* IGHG1*01 h-CH2-CH3, G1m1 (251"-481") [charnière 1-15 C5>S (255) (251- 265), CH2 (266-375), CH3 T6>V (385), D12 (391), L14 (393), T22>L (401), K79>L (427), T81>W (429) (376-480), CHS K2>del (481)]]; dimère (229-261":232- 264")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa; conjugué, sur 2 à 3 cystéinyl en moyenne, au monométhylauristatine E (MMAE), via un linker clivable de type maléimidécaproyl-valyl-citrullinyl-*p*-aminobenzylcarbonyl (mc-val-cit-PABC).
zanidatamab zovodotina	inmunoglobulina G1-kappa, anti-[*Homo sapiens* ERBB2 (receptor 2 del factor de crecimiento epidérmico, receptor tirosina-proteína kinasa erbB-2, EGFR2, HER2, HER-2, p185c-erbB2, NEU, CD340)], anticuerpo monoclonal humanizado, biparatópico (dirigiendo dos epítopos diferentes no superpuestos sobre ERBB2, respectivamente sobre los dominios extracelulares 2 (ECD2) y 4 (ECD4)), conjugado con la auristatina E; cadena pesada gamma1 anti-ERBB2 dominio extracelular 2 (ECD2), humanizada (1-449) [VH humanizado (*Homo sapiens* IGHV3-66*01 (78.8%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.12] (27-34.52-59.98-109) (1-120) -*Homo sapiens* IGHG1*01 G1m17,1 (CH1 K120 (217) (121-218), bisagra 1-15 (219-233), CH2 (234- 343), CH3 T6>V (353), L7>Y (354), D12 (359), L14 (361), F85.1>A (408), Y86>V (410) (344-448), CHS K2>del (449)) (121-449)], (223-215')-disulfuro con la cadena ligera kappa, anti ERBB2 ECD2, humanizada (1'-215') [V-KAPPA humanizado (*Homo sapiens* IGKV1-16*01 (84.2%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (28-33.51-53.90-98) (1'-108') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (154), V101 (192) (109'-215')]; IG scFv-h-CH2-CH3 cadena única, anti-ERBB2 dominio extracelular 4 (ECD4), humanizada (1"-481") [scFv V-kappa-VH anti-ERBB2 ECD4 (1'-248') [V-KAPPA humanizado (*Homo sapiens* IGKV1-39*01 (86.3%) - IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (28-33.51-53.90-98) (1'-108') -20-mer pentakis(diglicil-seril-glicil) linker (109"- 128") -VH humanizado (*Homo sapiens* IGHV3-66*01 (81.6%) -(IGHD) - IGHJ4*01 (100%)) CDR-IMGT [8.8.13] (154-161.179-186.225-237) (129"-248")] -dialanil linker (249"-250") -*Homo sapiens* IGHG1*01 h-CH2-CH3, G1m1 (251"-481") [bisagra 1-15 C5>S (255) (251- 265), CH2 (266-375), CH3 T6>V (385), D12 (391), L14 (393), T22>L (401), K79>L (427), T81>W (429) (376-480), CHS K2>del (481)]]; dímero (229-261":232- 264")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa; conjugado, sobre 2 a 3 restos cisteinil en término medio, con monometilauristatina E (MMAE), mediante un conector escindible de tipo maleimidecaproil-valil-citrulinil-*p*-aminobenzilcarbonil (mc-val-cit-PABC).

1.Heavy chain / Chaîne lourde / Cadena pesada (anti-ERBB2 ECD2)

```
GEVQLVESGG GLVQPGGSLR LSCAASGFTF ADYTMDWVRQ APGKGLEWVG  50
DVNPNSGGSI YNQRFKGRFT FSVDRSKNTL YLQMNSLRAE DTAVYYCARN 100
LGPSFYFDYW GQGTLVTVSS ASTKGPSVFP LAPSSKSTSG GTAALGCLVK 150
DYFPEPVTVS WNSGALTSGV HTFPAVLQSS GLYSLSSVVT VPSSSLGTQT 200
YICNVNHKPS NTKVDKKVEP KSCDKTHTCP PCPAPELLGG PSVFLFPPKP 250
KDTLMISRTP EVTCVVVDVS HEDPEVKFNW YVDGVEVHNA KTKPREEQYN 300
STYRVVSVLT VLHQDWLNGK EYKCKVSNKA LPAPIEKTIS KAKGQPREPQ 350
VYVYPPSRDE LTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPV 400
LDSDGSFALV SKLTVDKSRW QQGNVFSCSV MHEALHNHYT QKSLSLSPG  449
```

2. Light chain / Chaîne légère / Cadena ligera (anti-ERBB2 ECD2)

```
GDIQMTQSPS SLSASVGDRV TITCKASQDV SIGVAWYQQK PGKAPKLLIY  50
SASYRYTGVP SRFSGSGSGT DFTLTISSLQ PEDFATYYCQ QYYIYPATFG 100
QGTKVEIKRT VAAPSVFIFP PSDEQLKSGT ASVVCLLNNF YPREAKVQWK 150
VDNALQSGNS QESVTEQDSK DSTYSLSSTL TLSKADYEKH KVYACEVTHQ 200
GLSSPVTKSF NRGEC                                      215
```

3. Chain / Chaîne / Cadena: IG scFv-h-CH2-CH3 (anti-ERBB2 ECD4)

```
GDIQMTQSPS SLSASVGDRV TITCRASQDV NTAVAWYQQK PGKAPKLLIY  50
SASFLYSGVP SRFSGSRSGT DFTLTISSLQ PEDFATYYCQ QHYTTPPTFG 100
QGTKVEIKGG SGGGSGGGSG GGSGGGSGEV QLVESGGGLV QPGGSLRLSC 150
AASGFNIKDT YIHWVRQAPG KGLEWVARIY PTNGYTRYAD SVKGRFTISA 200
DTSKNTAYLQ MNSLRAEDTA VYYCSRWGGD GFYAMDYWGQ GTLVTVSSAA 250
EPKSSDKTHT CPPCPAPELL GGPSVFLFPP KPKDTLMISR TPEVTCVVVD 300
VSHEDPEVKF NWYVDGVEVH NAKTKPREEQ YNSTYRVVSV LTVLHQDWLN 350
GKEYKCKVSN KALPAPIEKT ISKAKGQPRE PQVYVLPPSR DELTKNQVSL 400
LCLVKGFYPS DIAVEWESNG QPENNYLTWP PVLDSDGSFF LYSKLTVDKS 450
RWQQGNVFSC SVMHEALHNH YTQKSLSLSP G                     481
```

Post-translational modifications

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

Intra-H (C23-C104) 23-97 147-203 264-324 370-428

Intra-L (C23-C104) 24'-89' 135'-195'

Intra-chain 3 24"-89" 150"-224" 296"-356" 402"-460"

Inter-H-L (h 5-CL 126)* 223-215'

Inter-H-chain 3 (h 11, h 14)* 229-261" 232-264"

*At least two of the three inter-chain disulfide bridges are not present, an average of 2 to 3 cysteinyl being conjugated each via a thioether bond to a drug linker.

*Au moins deux des trois ponts disulfures inter-chaînes ne sont pas présents, 2 à 3 cystéinyl en moyenne étant chacun conjugué via une liaison thioéther à un linker-principe actif.

*Al menos dos de los tres puentes disulfuro inter-catenarios no estan presentes, una media de 2 a 3 cisteinil está conjugada a conectores de principio activo.

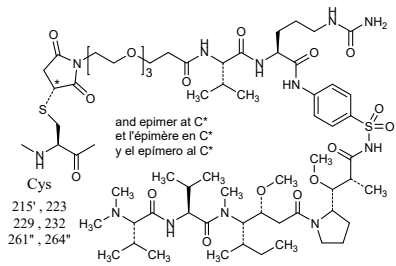
N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación

H CH2 N84.4:

300, 332"

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

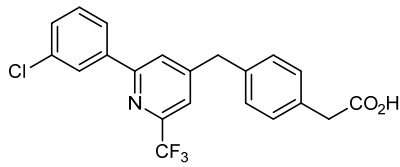
Modified residues / résidus modifiés / restos modificados:



zatolmilastum

zatolmilast	(4-{[2-(3-chlorophenyl)-6-(trifluoromethyl)pyridin-4-yl]methyl}phenyl)acetic acid
zatolmilast	acide (4-{[2-(3-chlorophényl)-6-(trifluorométhyl)pyridin-4-yl]méthyl}phényl)acétique
zatolmilast	ácido (4-{[2-(3-clorofenil)-6-(trifluorometil)piridin-4-il]metil}fenil)acético

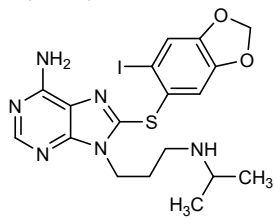
$C_{21}H_{15}ClF_3NO_2$



zelavespibum

zelavespib	8-[(6-iodo-2*H*-1,3-benzodioxol-5-yl)sulfanyl]-9-{3-[(propan-2-yl)amino]propyl}-9*H*-purin-6-amine
zélavespib	8-[(6-iodo-2*H*-1,3-benzodioxol-5-yl)sulfanyl]-9-{3-[(propan-2-yl)amino]propyl}-9*H*-purin-6-amine
zelavespib	8-[(6-iodo-2*H*-1,3-benzodioxol-5-il)sulfanil]-9-{3-[(propan-2-il)amino]propil}-9*H*-purin-6-amina

$C_{18}H_{21}IN_6O_2S$



zimberelimabum #

zimberelimab	immunoglobulin G4-lambda, anti-[*Homo sapiens* PDCD1 (programmed cell death 1, PD-1, PD1, CD279)], *Homo sapiens* monoclonal antibody; gamma4 heavy chain *Homo sapiens* (1-450) [VH (*Homo sapiens* IGHV4-39*01 (87.9%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [10.7.15] (26-35.53-59.98-112) (1-123)-*Homo sapiens* IGHG4*01 (CH1 (124-221), hinge 1-12 S10>P (231) (222-233), CH2 (234-343), CH3 (344-448), CHS (449-450) (124-450)], (137-215')-disulfide with lambda light chain *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV2-14*01 (94.9%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.10] (26-34.52-54.91-100) (1'-110') -*Homo sapiens* IGLC2*01 (100%) (111'-216')]; dimer (229-229":232-232")-bisdisulfide, produced in Chinese hamster ovary (CHO)-K1 cell line, glycoform alfa
zimbérélimab	immunoglobuline G4-lambda, anti-[*Homo sapiens* PDCD1 (protéine 1 de mort cellulaire programmée, PD-1, PD1, CD279], anticorps monoclonal *Homo sapiens*; chaîne lourde gamma4 *Homo sapiens* (1-450) [VH (*Homo sapiens* IGHV4-39*01 (87.9%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [10.7.15] (26-35.53-59.98-112) (1-123)-*Homo sapiens* IGHG4*01 (CH1 (124-221), charnière 1-12 S10>P (231) (222-233), CH2 (234-343), CH3 (344-448), CHS (449-450) (124-450)], (137-215')-disulfure avec la chaîne légère

lambda *Homo sapiens*(1'-216') [V-LAMBDA (*Homo sapiens* IGLV2-14*01 (94.9%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.10] (26-34.52-54.91-100) (1'-110') -*Homo sapiens* IGLC2*01 (100%) (111'-216')]; dímero (229-229":232-232")-bisdisulfuro, producido en células ováricas de hámster chino (CHO) línea celular CHO-K1, glicosilada alfa

zimberelimab

inmunoglobulina G4-lambda, anti-[*Homo sapiens* PDCD1 (proteína 1 de muerte celular programada PD-1, PD1, CD279], anticuerpo monoclonal *Homo sapiens*;
cadena pesada gamma4 *Homo sapiens* (1-450) [VH (*Homo sapiens* IGHV4-39*01 (87.9%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [10.7.15] (26-35.53-59.98-112) (1-123)-*Homo sapiens* IGHG4*01 (CH1 (124-221), bisagra 1-12 S10>P (231) (222-233), CH2 (234-343), CH3 (344-448), CHS (449-450) (124-450)], (137-215')-disulfuro con la cadena ligera lambda *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV2-14*01 (94.9%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.10] (26-34.52-54.91-100) (1'-110') -*Homo sapiens* IGLC2*01 (100%) (111'-216')]; dímero (229-229":232-232")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular CHO-K1, forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QLQLQESGPG LVKPSETLTL TCTVSADSIS STTYYWVWIR QPPGKGLEWI  50
GSISYSGSTY YNPSLKSRVT VSVDTSKNQF SLKLNSVAAT DTALYYCARH 100
LGYNGRYLPF DYWGQGTLVT VSSASTKGPS VFPLAPCSRS TSESTAALGC 150
LVKDYFPEPV TVSWNSGALT SGVHTFPAVL QSSGLYSLSS VVTVPSSSLG 200
TKTYTCNVDH KPSNTKVDKR VESKYGPPCP PCPAPEFLGG PSVFLFPPKP 250
KDTLMISRTP EVTCVVVDVS QEDPEVQFNW YVDGVEVHNA KTKPREEQFN 300
STYRVVSVLT VLHQDWLNGK EYKCKVSNKG LPSSIEKTIS KAKGQPREPQ 350
VYTLPPSQEE MTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPV 400
LDSDGSFFLY SRLTVDKSRW QEGNVFSCSV MHEALHNHYT QKSLSLSLGK 450
```

Light chain / Chaîne légère / Cadena ligera

```
QSALTQPASV SGSPGQSITI SCTGTSSDVG FYNYVSWYQQ HPGKAPELMI  50
YDVSNRPSGV SDRFSGSKSG NTASLTISGL QAEDEADYYC SSYTSISTWV 100
FGGGTKLTVL GQPKAAPSVT LFPPSSEELQ ANKATLVCLI SDFYPGAVTV 150
AWKADSSPVK AGVETTTPSK QSNNKYAASS YLSLTPEQWK SHRSYSCQVT 200
HEGSTVEKTV APTECS                                      216
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-97 150-206 264-324 370-428
22"-97" 150"-206" 264"-324" 370"-428"
Intra-L (C23-C104) 22'-90' 138'-197'
22'"-90'" 138'"-197'"
Inter-H-L (CH1 10-CL 126) 137-215' 137"-215'"
Inter-H-H (h 8, h 11) 229-229" 232-232"

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

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 / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
450, 450"

Please find below the names from proposed **INN List 124 – COVID-19 (special edition)** that have reached the status of recommended INN.
Veuillez trouver ci-dessous les noms de la **Liste 124 des DCI proposées – COVID-19 (édition spéciale)** ayant atteint le statut de DCI recommandées.
Por favor, abajo se encuentran los nombres de la **Lista 124 de DCI propuestas – COVID-19 (edición especial)** que han alcanzado el estatus de DCI recomendadas.

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

abdavomeranum #

abdavomeran	messenger RNA (mRNA), 5'-capped, encoding the codon-optimised receptor binding domain (RBD) of the SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2, GenBank: MN908947.3) spike (S) glycoprotein, expressed as a fusion protein 5' with an extended S glycoprotein signal peptide and connected 3' by a glycine/serine (GS)-rich linker peptide with a T4 fibritin trimerization domain, flanked by 5' and 3' untranslated regions and a 3' poly(A) tail; contains N1-methylpseudouridine instead of uridine (*all*-U>$m^1\Psi$).
abdavoméran	ARN messager (ARNm), protégé en 5', codant pour le domaine de liaison au récepteur (RBD) de la glycoprotéine spike (S) du SARS-CoV-2 (coronavirus 2 du syndrome respiratoire aigu sévère, GenBank: MN908947.3) avec des codons optimisés, exprimé comme une protéine de fusion 5'-avec un peptide signal de la glycoprotéine S allongé et lié en 3' par un peptide de liaison riche en glycine / sérine (GS) avec un domaine de trimérisation de la fibritine de T4, flanqué par des régions 5' et 3' non traduites et une queue poly(A); contient de la N1-méthylpseudouridine au lieu de l'uridine (*tout*-U>$m^1\Psi$).
abdavomerán	RNA mensajero (mRNA), protegido en 5', que codifica para el dominio de unión al receptor (RBD) de la glicoproteína de la espícula (S) de SRAS-CoV-2 (coronavirus 2 del síndrome respiratorio agudo severo, GenBank: MN908947.3) con codones optimizados, expresado como una proteína de fusión en 5' con un péptido señal de glicoproteína S extendido y conectado en 3' mediante un péptido enlazador (linker) rico en glicina/serina (GS) con un dominio fibritina de trimerización de T4, flanqueado por regiones 5' y 3' no traducidas y una cola poly(A); contiene N1-metilpseudouridina en lugar de uridina (*all*-U>$m^1\Psi$).

alunacedasum alfa #

alunacedase alfa	human angiotensin-converting enzyme 2 extracellular soluble domain (18-740, 1-723 in the current sequence), dimer, glycosylated, produced in Chinese hamster ovary (CHO) cells; human angiotensin-converting enzyme 2 (ACE2, angiotensin-converting enzyme homolog, ACEH, ACE-related carboxypeptidase, metalloprotease MPROT15, EC:3.4.17.23), soluble extracellular (18-740)-domain of the proprotein, non-covalent dimer, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

alunacédase alfa

domaine extracellulaire soluble de l'enzyme de conversion de l'angiotensine de type 2 humaine (18-740, 1-723 dans la séquence actuelle), dimère, glycosylé, produit dans des cellules ovariennes de hamster chinois (CHO);enzyme de conversion de l'angiotensine de type 2 humaine (ECA2, enzyme de conversion homologue de l'angiotensine, HECA, carboxypeptidase liée à l'ECA, métalloprotéase MPROT15, EC: 3.4.17.23), domaine protéique extracellulaire soluble (18-740), dimère non covalent, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

alunacedasa alfa

enzima humana convertidora de la angiotensina 2 dominio extracelular soluble (18-740, 1-723 en la secuencia actual) dímero, glicosilado, producido en células ováricas de hámster Chino (CHO);
enzima humana convertidora de la angiotensina 2 (ECA2, homológo enzima covertidora de angiotensina, HECA, ECA-carboxipeptidasa relacionada, metaloproteasa MPROT15, EC:3.4.17.23), soluble extracelular (18-740)-dominio de la proproteína, dímero no covalente, producido en células ováricas de hámster Chino (CHO), glicoforma alfa

Sequence / Séquence / Secuencia

```
QSTIEEQAKT FLDKFNHEAE DLFYQSSLAS WNYNTNITEE NVQNMNNAGD   50
KWSAFLKEQS TLAQMYPLQE IQNLTVKLQL QALQQNGSSV LSEDKSKRLN  100
TILNTMSTIY STGKVCNPDN PQECLLLEPG LNEIMANSLD YNERLWAWES  150
WRSEVGKQLR PLYEEYVVLK NEMARANHYE DYGDYWRGDY EVNGVDGYDY  200
SRGQLIEDVE HTFEEIKPLY EHLHAYVRAK LMNAYPSYIS PIGCLPAHLL  250
GDMWGRFWTN LYSLTVPFGQ KPNIDVTDAM VDQAWDAQRI FKEAEKFFVS  300
VGLPNMTQGF WENSMLTDPG NVQKAVCHPT AWDLGKGDFR ILMCTKVTMD  350
DFLTAHHEMG HIQYDMAYAA QPFLLRNGAN EGFHEAVGEI MSLSAATPKH  400
LKSIGLLSPD FQEDNETEIN FLLKQALTIV GTLPFTYMLE KWRWMVFKGE  450
IPKDQWMKKW WEMKREIVGV VEPVPHDETY CDPASLFHVS NDYSFIRYYT  500
RTLYQFQFQE ALCQAAKHEG PLHKCDISNS TEAGQKLFNM LRLGKSEPWT  550
LALENVVGAK NMNVRPLLNY FEPLFTWLKD QNKNSFVGWS TDWSPYADQS  600
IKVRISLKSA LGDKAYEWND NEMYLFRSSV AYAMRQYFLK VKNQMILFGE  650
EDVRVANLKP RISFNFFVTA PKNVSDIIPR TEVEKAIRMS RSRINDAFRL  700
NDNSLEFLGI QPTLGPPNQP PVS                                723
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
116-124, 327-344, 513-525 116'-124', 327'-344', 513'-525'
Cys-SH: 244, 481, 244', 481'

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
N36, N73, N86, N305, N415, N529, N36', N73', N86', N305', N415', N529' (97-100% each)
N673, N673' (4% each)

O-glycosylation sites / Sites de O-glycosylation / Posiciones de O-glicosilación
S704, S704' or T713, T713' or S723, S723'

Other modifications: Q1, Q1' >Glp (pyroGlu);
S723, S723': partially clipped (~4%)

atibuclimabum #

atibuclimab

immunoglobulin G4-kappa, anti-[*Homo sapiens* CD14, membrane (mCD14) and soluble (sCD14)], chimeric monoclonal antibody; gamma4 heavy chain chimeric (1-442) [VH *Mus musculus* (Musmus IGHV3-2*02 (95.9%) -(IGHD) -Musmus IGHJ3*01 (92.9%) A128>S (115)) CDR-IMGT [9.7.8] (26-34.52-58.97-104) (1-115) -*Homo sapiens* IGHG4*01 (100%), CH1 (116-213),hinge 1-12 (214-225), CH2 (226-335), CH3 (336-440), CHS (441-442)) (116-442)], (129-218')-disulfide with kappa light chain chimeric (1'-218') [V-KAPPA *Mus musculus* (Musmus IGKV3-5*01 (97.0%) -IGKJ2*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 (221-221":224-224")-bisdisulfide, produced in a Chinese hamster ovary (CHO)-DG44 cell line, glycoform alfa

atibuclimab

immunoglobuline G4-kappa anti-[*Homo sapiens* CD14, membrane (mCD14) et soluble (sCD14)], anticorps monoclonal chimérique; chaîne lourde gamma4 chimérique (1-442) [VH *Mus musculus* (Musmus IGHV3-2*02 (95.9%) -(IGHD) -Musmus IGHJ3*01 (92.9%) A128>S (115)) CDR-IMGT [9.7.8] (26-34.52-58.97-104) (1-115) - *Homo sapiens* IGHG4*01 (100%), CH1 (116-213), charnière 1-12 (214-225), CH2 (226-335), CH3 (336-440), CHS (441-442)) (116-442)], (129-218')-disulfure avec la chaîne légère kappa chimérique (1'-218') [V-KAPPA *Mus musculus* (Musmus IGKV3-5*01 (97.0%) - IGKJ2*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 (221-221":224-224")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) lignée cellulaire CHO-DG44, glycoforme alfa

atibuclimab

inmunoglobulina G4-kappa anti-[*Homo sapiens* CD14, membrana (mCD14) y soluble (sCD14)], anticuerpo monoclonal quimérico; cadena pesada gamma4 quimérico (1-442) [VH *Mus musculus* (Musmus IGHV3-2*02 (95.9%) -(IGHD) -Musmus IGHJ3*01 (92.9%) A128>S (115)) CDR-IMGT [9.7.8] (26-34.52-58.97-104) (1-115) - *Homo sapiens* IGHG4*01 (100%), CH1 (116-213), bisagra 1-12 (214-225), CH2 (226-335), CH3 (336-440), CHS (441-442)) (116-442)], (129-218')-disulfuro con la cadena ligera kappa quimérica (1'-218') [V-KAPPA *Mus musculus* (Musmus IGKV3-5*01 (97.0%) - IGKJ2*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 (221-221":224-224")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular CHO-DG44, forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
DVQLQQSGPG LVKPSQSLSL TCTVTGYSIT SDSAWNWIRQ FPGNRLEWMG   50
YISYSGSTSY NPSLKSRISI TRDTSKNQFF LQLNSVTTED TATYYCVRGL  100
RFAYWGQGTL VTVSSASTKG PSVFPLAPCS RSTSESTAAL GCLVKDYFPE  150
PVTVSWNSGA LTSGVHTFPA VLQSSGLYSL SSVVTVPSSS LGTKTYTCNV  200
DHKPSNTKVD KRVESKYGPP CPSCPAPEFL 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
```

Light chain / Chaîne légère / Cadena ligera

```
DIVLTQSPAS LAVSLGQRAT ISCRASESVD SYVNSFLHWY QQKPGQPPKL   50
LIYRASNLQS GIPARFSGSG SRTDFTLTIN PVEADDVATY 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) 22-96 142-198 256-316 362-420
22"-96" 142"-198" 256"-316" 362"-420"
Intra-L (C104) 23'-92' 138'-198'
23'"-92'" 138'"-198'"
Inter-H-L (CH1 10-CL 126) 129-218' 129"-218'"
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 (G0F predominant) / glycanes de type CHO bi-antennaires complexes fucosylés (G0F prédominant) / glicanos de tipo CHO biantenarios complejos fucosilados (G0F predominante).

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
442, 442"

bamlanivimabum #

bamlanivimab	immunoglobulin G1-kappa, anti-[*Homo sapiens* severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike (S) protein], *Homo sapiens* monoclonal antibody; gamma1 heavy chain *Homo sapiens* (1-455) [VH (*Homo sapiens* IGHV1-69*04 (99.0%) -(IGHD) -IGHJ6*01 (90.9%) T123>A (120)) CDR-IMGT [8.8.18] (26-33.51-58.97-114) (1-125) -*Homo sapiens* IGHG1*03 (100%) G1m3, nG1m1 (CH1 R120 (222) (126-223), hinge 1-15 (224-238), CH2 (239-348), CH3 E12 (364), M14 (366) (349-453), CHS (454-455)) (126-454)], (228-214')-disulfide with kappa light chain *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-39*01 (97.9%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (234-234":237-237")-bisdisulfide, produced in a Chinese hamster ovary (CHO) cell line derived from CHO-K1SV, lacking the glutamine synthetase (GS) gene, glycoform alfa
bamlanivimab	immunoglobuline G1-kappa anti-[*Homo sapiens* protéine spike (S) du coronavirus 2 du syndrome respiratoire aigu sévère (SARS-CoV-2)], anticorps monoclonal *Homo sapiens*; chaîne lourde gamma1 *Homo sapiens* (1-455) [VH (*Homo sapiens* IGHV1-69*04 (99%) -(IGHD) -IGHJ6*01 (90.9%) T123>A (120)) CDR-IMGT [8.8.18] (26-33.51-58.97-114) (1-125) -*Homo sapiens* IGHG1*03 (100%) G1m3, nG1m1 (CH1 R120 (222) (126-223), charnière 1-15 (224-238), CH2 (239-348), CH3 E12 (364), M14 (366) (349-453), CHS (454-455)) (126-454)], (228-214')-disulfure avec la chaîne légère kappa *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-39*01 (97.9%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (234-234":237-237")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) dérivant de la lignée cellulaire CHO-K1SV, ne présentant pas le gène de la glutamine synthétase, glycoforme alfa
bamlanivimab	inmunoglobulina G1-kappa anti-[*Homo sapiens* proteína espícula (S) del coronavirus 2 del síndrome respiratorio agudo severo (SRAS-CoV-2)], anticuerpo monoclonal *Homo sapiens*; cadena pesada gamma1 *Homo sapiens* (1-455) [VH (*Homo sapiens* IGHV1-69*04 (99%) -(IGHD) -IGHJ6*01 (90.9%) T123>A (120)) CDR-IMGT [8.8.18] (26-33.51-58.97-114) (1-125) -*Homo sapiens* IGHG1*03 (100%) G1m3, nG1m1 (CH1 R120 (222) (126-223), bisagra 1-15 (224-238), CH2 (239-348), CH3 E12 (364), M14 (366) (349-453), CHS (454-455)) (126-454)], (228-214')-disulfuro con la cadena ligera kappa *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-39*01 (97.9%) -IGKJ1*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (234-234":237-237")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular derivada de CHO-K1SV, en ausencia del gen glutamina sintetasa (GS), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGSSVKV SCKASGGTFS NYAISWVRQA PGQGLEWMGR  50
IIPILGIANY AQKFQGRVTI TADKSTSTAY MELSSLRSED TAVYYCARGY 100
YEARHYYYYY AMDVWGQGTA VTVSSASTKG PSVFPLAPSS KSTSGGTAAL 150
GCLVKDYFPE PVTVSWNSGA LTSGVHTFPA VLQSSGLYSL SSVVTVPSSS 200
LGTQTYICNV NHKPSNTKVD KRVEPKSCDK THTCPPCPAP ELLGGPSVFL 250
FPPKPKDTLM ISRTPEVTCV VVDVSHEDPE VKFNWYVDGV EVHNAKTKPR 300
EEQYNSTYRV VSVLTVLHQD WLNGKEYKCK VSNKALPAPI EKTISKAKGQ 350
PREPQVYTLP PSREEMTKNQ VSLTCLVKGF YPSDIAVEWE SNGQPENNYK 400
TTPPVLDSDG SFFLYSKLTV DKSRWQQGNV FSCSVMHEAL HNHYTQKSLS 450
LSPGK                                                   455
```

Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS LSASVGDRVT ITCRASQSIS SYLSWYQQKP GKAPKLLIYA  50
ASSLQSGVPS RFSGSGSGTD FTLTITSLQP EDFATYYCQQ SYSTPRTFGQ 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                         214
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Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 152-208 269-329 375-433
22"-96" 152"-208" 269"-329" 375"-433"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (h 5-CL 126) 228-214' 228"-214'"
Inter-H-H (h 11, h 14) 234-234" 237-237"

N-terminal glutamine 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:
305, 305"
Fucosylated complex bi-antennary CHO-type glycans (G0F predominant) / glycanes de type CHO bi-antennaires complexes fucosylés (G0F prédominant) / glicanos de tipo CHO biantenarios complejos fucosilados (G0F predominante).

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
455, 455"

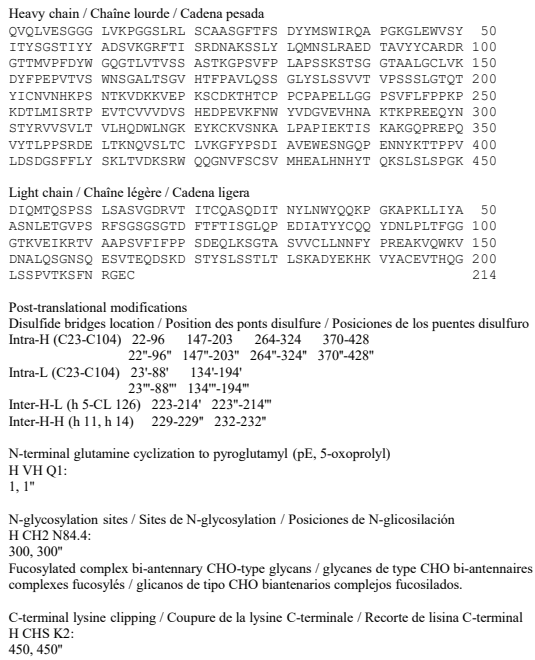
casirivimabum #

casirivimab	immunoglobulin G1-kappa, anti-[*Homo sapiens* severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike (S) protein, receptor binding domain (RBD)], *Homo sapiens* monoclonal antibody; gamma1 heavy chain *Homo sapiens* (1-450) [VH (*Homo sapiens* IGHV3-11*01 (96.9%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (217) (121-218),hinge 1-15 (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-214')-disulfide with kappa light chain *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-33*01 (96.8%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (229-229":232-232")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa
casirivimab	immunoglobuline G1-kappa anti-[*Homo sapiens* protéine spike (S) du coronavirus 2 du syndrome respiratoire aigu sévère (SARS-CoV-2), domaine de liaison au récepteur (RBD)], anticorps monoclonal *Homo sapiens*;

chaîne lourde gamma1 *Homo sapiens* (1-450) [VH (*Homo sapiens* IGHV3-11*01 (96.9%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (217) (121-218), charnière 1-15 (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-214')-disulfure avec la chaîne légère kappa *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-33*01 (96.8%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (229-229":232-232")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

casirivimab

inmunoglobulina G1-kappa anti-[*Homo sapiens* proteína espícula (S) del coronavirus 2 del síndrome respiratorio agudo severo (SRAS-CoV-2), dominio de unión al receptor (RBD)], anticuerpo monoclonal *Homo sapiens*;
cadena pesada gamma1 *Homo sapiens* (1-450) [VH (*Homo sapiens* IGHV3-11*01 (96.9%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (217) (121-218), bisagra 1-15 (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-214')-disulfuro con la cadena ligera kappa *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-33*01 (96.8%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (229-229":232-232")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa



Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVESGGG LVKPGGSLRL SCAASGFTFS DYYMSWIRQA PGKGLEWVSY  50
ITYSGSTIYY ADSVKGRFTI SRDNAKSSLY LQMNSLRAED TAVYYCARDR 100
GTTMVPFDYW GQGTLVTVSS ASTKGPSVFP LAPSSKSTSG GTAALGCLVK 150
DYFPEPVTVS WNSGALTSGV HTFPAVLQSS GLYSLSSVVT VPSSSLGTQT 200
YICNVNHKPS NTKVDKKVEP KSCDKTHTCP PCPAPELLGG PSVFLFPPKP 250
KDTLMISRTP EVTCVVVDVS HEDPEVKFNW YVDGVEVHNA KTKPREEQYN 300
STYRVVSVLT VLHQDWLNGK EYKCKVSNKA LPAPIEKTIS KAKGQPREPQ 350
VYTLPPSRDE LTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPV 400
LDSDGSFFLY SKLTVDKSRW QQGNVFSCSV MHEALHNHYT QKSLSLSPGK 450
```

Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS LSASVGDRVT ITCQASQDIT NYLNWYQQKP GKAPKLLIYA  50
ASNLETGVPS RFSGSGSGTD FTFTISGLQP EDIATYYCQQ YDNLPLTFGG 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 147-203 264-324 370-428
22"-96" 147"-203" 264"-324" 370"-428"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88'" 134'"-194'"
Inter-H-L (h 5-CL 126) 223-214' 223"-214'"
Inter-H-H (h 11, h 14) 229-229" 232-232"

N-terminal glutamine 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:
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 / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
450, 450"

cilgavimabum #

cilgavimab	immunoglobulin G1-kappa, anti-[*Homo sapiens* severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike (S) protein, receptor binding domain (RBD)], *Homo sapiens* monoclonal antibody; gamma1 heavy chain *Homo sapiens* (1-461) [VH (*Homo sapiens* IGHV3-15*01 (96.0%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.10.22] (26-33.51-60.99-120) (1-131) -*Homo sapiens* IGHG1*03 G1m3, nG1m1, G1v21 CH2 Y15.1, T16, E18, G1v39 CH2 F1.3, E1.2, S116 (CH1 R120 (228) (132-229),hinge 1-15 (230-244), CH2 L1.3>F (248), L1.2>E (249), M15.1>Y (266), S16>T (268), T18>E (270), P116>S (345) (245-354), CH3 E12 (370), M14 (372) (355-459), CHS (460-461)) (132-461)], (234-219')-disulfide with kappa light chain *Homo sapiens* (1'-219') [V-KAPPA (*Homo sapiens* IGKV4-1*01 (96.0%) -IGKJ4*01 (100%)) CDR-IMGT [12.3.8] (27-38.56-58.95-102) (1'-112') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (158), V101 (196) (113'-219')]; dimer (240-240":243-243")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa
cilgavimab	immunoglobuline G1-kappa anti-[*Homo sapiens* protéine spike (S) du coronavirus 2 du syndrome respiratoire aigu sévère (SARS-CoV-2), domaine de liaison au récepteur (RBD)], anticorps monoclonal *Homo sapiens*; chaîne lourde gamma1 *Homo sapiens* (1-461) [VH (*Homo sapiens* IGHV3-15*01 (96.0%) -(IGHD) - IGHJ4*01 (100%)) CDR-IMGT [8.10.22] (26-33.51-60.99-120) (1-131) -Homo sapiens IGHG1*03 G1m3, nG1m1, G1v21 CH2 Y15.1, T16, E18, G1v39 CH2 F1.3, E1.2, S116 (CH1 R120 (228) (132-229), charnière 1-15 (230-244), CH2 L1.3>F (248), L1.2>E (249), M15.1>Y (266), S16>T (268), T18>E (270), P116>S (345) (245-354), CH3 E12 (370), M14 (372) (355-459), CHS (460-461)) (132-461)], (234-219')-disulfure avec la chaîne légère kappa *Homo sapiens* (1'-219') [V-KAPPA (*Homo sapiens* IGKV4-1*01 (96.0%) -IGKJ4*01 (100%)) CDR-IMGT [12.3.8] (27-38.56-58.95-102) (1'-112') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (158), V101 (196) (113'-219')]; dimère (240-240":243-243")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa
cilgavimab	inmunoglobulina G1-kappa anti-[*Homo sapiens* proteína espícula (S) del coronavirus 2 del síndrome respiratorio agudo severo (SRAS-CoV-2), dominio de unión al receptor (RBD)], anticuerpo monoclonal *Homo sapiens*; cadena pesada gamma1 *Homo sapiens* (1-461) [VH (*Homo sapiens* IGHV3-15*01 (96.0%) -(IGHD) - IGHJ4*01 (100%)) CDR-IMGT [8.10.22] (26-33.51-60.99-120) (1-131) -*Homo sapiens* IGHG1*03 G1m3, nG1m1, G1v21 CH2 Y15.1, T16, E18, G1v39 CH2 F1.3, E1.2, S116 (CH1 R120 (228) (132-229), bisagra 1-15 (230-244), CH2 L1.3>F (248), L1.2>E (249), M15.1>Y (266), S16>T (268), T18>E (270), P116>S (345) (245-354), CH3 E12 (370), M14 (372) (355-459), CHS (460-461)) (132-461)], (234-219')-disulfuro con la cadena ligera kappa *Homo sapiens* (1'-219') [V-KAPPA (*Homo sapiens* IGKV4-1*01 (96.0%) -IGKJ4*01 (100%)) CDR-IMGT [12.3.8] (27-38.56-58.95-102) (1'-112') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (158), V101 (196) (113'-219')]; dímero (240-240":243-243")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVESGGG LVKPGGSLRL SCAASGFTFR DVWMSWVRQA PGKGLEWVGR  50
IKSKIDGGTT DYAAPVKGRF TISRDDSKNT LYLQMNSLKT EDTAVYYCTT 100
AGSYYYDTVG PGLPEGKFDY WGQGTLVTVS SASTKGPSVF PLAPSSKSTS 150
GGTAALGCLV KDYFPEPVTV SWNSGALTSG VHTFPAVLQS SGLYSLSSVV 200
TVPSSSLGTQ TYICNVNHKP SNTKVDKRVE PKSCDKTHTC PPCPAPEFEG 250
GPSVFLFPPK PKDTLYITRE PEVTCVVVDV SHEDPEVKFN WYVDGVEVHN 300
AKTKPREEQY NSTYRVVSVL TVLHQDWLNG KEYKCKVSNK ALPASIEKTI 350
SKAKGQPREP QVYTLPPSRE EMTKNQVSLT CLVKGFYPSD IAVEWESNGQ 400
PENNYKTTPP VLDSDGSFFL YSKLTVDKSR WQQGNVFSCS VMHEALHNHY 450
TQKSLSLSPG K                                          461
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Light chain / Chaîne légère / Cadena ligera

```
DIVMTQSPDS LAVSLGERAT INCKSSQSVL YSSNNKNYLA WYQQKPGQPP  50
KLLMYWASTR ESGVPDRFSG SGSGAEFTLT ISSLQAEDVA IYYCQQYYST 100
LTFGGGTKVE 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) 22-98 158-214 275-335 381-439
22"-98" 158"-214" 275"-335" 381"-439"
Intra-L (C23-C104) 23'-94' 139'-199'
23'"-94'" 139'"-199'"
Inter-H-L (h 5-CL 126) 234-219' 234"-219'"
Inter-H-H (h 11, h 14) 240-240" 243-243"

N-glycosylation sites / Sites de N-glycosylation / Posiciones de N-glicosilación
H CH2 N84.4:
311, 311"
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 / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
461, 461"

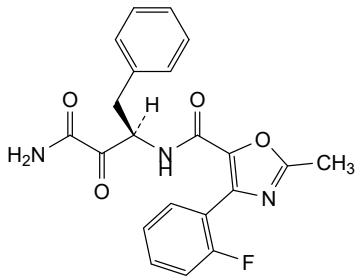
dazcapistatum

dazcapistat — *rac*-*N*-[(2*R*)-4-amino-3,4-dioxo-1-phenylbutan-2-yl]-4-(2-fluorophenyl)-2-methyl-1,3-oxazole-5-carboxamide

dazcapistat — *rac*-*N*-[(2*R*)-4-amino-3,4-dioxo-1-phénylbutan-2-yl]-4-(2-fluorophényl)-2-méthyl-1,3-oxazole-5-carboxamide

dazcapistat — *rac*-*N*-[(2*R*)-4-amino-3,4-dioxo-1-fenilbutan-2-il]-4-(2-fluorofenil)-2-metil-1,3-oxazol-5-carboxamida

$C_{21}H_{18}FN_3O_4$



and enantiomer
et énantiomère
y enantiómero

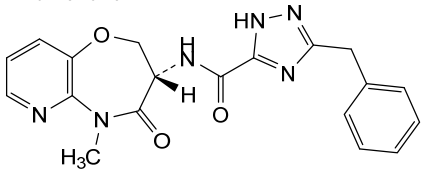
eclitasertibum

eclitasertib — 5-benzyl-*N*-[(3*S*)-5-methyl-4-oxo-2,3,4,5-tetrahydropyrido[3,2-*b*][1,4]oxazepin-3-yl]-1*H*-1,2,4-triazole-3-carboxamide

éclitasertib — 5-benzyl-*N*-[(3*S*)-5-méthyl-4-oxo-2,3,4,5-tétrahydropyrido[3,2-*b*][1,4]oxazépin-3-yl]-1*H*-1,2,4-triazole-3-carboxamide

eclitasertib — 5-bencil-*N*-[(3*S*)-5-metil-4-oxo-2,3,4,5-tetrahidropirido[3,2-*b*][1,4]oxazepin-3-il]-1*H*-1,2,4-triazol-3-carboxamida

$C_{19}H_{18}N_6O_3$



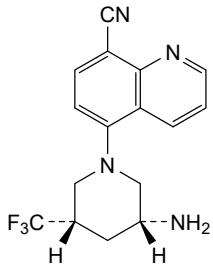
enpatoranum

enpatoran — 5-[(3*R*,5*S*)-3-amino-5-(trifluoromethyl)piperidin-1-yl]quinoline-8-carbonitrile

enpatoran — 5-[(3*R*,5*S*)-3-amino-5-(trifluorométhyl)pipéridin-1-yl]quinoléine-8-carbonitrile

enpatorán — 5-[(3*R*,5*S*)-3-amino-5-(trifluorometil)piperidin-1-il]quinoleína-8-carbonitrilo

$C_{16}H_{15}F_3N_4$



etesevimabum

etesevimab — immunoglobulin G1-kappa, anti-[*Homo sapiens* severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike (S) protein, receptor binding domain (RBD)], *Homo sapiens* monoclonal antibody; gamma1 heavy chain *Homo sapiens* (1-449) [VH (*Homo sapiens* IGHV3-66*01 (96.9%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.7.13] (26-33.51-57.96-108) (1-119) -*Homo sapiens* IGHG1*03 G1m3, nG1m1, G1v14 A1.3, A1.2 (CH1 R120 (216) (120-217), hinge 1-15 (218-232), CH2 L1.3>A (236), L1.2>A (237), (233-342), CH3 E12 (358), M14 (360) (343-447), CHS (448-449)) (120-449)], (222-216')-disulfide with kappa light chain *Homo sapiens* (1'-216') [V-KAPPA (*Homo sapiens* IGKV1-39*01 (97.9%) -IGKJ2*01 (100%)) CDR-IMGT [6.3.11] (27-32.50-52.89-99) (1'-109') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (155), V101 (193) (110'-216')]; dimer (228-228":231-231")-bisdisulfide, produced in a Chinese hamster ovary (CHO) cell line derived from CHO-K1SV, lacking the glutamine synthetase (GS) gene, glycoform alfa

étésévimab

immunoglobuline G1-kappa anti-[*Homo sapiens* protéine spike (S) du coronavirus 2 du syndrome respiratoire aigu sévère (SARS-CoV-2), domaine de liaison au récepteur (RBD)], anticorps monoclonal *Homo sapiens*;
chaîne lourde gamma1 *Homo sapiens* (1-449) [VH (*Homo sapiens* IGHV3-66*01 (96.9%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.7.13] (26-33.51-57.96-108) (1-119) -*Homo sapiens* IGHG1*03 G1m3, nG1m1, G1v14 A1.3, A1.2 (CH1 R120 (216) (120-217), charnière 1-15 (218-232), CH2 L1.3>A (236), L1.2>A (237), (233-342), CH3 E12 (358), M14 (360) (343-447), CHS (448-449)) (120-449)], (222-216')-disulfure avec la chaîne légère kappa *Homo sapiens* (1'-216') [V-KAPPA (*Homo sapiens* IGKV1-39*01 (97.9%) -IGKJ2*01 (100%)) CDR-IMGT [6.3.11] (27-32.50-52.89-99) (1'-109') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (155), V101 (193) (110'-216')]; dimère (228-228":231-231")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) dérivant de la lignée cellulaire CHO-K1SV, ne présentant pas le gène de la glutamine synthétase, glycoforme alfa

etesevimab

inmunoglobulina G1-kappa anti-[*Homo sapiens* proteína espícula (S) del coronavirus 2 del síndrome respiratorio agudo severo (SRAS-CoV-2), dominio de unión al receptor (RBD)], anticuerpo monoclonal *Homo sapiens*; cadena pesada gamma1 *Homo sapiens* (1-449) [VH (*Homo sapiens* IGHV3-66*01 (96.9%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.7.13] (26-33.51-57.96-108) (1-119) -*Homo sapiens* IGHG1*03 G1m3, nG1m1, G1v14 A1.3, A1.2 (CH1 R120 (216) (120-217), bisagra 1-15 (218-232), CH2 L1.3>A (236), L1.2>A (237), (233-342), CH3 E12 (358), M14 (360) (343-447), CHS (448-449)) (120-449)], (222-216')-disulfuro con la cadena ligera kappa *Homo sapiens* (1'-216') [V-KAPPA (*Homo sapiens* IGKV1-39*01 (97.9%) -IGKJ2*01 (100%)) CDR-IMGT [6.3.11] (27-32.50-52.89-99) (1'-109') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (155), V101 (193) (110'-216')]; dímero (228-228":231-231")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular derivada de CHO-K1SV, en ausencia del gen Glutamina Sintetasa (GS), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
EVQLVESGGG LVQPGGSLRL SCAASGFTVS SNYMSWVRQA PGKGLEWVSV  50
IYSGGSTFYA DSVKGRFTIS RDNSMNTLFL QMNSLRAEDT AVYYCARVLP 100
MYGDYLDYWG QGTLVTVSSA STKGPSVFPL APSSKSTSGG TAALGCLVKD 150
YFPEPVTVSW NSGALTSGVH TFPAVLQSSG LYSLSSVVTV PSSSLGTQTY 200
ICNVNHKPSN TKVDKRVEPK SCDKTHTCPP CPAPEAAGGP SVFLFPPKPK 250
DTLMISRTPE VTCVVVDVSH EDPEVKFNWY VDGVEVHNAK TKPREEQYNS 300
TYRVVSVLTV LHQDWLNGKE YKCKVSNKAL PAPIEKTISK AKGQPREPQV 350
YTLPPSREEM TKNQVSLTCL VKGFYPSDIA VEWESNGQPE NNYKTTPPVL 400
DSDGSFFLYS KLTVDKSRWQ QGNVFSCSVM HEALHNHYTQ KSLSLSPGK  449
```

Light chain / Chaîne légère / Cadena ligera

```
DIVMTQSPSS LSASVGDRVT ITCRASQSIS RYLNWYQQKP GKAPKLLIYA  50
ASSLQSGVPS RFSGSGSGTD FTLTISSLQP EDFATYYCQQ SYSTPPEYTF 100
GQGTKLEIKR TVAAPSVFIF PPSDEQLKSG TASVVCLLNN FYPREAKVQW 150
KVDNALQSGN SQESVTEQDS KDSTYSLSST LTLSKADYEK HKVYACEVTH 200
QGLSSPVTKS FNRGEC                                      216
```

Post-translational modifications

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

Intra-H (C23-C104) 22-95 146-202 263-323 369-427
22"-95" 146"-202" 263"-323" 369"-427"
Intra-L (C23-C104) 23'-88' 136'-196'
23'"-88'" 136'"-196'"
Inter-H-L (h 5-CL 126) 222-216' 222"-216'"
Inter-H-H (h 11, h 14) 228-228" 231-231"

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

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

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal

H CHS K2:
449, 449"

ganulameranum #

ganulameran

messenger RNA (mRNA), 5'-capped, encoding the codon-optimised receptor binding domain (RBD) of the SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2, GenBank: MN908947.3) spike (S) glycoprotein expressed as a fusion protein, 5' with an extended S glycoprotein signal peptide, and 3' with a T4 fibritin trimerization domain and the S glycoprotein transmembrane domain (TM) connected by two glycine/serine-rich (GS) linker peptides, flanked by 5' and 3' untranslated regions and a 3' poly(A) tail; contains N1-methylpseudouridine instead of uridine (*all*-U>$m^1\Psi$).

ganulaméran

ARN messager (ARNm), protégé en 5', codant pour le domaine de liaison au récepteur (RBD) de la glycoprotéine spike (S) du SARS-CoV-2 (coronavirus 2 du syndrome respiratoire aigu sévère, GenBank: MN908947.3) avec des codons optimisés, exprimés sous forme de protéine de fusion, 5' avec un peptide signal de la glycoprotéine S allongé et 3' avec un domaine de trimérisation de la fibritine de T4 et le domaine transmembranaire (TM) de la glycoprotéine S, liés au moyen de deux peptides de liaison (linker) riches en glycine / sérine (GS), flanqués de régions 5' et 3' non traduites et d'une queue poly(A); contient de la N1-méthylpseudouridine au lieu de l'uridine (*tout*-U>$m^1\Psi$).

ganulamerán

RNA mensajero (mRNA), protegido en 5', que codifica para el dominio de unión al receptor (RBD) de la glicoproteína de la espícula (S) de SRAS-CoV-2 (coronavirus 2 del síndrome respiratorio agudo severo, GenBank: MN908947.3) con codones optimizados, expresado como una proteína de fusión, en 5' con un péptido señal de glicoproteína S extendido y en 3' con un dominio fibritina de trimerización de T4 y el dominio transmembrana (TM) de la glicoproteína S, conectado mediante dos péptidos enlazadores (linker) ricos en glicina/serina (GS), flanqueado por regiones 5' y 3' no traducidas y una cola poly(A); contiene N1-metilpseudouridina en lugar de uridina (*all*-U>$m^1\Psi$).

goflikiceptum #

goflikicept

human interleukin-1 receptor accessory protein fragment (21-358, 1-338 in the current sequence) fused via peptidyl linker ^{339}GSGGG^{343} to a human immunoglobulin G1 Fc fragment (344-570, C-terminal Lys clipped) variant (S>C^{477}, T>W^{489}, K>A^{532}), covalent dimer with human interleukin-1 receptor type 1 fragment (21-333, 1-313 in the current sequence) fused via peptidyl linker ^{314}GSGG^{318} to a human immunoglobulin G1 Fc fragment (319-545, C-terminal Lys clipped) variant (Y>C^{447}, T>S^{464}, L>A^{466}, F>K^{503}, Y>V^{505}), glycosylated, produced in Chinese hamster ovary (CHO) cells;
fusion protein comprising the (1-338)-fragment of the human interleukin 1 receptor accessory protein (IL1RAP, IL-1RAcP, interleukin-1 receptor 3, IL1R3), a GSGGG linker (339-343), and the (S>C^{477}, T>W^{489}, K>A^{532}) variant of the C-terminal 227-peptide (Fc fragment) of human immunoglobulin G1 (344-570), (349-324':352-327':477-447')-trisdisulfide with a fusion protein comprising the (21-333)-fragment of the precursor of human interleukin 1 receptor type 1 (IL1R1, IL1Rα, IL1R type I, p80, CD121a) (1-313), a GSGGG linker (314-318), and the (Y>C^{447}, T>S^{464}, L>A^{466}, F>K^{503}, Y>V^{505}) variant of the C-terminal 227-peptide (Fc fragment) of human immunoglobulin G1 (319-545), produced in Chinese hamster ovary (CHO) cells, glycoform alfa

goflikicept	fragment de la protéine accessoire du récepteur de l'interleukine 1 humaine (21-358, 1-338 dans la séquence actuelle) fusionné via un peptide liant ^{339}GSGGG^{343} au fragment Fc de l'immunoglobuline humaine G1 (344-570, C-terminal attaché Lys) variant (S>C^{477}, T>W^{489}, K>A^{532}), dimère covalent avec fragment de récepteur de l'interleukine-1 humaine de type 1 (21-333, 1-313 dans la séquence actuelle) fusionné via un peptide liant ^{314}GSGG^{318} à un fragment Fc d'immunoglobuline humaine G1 (319-545, attaché au variant C-terminal Lys) (Y>C^{447}, T>S^{464}, L>A^{466}, F>K^{503}, Y>V^{505}), glycosylé, produit dans des cellules ovariennes de hamster chinois (CHO); une protéine de fusion comprenant le fragment (1-338) de la protéine accessoire du récepteur de l'interleukine 1 humaine (IL1RAP, IL-1RAcP, récepteur 3 de l'interleukine-1, IL1R3), un linker GSGGG (339-343), et le variant (S>C^{477}, T>W^{489}, K>A^{532}) du peptide C-terminal-227 (fragment Fc) de l'immunoglobuline humaine G1 (344-570), (349-324': 352-327': 477-447') -trisdisulfure avec une protéine de fusion comprenant le fragment- (21-333) du précurseur du récepteur de l'interleukine humaine de type 1 (IL1R1, IL1Rα, IL1R type I, p80, CD121a) (1-313), une liaison GSGGG (314-318) et le variant (Y>C^{447}, T>S^{464,} L>A^{466}, F>K^{503}, Y>V^{505}) du peptide C-terminal-227 (fragment Fc) de l'immunoglobuline humaine G1 (319-545), produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa
goflikicept	receptor de la interleukina-1 humana fragmento de la proteína complemento (21-358, 1-338 en la secuencia actual) fusionado a través de un enlace peptidil ^{339}GSGGG^{343} a la inmunoglobulina humana G1 Fc fragmento (344-570, fijado al C-terminal Lis) variante (S>C^{477}, T>W^{489}, K>A^{532}), dímero covalente con receptor de interleukina-1 humana fragmento tipo 1 (21-333, 1-313 en la secuencia actual) fusionado a través del enlace peptidil ^{314}GSGG^{318} a una inmunoglobulina humana G1 Fc fragmento (319-545, fijado al C-terminal Lis) variante (Y>C^{447}, T>S^{464}, L>A^{466}, F>K^{503}, Y>V^{505}), glicosilado, producido en células ováricas de hámster Chino (CHO). una proteína de fusión que comprende el fragmento-(1-338) del receptor humano de la interleukina 1 proteína accesorio (IL1RAP, IL-1RAcP, interleukina-1 receptor 3, IL1R3), un enlace GSGGG (339-343), y la variante (S>C^{477}, T>W^{489}, K>A^{532}) del termina-C péptido-227 (Fc fragmento) de la inmunoglobulina humana G1 (344-570), (349-324':352-327':477-447')-trisdisulfuro con una proteína de fusión que comprende el fragmento-(21-333) del precursor del receptor tipo 1 de la interleukina humana (IL1R1, IL1Rα, IL1R tipo I, p80, CD121a) (1-313), un enlace GSGGG (314-318), y la (Y>C^{447}, T>S^{464}, L>A^{466}, F>K^{503}, Y>V^{505}) variante del terminal-C péptido-227 (Fc fragmento) de inmunoglobulina humana G1 (319-545), producido en células ováricas de hámster Chino (CHO), glicoforma alfa

Sequence / Séquence / Secuencia

IL1RAP-GSG$_3$-Fc

```
SERCDDWGLD TMRQIQVFED EPARIKCPLF EHFLKFNYST AHSAGLTLIW   50
YWTRQDRDLE EPINFRLPEN RISKEKDVLW FRPTLLNDTG NYTCMLRNTT  100
YCSKVAFPLE VVQKDSCFNS PMKLPVHKLY IEYGIQRITC PNVDGYFPSS  150
VKPTITWYMG CYKIQNFNNV IPEGMNLSFL IALISNNGNY TCVVTYPENG  200
RTFHLTRTLT VKVVGSPKNA VPPVIHSPND HVVYEKEPGE ELLIPCTVYF  250
SFLMDSRNEV WWTIDGKKPD DITIDVTINE SISHSRTEDE TRTQILSIKK  300
VTSEDLKRSY VCHARSAKGE VAKAAKVKQK VPAPRYTVGS GGGDKTHTCP  350
PCPAPELLGG PSVFLFPPKP KDTLMISRTP EVTCVVVDVS HEDPEVKFNW  400
YVDGVEVHNA KTKPREEQYN STYRVVSVLT VLHQDWLNGK EYKCKVSNKA  450
LPAPIEKTIS KAKGQPREPQ VYTLPPCRDE LTKNQVSLWC LVKGFYPSDI  500
AVEWESNGQP ENNYKTTPPV LDSDGSFFLY SALTVDKSRW QQGNVFSCSV  550
MHEALHNHYT QKSLSLSPGK                                   570
```

IL1R1-GSG$_3$-Fc

```
DKCKEREEKI ILVSSANEID VRPCPLNPNE HKGTITWYKD DSKTPVSTEQ   50
ASRIHQHKEK LWFVPAKVED SGHYYCVVRN SSYCLRIKIS AKFVENEPNL  100
CYNAQAIFKQ KLPVAGDGGL VCPYMEFFKN ENNELPKLQW YKDCKPLLLD  150
NIHFSGVKDR LIVMNVAEKH RGNYTCHASY TYLGKQYPIT RVIEFITLEE  200
NKPTRPVIVS PANETMEVDL GSQIQLICNV TGQLSDIAYW KWNGSVIDED  250
DPVLGEDYYS VENPANKRRS TLITVLNISE IESRFYKHPF TCFAKNTHGI  300
DAAYIQLIYP VTNGSGGGDK THTCPPCPAP ELLGGPSVFL FPPKPKDTLM  350
ISRTPEVTCV VVDVSHEDPE VKFNWYVDGV EVHNAKTKPR EEQYNSTYRV  400
VSVLTVLHQD WLNGKEYKCK VSNKALPAPI EKTISKAKGQ PREPQVCTLP  450
PSRDELTKNQ VSLSCAVKGF YPSDIAVEWE SNGQPENNYK TTPPVLDSDG  500
SFKLVSKLTV DKSRWQQGNV FSCSVMHEAL HNHYTQKSLS LSPGK       545
```

Mutations / Mutations / Mutaciones

S^{477}>C, T^{489}>W, K^{532}>A
Y^{447}>C, $T^{464'}$>S, $L^{466'}$>A, $F^{503'}$>K, $Y^{505'}$>V

Post-translational modifications

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

Inter-chain: 349-324' 352-327' 477-447'

Intra-chain IL1RAP-GSG3-Fc : 4-102 27-94 117-161 140-192 246-312 384-444 490-548

Intra-chain IL1R1-GSG3-Fc : 3'-84' 24'-76' 101'-144' 122'-176' 228'-292' 359'-419' 465'-523'

Glycosylation sites / Sites de glycosylation / Posiciones de glicosilación

N37, N87, N91, N98, N176, N189, N279, N420;
N80', N173', N213', N229', N243', N277', N313', N395'

Other modifications: K570, K545' clipped

imdevimabum #

imdevimab	immunoglobulin G1-lambda, anti-[*Homo sapiens* severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike (S) protein, receptor binding domain (RBD)], *Homo sapiens* monoclonal antibody; gamma1 heavy chain *Homo sapiens* (1-450) [VH (*Homo sapiens* IGHV3-30*01 (96.9%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (217) (121-218),hinge 1-15 (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-215')-disulfide with lambda light chain *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV2-14*01 (93.9%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.10] (26-34.52-54.91-100) (1'-110') -*Homo sapiens* IGLC2*01 (100%) (111'-216')]; dimer (229-229":232-232")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa
imdévimab	immunoglobuline G1-lambda anti-[*Homo sapiens* protéine spike (S) du coronavirus 2 du syndrome respiratoire aigu sévère (SARS-CoV-2), domaine de liaison au récepteur (RBD)], anticorps monoclonal *Homo sapiens*;

chaîne lourde gamma1 *Homo sapiens* (1-450) [VH (*Homo sapiens* IGHV3-30*01 (96.9%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (217) (121-218), charnière 1-15 (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-215')-disulfure avec la chaîne légère lambda *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV2-14*01 (93.9%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.10] (26-34.52-54.91-100) (1'-110') -*Homo sapiens* IGLC2*01 (100%) (111'-216')]; dimère (229-229":232-232")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

imdevimab

inmunoglobulina G1-lambda anti-[*Homo sapiens* proteína espícula (S) del coronavirus 2 del síndrome respiratorio agudo severo (SRAS-CoV-2), dominio de unión al receptor (RBD)], anticuerpo monoclonal *Homo sapiens*;
cadena pesada gamma1 *Homo sapiens* (1-450) [VH (*Homo sapiens* IGHV3-30*01 (96.9%) -(IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) -*Homo sapiens* IGHG1*01 (100%) G1m17,1 (CH1 K120 (217) (121-218), bisagra 1-15 (219-233), CH2 (234-343), CH3 D12 (359), L14 (361) (344-448), CHS (449-450)) (121-450)], (223-215')-disulfuro con la cadena ligera lambda *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV2-14*01 (93.9%) -IGLJ3*02 (100%)) CDR-IMGT [9.3.10] (26-34.52-54.91-100) (1'-110') -*Homo sapiens* IGLC2*01 (100%) (111'-216')]; dímero (229-229":232-232")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVESGGG VVQPGRSLRL SCAASGFTFS NYAMYWVRQA PGKGLEWVAV  50
ISYDGSNKYY ADSVKGRFTI SRDNSKNTLY LQMNSLRTED TAVYYCASGS 100
DYGDYLLVYW GQGTLVTVSS ASTKGPSVFP LAPSSKSTSG GTAALGCLVK 150
DYFPEPVTVS WNSGALTSGV HTFPAVLQSS GLYSLSSVVT VPSSSLGTQT 200
YICNVNHKPS NTKVDKKVEP KSCDKTHTCP PCPAPELLGG PSVFLFPPKP 250
KDTLMISRTP EVTCVVVDVS HEDPEVKFNW YVDGVEVHNA KTKPREEQYN 300
STYRVVSVLT VLHQDWLNGK EYKCKVSNKA LPAPIEKTIS KAKGQPREPQ 350
VYTLPPSRDE LTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPV 400
LDSDGSFFLY SKLTVDKSRW QQGNVFSCSV MHEALHNHYT QKSLSLSPGK 450
```

Light chain / Chaîne légère / Cadena ligera

```
QSALTQPASV SGSPGQSITI SCTGTSSDVG GYNYVSWYQQ HPGKAPKLMI  50
YDVSKRPSGV SNRFSGSKSG NTASLTISGL QSEDEADYYC NSLTSISTWV 100
FGGGTKLTVL GQPKAAPSVT LFPPSSEELQ ANKATLVCLI SDFYPGAVTV 150
AWKADSSPVK AGVETTTPSK QSNNKYAASS YLSLTPEQWK SHRSYSCQVT 200
HEGSTVEKTV APTECS                                      216
```

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) 22'-90' 138'-197'
22'"-90'" 138'"-197'"
Inter-H-L (h 5-CL 126) 223-215' 223"-215'"
Inter-H-H (h 11, h 14) 229-229" 232-232"

N-terminal glutamine cyclization to pyroglutamyl (pE, 5-oxoprolyl)
H VH Q1:
1, 1"
L VL Q1:
1', 1'"

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 / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
450, 450"

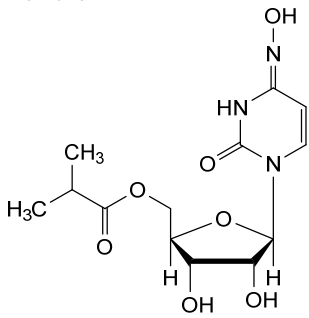
molnupiravirum

molnupiravir — N^4-hydroxycytidine 5'-(2-methylpropanoate)

molnupiravir — 5'-(2-méthylpropanoate) de N^4-hydroxycytidine

molnupiravir — 5'-(2-metilpropanoato) de N^4-hidroxicitidina

$C_{13}H_{19}N_3O_7$



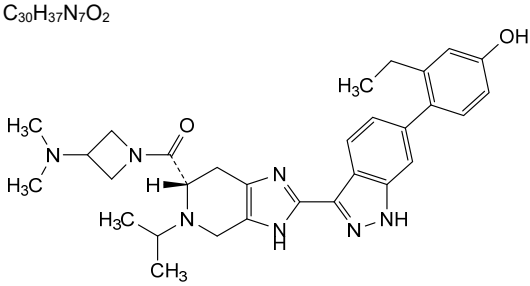
nezulcitinibum

nezulcitinib — [3-(dimethylamino)azetidin-1-yl]{(6*S*)-2-[6-(2-ethyl-4-hydroxyphenyl)-1*H*-indazol-3-yl]-5-(propan-2-yl)-4,5,6,7-tetrahydro-1*H*-imidazo[4,5-*c*]pyridin-6-yl}methanone

nézulcitinib — [3-(diméthylamino)azétidin-1-yl]{(6*S*)-2-[6-(2-éthyl-4-hydroxyphényl)-1*H*-indazol-3-yl]-5-(propan-2-yl)-4,5,6,7-tétrahydro-1*H*-imidazo[4,5-*c*]pyridin-6-yl}méthanone

nezulcitinib — [3-(dimetilamino)azetidin-1-il]{(6*S*)-2-[6-(2-etil-4-hidroxifenil)-1*H*-indazol-3-il]-5-(propan-2-il)-4,5,6,7-tetrahidro-1*H*-imidazo[4,5-*c*]piridin-6-il}metanona

$C_{30}H_{37}N_7O_2$



pemziviptadilum #

pemziviptadil — human L-methionyl vasoactive intestinal peptide (2-29) fused to 121 repeats of different elastin-derived pentapeptides (VPGVG, VPGGG, VPGAG, VPGWP) (30-634), produced in *Escherichia coli;*
fusion protein comprising L-methionyl (1)-vasoactive intestinal polypeptide (human VIP) (2-29) and an elastin-like artificial polymer (30-629) of 120 alternating pentapeptides of three types VPGVG, VPGGG, and VPGAG, and a C-terminal pentapeptide VPGWP (630-634), produced in *Escherichia coli*

pemziviptadil

L-méthionyl peptide vasoactif intestinal humain (2-29) fusionné à 121 répétitions de différents pentapeptides dérivés de l'élastine (VPGVG, VPGGG, VPGAG, VPGWP) (30-634), produits dans *Escherichia coli* ;
protéine de fusion comprenant le polypeptide intestinal vasoactif L-méthionyl (1) (VIP humain) (2-29) et un polymère artificiel de type élastine (30-629) de 120 pentapeptides alternés de trois types VPGVG, VPGGG et VPGAG, et un pentapeptide C-terminal VPGWP (630-634), produit dans *Escherichia coli*

pemziviptadil

péptido humano L-metionil vasoactivo intestinal (2-29) fusionado a 121 repeticiones de pentapéptidos derivados de elastina diferentes (VPGVG, VPGGG, VPGAG, VPGWP) (30-634), producido en *Escherichia coli;*
proteína de fusión que comprende polipéptido intestinal vasoactivo L-metionil (1) (humano VIP) (2-29) y un polímero artificial parecido a la elastina (30-629) de 120 pentapéptidos alternos de tres tipos VPGVG, VPGGG, y VPGAG, y un pentapéptido C-terminal VPGWP (630-634), producido en *Escherichia coli*

Sequence / Séquence / Secuencia

```
MHSDAVFTDN YTRLRKQMAV KKYLNSILNV PGVGVPGVGV PGGGVPGAGV   50
PGVGVPGVGV PGVGVPGGGV PGAGVPGGGV PGVGVPGVGV PGGGVPGAGV  100
PGVGVPGVGV PGVGVPGGGV PGAGVPGGGV PGVGVPGVGV PGGGVPGAGV  150
PGVGVPGVGV PGVGVPGGGV PGAGVPGGGV PGVGVPGVGV PGGGVPGAGV  200
PGVGVPGVGV PGVGVPGGGV PGAGVPGGGV PGVGVPGVGV PGGGVPGAGV  250
PGVGVPGVGV PGVGVPGGGV PGAGVPGGGV PGVGVPGVGV PGGGVPGAGV  300
PGVGVPGVGV PGVGVPGGGV PGAGVPGGGV PGVGVPGVGV PGGGVPGAGV  350
PGVGVPGVGV PGVGVPGGGV PGAGVPGGGV PGVGVPGVGV PGGGVPGAGV  400
PGVGVPGVGV PGVGVPGGGV PGAGVPGGGV PGVGVPGVGV PGGGVPGAGV  450
PGVGVPGVGV PGVGVPGGGV PGAGVPGGGV PGVGVPGVGV PGGGVPGAGV  500
PGVGVPGVGV PGVGVPGGGV PGAGVPGGGV PGVGVPGVGV PGGGVPGAGV  550
PGVGVPGVGV PGVGVPGGGV PGAGVPGGGV PGVGVPGVGV PGGGVPGAGV  600
PGVGVPGVGV PGVGVPGGGV PGAGVPGGGV PGWP                   634
```

positions 30-634: 12 × pattern AABCAAABCB of 10 pentapeptides of three types A = **VPGVG**, B = **VPGGG,** and C = **VPGAG** plus a C-terminal pentapeptide **VPGWP**

pidacmeranum #

pidacmeran

self-replicating messenger RNA (mRNA), 5'-capped, encoding *Venezuelan equine encephalitis virus* (VEEV) RNA-dependent RNA polymerase (VEEV proteins nsP1, nsP2, nsP3 and nsP4) and a full-length codon-optimised pre-fusion stabilised conformation variant (K986P and V987P) of the SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2, GenBank: MN908947.3) spike (S) glycoprotein, flanked by 5' and 3' untranslated regions and a 3' poly(A) tail; replication of the RNA is under control of a VEEV subgenomic promoter.

pidacméran

ARN messager (ARNm) auto-répliquant, protégé en 5', codant pour l'ARN polymérase ARN-dépendante du *virus de l'encéphalite équine vénézuélienne* (protéines VEEV nsP1, nsP2, nsP3 et nsP4) et une variante complète de pré-fusion de conformation stabilisée (K986P et V987P) de la glycoprotéine spike (S) du SARS-CoV-2 (coronavirus 2 du syndrome respiratoire aigu sévère, GenBank: MN908947.3) avec des codons optimisés, flanqués de régions 5 'et 3' non traduites une queue poly(A) 3'; la réplication de l'ARN est sous le contrôle du promoteur sous-génomique de VEEV.

pidacmerán	RNA mensajero auto replicativo (mRNA), protegido en 5', que codifica para la RNA polimerasa dependiente de RNA del *virus de la encefalitis equina venezolana* (proteínas VEEV nsP1, nsP2, nsP3 y nsP4) y una variante pre-fusión completa de conformación estabilizada (K986P and V987P) de la glicoproteína de la espícula (S) del SRAS-CoV-2 (coronavirus 2 del síndrome respiratorio agudo severo, GenBank: MN908947.3) con codones optimizados, flanqueada por regiones 5' y 3' no traducidas y una cola poly(A) en 3'; la replicación del ARN está bajo el control del promotor subgenómico de VEEV.
regdanvimabum #	
regdanvimab	immunoglobulin G1-lambda, anti-[*Homo sapiens* severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike (S) protein, receptor binding domain (RBD)], humanized and *Homo sapiens* monoclonal antibody; gamma1 heavy chain humanized (1-458) [VH (*Homo sapiens* IGHV2-70*12 (92.9%) -(IGHD) - IGHJ6*01 (100%)) CDR-IMGT [10.7.20] (26-35.53-59.98-117) (1-128) -*Homo sapiens* IGHG1*08p (100%) G1m3,1 (CH1 R120 (225) (129-226), hinge 1-15 (227-241), CH2 (242-351), CH3 D12 (367), L14 (369) (352-456), CHS (457-458)) (129-458)], (231-215')-disulfide with lambda light chain *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV1-51*01 (100%) - IGLJ2*01 (90.9%) K123>E (106)) CDR-IMGT [8.3.11] (26-33.51-53.90-100) (1'-110') -*Homo sapiens* IGLC2*01 (98.1%) S45>G (156), T82>K (167) (111'-216')]; dimer (237-237":240-240")-bisdisulfide, produced in a Chinese hamster ovary (CHO) cell line derived from CHO-K1, glycoform alfa
regdanvimab	immunoglobuline G1-lambda anti-[*Homo sapiens* protéine spike (S) du coronavirus 2 du syndrome respiratoire aigu sévère (SARS-CoV-2), domaine de liaison au récepteur (RBD)], anticorps monoclonal humanisé et *Homo sapiens*; chaîne lourde gamma1 humanisée (1-458) [VH (*Homo sapiens* IGHV2-70*12 (92.9%) -(IGHD) - IGHJ6*01 (100%)) CDR-IMGT [10.7.20] (26-35.53-59.98-117) (1-128) -*Homo sapiens* IGHG1*08p (100%) G1m3,1 (CH1 R120 (225) (129-226), charnière 1-15 (227-241), CH2 (242-351), CH3 D12 (367), L14 (369) (352-456), CHS (457-458)) (129-458)], (231-215')-disulfure avec la chaîne légère lambda *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV1-51*01 (100%) -IGLJ2*01 (90.9%) K123>E (106)) CDR-IMGT [8.3.11] (26-33.51-53.90-100) (1'-110') -*Homo sapiens* IGLC2*01 (98.1%) S45>G (156), T82>K (167) (111'-216')]; dimère (237-237":240-240")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) dérivant de la lignée cellulaire CHO-K1, glycoforme alfa

regdanvimab

inmunoglobulina G1-lambda anti-[*Homo sapiens* proteína espícula (S) del coronavirus 2 del síndrome respiratorio agudo severo (SRAS-CoV-2), dominio de unión al receptor (RBD)], anticuerpo monoclonal humanizado y *Homo sapiens*; cadena pesada gamma1 humanizada (1-458) [VH (*Homo sapiens* IGHV2-70*12 (92.9%) -(IGHD) -IGHJ6*01 (100%)) CDR-IMGT [10.7.20] (26-35.53-59.98-117) (1-128) -*Homo sapiens* IGHG1*08p (100%) G1m3,1 (CH1 R120 (225) (129-226), bisagra 1-15 (227-241), CH2 (242-351), CH3 D12 (367), L14 (369) (352-456), CHS (457-458)) (129-458)], (231-215')-disulfuro con la cadena ligera lambda *Homo sapiens* (1'-216') [V-LAMBDA (*Homo sapiens* IGLV1-51*01 (100%) -IGLJ2*01 (90.9%) K123>E (106)) CDR-IMGT [8.3.11] (26-33.51-53.90-100) (1'-110') -*Homo sapiens* IGLC2*01 (98.1%) S45>G (156), T82>K (167) (111'-216')]; dímero (237-237":240-240")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular derivada de CHO-K1, forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QITLKESGPT LVKPTQTLTL TCSFSGFSLS TSGVGVGWIR QPPGKALEWL  50
ALIDWDDNKY HTTSLKTRLT ISKDTSKNQV VLTMTNMDPV DTATYYCARI 100
PGFLRYRNRY YYYGMDVWGQ GTTVTVSSAS TKGPSVFPLA PSSKSTSGGT 150
AALGCLVKDY FPEPVTVSWN SGALTSGVHT FPAVLQSSGL YSLSSVVTVP 200
SSSLGTQTYI CNVNHKPSNT KVDKRVEPKS CDKTHTCPPC PAPELLGGPS 250
VFLFPPKPKD TLMISRTPEV TCVVVDVSHE DPEVKFNWYV DGVEVHNAKT 300
KPREEQYNST YRVVSVLTVL HQDWLNGKEY KCKVSNKALP APIEKTISKA 350
KGQPREPQVY TLPPSRDELT KNQVSLTCLV KGFYPSDIAV EWESNGQPEN 400
NYKTTPPVLD SDGSFFLYSK LTVDKSRWQQ GNVFSCSVMH EALHNHYTQK 450
SLSLSPGK                                               458
```

Light chain / Chaîne légère / Cadena ligera

```
ELVLTQPPSV SAAPGQKVTI SCSGSSSNIG NNYVSWYQQL PGTAPKLLIY  50
DNNKRPSGIP DRFSGSKSGT SATLGITGLQ TGDEADYYCG TWDSSLSAGV 100
FGGGTELTVL GQPKAAPSVT LFPPSSEELQ ANKATLVCLI SDFYPGAVTV 150
AWKADGSPVK AGVETTKPSK QSNNKYAASS YLSLTPEQWK SHRSYSCQVT 200
HEGSTVEKTV APTECS                                      216
```

Post-translational modifications

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

Intra-H (C23-C104) 22-97 155-211 272-332 378-436
22"-97" 155"-211" 272"-332" 378"-436"

Intra-L (C23-C104) 22'-89' 138'-197'
22'"-89'" 138'"-197'"

Inter-H-L (h 5-CL 126) 231-215' 231"-215'"

Inter-H-H (h 11, h 14) 237-237" 240-240"

N-terminal glutamine 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:
308, 308"

Fucosylated complex bi-antennary CHO-type glycans (G0F predominant) / glycanes de type CHO bi-antennaires complexes fucosylés (G0F prédominant) / glicanos de tipo CHO biantenarios complejos fucosilados (G0F predominante).

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal

H CHS K2:
458, 458"

reluscovtogenum ralaplasmidum

reluscovtogene ralaplasmid

DNA plasmid expressing a consensus sequence* of the full-length SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) spike (S) glycoprotein, with an N-terminal IgE leader sequence, under control of the human CMV promoter (hCMV promoter) and a bovine growth hormone poly-adenylation signal (bGH poly(A)). The plasmid also contains a pUC origin of replication and a kanamycin antibiotic resistance gene.
*based upon sequences published on GISAID (Global Initiative on Sharing All Influenza Data) in early 2020.

réluscovtogène ralaplasmide	plasmide d'ADN exprimant une séquence consensus* complète de la glycoprotéine spike (S) du SARS-CoV-2 (coronavirus 2 du syndrome respiratoire aigu sévère), avec une séquence leader N-terminale d'IgE, sous contrôle du promoteur du CMV humain (promoteur hCMV) et d'un signal de polyadénylation de l'hormone de croissance bovine (bGH poly(A)). Le plasmide contient également une origine de réplication pUC et un gène de résistance à la kanamycine. *basé sur des séquences publiées dans GISAID (Global Initiative on Sharing All Influenza Data) début 2020.
reluscovtogén ralaplasmida	plásmido de DNA que expresa una secuencia consenso* completa de la glicoproteína de la espícula (S) de SARS-CoV-2 (coronavirus 2 del síndrome respiratorio agudo severo), con una secuencia líder N-terminal de la IgE, bajo el control del promotor de CMV humano (promotor hCMV) y una señal de poliadenilación de la hormona de crecimiento bovina (bGH poly(A)). El plásmido contiene también un origen de replicación pUC y un gen de resistencia al antibiótico kanamicina. *basada en secuencias publicadas en GISAID (Global Initiative on Sharing All Influenza Data) a principios de 2020.

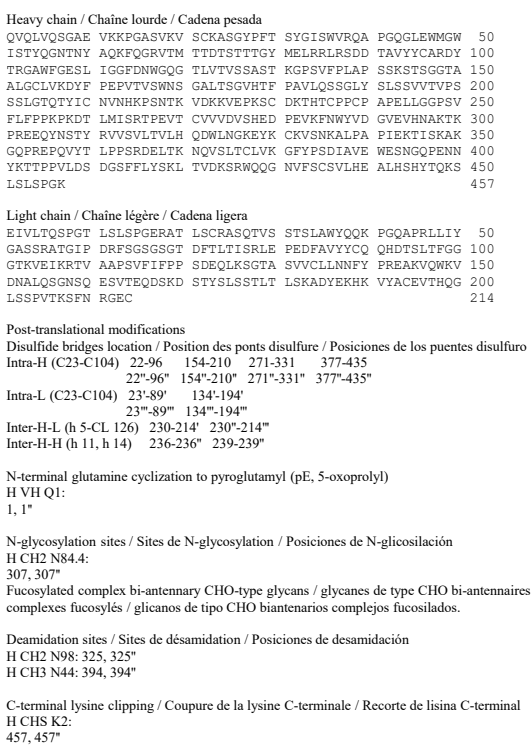
sotrovimabum #

sotrovimab	immunoglobulin G1-kappa, anti-[*Homo sapiens* severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike (S) protein, receptor binding domain (RBD)], *Homo sapiens* monoclonal antibody; gamma1 heavy chain *Homo sapiens* (1-457) [VH (*Homo sapiens* IGHV1-18*01 (92.9%) -(IGHD) -IGHJ5*01 (92.9%)) CDR-IMGT [8.8.20] (26-33.51-58.97-116) (1-127) -*Homo sapiens* IGHG1*01 G1m17,1, G1v24 CH3 L107, S114(CH1 K120 (224) (128-225), hinge 1-15 (226-240), CH2 (241-350), CH3 D12 (366), L14 (368), M107>L (438), N114>S (444) (351-455), CHS (456-457)) (128-457)], (230-214')-disulfide with kappa light chain *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (96.7%) -IGKJ4*01 (100%)) CDR-IMGT [7.3.8] (27-33.51-53.90-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (236-236":239-239")-bisdisulfide, produced in a Chinese hamster ovary (CHO)-K1 cell line, glycoform alfa
sotrovimab	immunoglobuline G1-kappa anti-[*Homo sapiens* protéine spike (S) du coronavirus 2 du syndrome respiratoire aigu sévère (SARS-CoV-2), domaine de liaison au récepteur (RBD)], anticorps monoclonal *Homo sapiens*;

chaîne lourde gamma1 *Homo sapiens* (1-457) [VH (*Homo sapiens* IGHV1-18*01 (92.9%) -(IGHD) -IGHJ5*01 (92.9%)) CDR-IMGT [8.8.20] (26-33.51-58.97-116) (1-127) -*Homo sapiens* IGHG1*01 G1m17,1, G1v24 CH3 L107, S114 (CH1 K120 (224) (128-225), charnière 1-15 (226-240), CH2 (241-350), CH3 D12 (366), L14 (368), M107>L (438), N114>S (444) (351-455), CHS (456-457)) (128-457)], (230-214')-disulfure avec la chaîne légère kappa *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (96.7%) -IGKJ4*01 (100%)) CDR-IMGT [7.3.8] (27-33.51-53.90-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (236-236":239-239")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) lignée cellulaire CHO-K1, glycoforme alfa

sotrovimab

inmunoglobulina G1-kappa anti-[*Homo sapiens* proteína espícula (S) del coronavirus 2 del síndrome respiratorio agudo severo (SRAS-CoV-2), dominio de unión al receptor (RBD)], anticuerpo monoclonal *Homo sapiens*;
cadena pesada gamma1 *Homo sapiens* (1-457) [VH (*Homo sapiens* IGHV1-18*01 (92.9%) -(IGHD) -IGHJ5*01 (92.9%)) CDR-IMGT [8.8.20] (26-33.51-58.97-116) (1-127) -*Homo sapiens* IGHG1*01 G1m17,1, G1v24 CH3 L107, S114 (CH1 K120 (224) (128-225), bisagra 1-15 (226-240), CH2 (241-350), CH3 D12 (366), L14 (368), M107>L (438), N114>S (444) (351-455), CHS (456-457)) (128-457)], (230-214')-disulfuro con la cadena ligera kappa *Homo sapiens* (1'-214') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (96.7%) -IGKJ4*01 (100%)) CDR-IMGT [7.3.8] (27-33.51-53.90-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (236-236":239-239")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular CHO-K1, forma glicosilada alfa



Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGASVKV SCKASGYPFT SYGISWVRQA PGQGLEWMGW  50
ISTYQGNTNY AQKFQGRVTM TTDTSTTTGY MELRRLRSDD TAVYYCARDY 100
TRGAWFGESL IGGFDNWGQG TLVTVSSAST KGPSVFPLAP SSKSTSGGTA 150
ALGCLVKDYF PEPVTVSWNS GALTSGVHTF PAVLQSSGLY SLSSVVTVPS 200
SSLGTQTYIC NVNHKPSNTK VDKKVEPKSC DKTHTCPPCP APELLGGPSV 250
FLFPPKPKDT LMISRTPEVT CVVVDVSHED PEVKFNWYVD GVEVHNAKTK 300
PREEQYNSTY RVVSVLTVLH QDWLNGKEYK CKVSNKALPA PIEKTISKAK 350
GQPREPQVYT LPPSRDELTK NQVSLTCLVK GFYPSDIAVE WESNGQPENN 400
YKTTPPVLDS DGSFFLYSKL TVDKSRWQQG NVFSCSVLHE ALHSHYTQKS 450
LSLSPGK                                               457
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Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPGT LSLSPGERAT LSCRASQTVS STSLAWYQQK PGQAPRLLIY  50
GASSRATGIP DRFSGSGSGT DFTLTISRLE PEDFAVYYCQ QHDTSLTFGG 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                       214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 154-210 271-331 377-435
22"-96" 154"-210" 271"-331" 377"-435"
Intra-L (C23-C104) 23'-89' 134'-194'
23'"-89'" 134'"-194'"
Inter-H-L (h 5-CL 126) 230-214' 230"-214'"
Inter-H-H (h 11, h 14) 236-236" 239-239"

N-terminal glutamine 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:
307, 307"
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 désamidation / Posiciones de desamidación
H CH2 N98: 325, 325"
H CH3 N44: 394, 394"

C-terminal lysine clipping / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
457, 457"

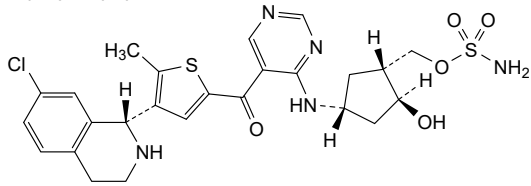
subasumstatum

subasumstat — {(1*R*,2*S*,4*R*)-4-[(5-{4-[(1*R*)-7-chloro-1,2,3,4-tetrahydroisoquinolin-1-yl]-5-methylthiophene-2-carbonyl}pyrimidin-4-yl)amino]-2-hydroxycyclopentyl}methyl sulfamate

subasumstat — sulfamate de {(1*R*,2*S*,4*R*)-4-[(5-{4-[(1*R*)-7-chloro-1,2,3,4-tétrahydroisoquinoléin-1-yl]-5-méthylthiophène-2-carbonyl}pyrimidin-4-yl)amino]-2-hydroxycyclopentyl}méthyle

subasumstat — sulfamato de {(1*R*,2*S*,4*R*)-4-[(5-{4-[(1*R*)-7-cloro-1,2,3,4-tetrahidroisoquinolein-1-il]-5-metiltiofeno-2-carbonil}pirimidin-4-il)amino]-2-hidroxiciclopentil}metilo

$C_{25}H_{28}ClN_5O_5S_2$



tixagevimabum #

tixagevimab — immunoglobulin G1-kappa, anti-[*Homo sapiens* severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike (S) protein, receptor binding domain (RBD)], *Homo sapiens* monoclonal antibody; gamma1 heavy chain *Homo sapiens* (1-453) [VH (*Homo sapiens* IGHV1-58*01 (98.0%) -(IGHD) -IGHJ3*02 (93.8%)) CDR-IMGT [8.8.16] (26-33.51-58.97-112) (1-123) -*Homo sapiens* IGHG1*03 G1m3, nG1m1, G1v21 CH2 Y15.1, T16, E18, G1v39 CH2 F1.3, E1.2, S116 (CH1 R120 (220) (124-221), hinge 1-15 (222-236), CH2 L1.3>F (240), L1.2>E (241), M15.1>Y (258), S16>T (260), T18>E (262), P116>S (337) (237-346), CH3 E12 (362), M14 (364) (347-451), CHS (452-453)) (124-453)], (226-216')-disulfide with kappa light chain *Homo sapiens* (1'-216') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (98.9%) -IGKJ1*01 (100%)) CDR-IMGT [7.3.10] (27-33.51-53.90-99) (1'-109') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (155), V101 (193) (110'-216')]; dimer (232-232":235-235")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

tixagévimab — immunoglobuline G1-kappa anti-[*Homo sapiens* protéine spike (S) du coronavirus 2 du syndrome respiratoire aigu sévère (SARS-CoV-2), domaine de liaison au récepteur (RBD)], anticorps monoclonal *Homo sapiens;*
chaîne lourde gamma1 *Homo sapiens* (1-453) [VH (*Homo sapiens* IGHV1-58*01 (98.0%) -(IGHD) -IGHJ3*02 (93.8%)) CDR-IMGT [8.8.16] (26-33.51-58.97-112) (1-123) -*Homo sapiens* IGHG1*03 G1m3, nG1m1, G1v21 CH2 Y15.1, T16, E18, G1v39 CH2 F1.3, E1.2, S116 (CH1 R120 (220) (124-221), charnière 1-15 (222-236), CH2 L1.3>F (240), L1.2>E (241), M15.1>Y (258), S16>T (260), T18>E (262), P116>S (337) (237-346), CH3 E12 (362), M14 (364) (347-451), CHS (452-453)) (124-453)], (226-216')-disulfure avec la chaîne légère kappa *Homo sapiens* (1'-216') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (98.9%) -IGKJ1*01 (100%)) CDR-IMGT [7.3.10] (27-33.51-53.90-99) (1'-109') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (155), V101 (193) (110'-216')]; dimère (232-232":235-235")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

tixagevimab

inmunoglobulina G1-kappa anti-[*Homo sapiens* proteína espícula (S) del coronavirus 2 del síndrome respiratorio agudo severo (SRAS-CoV-2), dominio de unión al receptor (RBD)], anticuerpo monoclonal *Homo sapiens*;
cadena pesada gamma1 *Homo sapiens* (1-453) [VH (*Homo sapiens* IGHV1-58*01 (98.0%) -(IGHD) -IGHJ3*02 (93.8%)) CDR-IMGT [8.8.16] (26-33.51-58.97-112) (1-123) -*Homo sapiens* IGHG1*03 G1m3, nG1m1, G1v21 CH2 Y15.1, T16, E18, G1v39 CH2 F1.3, E1.2, S116 (CH1 R120 (220) (124-221), bisagra 1-15 (222-236), CH2 L1.3>F (240), L1.2>E (241), M15.1>Y (258), S16>T (260), T18>E (262), P116>S (337) (237-346), CH3 E12 (362), M14 (364) (347-451), CHS (452-453)) (124-453)], (226-216')-disulfuro con la cadena ligera kappa *Homo sapiens* (1'-216') [V-KAPPA (*Homo sapiens* IGKV3-20*01 (98.9%) -IGKJ1*01 (100%)) CDR-IMGT [7.3.10] (27-33.51-53.90-99) (1'-109') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (155), V101 (193) (110'-216')]; dímero (232-232":235-235")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO), forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QMQLVQSGPE VKKPGTSVKV SCKASGFTFM SSAVQWVRQA RGQRLEWIGW  50
IVIGSGNTNY AQKFQERVTI TRDMSTSTAY MELSSLRSED TAVYYCAAPY 100
CSSISCNDGF DIWGQGTMVT VSSASTKGPS VFPLAPSSKS TSGGTAALGC 150
LVKDYFPEPV TVSWNSGALT SGVHTFPAVL QSSGLYSLSS VVTVPSSSLG 200
TQTYICNVNH KPSNTKVDKR VEPKSCDKTH TCPPCPAPEF EGGPSVFLFP 250
PKPKDTLYIT REPEVTCVVV DVSHEDPEVK FNWYVDGVEV HNAKTKPREE 300
QYNSTYRVVS VLTVLHQDWL NGKEYKCKVS NKALPASIEK TISKAKGQPR 350
EPQVYTLPPS REEMTKNQVS LTCLVKGFYP SDIAVEWESN GQPENNYKTT 400
PPVLDSDGSF FLYSKLTVDK SRWQQGNVFS CSVMHEALHN HYTQKSLSLS 450
PGK                                                     453
```

Light chain / Chaîne légère / Cadena ligera

```
EIVLTQSPGT LSLSPGERAT LSCRASQSVS SSYLAWYQQK PGQAPRLLIY  50
GASSRATGIP DRFSGSGSGT DFTLTISRLE PEDFAVYYCQ HYGSSRGWTF 100
GQGTKVEIKR TVAAPSVFIF PPSDEQLKSG TASVVCLLNN FYPREAKVQW 150
KVDNALQSGN SQESVTEQDS KDSTYSLSST LTLSKADYEK HKVYACEVTH 200
QGLSSPVTKS FNRGEC                                       216
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 101-106 150-206 267-327 373-431
22"-96" 101"-106" 150"-206" 267"-327" 373"-431"
Intra- H (CDR3) 101-106
101"-106"
Intra-L (C23-C104) 23'-89' 136'-196'
23'"-89'" 136'"-196'"
Inter-H-L (h 5-CL 126) 226-216' 226"-216'"
Inter-H-H (h 11, h 14) 232-232" 235-235"

N-terminal glutamine 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:
303, 303"
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 / Coupure de la lysine C-terminale / Recorte de lisina C-terminal
H CHS K2:
453, 453"

tozinameranum #

tozinameran

messenger RNA (mRNA), 5'-capped, encoding a full-length, codon-optimised pre-fusion stabilised conformation variant (K986P and V987P) of the SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2, GenBank: MN908947.3) spike (S) glycoprotein, flanked by 5' and 3' untranslated regions and a 3' poly(A) tail; contains N1-methylpseudouridine instead of uridine (*all*-U>$m^1\Psi$).

tozinaméran	ARN messager (ARNm), protégé en 5', codant pour un variant de pré-fusion stabilisé en conformation (K986P et V987P) de la glycoprotéine spike (S) du SARS-CoV-2 (coronavirus 2 du syndrome respiratoire aigu sévère, GenBank: MN908947.3) complet, avec des codons optimisés, flanqués de régions 5' et 3' non traduites et d'une queue poly(A) 3'; contient de la N1-méthylpseudouridine au lieu de l'uridine (*tout*-U>m$^1\Psi$).
tozinamerán	RNA mensajero (mRNA), protegido en 5', que codifica para una variante pre-fusión de conformación estabilizada (K986P and V987P) de la glicoproteína de la espícula (S) del SRAS-CoV-2 (coronavirus 2 del síndrome respiratorio agudo severo, GenBank: MN908947.3) completa, con codones optimizados, flanqueada por regiones 5' y 3' no traducidas y una cola poly(A) en 3'; contiene N1-metilpseudouridina en lugar de uridina (*all*-U>m$^1\Psi$).

zansecimabum #

zansecimab	immunoglobulin G4-kappa, anti-[*Homo sapiens* ANGPT2 (angiopoietin 2)], humanized monoclonal antibody; gamma4 heavy chain humanized (1-447) [VH (*Homo sapiens* IGHV1-18*01 (86.7%) -(IGHD) -IGHJ4*01 (93.3%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -*Homo sapiens* IGHG4*01, G4v5 h P10,G4v4 CH2 A1.3, A1.2 (CH1 (122-219), hinge 1-12 S10>P (229) (220-231), CH2 F1.3>A (235), L1.2>A (236) (232-341), CH3 (342-446), CHS K>del (447)) (122-447)], (135-214')-disulfide with kappa light chain humanized (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-12*01 (83.2%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (227-227":230-230")-bisdisulfide, produced in a Chinese hamster ovary (CHO) cell line derived from CHO-GSKO, glycoform alfa
zansécimab	immunoglobuline G4-kappa anti-[*Homo sapiens* ANGPT2 (angiopoietin 2)], anticorps monoclonal humanisé; chaîne lourde gamma4 humanisée (1-447) [VH (*Homo sapiens* IGHV1-18*01 (86.7%) -(IGHD) - IGHJ4*01 (93.3%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -*Homo sapiens* IGHG4*01 G4v5 h P10,G4v4 CH2 A1.3, A1.2 (CH1 (122-219), charnière 1-12 S10>P (229) (220-231), CH2 F1.3>A (235), L1.2>A (236) (232-341), CH3 (342-446), CHS K>del (447)) (122-447)], (135-214')-disulfure avec la chaîne légère kappa humanisée (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-12*01 (83.2%) - IGKJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dimère (227-227":230-230")-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO) dérivant de la lignée cellulaire CHO-GSKO, glycoforme alfa
zansecimab	inmunoglobulina G4-kappa anti-[*Homo sapiens* ANGPT2 (angiopoyetina 2)], anticuerpo monoclonal humanizado;

cadena pesada gamma4 humanizada (1-447) [VH (*Homo sapiens* IGHV1-18*01 (86.7%) -(IGHD) - IGHJ4*01 (93.3%)) CDR-IMGT [8.8.14] (26-33.51-58.97-110) (1-121) -*Homo sapiens* IGHG4*01 G4v5 h P10,G4v4 CH2 A1.3, A1.2 (CH1 (122-219), bisagra 1-12 S10>P (229) (220-231), CH2 F1.3>A (235), L1.2>A (236) (232-341), CH3 (342-446), CHS K>del (447)) (122-447)], (135-214')-disulfuro con la cadena ligera kappa humanizada (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-12*01 (83.2%) -IGKJ4*01 (100%)) CDR-IMGT [6.3.9] (27-32.50-52.89-97) (1'-107') -*Homo sapiens* IGKC*01 (100%) Km3 A45.1 (153), V101 (191) (108'-214')]; dímero (227-227":230-230")-bisdisulfuro, producido en las células ováricas de hámster chino (CHO) línea celular derivada de CHO-GSKO, forma glicosilada alfa

Heavy chain / Chaîne lourde / Cadena pesada

```
QVQLVQSGAE VKKPGASVKV SCKASGYSFT DYNMVWVRQA PGQGLEWMGY  50
IDPYNGGTGY NQKFEGRVTM TTDTSTSTAY MELRSLRSDD TAVYYCARTR 100
DRYDVWYFDV WGQGTLVTVS SASTKGPSVF PLAPCSRSTS ESTAALGCLV 150
KDYFPEPVTV SWNSGALTSG VHTFPAVLQS SGLYSLSSVV TVPSSSLGTK 200
TYTCNVDHKP SNTKVDKRVE SKYGPPCPPC PAPEAAGGPS VFLFPPKPKD 250
TLMISRTPEV TCVVVDVSQE DPEVQFNWYV DGVEVHNAKT KPREEQFNST 300
YRVVSVLTVL HQDWLNGKEY KCKVSNKGLP SSIEKTISKA KGQPREPQVY 350
TLPPSQEEMT KNQVSLTCLV KGFYPSDIAV EWESNGQPEN NYKTTPPVLD 400
SDGSFFLYSR LTVDKSRWQE GNVFSCSVMH EALHNHYTQK SLSLSLG    447
```

Light chain / Chaîne légère / Cadena ligera

```
DIQMTQSPSS VSASVGDRVT ITCKASQDVY IAVAWYQQKP GKAPKLLIYW  50
ASTRDTGVPS RFSGSGSGTD FTLTISSLQP EDFATYYCHQ YSSYPPTFGG 100
GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150
DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200
LSSPVTKSFN RGEC                                        214
```

Post-translational modifications
Disulfide bridges location / Position des ponts disulfure / Posiciones de los puentes disulfuro
Intra-H (C23-C104) 22-96 148-204 262-322 368-426
22"-96" 148"-204" 262"-322" 368"-426"
Intra-L (C23-C104) 23'-88' 134'-194'
23'"-88"' 134'"-194'"
Inter-H-L (CH1 10-CL 126) 135-214' 135"-214'"
Inter-H-H (h 8, h 11) 227-227" 230-230"

N-terminal glutamine 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 (G0F predominant) / glycanes de type CHO bi-antennaires complexes fucosylés (G0F prédominant) / glicanos de tipo CHO biantenarios complejos fucosilados (G0F predominante).

zorecimeranum #

zorecimeran — messenger RNA (mRNA), 5'-capped, encoding a full-length codon-optimised pre-fusion stabilized conformation variant (K986P and V987P) of the SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2; NC_045512.2) spike (S) glycoprotein, flanked by 5' and 3' untranslated regions; the 3' untranslated region comprises a part of the human alpha globin gene 3' UTR sequence element, a synthetic poly(A) tail and a poly(C)-rich sequence followed by a histone stem loop sequence as a 3' tail.

zoréciméran — ARN messager (ARNm), protégé en 5', codant pour un variant de pré-fusion stabilisé en conformation (K986P et V987P) de la glycoprotéine spike (S) du SARS-CoV-2 (coronavirus 2 du syndrome respiratoire aigu sévère), NC_045512.2) complet, avec des codons optimisés, flanqués de régions 5' et 3' non traduites. La région 3' non traduite comprend une partie de l'élément de séquence 3' UTR du gène de l'alpha globine humaine, une queue poly(A) synthétique et une séquence riche en poly(C) suivie d'une séquence d'histones stem-loop comme extrémité en 3'.

zorecimerán	RNA mensajero (mRNA), protegido en 5', que codifica para una variante pre-fusión de conformación estabilizada (K986P and V987P) de la glicoproteína de la espícula (S) del SRAS-Cov-2 (coronavirus 2 del síndrome respiratorio agudo severo, NC_045512.2) completa, con codones optimizados, flanqueada por regiones 5' y 3' no traducidas. La región 3' no traducida comprende una parte del elemento secuencia 3' UTR del gen de la alfa globina humana, una cola poly(A) sintética y una secuencia rica en poly(C) seguida de una secuencia de histona stem-loop cola 3'.

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

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

Recommended International Nonproprietary Names (Rec. INN): List 76
Dénominations communes internationales recommandées (DCI Rec.): Liste 76
Denominaciones Comunes Internacionales Recomendadas (DCI Rec.): Lista 76
(WHO Drug Information, Vol. 30, No. 3, 2016)

p.483 **blontuvetmabum #**

blontuvetmab *replace the description by the following one*
blontuvetmab *remplacer la description par la suivante*
blontuvetmab *sustitúyase la descripción por la siguiente*

immunoglobulin G2_V-kappa-C-lambda, anti-[***Canis lupus familiaris*** MS4A1 (membrane-spanning 4-domains subfamily A member 1, CD20)], caninized monoclonal antibody; gamma2 heavy chain chimeric (1-448) [*Mus musculus* VH (*Mus musculus* IGHV1-15*01 -(IGHD) -IGHJ1*03) [8.8.6] (1-113) -*Canis lupus familiaris* IGHG2*02 (CH1 T26>Q (131) (114-211), hinge (212-229), CH2 (230-339), CH3 (340-446), CHS (447-448)) (114-448)], (128-218')-disulfide with V-kappa-C-lambda light chain chimeric (1'-219') [*Mus musculus* V-KAPPA (*Mus musculus* IGKV8-30*01 -IGKJ5*01) [12.3.9] (1'-112') -*Canis lupus familiaris* IGL1CS1*01 V45.3>I (162) (114'-219')]; dimer (225-225'':228-228'')-bisdisulfide

immunoglobuline G2_V-kappa-C-lambda, anti-[***Canis lupus familiaris*** MS4A1 (membre 1 de la sous-famille A à 4 domaines transmembranaires, CD20)], anticorps monoclonal caninisé;
chaîne lourde gamma2 chimérique (1-448) [*Mus musculus* VH (*Mus musculus* IGHV1-15*01 -(IGHD) -IGHJ1*03) [8.8.6] (1-113) -*Canis lupus familiaris* IGHG2*02 (CH1 T26>Q (131) (114-211), charnière (212-229), CH2 (230-339), CH3 (340-446), CHS (447-448)) (114-448)], (128-218')-disulfure avec la chaîne légère V-kappa-C-lambda chimérique (1'-219') [*Mus musculus* V-KAPPA (*Mus musculus* IGKV8-30*01 -IGKJ5*01) [12.3.9] (1'-112') -*Canis lupus familiaris* IGL1CS1*01 V45.3>I (162) (114'-219')]; dimère (225-225'':228-228'')-bisdisulfure

inmunoglobulina G2_V-kappa-C-lambda, anti-[***Canis lupus familiaris*** MS4A1 (miembro 1 de la subfamilia A con 4 dominios transmembranarios, CD20)], anticuerpo monoclonal caninizado;
cadena pesada gamma2 quimérica (1-448) [*Mus musculus* VH (*Mus musculus* IGHV1-15*01 -(IGHD) -IGHJ1*03) [8.8.6] (1-113) -*Canis lupus familiaris* IGHG2*02 (CH1 T26>Q (131) (114-211), bisagra (212-229), CH2 (230-339), CH3 (340-446), CHS (447-448)) (114-448)], (128-218')-disulfuro con la cadena ligera V-kappa-C-lambda quimérica (1'-219') [*Mus musculus* V-KAPPA (*Mus musculus* IGKV8-30*01 -IGKJ5*01) [12.3.9] (1'-112') -*Canis lupus familiaris* IGL1CS1*01 V45.3>I (162) (114'-219')]; dímero (225-225'':228-228'')-bisdisulfuro

p.534 **tamtuvetmabum #**
-535 tamtuvetmab *replace the description by the following one*
tamtuvetmab *remplacer la description par la suivante*
tamtuvetmab *sustitúyase la descripción por la siguiente*

immunoglobulin G2_V-kappa-C-lambda, anti-[***Canis lupus familiaris*** CD52], caninized monoclonal antibody;
gamma2 heavy chain chimeric (1-456) [chimeric VH (*Rattus norvegicus* IGHV7S6*01 (97.00%) -(IGHD) -*Canis lupus familiaris* IGHJ-E2RCC8) [8.10.12] (1-121) -*Canis lupus familiaris* IGHG2*02 (CH1 (122-219), hinge (220-237), CH2 (238-347), CH3 (348-454), CHS (455-456))(122-456)], (136-212')-disulfide with V-kappa-C-lambda light chain chimeric (1'-213') [*Rattus norvegicus* V-KAPPA (*Rattus norvegicus* IGKV22S7 (93.70%) -IGKJ1*01) [6.3.9] (1'-107') -*Canis lupus familiaris* IGLC1S1*01 V45.3>I (156) (108'-213')]; dimer (233-233":236-236")-bisdisulfide

immunoglobuline G2_V-kappa-C-lambda, anti-[***Canis lupus familiaris*** CD52], anticorps monoclonal caninisé;
chaîne lourde gamma2 chimérique (1-456) [VH chimérique (*Rattus norvegicus* IGHV7S6*01 (97.00%) -(IGHD) -*Canis lupus familiaris* IGHJ-E2RCC8) [8.10.12] (1-121) -*Canis lupus familiaris* IGHG2*02 (CH1 (122-219), charnière (220-237), CH2 (238-347), CH3 (348-454), CHS (455-456)) (122-456)], (136-212')-disulfure avec la chaîne légère V-kappa-C-lambda chimérique (1'-213') [*Rattus norvegicus* V-KAPPA (*Rattus norvegicus* IGKV22S7 (93.70%) -IGKJ1*01) [6.3.9] (1'-107') -*Canis lupus familiaris* IGLC1S1*01 V45.3>I (156) (108'-213')]; dimère (233-233":236-236")-bisdisulfure

inmunoglobulina G2_V-kappa-C-lambda, anti-[***Canis lupus familiaris*** CD52], anticuerpo monoclonal caninizado;
cadena pesada gamma2 quimérica (1-456) [VH quimérico (*Rattus norvegicus* IGHV7S6*01 (97.00%) -(IGHD) -*Canis lupus familiaris* IGHJ-E2RCC8) [8.10.12] (1-121) -*Canis lupus familiaris* IGHG2*02 (CH1 (122-219), bisagra (220-237), CH2 (238-347), CH3 (348-454), CHS (455-456))(122-456)], (136-212')-disulfuro con la cadena ligera V-kappa-C-lambda quimérica (1'-213') [*Rattus norvegicus* V-KAPPA (*Rattus norvegicus* IGKV22S7 (93.70%) -IGKJ1*01) [6.3.9] (1'-107') -*Canis lupus familiaris* IGLC1S1*01 V45.3>I (156) (108'-213')]; dímero (233-233":236-236")-bisdisulfuro

Recommended International Nonproprietary Names (Rec. INN): List 77
Dénominations communes internationales recommandées (DCI Rec.): Liste 77
Denominaciones Comunes Internacionales Recomendadas (DCI Rec.): Lista 77
(WHO Drug Information, Vol. 31, No. 1, 2017)

p.118 **ranevetmabum #**
-119 ranevetmab *replace the description by the following one*
ranevetmab *remplacer la description par la suivante*
ranevetmab *sustitúyase la descripción por la siguiente*

immunoglobulin G1-kappa, anti-[***Canis lupus familiaris*** NGF (nerve growth factor, nerve growth factor beta polypeptide, NGFB, beta-NGF)], caninized monoclonal antibody;
gamma1 heavy chain (1-453) [caninized VH (*Rattus norvegicus* IGHV5S13*01 (71.40%) -(IGHD)-IGHJ4*01) [8.7.16] (1-122) -*Canis lupus familiaris* IGHG1*01 (CH1 (123-219), hinge (220-233), CH2 (234-343), CH3 (344-451), CHS (452-453)) (123-453)], (137-213')-disulfide with kappa light chain (1'-217') [caninized V-KAPPA (*Rattus norvegicus* IGKV12S34*01 (76.80%) -IGKJ2-3*01) [6.3.9] (1'-107') -*Canis lupus familiaris* IGKC*01 (108'-213') -4-mer (214'-217')]; dimer (224-224'':226-226'':232-232'')-trisdisulfide

immunoglobuline G2-kappa, anti-[***Canis lupus familiaris*** NGF (facteur de croissance du nerf, facteur de croissance du nerf polypeptide bêta, NGFB, bêta-NGF)], anticorps monoclonal caninisé;
chaîne lourde gamma2 (1-453) [VH caninisé (*Rattus norvegicus* IGHV5S13*01 (71.40%) -(IGHD)-IGHJ4*01) [8.7.16] (1-122) -*Canis lupus familiaris* IGHG1*01 (CH1 (123-219), charnière (220-233), CH2 (234-343), CH3 (344-451), CHS (452-453)) (123-453)], (137-213')-disulfure avec la chaîne légère kappa (1'-217') [V-KAPPA caninisé (*Rattus norvegicus* IGKV12S34*01 (76.80%) -IGKJ2-3*01) [6.3.9] (1'-107') -*Canis lupus familiaris* IGKC*01 (108'-213') -4-mer (214'-217')]; dimère (224-224'':226-226'':232-232'')-trisdisulfure

inmunoglobulina G2-kappa, anti-[***Canis lupus familiaris*** NGF (factor de crecimiento de los nervios, factor de crecimiento de nervios polipéptido beta, NGFB, beta-NGF)], anticuerpo monoclonal caninizado;
cadena pesada gamma2 (1-453) [VH caninizado (*Rattus norvegicus* IGHV5S13*01 (71.40%) -(IGHD)-IGHJ4*01) [8.7.16] (1-122) -*Canis lupus familiaris* IGHG1*01 (CH1 (123-219), bisagra (220-233), CH2 (234-343), CH3 (344-451), CHS (452-453)) (123-453)], (137-213')-disulfuro con la cadena ligera kappa (1'-217') [V-KAPPA caninizado (*Rattus norvegicus* IGKV12S34*01 (76.80%) -IGKJ2-3*01) [6.3.9] (1'-107') -*Canis lupus familiaris* IGKC*01 (108'-213') -4-mer (214'-217')]; dímero (224-224'':226-226'':232-232'')-trisdisulfuro

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.170	*suprimáse*	*insertese*
	t**o**glato de tigilanol	t**i**glato de tigilanol

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. 31, No. 1, 2017)

olenasufligenum relduparvovecum #

olenasufligene relduparvovec	*A revised sequence has been uploaded to the INN MedNet, which includes three nucleotide insertions within the CAG promoter compared to the previous version, increasing the total length of the vector to 4075bp. The table of features was revised accordingly.*
olénasufligène relduparvovec	*Une séquence révisée a été téléchargée sur MedNet DCI, et comprend trois insertions de nucléotides dans le promoteur CAG par rapport à la version précédente, augmentant la longueur totale du vecteur à 4075 pb. Le tableau des caractéristiques a été révisé en conséquence.*
olenasufligén relduparvovec	*Se cargó una secuencia revisada en MedNet DCI e incluye tres inserciones de nucleótidos dentro del promotor CAG en comparación con la versión anterior, aumentando la longitud total del vector a 4075 pb. La tabla de características se revisó en consecuencia.*

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.41 -42 **efbemalenograstimum alfa #**

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

human granulocyte colony-stimulating factor (G-CSF) fragment fused via a peptidyl linker to a human immunoglobulin G2 Fc fragment variant, dimer:
[human granulocyte colony-stimulating factor (G-CSF, pluripoietin) short **[V^{36}, S^{37}, E^{38}>del]** isoform (1-174)]-[GSG$_3$S(G$_4$S)$_2$ linker (175-190)]-[human immunoglobulin G2 Fc fragment (223 C-terminal residues) (*Homo sapiens* IGHG2*01 (natural S^{344}>A variant); hinge (191-197), CH2 (P^{297}>S) (198-306), CH3 (307-411), CHS (412-413) (191-413)] fusion protein, dimer (193-193':196-196')-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

fragment du facteur de stimulation des colonies de granulocytes humain (G-CSF) lié par un peptide à un variant du fragment Fc de l'immunoglobuline humaine G2, dimère:
[facteur humain de stimulation des colonies de granulocytes (G-CSF, pluripoïétine) **[V^{36}, S^{37}, E^{38}>del]** isoforme courte (1-174)]-[GSG$_3$S(G$_4$S)$_2$ linker (175-190)]-[fragment Fc de l'immunoglobuline humaine G2 (résidus 223 C-terminaux) (*Homo sapiens* IGHG2*01 (variant natural S^{344}>A); charnière (191-197), CH2 (P^{297}>S) (198-306), CH3 (307-411), CHS (412-413) (191-413)] protéine de fusion, dimère (193-193':196-196')-bisdisulfure, produit par des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

fragmento del factor de estimulación de las colonias de granulocitos humano (G-CSF) que se une por un péptido a una variante del fragment Fc de la inmunoglobulina humana G2, dímero:
[factor humano de estimulación de las colonias de granulocitos (G-CSF, pluripoyetina) [**V^{36}, S^{37}, E^{38}**>del] isoforma corta (1-174)]-[$GSG_3S(G_4S)_2$ conector (175-190)]-[fragmento Fc de la inmunoglobulina humana G2 (residuo 223 C-terminal) (*Homo sapiens* IGHG2*01 (variante natural S^{344}>A); bisagra (191-197), CH2 (P^{297}>S) (198-306), CH3 (307-411), CHS (412-413) (191-413)] proteína de fusión, dímero (193-193':196-196')-bisdisulfuro, producido en las células ováricas de hamsters chinos (CHO), glicoforma alfa

Sequence / Séquence / Secuencia:

```
TPLGPASSLP QSFLLKCLEQ VRKIQGDGAA LQEKLCATYK LCHPEELVLL  50
GHSLGIPWAP LSSCPSQALQ LAGCLSQLHS GLFLYQGLLQ ALEGISPELG 100
PTLDTLQLDV ADFATTIWQQ MEELGMAPAL QPTQGAMPAF ASAFQRRAGG 150
VLVASHLQSF LEVSYRVLRH LAQPGSGGGS GGGGSGGGGS VECPPCPAPP 200
VAGPSVFLFP PKPKDTLMIS RTPEVTCVVV DVSHEDPEVQ FNWYVDGVEV 250
HNAKTKPREE QFNSTFRVVS VLTVVHQDWL NGKEYKCKVS NKGLPASIEK 300
TISKTKGQPR EPQVYTLPPS REEMTKNQVS LTCLVKGFYP SDIAVEWESN 350
GQPENNYKTT PPMLDSDGSF FLYSKLTVDK SRWQQGNVFS CSVMHEALHN 400
HYTQKSLSLS PGK                                         413
```

Disulfide bridge location / Position de la pont disulfure / Posición del puente disulfuro:
intra-G-CSF: 36-42, 64-74, 36'-42', 64'-74'
intra-IgG2 Fc: 227-287, 333-391, 227'-287', 333'-391'
inter-IgG2 Fc: 193-193', 196-196'

Glycosylation sites / Sites de glycosylation / Posiciones de glicosilación
N-linked glycans: Asn263, Asn263'
O-linked glycans: Thr133, Thr133'

p.298 -299 **narsoplimabum #**

narsoplimab		*replace the description by the following one*
narsoplimab		*remplacer la description par la suivante*
narsoplimab		*sustitúyase la descripción por la siguiente*

immunoglobulin G4-lambda, anti-[*Homo sapiens* MASP2 (mannan-binding lectin serine peptidase 2, mannan-binding lectin serine protease 2, mannan-binding lectin serine protease 1 pseudogene 1, MASP1P1)], *Homo sapiens* monoclonal antibody; gamma**4** heavy chain *Homo sapiens* (1-445) [VH (*Homo sapiens* IGHV2-26*01 (94.0%) -(IGHD) -IGHJ4*01 (100%)) [10.7.10] (1-118) -*Homo sapiens* IGHG4*01 (CH1 (119-216), hinge 1-12 S10>P (226) (217-228), CH2 (229-338), CH3 (339-443), CHS (444-445)) (119-445)], (132-211')-disulfide with lambda light chain *Homo sapiens* (1'-212') [V-LAMBDA (*Homo sapiens* IGLV3-1*01 (93.5%) -IGLJ2*01 (100%)) [6.3.9] (1'-106') -*Homo sapiens* IGLC2*01 (100%) (107'-212')];
dimer (224-224":227-227")-bisdisulfide, produced in Chinese hamster ovary (CHO)-S cell line, glycoform alfa

immunoglobuline G4-lambda, anti-[*Homo sapiens* MASP2 (sérine peptidase 2 de la lectine liant le mannane, sérine protéase 2 de la lectine liant le mannane, pseudogène 1 de la protéase 1 de la lectine liant le mannane, MASP1P1)], anticorps monoclonal *Homo sapiens*;
chaîne lourde gamma**4** *Homo sapiens* (1-445) [VH (*Homo sapiens* IGHV2-26*01 (94.0%) -(IGHD) -IGHJ4*01 (100%)) [10.7.10] (1-118) -*Homo sapiens* IGHG4*01 (CH1 (119-216), charnière 1-12 S10>P (226) (217-228), CH2 (229-338), CH3 (339-443), CHS (444-445)) (119-445)], (132-211')-disulfure avec la chaîne légère lambda *Homo sapiens* (1'-212') [V-LAMBDA (*Homo sapiens* IGLV3-1*01 (93.5%) -IGLJ2*01 (100%)) [6.3.9] (1'-106') -*Homo sapiens* IGLC2*01 (100%) (107'-212')];
dimère (224-224":227-227")-bisdisulfure, produit dans des cellules ovariennes de hamsters chinois (CHO) lignée cellulaire S, glycoforme alfa

inmunoglobulina G4-lambda, anti-[*Homo sapiens* MASP2 (serina peptidasa 2 de la lectina que se une al manano, serina proteasa 2 de la lectina unida al manano, pseudogen 1 de la proteasa 1 de la lectina unida al manano, MASP1P1)], anticuerpo monoclonal *Homo sapiens*; cadena pesada gamma**4** *Homo sapiens* (1-445) [VH (*Homo sapiens* IGHV2-26*01 (94.0%) -(IGHD) -IGHJ4*01 (100%)) [10.7.10] (1-118) -*Homo sapiens* IGHG4*01 (CH1 (119-216), bisagra 1-12 S10>P (226) (217-228), CH2 (229-338), CH3 (339-443), CHS (444-445)) (119-445)], (132-211')-disulfuro con la cadena ligera lambda *Homo sapiens* (1'-212') [V-LAMBDA (*Homo sapiens* IGLV3-1*01 (93.5%) -IGLJ2*01 (100%)) [6.3.9] (1'-106') -*Homo sapiens* IGLC2*01 (100%) (107'-212')]; dímero (224-224":227-227")-bisdisulfuro, producido en las células ováricas de hamsters chinos (CHO) línea celular S, glicoforma alfa

Proposed International Nonproprietary Names (Prop. INN): List 122
Dénominations communes internationales proposées (DCI Prop.): Liste 122
Denominaciones Comunes Internacionales Propuestas (DCI Prop.): Lista 122
(WHO Drug Information, Vol. 33, No. 2, 2019)

p.831 **eflepedocokinum alfa#**
-832 eflépédocokine alfa *remplacer la description par la suivante*
eflepedocokina alfa *sustitúyase la descripción por la siguiente*

interleukine 22 humaine (IL22, cytokine Zcyto18, facteur inductible dérivé des lymphocytes T lié à IL10, IL-TIF) (1-146), fusionnée via un peptide liant $GSG_3S(G_4S)_2$ (147-162) au fragment Fc C-terminal de l'immunoglobuline G2 humaine (163-385), P^{269}>S-mutant **S**^{316}>A-variant, dimère (165-165':168-168')-bisdisulfure, produit dans des cellules ovariennes de hamster chinois (CHO), glycoforme alfa

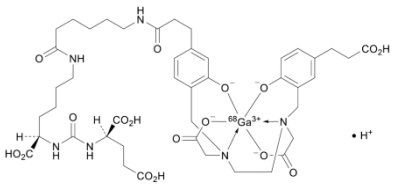
interleukina 22 humana (IL22, citoquina Zcyto18, factor inducible derivado de los linfocitos T relacionado con IL10, IL-TIF) (1-146), fusionada a través de un péptido que se une a $GSG_3S(G_4S)_2$ (147-162) con el fragmento Fc C-terminal de la inmunoglobulina G2 humana (163-385), P^{269}>S-mutante **S**^{316}>A-variante, dímero (165-165':168-168')-bisdisulfuro, producido en las células ováricas de hamster chino (CHO), glicoforma alfa

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.

<table>
<tr><td>化学名・別名</td><td>【日本名】ゴゼトチド
【英名】Gozetotide
【化学名】
日本名：{N-[(N⁶-{6-[3-(3-{[{2-[{[5-(2-カルボキシエチル)-2-ヒドロキシ-κO-フェニル]メチル}(カルボキシ-κO-メチル)アミノ-κN]エチル}(カルボキシ-κO-メチル)アミノ-κN]メチル}-4-ヒドロキシ-κO-フェニル)プロパンアミド]ヘキサノイル}-L-リシン-N²-イル)カルボニル]-L-グルタマト(3−)}
英名：{N-[(N⁶-{6-[3-(3-{[{2-[{[5-(2-Carboxyethyl)-2-hydroxy-κO-phenyl]methyl}(carboxy-κO-methyl)amino-κN]ethyl}(carboxy-κO-methyl)amino-κN]methyl}-4-hydroxy-κO-phenyl)propanamido]hexanoyl}-L-lysin-N²-yl)carbonyl]-L-glutamato(3−)}</td></tr>
<tr><td>構造式</td><td></td></tr>
<tr><td>効能・効果</td><td>PSMA 標的療法の前立腺癌患者への適応判定の補助</td></tr>
<tr><td>用法・用量</td><td>通常、成人にはガリウム（⁶⁸Ga）ゴゼトチドとして 111～259MBq を静脈内投与し、投与 50～100 分後に陽電子放出断層撮影（PET）法により撮像を開始する。</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>ロカメッツキット（1 バイアル中ゴゼトチド 25 μg）</td></tr>
<tr><td>毒性</td><td>拡張型単回投与毒性試験
被験物質：PSMA-11
<table>
<tr><th>動物種</th><th>投与経路</th><th>投与量 (mg/kg)</th><th>無毒性量 (mg/kg)</th><th>主な所見</th></tr>
<tr><td>ラット</td><td>静脈内</td><td>0, 0.67, 1.33</td><td>1.33</td><td>瀕死・死亡例なし
毒性所見なし</td></tr>
</table>
反復投与毒性試験
該当資料なし</td></tr>
<tr><td>副作用</td><td>【前立腺特異的膜抗原（PSMA）陽性の遠隔転移を有する去勢抵抗性前立腺癌対象の国内臨床試験における日本人の副作用発現率】
副作用発現率　2/35＝5.7%
副作用の種類　　件数
血小板減少症　　1 例（2.9%）
白血球減少症　　1 例（2.9%）
（承認申請時までの集計）</td></tr>
<tr><td>会社</td><td>ノバルティスファーマ株式会社　製剤：輸入</td></tr>
</table>

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2　第 4 部 9
3　第 5 部 17

1 第 3 部

添付資料番号	タイトル	試験実施期間及び試験実施場所	報種類（国内／外国）	評価／参考
3.2 データ又は報告書				
3.2.S 原薬				
3.2.S.1 一般情報				
3.2.S.1.1	5004912_SM_A_S11_[redacted]	—	外国	参考
3.2.S.1.2	5004912_SM_A_S12_[redacted]	—	外国	参考
3.2.S.1.3	5004912_SM_A_S13_[redacted]	—	外国	参考
3.2.S.2 製造				
3.2.S.2.1_1	5004912_SM_A_S21_[redacted]	—	外国	参考
3.2.S.2.1_2	5004912_SM_A_S21_[redacted]	—	外国	参考
3.2.S.2.2_1	5004912_SM_A_S22_[redacted]	—	外国	参考
3.2.S.2.2_2	5004912_AF_DS_MANU_[redacted]	—	外国	参考
3.2.S.2.3	5004912_SM_A_S23_[redacted]	—	外国	参考
3.2.S.2.4	5004912_SM_A_S24_[redacted]	—	外国	参考
3.2.S.2.5	5004912_SM_A_S25_[redacted]	—	外国	参考
3.2.S.2.6	5004912_SM_A_S26_[redacted]	—	外国	参考
3.2.S.3 特性				
3.2.S.3.1	5004912_SM_A_S31_[redacted]	—	外国	参考
3.2.S.3.2	5004912_SM_A_S32_[redacted]	—	外国	参考
3.2.S.4 原薬の管理				
3.2.S.4.1	5004912_SM_A_S41_[redacted]	—	外国	参考
3.2.S.4.2_1	5004912_SM_A_S42_[redacted]	—	外国	参考
3.2.S.4.2_2	5004912_AF_DS_SPTM_[redacted]	—	外国	参考

添付資料番号	タイトル	試験実施期間及び試験実施場所	報種類（国内／外国）	評価／参考
3.2.S.4.3	5004912_SM_A_S43_[redacted]	—	外国	参考
3.2.S.4.4	5004912_SM_A_S44_[redacted]	—	外国	参考
3.2.S.4.5	5004912_SM_A_S45_[redacted]	—	外国	参考
3.2.S.5　標準品又は標準物質				
3.2.S.5	5004912_SM_A_S5_[redacted]	—	外国	参考
3.2.S.6　容器及び施栓系				
3.2.S.6	5004912_SM_A_S6_[redacted]	—	外国	参考
3.2.S.7　安定性				
3.2.S.7.1_1	5004912_SM_A_S71_[redacted]	—	外国	参考
3.2.S.7.1_2	5004912_AF_DS_SCSL_[redacted]	—	外国	参考
3.2.S.7.2	5004912_SM_A_S72_[redacted]	—	外国	参考
3.2.S.7.3	5004912_SM_A_S73_[redacted]	—	外国	参考
3.2.P　製剤				
3.2.P.1　製剤及び処方				
3.2.P.1_1	7011242_SM_A_P1_[redacted]	—	外国	評価
3.2.P.1_2	7011242_AF_DP_COMP_[redacted]	—	外国	評価
3.2.P.2　製剤開発の経緯				
3.2.P.2.1_1	7011242_SM_A_P21_[redacted]	—	外国	評価
3.2.P.2.1_2	Components_Bauwens et al., 2010	—	外国	評価
3.2.P.2.2_1	7011242_SM_A_P22_[redacted]	—	外国	評価
3.2.P.2.3_1	7011242_SM_A_P23_[redacted]	—	外国	評価
3.2.P.2.4_1	7011242_SM_A_P24_[redacted]	—	外国	評価
3.2.P.2.4_2	[redacted]	—	外国	評価
3.2.P.2.4_3	[redacted]	—	外国	評価

添付資料番号	タイトル	試験実施期間及び試験実施場所	報種類（国内／外国）	評価／参考
3.2.P.2.5_1	7011242_SM_A_P25_[redacted]	—	外国	評価
3.2.P.2.6_1	7011242_SM_A_P26_[redacted]	—	外国	評価
3.2.P.3　製造				
3.2.P.3.1	7011242_SM_A_P31_[redacted]	—	外国	評価
3.2.P.3.2	7011242_SM_A_P32_[redacted]	—	外国	評価
3.2.P.3.3_1	7011242_SM_A_P33_[redacted]	—	外国	評価
3.2.P.3.3_2	7011242_AF_DP_MANU[redacted]	—	外国	評価
3.2.P.3.4	7011242_SM_A_P34_[redacted]	—	外国	評価
3.2.P.3.5_1	7011242_SM_A_P35_[redacted]	—	外国	評価
3.2.P.3.5_2	[redacted]	—	外国	評価
3.2.P.3.5_3	[redacted]	—	外国	評価
3.2.P.3.5_4	[redacted]	—	外国	評価
3.2.P.3.5_5	[redacted]	—	外国	評価
3.2.P.3.5_6	[redacted]	—	外国	評価
3.2.P.4　添加剤の管理				
3.2.P.4.1_1	7011242_SM_A_P41_[redacted]	—	外国	評価
3.2.P.4.1_2	7011242_SM_A_P41[redacted]	—	外国	評価
3.2.P.4.2_1	7011242_SM_A_P42_[redacted]	—	外国	評価
3.2.P.4.2_2	7011242_AF_DP_EXP_[redacted]	—	外国	評価
3.2.P.4.3_1	AP261_R_RevC	—	外国	評価
3.2.P.4.3_2	AP235_R_RevB	—	外国	評価
3.2.P.4.3_3	7011242_SM_A_P43_[redacted]	—	外国	評価
3.2.P.4.3_4	[redacted]_R448_rev_B	—	外国	評価
3.2.P.4.3_5	Method_validation_report_[redacted]_AP048_22-R_Rev-A	—	外国	評価

添付資料番号	タイトル	試験実施期間及び試験実施場所	報種類（国内／外国）	評価／参考
3.2.P.4.3_6	Method_validation_report_[redacted]_AP199	—	外国	評価
3.2.P.4.3_7	Method_validation_report_[redacted]_AP183	—	外国	評価
3.2.P.4.4_1	AAA517_[redacted]_R61019001_SAL_EN	—	外国	評価
3.2.P.4.4_2	[redacted]_R602	—	外国	評価
3.2.P.4.4_3	7011242_SM_A_P44_[redacted]	—	外国	評価
3.2.P.4.4_4	[redacted]_R44823005_for_submission	—	外国	評価
3.2.P.4.5	7011242_SM_A_P45_[redacted]	—	外国	評価
3.2.P.4.6	7011242_SM_A_P46_[redacted]	—	外国	評価
3.2.P.5　製剤の管理				
3.2.P.5.1_1	7011242_SM_A_P51_[redacted]	—	外国	評価
3.2.P.5.2_1	7011242_SM_A_P52_[redacted]	—	外国	評価
3.2.P.5.2_2	7011242_AF_DP_SPTM_[redacted]	—	外国	評価
3.2.P.5.3_1	7011242_SM_A_P53_[redacted]	—	外国	評価
3.2.P.5.3_2	Method_validation_report_[redacted]_AP311	—	外国	評価
3.2.P.5.3_3	Method_validation_report_[redacted]_AP311_addendum	—	外国	評価
3.2.P.5.3_4	Method_validation_report_[redacted]_AP048_21	—	外国	評価
3.2.P.5.3_5	Method_validation_ report_[redacted]_AP306	—	外国	評価
3.2.P.5.3_6	Method_validation_report_[redacted]_AP307	—	外国	評価
3.2.P.5.3_7	Method_validation_report_[redacted]_AP307_addendum-1	—	外国	評価
3.2.P.5.3_8	Method_validation_report_[redacted]_AP307_addendum-2	—	外国	評価
3.2.P.5.3_9	AP008_21_R_Rev C	—	外国	評価
3.2.P.5.3_10	[redacted]_final_report_AP313_revB	—	外国	評価
3.2.P.5.3_11	Method_validation_report_[redacted]_AP313_addendum	—	外国	評価
3.2.P.5.3_12	Method_validation_report_[redacted]_QP-IOPQ-134-rev-c	—	外国	評価

添付資料番号	タイトル	試験実施期間及び試験実施場所	報種類（国内／外国）	評価／参考
3.2.P.5.4_1	7011242_SM_A_P54_[redacted]	—	外国	評価
3.2.P.5.5_1	7011242_SM_A_P55_[redacted]	—	外国	評価
3.2.P.5.5_2	[redacted]_RE_AAA517_Gozetotide_PSMA-11 25 µg kit for radiopharmaceutical preparation-glass vial_v01	—	外国	評価
3.2.P.5.6_1	7011242_SM_A_P56_[redacted]	—	外国	評価
3.2.P.6　標準品又は標準物質				
3.2.P.6	7011242_SM_A_P6_[redacted]	—	外国	評価
3.2.P.7　容器及び施栓系				
3.2.P.7	[redacted] - Drug Product-7011242_SM_A_P7_[redacted]-0012429799	—	外国	評価
3.2.P.8　安定性				
3.2.P.8.1_1	7011242_SM_A_P81_[redacted]	—	外国	評価
3.2.P.8.1_2	7011242_AF_DP_SCSL_[redacted]	—	外国	評価
3.2.P.8.2	7011242_SM_A_P82_[redacted]	—	外国	評価
3.2.P.8.3_1	7011242_SM_A_P83_[redacted]	—	—	—
3.2.P.8.3_1-1	Stability data-[redacted]	—	外国	評価
3.2.P.8.3_1-2	Stability data-[redacted]	—	外国	評価
3.2.P.8.3_1-3	Stability data-[redacted]	—	外国	評価
3.2.P.8.3_1-4	Stability data-[redacted]	—	外国	評価
3.2.P.8.3_1-5	Stability data-[redacted]	—	外国	評価
3.2.P.8.3_1-6	Stability data-[redacted]	—	外国	評価
3.2.P.8.3_1-7	Stability data-[redacted]	—	外国	評価
3.2.P.8.3_1-8	Stability data-[redacted]	—	外国	評価
3.2.P.8.3_1-9	Stability data-[redacted]	—	外国	評価
3.2.P.8.3_1-10	Stability data-[redacted]	—	外国	評価

添付資料番号	タイトル	試験実施期間及び試験実施場所	報種類（国内／外国）	評価／参考
3.2.P.8.3_1-11	Stability data-[redacted]	－	外国	評価
3.2.P.8.3_1-12	Stability data-[redacted]	－	外国	評価
3.2.P.8.3_1-13	Stability data-[redacted]	－	外国	評価
3.2.P.8.3_1-14	Stability data-[redacted]	－	外国	評価
3.2.P.8.3_1-15	Stability data-[redacted]	－	外国	評価
3.2.P.8.3_2	[redacted]_VP050_21	－	外国	評価
3.2.A　その他				
－	当該資料なし	－	－	－
3.2.R　各極の要求資料				
－	当該資料なし	－	－	－
3.3　参考文献				
－	当該資料なし	－	－	－

2 第 4 部

添付資料番号	Report No./Study No.	タイトル	試験実施期間	試験実施場所	報種類（国内／外国）	評価／参考
4.2 試験報告書						
4.2.1 薬理試験						
4.2.1.1 効力を裏付ける試験						
－	－	該当資料なし	－	－	－	－
4.2.1.2 副次的薬理試験						
4.2.1.2-1	100053460-3	PSMA-11off-target receptor binding and functional profiling	20[redacted]年[redacted]月	フランス	外国	参考
4.2.1.2-2	R-0587	In Vitro Activity of PSMA-11 on 22RV1 and KB Cells	20[redacted]年[redacted]月	米国	外国	参考
4.2.1.3 安全性薬理試験						
4.2.1.3-1	20200008PEHPP	Evaluation of effects on hERG current in stably transfected HEK-293 cells	20[redacted]年[redacted]月～ 20[redacted]年[redacted]月	フランス	外国	評価
4.2.1.3-2	A3756	IRWIN DOSE RANGE STUDY FOLLOWING INTRAVENOUS ADMINISTRATION IN RATS	20[redacted]年[redacted]月～ 20[redacted]年[redacted]月	イタリア	外国	評価
4.2.1.3-3	A3757	EFFECTS ON RESPIRATORY FUNCTION OF THE CONSCIOUS RAT (WHOLE BODY PLETHYSMOGRAPHY)	20[redacted]年[redacted]月～ 20[redacted]年[redacted]月	イタリア	外国	評価
4.2.1.3-4	A3758	EFFECTS ON THE CARDIOVASCULAR FUNCTION OF THE CONSCIOUS MINIPIG FOLLOWING INTRAVENOUS ADMINISTRATION	20[redacted]年[redacted]月～ 20[redacted]年[redacted]月	イタリア	外国	評価
4.2.1.4 薬力学的薬物相互作用試験						
－	－	該当資料なし	－	－	－	－
4.2.2 薬物動態試験						
4.2.2.1 分析法及びバリデーション報告書						
4.2.2.1-1	A3753	VALIDATION OF THE ANALYTICAL METHOD FOR TEST ITEM PREPARATIONS IN THE VEHICLE	20[redacted]年[redacted]月～ 20[redacted]年[redacted]月	イタリア	外国	参考

添付資料番号	Report No./Study No.	タイトル	試験実施期間	試験実施場所	報種類（国内／外国）	評価／参考
4.2.2.1-2	A3759	VALIDATION OF THE ANALYTICAL METHOD FOR TEST ITEM PREPARATIONS IN TYRODE'S SOLUTION	20[redacted]年[redacted]月～20[redacted]年[redacted]月	イタリア	外国	参考
4.2.2.1-3	A3754	VALIDATION OF THE LC-MS/MS ANALYTICAL METHOD IN RAT PLASMA	20[redacted]年[redacted]月～20[redacted]年[redacted]月	イタリア	外国	参考
4.2.2.2　吸収						
―	―	該当資料なし	―	―	―	―
4.2.2.3　分布						
4.2.2.3-1	0596	Non-GLP PSMA-11 Protein Binding in Human, Rat, and Mini-pig Plasma	20[redacted]年[redacted]月	米国	外国	評価
4.2.2.3-2	Q19_093	Estimation of PSMA-11 molecule Blood/Plasma partitioning in human, mouse, rat, mini-pig and dog bloods.	20[redacted]年[redacted]月～20[redacted]年[redacted]月	イタリア	外国	参考
4.2.2.4　代謝						
4.2.2.4-1	0595	Non-GLP Stability of PSMA-11 in Human, Rat, and Mini-pig Plasma	20[redacted]年[redacted]月	米国	外国	参考
4.2.2.4-2	AAA-RD-Preclin-019-DMPK_R	^{Nat}Ga-PSMA-11 stability in human, mouse, rat and minipig plasma	20[redacted]年[redacted]月～20[redacted]年[redacted]月	イタリア	外国	参考
4.2.2.4-3	0592	Non-GLP Stability of PSMA-11 in Human, Rat, and Mini-Pig Liver S9 Fractions	20[redacted]年[redacted]月	米国	外国	参考
4.2.2.4-4	0593	Non-GLP Stability of PSMA-11 in Human, Rat, and Mini-Pig Kidney S9 Fractions	20[redacted]年[redacted]月	米国	外国	参考
4.2.2.5　排泄						
4.2.2.5-1	―	該当資料なし	―	―	―	―
4.2.2.6　薬物動態学的薬物相互作用（非臨床）						
4.2.2.6-1	―	該当資料なし	―	―	―	―

添付資料番号	Report No./Study No.	タイトル	試験実施期間	試験実施場所	報種類（国内／外国）	評価／参考
4.2.2.7 その他の薬物動態試験						
4.2.2.7-1	－	該当資料なし	－	－	－	－
4.2.3 毒性試験						
4.2.3.1 単回投与毒性試験						
4.2.3.1-1	A3755	SINGLE DOSE INTRAVENOUS EXTENDED TOXICITY STUDY IN RATS	20[redacted]年[redacted]月～ 20[redacted]年[redacted]月	イタリア	外国	評価
4.2.3.2 反復投与毒性試験						
－	－	該当資料なし	－	－	－	－
4.2.3.3 遺伝毒性試験						
4.2.3.3.1 In Vitro 試験						
－	－	該当資料なし	－	－	－	－
4.2.3.3.2 In Vivo 試験						
－	－	該当資料なし	－	－	－	－
4.2.3.4 がん原性試験						
4.2.3.4.1 長期がん原性試験						
－	－	該当資料なし	－	－	－	－
4.2.3.4.2 短期又は中期がん原性試験						
－	－	該当資料なし	－	－	－	－
4.2.3.4.3 その他の試験						
－	－	該当資料なし	－	－	－	－

添付資料番号	Report No./Study No.	タイトル	試験実施期間	試験実施場所	報種類（国内／外国）	評価／参考
4.2.3.5 生殖発生毒性試験						
4.2.3.5.1 受胎能及び着床までの初期胚発生に関する試験						
－	－	該当資料なし	－	－	－	－
4.2.3.5.2 胚・胎児発生に関する試験						
－	－	該当資料なし	－	－	－	－
4.2.3.5.3 出生前及び出生後の発生並びに母体の機能に関する試験						
－	－	該当資料なし	－	－	－	－
4.2.3.5.4 新生児を用いた試験						
－	－	該当資料なし	－	－	－	－
4.2.3.6 局所刺激性試験						
－	－	該当資料なし	－	－	－	－
4.2.3.7 その他の毒性試験						
4.2.3.7.1 抗原性試験						
－	－	該当資料なし	－	－	－	－
4.2.3.7.2 免疫毒性試験						
－	－	該当資料なし	－	－	－	－
4.2.3.7.3 毒性発現の機序に関する試験						
－	－	該当資料なし	－	－	－	－
4.2.3.7.4 依存性試験						
－	－	該当資料なし	－	－	－	－
4.2.3.7.5 代謝物の毒性試験						
－	－	該当資料なし	－	－	－	－
4.2.3.7.6 不純物の毒性試験						
－	－	該当資料なし	－	－	－	－

添付資料番号	Report No./Study No.	タイトル	試験実施期間	試験実施場所	報種類（国内／外国）	評価／参考
4.2.3.7.7 その他の試験						
4.2.3.7.7-1	20226364	In Silico Bacterial Mutagenicity Assessment of PSMA-11 using DEREK and SARAH	20[redacted]年[redacted]月	オランダ	外国	参考

添付資料番号	著者・タイトル・掲載誌	報種類（国内／外国）
4.3 参考文献 （評価／参考の別：参考資料）		
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添付資料番号	著者・タイトル・掲載誌	報種類（国内／外国）
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3 第 5 部

添付資料番号	Report No./Study No.	タイトル	試験実施期間	試験実施場所	報種類（国内／外国）	評価／参考	電子データの提出
5.2 全臨床試験一覧表							
5.2	－	全臨床試験一覧表	－	－	国内	評価	－
5.3 臨床試験報告書							
5.3.1 生物薬剤学試験報告書							
5.3.1.1 バイオアベイラビリティ（BA）試験報告書							
－	－	該当資料なし	－	－	－	－	－
5.3.1.2 比較 BA 試験及び生物学的同等性（BE）試験報告書							
－	－	該当資料なし	－	－	－	－	－
5.3.1.3 In Vitro-In Vivo の関連を検討した試験報告書							
－	－	該当資料なし	－	－	－	－	－
5.3.1.4 生物学的及び理化学的分析法検討報告書							
－	－	該当資料なし	－	－	－	－	－
5.3.2 ヒト生体試料を用いた薬物動態関連の試験報告書							
5.3.2.1 血漿蛋白結合試験報告書							
－	－	該当資料なし	－	－	－	－	－
5.3.2.2 肝代謝及び薬物相互作用試験報告書							
5.3.2.2-1	E0460	PSMA-11 HUMAN LIVER CYP INDUCTION STUDY	20[redacted]年[redacted]月～ 20[redacted]年[redacted]月	イタリア	外国	参考	－
5.3.2.2-2	E0461	PSMA-11 HUMAN LIVER CYP INHIBITION STUDY	20[redacted]年[redacted]月～ 20[redacted]年[redacted]月	イタリア	外国	参考	－

添付資料番号	Report No./Study No.	タイトル	試験実施期間	試験実施場所	報種類（国内／外国）	評価／参考	電子データの提出
5.3.2.2-3	AdAcAp-03-20Nov2019	*In vitro* Interaction Studies of PSMA-11 with selected human ABC (Efflux) Transporters and SLC (Uptake) Transporters	20[redacted]年[redacted]月～20[redacted]年[redacted]月	ハンガリー	外国	参考	－
5.3.2.3　他のヒト生体試料を用いた試験報告書							
－	－	該当資料なし	－	－	－	－	－
5.3.3　臨床薬物動態（PK）試験報告書							
5.3.3.1　健康被験者における PK 及び初期忍容性試験報告書							
－	－	該当資料なし	－	－	－	－	－
5.3.3.2　患者における PK 及び初期忍容性試験報告書							
－	－	該当資料なし	－	－	－	－	－
5.3.3.3　内因性要因を検討した PK 試験報告書							
－	－	該当資料なし	－	－	－	－	－
5.3.3.4　外因性要因を検討した PK 試験報告書							
－	－	該当資料なし	－	－	－	－	－
5.3.3.5　ポピュレーション PK 試験報告書							
－	－	該当資料なし	－	－	－	－	－
5.3.4　臨床薬力学（PD）試験報告書							
5.3.4.1　健康被験者における PD 試験及び PK/PD 試験報告書							
－	－	該当資料なし	－	－	－	－	－
5.3.4.2　患者における PD 試験及び PK/PD 試験報告書							
－	－	該当資料なし	－	－	－	－	－

添付資料番号	Report No./Study No.	タイトル	試験実施期間	試験実施場所	報種類（国内／外国）	評価／参考	電子データの提出
5.3.5 有効性及び安全性試験報告書							
5.3.5.1 申請する適応症に関する比較対照試験報告書							
5.3.5.1-1	VISION (CAAA617A12301)-PA 総括報告書		2018 年 5 月～2021 年 1 月	ベルギー，カナダ，デンマーク，フランス，オランダ，スウェーデン，英国，米国，ドイツ	外国	評価	あり
	VISION (CAAA617A12301)-FA 総括報告書		2018 年 5 月～2023 年 12 月	ベルギー，カナダ，デンマーク，フランス，オランダ，スウェーデン，英国，米国，ドイツ	外国	評価	－
	VISION (CAAA617A12301) Imaging Study Report: Reviewer variability					評価	あり
	VISION (CAAA617A12301) Imaging Study Report: Reviewer variability Statistical Methods					－	－
	VISION (CAAA617A12301) Imaging Study Report: Quantitative analysis					参考	－
	VISION (CAAA617A12301) Imaging Study Report: Quantitative analysis errata					－	－
	VISION (CAAA617A12301) Imaging Study Report: Quantitative analysis Statistical Methods					－	－
	VISION (CAAA617A12301) Imaging Study Report: Quantitative analysis Independent Review Charter					－	－

添付資料番号	Report No./Study No.	タイトル	試験実施期間	試験実施場所	報種類（国内／外国）	評価／参考	電子データの提出
5.3.5.1-2	PSMAfore (CAAA617B12302) 総括報告書		2021 年 6 月～2024 年 2 月（データカットオフ日） 本報告時点で継続中	オーストリア，ベルギー，カナダ，チェコ，フランス，ドイツ，オランダ，ポーランド，スロバキア，スペイン，スウェーデン，スイス，英国，米国	外国	評価	あり
	PSMAfore (CAAA617B12302) Errata						
	PSMAfore (CAAA617B12302) C1 Kidney Dosimetry Report						
5.3.5.2　非対照試験報告書							
5.3.5.2-1	CAAA617A11201 総括報告書		2022 年 1 月～2023 年 12 月（データカットオフ日） 本報告時点で継続中	日本	国内	評価	あり
5.3.5.3　複数の試験成績を併せて解析した報告書							
5.3.5.3-1	SCS Appendix 1		—	—	—	—	—
	SCS Appendix 1 Errata						
5.3.5.4　その他の臨床試験報告書							
—	該当資料なし		—	—	—	—	—
5.3.6　市販後の使用経験に関する報告書							
5.3.6-1	PSUR (23-Sep-2023 to 22-Mar-2024)		—	—	—	—	—

添付資料番号	Report No./Study No.	タイトル	試験実施期間	試験実施場所	報種類（国内／外国）	評価／参考	電子データの提出
5.3.7 患者データ一覧表及び症例記録							
－	該当資料なし		－	－	－	－	－

添付資料番号	著者・タイトル・掲載誌	報種類（国内／外国）
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