



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Immunoglobulin G1, anti-(human tumour-associated calcium signal transducer 2)(human-Mus musculus monoclonal hRS7 heavy chain), disulfide with human-Mus musculus monoclonal hRS7 κ -chain, dimer, hexakis (thioether) with (4S)-4-[[[4-[[[(2S)-2-(4-aminobutyl)-2-[[2-[2-[[26-[4-[[[4-[(3-mercapto-2,5-dioxo-1-pyrrolidinyl)methyl]cyclohexyl]carbonyl]amino]methyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoxahexacos-1-yl]amino]-2-oxoethoxy]acetyl]amino]-1-oxoethyl]amino]phenyl]methoxy]carbonyl]oxy]-4,11-diethyl-9-hydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione for the treatment of pancreatic cancer

On 15 October 2014, orphan designation (EU/3/14/1343) was granted by the European Commission to Immunomedics GmbH, Germany, for immunoglobulin G1, anti-(human tumour-associated calcium signal transducer 2)(human-Mus musculus monoclonal hRS7 heavy chain), disulfide with human-Mus musculus monoclonal hRS7 κ -chain, dimer, hexakis(thioether) with (4S)-4-[[[4-[[[(2S)-2-(4-aminobutyl)-2-[[2-[2-[[26-[4-[[[4-[(3-mercapto-2,5-dioxo-1-pyrrolidinyl)methyl]cyclohexyl]carbonyl]amino]methyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoxahexacos-1-yl]amino]-2-oxoethoxy]acetyl]amino]-1-oxoethyl]amino]phenyl]methoxy]carbonyl]oxy]-4,11-diethyl-9-hydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione for the treatment of pancreatic cancer.

What is pancreatic cancer?

Pancreatic cancer is cancer of the pancreas, a small organ that lies behind the stomach. The pancreas has two functions: to produce a juice that helps with the digestion of food, and to produce hormones such as insulin. Due to the absence of symptoms in the early stages of pancreatic cancer, the majority of patients are diagnosed when the cancer has spread locally or to other parts of the body.

Pancreatic cancer is a very severe and life-threatening disease that is associated with shortened life expectancy.



What is the estimated number of patients affected by the condition?

At the time of designation, pancreatic cancer affected approximately 0.4 in 10,000 people in the European Union (EU). This was equivalent to a total of around 21,000 people*, and is below the ceiling for orphan designation, which is 5 people in 10,000. This is based on the information provided by the sponsor and the knowledge of the Committee for Orphan Medicinal Products (COMP).

What treatments are available?

At the time of designation, several medicines were authorised in the EU for treating pancreatic cancer. The choice of treatment depended on several factors, including how far the disease had advanced. Treatments included surgery, radiotherapy (treatment with radiation) and chemotherapy (medicines to treat cancer).

The sponsor has provided sufficient information to show that this medicine might be of significant benefit for patients with pancreatic cancer because early results in patients with pancreatic cancer that had failed to respond or come back after conventional treatment showed that treatment with the medicine could prolong the time before their disease got worse. This assumption will need to be confirmed at the time of marketing authorisation, in order to maintain the orphan status.

How is this medicine expected to work?

This medicine contains a monoclonal antibody (a type of protein) that is able to recognise and attach to a target substance called Trop-2, which is found on the surface of pancreatic cancer cells. The antibody has been linked to the activated form of an existing cancer medicine called irinotecan. When the antibody attaches to Trop-2, the activated irinotecan is delivered into the cancer cells where it blocks the action of topoisomerase I, an enzyme needed for the cells to divide and grow, and so leads to their death. By specifically targeting the cancer cells, side effects on normal cells should be reduced.

What is the stage of development of this medicine?

The effects of the medicine have been evaluated in experimental models.

At the time of submission of the application for orphan designation, clinical trials with the medicine in patients with pancreatic cancer were ongoing.

At the time of submission, this medicine was not authorised anywhere in the EU for treatment of pancreatic cancer. Orphan designation of the medicine had been granted in the United States for treatment of the condition.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 4 September 2014 recommending the granting of this designation.

*Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed on the basis of data from the European Union (EU 28), Norway, Iceland and Liechtenstein. This represents a population of 511,100,000 (Eurostat 2014).

Opinions on orphan medicinal product designations are based on the following three criteria:

- the seriousness of the condition;
- the existence of alternative methods of diagnosis, prevention or treatment;
- either the rarity of the condition (affecting not more than 5 in 10,000 people in the EU) or insufficient returns on investment.

Designated orphan medicinal products are products that are still under investigation and are considered for orphan designation on the basis of potential activity. An orphan designation is not a marketing authorisation. As a consequence, demonstration of quality, safety and efficacy is necessary before a product can be granted a marketing authorisation.

For more information

Sponsor's contact details:

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For contact details of patients' organisations whose activities are targeted at rare diseases see:

- [Orphanet](#), a database containing information on rare diseases, which includes a directory of patients' organisations registered in Europe;
- [European Organisation for Rare Diseases \(EURORDIS\)](#), a non-governmental alliance of patient organisations and individuals active in the field of rare diseases.

Translations of the active ingredient and indication in all official EU languages¹, Norwegian and Icelandic

Language	Active ingredient	Indication
English	Immunoglobulin G1, anti-(human tumour-associated calcium signal transducer 2)(human-Mus musculus monoclonal hRS7 heavy chain), disulfide with human-Mus musculus monoclonal hRS7 κ -chain, dimer, hexakis(thioether) with (4S)-4-[[[[4-[[[(2S)-2-(4-aminobutyl)-2-[[2-[2-[[26-[4-[[[4-[(3-mercapto-2,5-dioxo-1-pyrrolidinyl)methyl]cyclohexyl]carbonyl]amino]methyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoxahexacos-1-yl]amino]-2-oxoethoxy]acetyl]amino]-1-oxoethyl]amino]phenyl]methoxy]carbonyl]oxy]-4,11-diethyl-9-hydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione	Treatment of pancreatic cancer
Bulgarian	Имуноглобулин G1, анти-(човешки тумор-асоцииран цалциевтрансдюсер на сигнал тип 2) (човешка-миша (Mus musculus) моноклонална тежковерижна hRS7), дисулфид с човешка-миша моноклонална hRS7 κ -верига, димер, хексакис(тиоетер) с (4S)-4-[[[[4-[[[(2S)-2-(4-аминобутил)-2-[[2-[2-[[26-[4-[[[4-[(3-меркапто-2,5-диоксо-1-пиролидинил)метил]циклохексил]карбонил]амино]метил]-1H-1,2,3-триазол-1-ил]-3,6,9,12,15,18,21,24-октаоксахексакос-1-ил]амино]-2-оксоетокси]ацетил]амино]-1-оксоетил]амино]фенил]метокси]карбонил]окси]-4,11-диетил-9-хидрокс-1H-пирано[3',4':6,7]индолизино[1,2-b]хинолин-3,14(4H,12H)-дион	Лечение на рак на панкреаса
Croatian	Imunoglobulin G1, protu-(prijenosnik 2 kalcijevih signala povezanog sa ljudskim tumorom)(ljudsko-mišji monoklonalni hRS7 teški lanac), disulfid s ljudsko-mišjim monoklonalnim hRS7 κ -lancem, dimer, heksakis(tioeter) sa (4S)-4-[[[[4-[[[(2S)-2-(4-aminobutil)-2-[[2-[2-[[26-[4-[[[4-[(3-merkapto-2,5-diokso-1-pirolidinil)metil]cikloheksil]karbonil]amino]metil]-1H-1,2,3-triazol-1-il]-3,6,9,12,15,18,21,24-oktaoksaheksakos-1-il]amino]-2-oksoetoksi]acetil]amino]-1-oksoetil]amino]fenil]metoksi]karbonil]oksi]-4,11-dietil-9-hidroksi-1H-pirano[3',4':6,7]indolizino[1,2-b]kinolin-3,14(4H,12H)-dionom	Liječenje raka gušterače

¹ At the time of designation

Language	Active ingredient	Indication
Czech	Immunoglobulin G1, anti-(human tumour-associated calcium signal transducer 2)(human-Mus musculus monoclonal hRS7 heavy chain), disulfide with human-Mus musculus monoclonal hRS7 κ -chain, dimer, hexakis(thioether) with (4S)-4-[[[4-[[[(2S)-2-(4-aminobutyl)-2-[[2-[2-[[26-[4-[[[4-[(3-mercapto-2,5-dioxo-1-pyrrolidinyl)methyl]cyclohexyl]carbonyl]amino]methyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoxahexacos-1-yl]amino]-2-oxoethoxy]acetyl]amino]-1-oxoethyl]amino]phenyl]methoxy]carbonyl]oxy]-4,11-diethyl-9-hydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione	Léčba karcinomu pankreatu
Danish	Immunoglobulin G1, (anti-(human tumor-associeret calcium signal transducer 2))(human-Mus musculus monoclonal hRS7 heavy chain), disulfide med human-Mus musculus monoclonal hRS7 κ -chain, dimer, hexakis(thioether) with (4S)-4-[[[4-[[[(2S)-2-(4-aminobutyl)-2-[[2-[2-[[26-[4-[[[4-[(3-mercapto-2,5-dioxo-1-pyrrolidinyl)methyl]cyclohexyl]carbonyl]amino]methyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoxahexacos-1-yl]amino]-2-oxoethoxy]acetyl]amino]-1-oxoethyl]amino]phenyl]methoxy]carbonyl]oxy]-4,11-diethyl-9-hydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione	Behandling af pancreascancer
Dutch	Immunoglobuline G1, anti-(humaan tumor-geassocieerd calcium signaal transducer 2)(humaan-Mus musculus monoclonaal hRS7 zware keten), disulfide met humaan-Mus musculus monoclonaal hRS7 κ -keten, dimeer, hexakis(thioether) met (4S)-4-[[[4-[[[(2S)-2-(4-aminobutyl)-2-[[2-[2-[[26-[4-[[[4-[(3-mercapto-2,5-dioxo-1-pyrrolidinyl)methyl]cyclohexyl]carbonyl]amino]methyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoxahexacos-1-yl]amino]-2-oxoethoxy]acetyl]amino]-1-oxoethyl]amino]phenyl]methoxy]carbonyl]oxy]-4,11-diethyl-9-hydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione	Behandeling van pancreaskanker

Language	Active ingredient	Indication
Estonian	Immunoglobuliin G1, anti-(inimese tuumoriga-seotud kaltsiumi signaali esilekutsuja 2)(inimese-Mus muskuluse monoklonaalne hRS7 raske ahel), disulfiid koos inimese-Mus muskuluse monoklonaalne hRS7 κ-ahel, dimeer, heksakis(thioeeter) koos (4S)-4-[[[[4-[(2S)-2-(4-aminobutüül)-2-[[2-[[26-[4-[[[4-[(3-merkpto-2,5-diokso-1-pürrolidinüül)metüül]tsükloheksüül]karbonüül]amino]metüül]-1H-1,2,3-triazool-1-üül]-3,6,9,12,15,18,21,24-oktaoksaheksakoos-1-üül]amino]-2-oksoetoksü]atsetüül]amino]-1-oksoetüül]amino]fenüül]metoksüül]karbonüül]oksü]-4,11-dietüül-9-hüdroksü-1H-pürano[3',4':6,7]indolizino[1,2-b]kinoliin-3,14(4H,12H)-dioon	Pankreasevähi ravi
Finnish	Immunoglobuliini G1, (ihmisen kasvaimen-liityvän kalsiumsignaalitransducer 2:a) vastaan(ihmis-hiiri lihas monoklonaali hRS7 raskas ketju), disulfidi ihmis-hiiri lihas monoklonaalisen hRS7 κ-ketjun kanssa, dimeeri, hexakis(tioeetteri) liitettynä (4S)-4-[[[[4-[(2S)-2-(4-aminobutyyli)-2-[[2-[[26-[4-[[[4-[(3-merkpto-2,5-diokso-1-pyrrolidinyyl)metyyl]sykloheksyyll]karbonyl]amino]metyyl]-1H-1,2,3-triatsol-1-yl]-3,6,9,12,15,18,21,24-oktaoksaheksakos-1-yl]amino]-2-oksoetooksy]asetyl]amino]-1-oksoetyl]amino]fenyl]metoksyl]karbonyl]oxy]-4,11-dietyl-9-hydroksi-1H-pyrano[3',4':6,7]indolitsino[1,2-b]kinolin-3,14(4H,12H)-dioni	Haimasyövän hoito
French	Immunoglobuline G1 anti-(tumeur humaine – associée à un transducteur 2 de signal du calcium)(chaîne lourde hRS7 monoclonale humaine de <i>Mus musculus</i>), disulfure avec une chaîne κ monoclonale humaine hRS7 de <i>Mus musculus</i> , dimère, hexakis(thioéther) avec (4S)-4-[[[[4-[(2S)-2-(4-aminobutyl)-2-[[2-[[26-[4-[[[4-[(3-mercpto-2,5-dioxo-1-pyrrolidinyl)méthyl]cyclohexyl]carbonyl]amino]méthyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaohexacos-1-yl]amino]-2-oxoéthoxy]acétyl]amino]-1-oxoéthyl]amino]phényl]méthoxy]carbonyl]oxy]-4,11-diéthyl-9-hydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinolin-3,14(4H,12H)-dione	Traitement du cancer pancréatique

Language	Active ingredient	Indication
German	Immunoglobulin G1, Anti-(human tumour-associated calcium signal transducer 2)(humaner-Mus musculus monoklonaler hRS7 heavy chain) Disulfid mit humanem-Mus musculus monoklonalem hRS7 κ-Kette, Dimer, hexakis(thioether) mit (4S)-4-[[[[4-[[[(2S)-2-(4-aminobutyl)-2-[[2-[2-[[26-[4-[[[[4-[(3-mercapto-2,5-dioxo-1-pyrrolidiny]methyl]cyclohexyl]carbonyl]amino]methyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoxahexacos-1-yl]amino]-2-oxoethoxy]acetyl]amino]-1-oxoethyl]amino]phenyl]methoxy]carbonyl]oxy]-4,11-diethyl-9-hydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione	Behandlung des Pankreaskarzinoms
Greek	Ανοσοσφαιρίνη G1, αντι (ανθρώπινο ογκο-σχετιζόμενο μετατροπέα σήματος ασβεστίου 2) (βαριά αλυσίδα ανθρωποποιημένου μονοκλωνικού hRS7), δισουλφίδιο με ανθρωποποιημένο μονοκλωνικό hRS7 (-αλυσίδα, διμερές, εξάκις (θειοαιθέρα), με (4S)-4-[[[[4-[[[(2S)-2-(4-αμινοβουτυλ)-2-[[2-[2-[[26-[4-[[[[4-[(3-μερκαπτο-2,5-διοξο-1-πυρρολιδινυλ]μεθυλ]κυκλοεξυλ]καρβονυλ]αμινο]μεθυλ]-1H-1,2,3-τριαζολ-1-yl]-3,6,9,12,15,18,21,24-οκταοξαεξακος-1-yl]αμινο]-2-οξοεθοξυ]ακετυλ]αμινο]-1-οξοεθυλ]αμινο]φενυλ]μεθοξυ]καρβονυλ]οξυ]-4,11-διεθυλ-9-υδροξυ-1H-πυρανο[3',4':6,7]ινδολιζινο[1,2-b]κινολινη-3,14(4H,12H)-διονη	Θεραπεία καρκίνου του παγκρέατος
Hungarian	Immunoglobulin G1, anti-(humán tumor-asszociált kalcium signal transducer 2)(humán-Mus musculus monoklonális hRS7 nehéz lánc), diszulfid humán-Mus musculus monoklonális hRS7 kappa-lánc dimerrel, hexakis (thioether) (4S)-4-[[[[4-[[[(2S)-2-(4-aminobutyl)-2-[[2-[2-[[26-[4-[[[[4-[(3-merkaptó-2,5-dioxo-1-pyrrolidiny]methyl]cyclohexyl]carbonyl]amino]methyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoxahexacos-1-yl]amino]-2-oxoethoxy]acetyl]amino]-1-oxoethyl]amino]phenyl]methoxy]carbonyl]oxy]-4,11-diethyl-9-hydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione	Hasnyálmirigyrák kezelése

Language	Active ingredient	Indication
Italian	Immunoglobuline G1 anti-(tumore umaio – associate a un trasduttore 2 del segnale del calcio) (catena pesante hRS7 monoclonale umana di <i>Mus musculus</i>), disulfide con una catena κ monoclonale umana hRS7 di <i>Mus musculus</i> , dimero, hexakis(thioethere) con (4S)-4-[[[[4-[(2S)-2-(4-aminobutyl)-2-[[2-[[26-[4-[[[4-[(3-mercapto-2,5-dioxo-1-pyrrolidiny]méehyl]cyclohexyl]carbonyl]amino]methyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoxahehexacos-1-yl]amino]-2-oxoethoxy]acetyl]amino]-1-oxoethyl]amino]phenyl]methoxy]carbonyl]oxy]-4,11-diethyl-9-hydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinolin-3,14(4H,12H)-dione	Trattamento del cancro del pancreas
Latvian	Immunoglobulīns G1, anti-(cilvēka audzēja-saistītais kalcija signālu pārnēsējs 2) (cilvēka- <i>Mus musculus</i> monoklonāla hRS7 smagā ķēde), ar disulfīda saiti saistīts ar cilvēka- <i>Mus musculus</i> monoklonālu hRS7 κ-ķēdi, dimērs, heksakis(tioētera) ar (4S)-4-[[[[4-[(2S)-2-(4-aminobutyl)-2-[[2-[[26-[4-[[[4-[(3-merkapto-2,5-diokso-1-pirolidinil]metil]cikloheksil]karbonil]amino]metil]-1H-1,2,3-triazol-1-il]-3,6,9,12,15,18,21,24-oktaoksaheksakos-1-il]amino]-2-oksoetoksi]acetil]amino]-1-oksoetil]amino]fenil]methoksi]karbonil]oksi]-4,11-dietil-9-hidroksi-1H-pirano[3',4':6,7]indolizino[1,2-b]kvinoīna-3,14(4H,12H)-dions	Aizkuņģa dziedzerā vēža ārstēšana
Lithuanian	Imunoglobulinas G1, anti-(kalcio signalo keitiklis 2, susijęs su žmogaus navikais)(žmogaus - pelės monokloninė hRS7 sunkioji grandinė), disulfidas su žmogaus – pelės monoklonine hRS7 κ-grandine, dimeras, heksakis (tioeteris) su (4S)-4-[[[[4-[(2S)-2-(4-aminobutyl)-2-[[2-[[26-[4-[[[4-[(3-merkapto-2,5-diokso-1-pirolidinil]metil]cikloheksil]karbonil]amino]metil]-1H-1,2,3-triazol-1-il]-3,6,9,12,15,18,21,24-oktaoksaheksakoz-1-il]amino]-2-oksoetoksi]acetil]amino]-1-oksoetil]amino]fenil]metoksi]karbonil]oksi]-4,11-dietil-9-hidroksi-1H-pirano[3',4':6,7]indolizin[1,2-b]kvinolin-3,14(4H,12H)-dionas	Kasos vėžio gydymas

Language	Active ingredient	Indication
Maltese	Immunoglobulina G1, kontra (<i>transducer 2</i> tas-sinjal tal-kalċju assoċjat ma' tumur uman)(katina tqila hRS7 monoklonali umana ta' Mus musculus), disulfide ma' katina κ monoklonali hRS7 ta' Mus musculus, dimer, hexakis(thioether) ma' (4S)-4-[[[[4-[[[(2S)-2-(4-aminobutyl)-2-[[2-[2-[[26-[4-[[[[4-[(3-mercapto-2,5-dioxo-1-pyrrolidinyl)methyl]cyclohexyl]carbonyl]amino]methyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoxahexacos-1-yl]amino]-2-oxoethoxy]acetyl]amino]-1-oxoethyl]amino]phenyl]methoxy]carbonyl]oxy]-4,11-diethyl-9-hydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione	Kura tal-kanċer tal-frixa
Polish	Immunoglobulina G1, przeciw-(ludzki związany z nowotworem zależny od wapnia transduktor sygnału 2)(łańcuch ciężki przeciwciała monoklonalego ludzki-Mus musculus hRS7), dwusiarczek z łańcuchem κ przeciwciała ludzki-Mus musculus hRS7, dimer, hekso(tioeter) z (4S)-4-[[[[4-[[[(2S)-2-(4-aminobutyl)-2-[[2-[2-[[26-[4-[[[[4-[(3-merkapto-2,5-diokso-1-pyrrolidiny]metyl]cykloheksyl]karbonyl]amino]metyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoksoheksako-1-yl]amino]-2-oksoetoksy]acetyl]amino]-1-oksoetyl]amino]fenyl]metoksy]karbonyl]oksy]-4,11-dietyl-9-hydroksy-1H-pirano[3',4':6,7]indolizyno[1,2-b]chinolino-3,14(4H,12H)-dion	Leczenie raka trzustki
Portuguese	Imunoglobulina G1, anti-(tumor humano associado ao transdutor 2 do sinal cálcico) (-cadeia pesada monoclonal hRS7 humano-Mus musculus), dissulfeto com humano-Mus musculus monoclonal hRS7 de cadeia κ, dímero, hexaquis (tioéter) com (4S)-4-[[[[4-[[[(2S)-2-(4-aminobutilo)-2-[[2-[2-[[26-[4-[[[[4-[(3-mercapto-2,5-dioxo-1-pirrolidinil)methyl]ciclohexil]carbonil]amino]methyl]-1H-1,2,3-triazol-1-il]-3,6,9,12,15,18,21,24-octaoxahexacos-1-il]amino]-2-oxoetoxi]acetil]amino]-1-oxoetil]amino]phenil]metoxi]carbonil]oxi]-4,11-dietil-9-hidroxi-1H-pirano[3',4':6,7]indolizino[1,2-b]quinolina-3,14(4H,12H)-diona	Tratamento do carcinoma do pâncreas

Language	Active ingredient	Indication
Romanian	Imunoglobulină G1, anti-(transductor uman 2 al semnalului de calciu asociat tumorilor)(lanț greu Mus musculus monoclonal hRS7 uman), disulfid cu lanț κ-chai Mus musculus monoclonal hRS7 uman, dimer, hexakis(tioeter) cu (4S)-4-[[[[4-[[[(2S)-2-(4-aminobutil)-2-[[2-[2-[[26-[4-[[[[4-[(3-mercapto-2,5-dioxo-1-pirolidinil)metil]ciclohexil]carbonil]amino]metil]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoxahexacos-1-il]amino]-2-oxoetoxi]acetil]amino]-1-oxoetil]amino]fenil]metoxi]carbonil]oxi]-4,11-dietil-9-hidroxi-1H-pirano[3',4':6,7]indolizino[1,2-b]qinolin-3,14(4H,12H)-dionă	Tratamentul cancerului pancreatic
Slovak	Imunoglobulín G1, anti-(ľudský vápnikový prenášač signálu spojený s nádorom 2)(ľudský-mus musculus monoklonálny hRS7 ťažký reťazec), disulfid s ľudským mus musculus monoklonálnym hRS7 κ-reťazcom, dimér, hexakis(tioéter) s (4S)-4-[[[[4-[[[(2S)-2-(4-aminobutil)-2-[[2-[2-[[26-[4-[[[[4-[(3-merkapto-2,5-dioxo-1-pyrolidiny]l)metyl]cyklohexyl]karbonyl]amino]metyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-oktaoxahexakos-1-yl]amino]-2-oxoetoxi]acetyl]amino]-1-oxoetyl]amino]fenyl]metoxy]karbonyl]oxy]-4,11-dietyl-9-hydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]chinolín-3,14(4H,12H)-dión	Liečba rakoviny pankreasu
Slovenian	Imunoglobulin G1, anti-(humani tumor-povezani prenašalec kalcijevih signalov 2 (humana težka monoklonsko veriga κ hRS7-Mus musculus), disulfide s humano Mus musculus monoclonsko hRS7 κ-verigo, dimer, heksakis(tioeter) s (4S)-4-[[[[4-[[[(2S)-2-(4-aminobutil)-2-[[2-[2-[[26-[4-[[[[4-[(3-merkapto-2,5-dioksoo-1-pirrolidinil)metil]cikloheksil]karbonil]amino]metil]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-oktaoksaheksakos-1-yl]amino]-2-oksoetoksi]acetil]amino]-1-oksoetil]amino]fenil]metoksi]karbonil]oksi]-4,11-dietil-9-hidroksi-1H-pirano[3',4':6,7]indolizino[1,2-b]kinolin-3,14(4H,12H)-dion	Zdravljenje raka trebušne slinavke

Language	Active ingredient	Indication
Spanish	Inmunoglobulina G1, anti-(transductor 2 de señales de calcio asociado a tumores humano)(cadena pesada del anticuerpo monoclonal humano- <i>Mus musculus</i> hRS7), union disulfuro con cadena κ del anticuerpo monoclonal humano- <i>Mus musculus</i> hRS7, dímero, hexakis(tioéter) con (4S)-4-[[[4-[[[(2S)-2-(4-aminobutil)-2-[[2-[[26-[4-[[[4-[(3-mercapto-2,5-dioxo-1-pirrolidinil)metil]ciclohexil]carbonil]amino]metil]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoxahexacos-1-il]amino]-2-oxoetoxi]acetil]amino]-1-oxoetil]amino]fenil]metoxi]carbonil]oxi]-4,11-dietil-9-hidroxi-1H-pirano[3',4':6,7]indolizino[1,2-b]quinolin-3,14(4H,12H)-diona	Tratamiento del cáncer de páncreas
Swedish	Immunglobulin G1, anti-(human tumör-associerad kalciumsignalomvandlare 2) (human- <i>Mus musculus</i> monoklonal hRS7 tung kedja), disulfid med human- <i>Mus musculus</i> monoklonal hRS7-kedja, dimer, hexakis(tioeter) med (4S)-4-[[[4-[[[(2S)-2-(4-aminobutil)-2-[[2-[[26-[4-[[[4-[(3-merkapto-2,5-dioxo-1-pyrrolidinyl)metyl]cyclohexyl]karbonyl]amino]metyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoxahexacos-1-yl]amino]-2-oxoetoxi]acetyl]amino]-1-oxoetyl]amino]fenyl]metoxy]karbonyl]oxy]-4,11-dietyl-9-hydroxi-1H-pyrano[3',4':6,7]indolizino[1,2-b]kinolin-3,14(4H,12H)-dion	Behandling av pankreascancer
Norwegian	Humanisert RS7 monoklonalt antistoff mot Trop-2 antigen konjugert via linker til (4S)-4-[[[4-[[[(2S)-2-(4-aminobutil)-2-[[2-[[26-[4-[[[4-[(3-merkapto-2,5-diokso-1-pyrrolidinyl)metyl]sykloheksyl]karbonyl]amino]metyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-oktaoksaheksakos-1-yl]amino]-2-oksoetoksy]acetyl]amino]-1-oksoetyl]amino]fenyl]metoksy]karbonyl]oksy]-4,11-dietyl-9-hydroksy-1H-pyrano[3',4':6,7]indolizino[1,2-b]kinolin-3,14(4H,12H)-dion	Behandling av pankreascancer
Icelandic	Immúnóglóbúlín G1,anti-(manna æxlis-tengd kalsíum merki transducer 2)(manna- <i>Mus musculus</i> einstofna hRS7 κ-keðju, dímer, hexakis(thíóeter) með (4S)-4-[[[4-[(3-mercaptó-2,5-díoxó-pýrrólídínýl)metýl]cýklóhexýl]karbónýl]amínó]metýl]-1H-1,2,3,tríasól-1-ýl]-3,6,9,12,15,18,21,24-oktaoxahexakos-1-ýl]amínó]-2-oxóethoxý]acetýl]amínó]-1-oxoetýl]amínó]fenýl]methoxý]karbónýl]oxý]-4,11,díetýl-9-hýdroxý-1H-pýrranól[3',4':6,7[indólízíó[1,2-b]quínólín-3,14(4H,12H)-díón	Meðferð briskrabbameins