Version 1.1, 02/2024

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Deleted: 2022

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

{(Invented) name strength pharmaceutical form}

[No ® ™ symbols included here and throughout the text; “cells” and “viral genomes” in plural.]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 General description

{X} {<(INN)><(common name)>} is a genetically modified <autologous><allogeneic> cell-based product containing T cells <transfected><transduced><edited> *ex vivo* using a <{name of editing method}><{type of vector}> expressing an anti-{A} chimeric antigen receptor (CAR) comprising a <murine><human> <anti-{A} single chain variable fragment (scFv) linked to {B} co-stimulatory domain and {C} signalling domain>.

{X} {<(INN)><(common name)>} is a genetically modified autologous $CD34^+$ cells enriched population that contains haematopoietic stem <and progenitor> cells (HS<P>C) <transduced><edited> *ex vivo* using a **<{**name of editing method}**>** <{type of vector}> expressing the {gene name} <gene>.

2.2 Qualitative and quantitative composition

Each <patient-specific> {container} of {X} contains {<(INN)><(common name)>} at a <batch-dependent> concentration of <autologous><allogeneic>T cells genetically modified to express an anti-{A} chimeric antigen receptor (CAR-positive viable T cells). The medicinal product is packaged in one or more {container(s)} overall containing a cell {<pharmaceutical form>} of {n} CAR-positive viable T cells suspended in a <cryopreservative> solution.

Each {container}contains {volume} of {pharmaceutical form}.

<The quantitative information of medicinal product, including the number of {containers} (see section 6) to be administered, is presented in the <Lot information sheet (LIS)><Release for <infusion><injection> certificate (RfIC)> < located inside the lid of the cryoshipper used for transport> <accompanying the medicinal product for treatment>>.

Each <patient-specific> {container} of {X} contains {<(INN)><(common name)>} at a <batch-dependent> concentration of genetically modified autologous $CD34^+$ cells enriched population. The medicinal product is packaged in one or more {container(s)} overall containing a {pharmaceutical form}of {n} of viable $CD34^+$ cells enriched population suspended in a <cryopreservative> solution.

Each {container} contains {volume} of {X}.

<The quantitative information of medicinal product, including the number of {containers} (see section 6) to be administered, is presented in the <Lot information sheet (LIS)><Release for <infusion><injection> certificate (RfIC)> < located inside the lid of the cryoshipper used for transport> <accompanying the medicinal product for treatment>>.

<Excipient(s) with known effect:>

<For the full list of excipients, see section 6.1.>

3. PHARMACEUTICAL FORM

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

4.2 Posology and method of administration

<{X} must be administered in a qualified treatment centre by a physician with experience in <therapeutic intervention><the <treatment><prophylaxis> of <indication>> and trained for administration and management of patients treated with the medicinal product.>

<In the event of <cytokine release syndrome (CRS)><…> <at least> one dose of <{Y}><{Z}>, and emergency equipment, must be available prior to infusion. The treatment centre must have access to additional doses of <{Y}><{Z}> within <…><8> hours.>>

Posology

<{X} is intended for autologous use (see section 4.4).>

<The dose of {X} must be determined on the patient's body weight at the time of infusion.>

Treatment consists of a <single><multiple> dose(s) for <infusion><injection> containing a {pharmaceutical form}> of CAR-positive viable T cells in <one><or more>{container(s)}.
The target dose is {total amount of cells per dose} CAR-positive viable T cells within a range of {n-m} CAR-positive viable T cells. See the accompanying <Lot information sheet (LIS)><Release for <infusion><injection> certificate (RfIC)> for additional information pertaining to dose.

Treatment consists of a <single><multiple> dose(s) for <infusion><injection> containing a {pharmaceutical form} of viable $CD34^+$ cells in <one><or more> {container(s)}.

The minimum recommended dose of {X} is {*n*} $CD34^+$ cells/kg of body weight.

See the accompanying < Lot information sheet (LIS)>< Release for <infusion><injection> certificate (RfIC)> for additional information pertaining to dose.

<Pre-treatment <(lymphodepleting chemotherapy)><(conditioning)>>

<Pre-medication>

<It is recommended that pre-medication with {Y} <and {Z}>, or equivalent medicinal products, be administered {number of minutes} before the <infusion><injection> of {X} to reduce the possibility of an infusion reaction.>

<Monitoring>

Paediatric population

Method of administration

<Before administration, it must be confirmed that the patient's identity matches the unique patient information on the {X} {container(s)} and accompanying documentation. The total number of {containers} to be administered must also be confirmed with the patient specific information on the

<Lot information sheet (LIS)><Release for <infusion><injection> certificate (RfIC)> (see section 4.4).>

For detailed instructions on preparation, administration, measures to take in case of accidental exposure and disposal of {X}, see section 6.6.

4.3 Contraindications

<Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1 <or {name of the residue(s)}>.>

4.4 Special warnings and precautions for use

Traceability

The traceability requirements of cell-based advanced therapy medicinal products must apply. To ensure traceability the name of the product, the batch number and the name of the treated patient must be kept for a period of 30 years after expiry date of the product.

<Autologous use

{X} is intended solely for autologous use and must not, under any circumstances, be administered to other patients. {X} must not be administered if the information on the product labels <and> <Lot information sheet (LIS)><Release for <infusion><injection> certificate (RfIC)> <do><does> not match the patient's identity.>

< Reasons to delay treatment>

<Transmission of an infectious agent

Although {X} is tested for sterility <and mycoplasma>, a risk of transmission of infectious agents exists. Healthcare professionals administering {X} must, therefore, monitor patients for signs and symptoms of infections after treatment and treat appropriately, if needed.>

<Interference with virological testing

Due to limited and short spans of identical genetic information between the lentiviral vector used to create {X} and HIV, some HIV nucleic acid tests (NAT) may give a false positive result.>

Blood, organ, tissue and cell donation

Patients treated with {X} must not donate blood, organs, tissues and cells for transplantation. <This information is provided in the Patient <Alert> Card which must be given to the patient after treatment.>

<Hypersensitivity reactions

Serious hypersensitivity reactions, including anaphylaxis, may be due to <cryopreservant> in {X}.>

<Long-term follow-up

Patients are expected to be enrolled in a <registry><long-term follow-up scheme> in order to better understand the long-term safety and efficacy of {X}.>

<Paediatric population>

4.5 Interaction with other medicinal products and other forms of interaction

<No interaction studies have been performed.>

<Live vaccines

The safety of immunisation with live viral vaccines during or following treatment with {X} has not been studied. As a precautionary measure, vaccination with live vaccines is not recommended <for at least 6 weeks><{specified time}> prior to the start of <conditioning regimens><lymphodepleting chemotherapy>, during {X} treatment, and until <immune>< haematological> recovery following treatment.>

<Paediatric population>

<Interaction studies have only been performed in adults.>

4.6 Fertility, pregnancy and lactation

<Women of childbearing potential / Contraception in males and females>

<Pregnancy>

<Breast-feeding>

<Fertility>

4.7 Effects on ability to drive and use machines

<{Invented) name} has <no or negligible influence><minor influence><moderate influence><major influence> on the ability to drive and use machines.>

<Not relevant.>

4.8 Undesirable effects

<Paediatric population>

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

<No data from clinical studies are available regarding overdose of {X}.>

<Paediatric population>

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: {group}, ATC code: <{code}> <not yet assigned>

<Mechanism of action>

<Pharmacodynamic effects>

<Clinical efficacy and safety>

<Paediatric population>

<The European Medicines Agency has waived the obligation to submit the results of studies with <{(Invented) name}> in all subsets of the paediatric population in {condition as per paediatric investigation plan (PIP) decision, for the granted indication} (see section 4.2 for information on paediatric use).>

<The European Medicines Agency has deferred the obligation to submit the results of studies with {(Invented) name}> in one or more subsets of the paediatric population in {condition as per paediatric investigation plan (PIP) decision, for the granted indication} (see section 4.2 for information on paediatric use).>

<This medicinal product has been authorised under a so-called 'conditional approval' scheme. This means that further evidence on this medicinal product is awaited.
The European Medicines Agency will review new information on this medicinal product at least every year and this SmPC will be updated as necessary.>

<This medicinal product has been authorised under 'exceptional circumstances'.
This means that <due to the rarity of the disease> <for scientific reasons> <for ethical reasons> it has not been possible to obtain complete information on this medicinal product.
The European Medicines Agency will review any new information which may become available every year and this SmPC will be updated as necessary.>

5.2 Pharmacokinetic properties

<Cellular kinetics>
<Biodistribution>
<Persistence>

5.3 Preclinical safety data

<Environmental risk assessment (ERA)>

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

<None.>

6.2 Incompatibilities

<Not applicable.>

<In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.>

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

6.3 Shelf life

<6 hours> <...> <6 months> <...> <1 year> <18 months> <2 years> <30 months> <3 years> <...>

<Once <thawed><reconstituted><diluted>: <1 hour><3 hours><…> at room temperature {({T range} °C).}>

6.4 Special precautions for storage

<{X} must be stored in <the vapour phase of liquid nitrogen {(≤ − {T} °C)}><…> and must remain frozen until the patient is ready for treatment to ensure viable cells are available for patient administration. Thawed medicinal product should not be refrozen.>

<For storage conditions after <thawing><reconstitution><dilution> of the medicinal product, see section 6.3.>

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

<Not all pack sizes may be marketed.>

6.6 Special precautions for disposal and other handling

Precautions to be taken before handling or administering the medicinal product

<{X} must be transported within the facility in closed, break-proof, leak-proof containers.>

This medicinal product contains human <blood> cells. Healthcare professionals handling {X} must take appropriate precautions (wearing <gloves><protective clothing><and><eye protection>) to avoid potential transmission of infectious diseases.

Preparation prior to administration

<Thawing>

Administration

Measures to take in case of accidental exposure
In case of accidental exposure local guidelines on handling of human-derived material must be followed. Work surfaces and materials which have potentially been in contact with {X} must be decontaminated with appropriate disinfectant.

Precautions to be taken for the disposal of the medicinal product
Unused medicinal product and all material that has been in contact with {X} (solid and liquid waste) must be handled and disposed of as potentially infectious waste in accordance with local guidelines on handling of human-derived material.

<Use in the paediatric population>

7. MARKETING AUTHORISATION HOLDER

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Date of first authorisation: {DD month YYYY}>
<Date of latest renewal: {DD month YYYY}>

10. DATE OF REVISION OF THE TEXT

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON <THE OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>

{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}
{active substance(s)}

2. STATEMENT OF ACTIVE SUBSTANCE(S)

This medicine contains cells of <human> <animal> origin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

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

<For autologous use only.>

8. EXPIRY DATE

9. SPECIAL STORAGE CONDITIONS

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

This medicine contains <human> <blood> cells. Unused medicine or waste material must be disposed of in compliance with the local guidelines on handling of waste of human-derived material.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

{Name and address}
<{tel}><{fax}>
<{e-mail}>

12. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

13. BATCH NUMBER, DONATION AND PRODUCT CODES

{SEC}:
<{First name}:>
<{Last name}:>
<{Patient DOB}:>
<{Patient ID}:>
<{Aph ID/DIN}:>
<{COI ID}:>
<{Bag ID}:>
<{Order ID}:>

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 BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}
{active substance(s)}

2. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name}

3. EXPIRY DATE

4. BATCH NUMBER, DONATION AND PRODUCT CODES

{SEC}:
<{First name}:>
<{Last name}:>
<{Patient DOB}:>
<{Patient ID}:>
<{Aph ID/DIN}:>
<{COI ID}:>
<{Bag ID}:>
<{Order ID}:>

5. OTHER

<For autologous use only.>

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

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

{(Invented) name strength pharmaceutical form}
{active substance(s)}
{Route of administration}

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

4. BATCH NUMBER, DONATION AND PRODUCT CODES

{SEC}:
<{First name}:>
<{Last name}:>
<{Patient DOB}:>
<{Patient ID}:>
<{Aph ID/DIN}:>
<{COI ID}:>
<{Bag ID}:>
<{Order ID}:>

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

6. OTHER

<For autologous use only.>

PARTICULARS TO APPEAR ON THE <LOT INFORMATION SHEET (LIS)><RELEASE FOR <INFUSION><INJECTION> CERTIFICATE (RfIC)> INCLUDED WITH EACH SHIPMENT FOR ONE PATIENT

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}

2. STATEMENT OF ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT, AND DOSE OF THE MEDICINAL PRODUCT

4. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

5. OTHER SPECIAL WARNING(S), IF NECESSARY

Save this document and have it available when preparing for administration of {X}.

<For autologous use only.>

6. SPECIAL STORAGE CONDITIONS

7. EXPIRY DATE AND OTHER BATCH SPECIFIC INFORMATION

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

This medicine contains <human> <blood> cells. Unused medicine or waste material must be disposed of in compliance with the local guidelines on handling of waste of human-derived material.

9. BATCH NUMBER, DONATION AND PRODUCT CODES

{SEC}:
<{First name}:>
<{Last name}:>
<{Patient DOB}:>
<{Patient ID}:>
<{Aph ID/DIN}:>
<{COI ID}:>
<{Bag ID}:>
<{Order ID}:>

10. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

11. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

B. PACKAGE LEAFLET

Package leaflet: Information for the <patient> <user>

{(Invented) name strength pharmaceutical form}
{active substance(s)}

< ▼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 start <taking> <using> 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 <doctor> <,> <or> <pharmacist> <or nurse>.
- <Your doctor will give you a Patient <Alert> Card. Read it carefully and follow the instructions on it.>
- Always show the Patient <Alert> Card to the doctor or nurse when you see them or if you go to hospital.>
- If you get any side effects, talk to your <doctor> <,> <or> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. See section 4.>

What is in this leaflet

1. What X is and what it is used for

2. What you need to know before you <receive> <are given> X

You must not <receive><be given> X

<if you are allergic to {active substance(s)} or any of the other ingredients of this medicine (listed in section 6).>

Warnings and precautions

Talk to your doctor <or> <,> <pharmacist> <or nurse> before you <receive><are given>X

Children <and adolescents>

Other medicines and X

<Tell your <doctor> <or> <pharmacist> if you are <taking> <using>, have recently <taken> <used> or might <take> <use> any other medicines.>

X with <food> <and> <,> <drink> <and> <alcohol>

Pregnancy <and> <,> breast-feeding <and fertility>

<If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your <doctor> <or> <pharmacist> for advice before receivingthis medicine.>

Driving and using machines

<X contains {name the excipient(s)}>

3. How X is given

<Use in children <and adolescents>>

When	What <happens><is done>	Why
At least <…><3 weeks><…><2 months> before X infusion		
At least <…><3 weeks><…><2 months> before X infusion		
<About><At least><…><3 days><4 days><…> before treatment		
Start of X treatment		
After X treatment		

< Other medicines you will be given before X>

<How X is given>

<After X is given>

<If you <are given> more X than you should>

<If you miss an appointment>

< Call your doctor or the treatment centre as soon as possible to make another appointment.>

<If you have any further questions on the use of this medicine, ask your <doctor> <,> <or> <pharmacist> <or nurse>.>

4. Possible side effects

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

<Additional side effects in children <and adolescents>>

Reporting of side effects

If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. 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 to store X

<The following information is intended for doctors only.>

Do not use this medicine after the expiry date which is stated on the <label> <carton> <bottle> <…> <after {abbreviation used for expiry date}.>

<Do not use this medicine if you notice {description of the visible signs of deterioration}.>

6. Contents of the pack and other information

What X contains

- The active substance(s) is (are)…
- The other <ingredient(s)> <(excipient(s))> is (are)...

This medicine contains genetically modified human <blood> cells.

What X looks like and contents of the pack

Marketing Authorisation Holder and Manufacturer

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

<For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien
{Nom/Naam/Name}
<{Adresse/Adres/Anschrift }
B-0000 {Localité/Stad/Stadt}>
Tél/Tel: +{N° de téléphone/Telefoonnummer/ Telefonnummer}
<{e-mail}>

Lietuva
{pavadinimas}
<{adresas}
LT {pašto indeksas} {miestas}>
Tel: + {telefono numeris}
<{e-mail}>

България
{Име}
<{Адрес}
{Град} {Пощенски код}>
Тел.: +{Телефонен номер}
<{e-mail}>

Luxembourg/Luxemburg
{Nom}
<{Adresse}
L-0000 {Localité/Stadt}>
Tél/Tel: +{N° de téléphone/Telefonnummer}
<{e-mail}>

Česká republika
{Název}
<{Adresa}
CZ {město}>
Tel: +{telefonní číslo}
<{e-mail}>

Magyarország
{Név}
<{Cím}
H-0000 {Város}>
Tel.: +{Telefonszám}
<{e-mail}>

Danmark
{Navn}
<{Adresse}
DK-0000 {by}>

Malta
{Isem}
<{Indirizz}
MT-0000 {Belt/Raħal}>

Tlf.: +{Telefonnummer}
<{e-mail}>

Deutschland
{Name}
<{Anschrift}
D-00000 {Stadt}>
Tel: +{Telefonnummer}
<{e-mail}>

Eesti
{Nimi}
<{Aadress}
EE - {Postiindeks} {Linn}>
Tel: +{Telefoninumber}
<{e-mail}>

Ελλάδα
{Όνομα}
<{Διεύθυνση}
GR-000 00 {πόλη}>
Τηλ: +{Αριθμός τηλεφώνου}
<{e-mail}>

España
{Nombre}
<{Dirección}
E-00000 {Ciudad}>
Tel: +{Teléfono}
<{e-mail}>

France
{Nom}
<{Adresse}
F-00000 {Localité}>
Tél: +{Numéro de téléphone}
<{e-mail}>

Hrvatska
{Ime}
<{Adresa}
{Poštanski broj} {grad}>
Tel: +{Telefonski broj}
<{e-mail}>

Ireland
{Name}
<{Address}
IRL - {Town} {Code for Dublin}>
Tel: +{Telephone number}
<{e-mail}>

Ísland
{Nafn}
<{Heimilisfang}
IS-000 {Borg/Bær}>
Sími: +{Símanúmer}

Tel: +{Numru tat-telefon}
<{e-mail}>

Nederland
{Naam}
<{Adres}
NL-0000 XX {stad}>
Tel: +{Telefoonnummer}
<{e-mail}>

Norge
{Navn}
<{Adresse}
N-0000 {poststed}>
Tlf: +{Telefonnummer}
<{e-mail}>

Österreich
{Name}
<{Anschrift}
A-0000 {Stadt}>
Tel: +{Telefonnummer}
<{e-mail}>

Polska
{Nazwa/ Nazwisko}
<{Adres:
PL-00 000{Miasto}>
Tel.: +{Numer telefonu}
<{e-mail}>

Portugal
{Nome}
<{Morada}
P-0000–000 {Cidade}>
Tel: +{Número de telefone}
<{e-mail}>

România
{Nume}
<{Adresă}
{Oraş} {Cod poştal} – RO>
Tel: +{Număr de telefon}
<{e-mail}>

Slovenija
{Ime}
<{Naslov}
SI-0000 {Mesto}>
Tel: +{telefonska številka}
<{e-mail}>

Slovenská republika
{Názov}
<{Adresa}
SK-000 00 {Mesto}>
Tel: +{Telefónne číslo}

<{Netfang }>

<{e-mail}>

Italia
{Nome}
<{Indirizzo}
I-00000 {Località}>
Tel: +{Numero di telefono}
<{e-mail}>

Suomi/Finland
{Nimi/Namn}
<{Osoite/Adress}
FIN-00000 {Postitoimipaikka/Stad}>
Puh/Tel: +{Puhelinnumero/Telefonnummer}
<{e-mail}>

Κύπρος
{Ονομα}
<{Διεύθυνση}
CY-000 00 {πόλη}>
Τηλ: +{Αριθμός τηλεφώνου}
<{e-mail}>

Sverige
{Namn}
<{Adress}
S-000 00 {Stad}>
Tel: +{Telefonnummer}
<{e-mail}>

Latvija
{Nosaukums}
<{Adrese}
{Pilsēta}, LV{pasta indekss }>
Tel: +{telefona numurs}
<{e-mail}>

Deleted: **United Kingdom (Northern Ireland)**¶
{Name}¶
<{Address}¶
{Town} {Postal code} – UK>¶
Tel: +{Telephone number}¶
<{e-mail}>

This leaflet was last revised in <{MM/YYYY}><{month YYYY}>.

<This medicine has been given 'conditional approval'.
This means that there is more evidence to come about this medicine.
The European Medicines Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.>

<This medicine has been authorised under 'exceptional circumstances'.
This means that <because of the rarity of this disease> <for scientific reasons> <for ethical reasons> it has been impossible to get complete information on this medicine.
The European Medicines Agency will review any new information on this medicine every year and this leaflet will be updated as necessary.>

<Other sources of information>

Detailed information on this medicine is available on the European Medicines Agency web site: https://www.ema.europa.eu<, and on the website of {name of Member State Agency (link)}>.*
<There are also links to other websites about rare diseases and treatments.>

<This leaflet is available in all EU/EEA languages on the European Medicines Agency website.>

The following information is intended for healthcare professionals only
Precautions to be taken before handling or administering the medicinal product

<{X} must be transported within the facility in closed, break-proof, leak-proof containers.>

This medicinal product contains human <blood> cells. Healthcare professionals handling {X} must take appropriate precautions (wearing <gloves><protective clothing><and><eye protection>) to avoid potential transmission of infectious diseases.

Preparation prior to administration

<Thawing>

Administration

Measures to take in case of accidental exposure

In case of accidental exposure local guidelines on handling of human-derived material must be followed. Work surfaces and materials which have potentially been in contact with {X} must be decontaminated with appropriate disinfectant.

Precautions to be taken for the disposal of the medicinal product

Unused medicinal product and all material that has been in contact with {X} (solid and liquid waste) must be handled and disposed of as potentially infectious waste in accordance with local guidelines on handling of human-derived material.