ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

LysaKare 25 g/25 g solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 1,000 mL bag contains 25 g of L-arginine hydrochloride and 25 g of L-lysine hydrochloride.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion (infusion).
Clear, colourless solution, free from visible particles
pH: 5.1 – 6.1
Osmolarity: 420 – 480 mOsm/L

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LysaKare is indicated for reduction of renal radiation exposure during peptide-receptor radionuclide therapy (PRRT) with lutetium (^{177}Lu) oxodotreotide in adults.

4.2 Posology and method of administration

LysaKare is indicated for administration with PRRT with lutetium (^{177}Lu) oxodotreotide therefore, it should only be administered by a health care provider experienced in the use of PRRT.

Posology

Adults

The recommended treatment regimen in adults consists of infusion of full bag of LysaKare concomitantly with lutetium (^{177}Lu) oxodotreotide infusion, even when patients require PRRT dose reduction.

Pre-treatment with an anti-emetic 30 minutes prior to start of LysaKare infusion is recommended to reduce the incidence of nausea and vomiting.

Special populations

Renal impairment

Due to the potential for clinical complications related to volume overload and an increase of potassium in blood associated with the use of LysaKare, this product should not be administered in patients with creatinine clearance <30 mL/min.
Care should be taken with LysaKare use in patients with creatinine clearance between 30 and 50 mL/min. Treatment with lutetium (^{177}Lu) oxodotreotide is not recommended for patients with renal function between 30 and 50 mL/min therefore, the benefit risk for these patients will always need to be weighed carefully, which should include consideration of an increased risk for transient hyperkalaemia in these patients (see section 4.4).

Paediatric population

The safety and efficacy of LysaKare in children less than 18 years have not been established.
No data are available.

Method of administration

For intravenous use.
LysaKare should be administered as a 4-hour infusion (250 mL/hour) starting 30 minutes prior to administration of lutetium (^{177}Lu) oxodotreotide to achieve optimal renal protection.
LysaKare and lutetium (^{177}Lu) oxodotreotide must be given through a separate infusion line.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Pre-existing clinically significant hyperkalaemia if not adequately corrected before starting the LysaKare infusion (see section 4.4).

4.4 Special warnings and precautions for use

Hyperkalaemia

An increase of serum potassium levels may occur in patients receiving arginine and lysine. Serum potassium level increases are generally mild and transient. According to limited available data maximum levels should be reached approximatively by 4 to 5 hours after start of the infusion and should return to normal levels by 24 hours.
Serum potassium levels must be tested before each treatment with LysaKare. In case of hyperkalaemia, patient's history of hyperkalaemia and concomitant medication should be checked. Hyperkalaemia must be corrected accordingly before starting the infusion (see section 4.3).
In case of pre-existing clinically significant hyperkalaemia, a second monitoring prior to LysaKare infusion must confirm that hyperkalaemia has been successfully corrected. The patient should be monitored closely for signs and symptoms of hyperkalaemia, e.g. dyspnoea, weakness, numbness, chest pain and cardiac manifestations (conduction abnormalities and cardiac arrhythmias). An ECG should be performed prior to discharging the patient.
Vital signs should be monitored during the infusion regardless of baseline serum potassium levels.
Patients should be instructed to drink substantial quantities of water (at least 1 glass every hour) on the day of infusion to remain hydrated and facilitate excretion of excess serum potassium.
In case hyperkalaemia symptoms develop during LysaKare infusion, appropriate corrective measures must be taken. In case of severe symptomatic hyperkalaemia, discontinuation of LysaKare infusion should be considered, taking into consideration the risk-benefit of renal protection versus acute hyperkalaemia.

Patients with renal impairment

The use of arginine and lysine has not been specifically studied in patients with renal impairment. Arginine and lysine are substantially excreted and reabsorbed by the kidney, and their efficacy in the reduction of renal radiation exposure is dependent on this. Due to the potential for clinical complications related to volume overload and an increase of potassium in blood associated with the use of LysaKare, this product should not be administered in patients with creatinine clearance <30 mL/min. Kidney function (creatinine and creatinine clearance) should be tested before each administration.
Care should be taken with LysaKare use in patients with creatinine clearance between 30 and 50 mL/min. Treatment with lutetium (^{177}Lu) oxodotreotide is not recommended for patients with renal function between 30 and 50 mL/min therefore, the benefit risk for these patients will always need to be weighed carefully, which should include consideration of an increased risk for transient hyperkalemia in these patients.

Patients with hepatic impairment

The use of arginine and lysine has not been studied in patients with severe hepatic impairment. Liver function (alanine aminotransferase [ALAT], aspartate aminotransferase [ASAT], albumin, bilirubin) should be tested before each administration.
Care should be taken with LysaKare use in patients with severe hepatic impairment and in case of either total bilirubinemia >3 times the upper limit of normal or albuminemia <30 g/L and prothrombin ratio <70% during treatment. Treatment with lutetium (^{177}Lu) oxodotreotide is not recommended in these circumstances.

Heart failure

Due to potential for clinical complications related to volume overload care should be taken with use of arginine and lysine in patients with severe heart failure defined as class III or class IV in the NYHA classification.
Treatment with lutetium (^{177}Lu) oxodotreotide is not recommended for patients with severe heart failure defined as class III or class IV in the NYHA classification therefore, the benefit risk for these patients will always need to be weighed carefully.

Elderly

Because elderly patients are more likely to have decreased renal function, care should be taken in determining eligibility based on creatinine clearance.

Metabolic acidosis

Metabolic acidosis has been observed with complex amino-acid solutions administered as part of total parenteral nutrition (TPN) protocols. Shifts in acid-base balance alter the balance of extracellular-intracellular potassium and the development of acidosis may be associated with rapid increases in plasma potassium.

As LysaKare is administered with lutetium (^{177}Lu) oxodotreotide, please also refer to section 4.4 of the lutetium (^{177}Lu) oxodotreotide SmPC for further warnings specific to treatment with lutetium (^{177}Lu) oxodotreotide.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.
No interaction with other medicinal product is expected since there is no information that other drugs are re-absorbed by the same kidney re-absorption mechanism.

4.6 Fertility, pregnancy and lactation

There is no relevant use of this medicinal product in women of childbearing potential since lutetium (^{177}Lu) oxodotreotide is contraindicated during established or suspected pregnancy or when pregnancy has not been excluded due to the risk associated with the ionizing radiation (see section 4.1).

Pregnancy

There are no data on the use of arginine and lysine in pregnant women.
Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

Breast-feeding

Arginine and lysine, being naturally occurring amino acids, are excreted in human milk, but effects on the breastfed newborns/infants are unlikely. Breast-feeding should be avoided during treatment with lutetium (^{177}Lu) oxodotreotide.

Fertility

There are no data on the effects of arginine and lysine on fertility.

4.7 Effects on ability to drive and use machines

LysaKare has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

There are very limited data on the safety profile of arginine and lysine solution for infusion without concomitant administration of PRRT, which also includes the use of anti-emetics as pre-medication and often the concomitant use of short acting somatostatin analogues.
The main adverse reactions which are related mainly to the amino acid solution are nausea (approximately 25%), vomiting (approximately 10%) and hyperkalaemia. These adverse reactions are mostly mild to moderate.

Tabulated list of adverse reactions

The adverse reactions listed below have been identified in publications of studies with amino acid solutions with the same composition with regards to the amino acid content, involving over 900 patients receiving more than 2,500 doses of arginine and lysine during PRRT with various radiolabelled somatostatin analogues.

The adverse reactions are listed according to the frequency. The frequencies are categorised as follows: 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) and not known (cannot be estimated from the available data).

Table 1 Adverse drug reactions

Adverse drug reaction	**Frequency category**
Metabolism and nutrition disorders	
Hyperkalaemia	Not known
Nervous system disorders	
Dizziness	Not known
Headache	Not known
Vascular disorders	
Flushing	Not known
Gastrointestinal disorders	
Nausea	Very common
Vomiting	Very common
Abdominal pain	Not known

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 over-hydration or solute overload, the elimination should be promoted by frequent micturition or by forced diuresis and frequent bladder voiding.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: All other therapeutic products, detoxifying agents for antineoplastic treatment, ATC code: V03AF11

Mechanism of action

Arginine and lysine undergo glomerular filtration and, via competition, interfere with renal resorption of lutetium (^{177}Lu) oxodotreotide, reducing the radiation dose delivered to the kidney.

Clinical efficacy and safety

Clinical efficacy and safety for arginine and lysine are based on published literature of studies using solutions with the same arginine and lysine content as LysaKare.
The toxicities that are observed following administration of PRRT are directly due to radiation-absorbed dose to organs. The kidneys are the critical organs for toxicity for lutetium (^{177}Lu) oxodotreotide and dose limiting if amino acids are not administered to reduce renal uptake and retention.
A dosimetry study including 6 patients showed that a 2.5% Lysine-Arginine amino acid solution reduced renal radiation exposure by about 47% as compared to no treatment, without having an effect on tumour uptake of lutetium (^{177}Lu) oxodotreotide. This reduction in renal radiation exposure mitigates the risk for radiation-induced renal injury.
Based on a publication of the largest study using arginine and lysine in the same quantities as LysaKare, the average kidney absorbed dose, as determined by planar imaging dosimetry, was 20.1±4.9 Gy, which is below the established threshold for the occurrence of renal toxicities of 23 Gy.

5.2 Pharmacokinetic properties

Arginine and lysine are naturally occurring amino acids that follow physiological pharmacokinetic steps and biochemical processes after infusion.

Absorption

Due to the intravenous route of administration, LysaKare is 100% bioavailable.

Distribution

Transient elevations in plasma arginine and lysine are observed after intravenous administration, whereupon the highly water soluble amino acids are quickly distributed throughout tissues and body fluid.

Biotransformation

Like other naturally occurring amino acids, arginine and lysine serve as building blocks in protein anabolism and serve as precursors for several other products, including nitric oxide, urea, creatinine, and Acetyl-Coenzyme A.

Elimination

Arginine and lysine are rapidly distributed. Based on a study with 30 g arginine infused over 30 minutes, plasma elimination of amino acids follows at least a biphasic or triphasic decline, with levels returning to baseline within 6 hours post-dose. Initial rapid clearance is through glomerular filtration in the kidney in the first 90 minutes post-infusion. Remaining amino acid is removed by non-renal clearance.

Paediatric population

No pharmacokinetic data are available on the use of arginine and lysine at the same dose as LysaKare and for the same indication in paediatric patients.

5.3 Preclinical safety data

There were no non-clinical studies conducted with LysaKare.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Infusion bag made of polyvinyl chloride (PVC) containing 1,000 mL of solution, wrapped in a polyethylene polyamine/aluminium foil.

6.6 Special precautions for disposal

This medicinal product is for single use only.
Do not remove unit from overwrap until ready to use.
Do not use if overwrap has been previously opened or damaged. The overwrap is a moisture barrier.
Do not reconnect partially used bags.
LysaKare must not be diluted.
Do not use solutions which are cloudy or have deposits. This may indicate that the product is unstable or that the solution has become contaminated.
Once the container has been opened, the contents should be used immediately.

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

7. MARKETING AUTHORISATION HOLDER

Advanced Accelerator Applications
8-10 Rue Henri Sainte-Claire Deville
92500 Rueil-Malmaison
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/19/1381/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 July 2019

10. DATE OF REVISION OF THE TEXT

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

Laboratoire Bioluz
Zone Industrielle de Jalday
64500 Saint Jean de Luz
France

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**

The requirements for submission of periodic safety update reports 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 shall submit the first periodic safety update report 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 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

Polyethylene polyamine/aluminium foil

1. NAME OF THE MEDICINAL PRODUCT

LysaKare 25 g/25 g solution for infusion
L-arginine hydrochloride/L-lysine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each bag of 1,000 mL contains 25 g of L-arginine hydrochloride and 25 g of L-lysine hydrochloride.

3. LIST OF EXCIPIENTS

Excipient: water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for infusion

1,000 mL

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intravenous use.
For single use only.
Do not remove from overwrap until ready for 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

Do not reconnect partially used bags.

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

Store below 25°C.

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Advanced Accelerator Applications
8-10 Rue Henri Sainte-Claire Deville
92500 Rueil-Malmaison
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/19/1381/001

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

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Polyvinyl chloride (PVC) infusion bag

1. NAME OF THE MEDICINAL PRODUCT

LysaKare 25 g/25 g solution for infusion
L-arginine hydrochloride/L-lysine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each bag of 1,000 mL contains 25 g of L-arginine hydrochloride and 25 g of L-lysine hydrochloride.

3. LIST OF EXCIPIENTS

Excipient: water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for infusion

1,000 mL

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intravenous use.
For single use only.
Do not remove from overwrap until ready for 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

Do not reconnect partially used bags.

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

Store below 25°C.

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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12. MARKETING AUTHORISATION NUMBER(S)

EU/1/19/1381/001

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

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

LysaKare 25 g/25 g solution for infusion
L-arginine hydrochloride/L-lysine hydrochloride

Read all of this leaflet carefully before you start 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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What LysaKare is and what it is used for

What LysaKare is
LysaKare contains the active substances arginine and lysine, two different amino acids. It belongs to a group of medicines which are used to reduce the side effects of anti-cancer medicine.

What LysaKare is used for
LysaKare is used in adult patients to protect kidneys from unnecessary radiation during treatment with Lutathera (lutetium (^{177}Lu) oxodotreotide), a radioactive medicine used to treat certain tumours.

2. What you need to know before you take LysaKare

Follow all of your doctor's instructions carefully. As you will receive another treatment, Lutathera, with LysaKare, **read the Lutathera leaflet carefully as well as this leaflet.**
If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

You should not be given LysaKare
- if you are allergic to arginine and lysine or any of the other ingredients of this medicine (listed in section 6).
- If you have high blood levels of potassium (hyperkalaemia).

Warnings and precautions
Talk to your doctor before taking LysaKare if your kidneys, heart or liver are severely impaired or if you have a history of high blood levels of potassium (hyperkalaemia).
Because feeling sick (nausea) and vomiting are commonly seen with amino acid infusions, you will be given medicines to prevent nausea and vomitting 30 minutes before the LysaKare infusion.

The doctor will check your blood potassium levels, and will correct them if they are too high before starting the infusion. The doctor will also check your kidney and liver function before starting the infusion. For other tests which need to be performed before your treatment, please read the Lutathera leaflet.
Follow your doctor's advice on how much fluid to drink on the day of your treatment so you stay well hydrated.

Children and adolescents
This medicine should not be given to children and adolescents under 18 years old because it is not known whether it is safe and effective in this age group.

Other medicines and LysaKare
Tell your doctor if you are taking, have recently taken, or might take any other medicines.

Pregnancy, 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 for advice before taking this medicine.

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

3. How to take LysaKare

The recommended dose of LysaKare solution is 1 L (1,000 mL). You should receive the full LysaKare dose, regardless of any Lutathera dose adjustments.
LysaKare is given as an infusion (drip) into a vein. The infusion of LysaKare will start 30 minutes before you are given Lutathera, and will last over a 4 hour period.

If you receive more LysaKare than you should
LysaKare will be given in a controlled clinical setting and is provided as a single dose bag. It is therefore unlikely that you will receive more of the infusion than you should as your doctor will monitor you during the treatment. However, in the case of an overdose, you will receive the appropriate treatment.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

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

Very common (may affect more than 1 in 10 people):
- nausea (feeling sick) and vomiting

Not known (frequency cannot be estimated from the available data):
- high potassium levels seen in blood tests, abdominal (belly) pain, headache, dizziness and flushing.

Reporting of side effects
If you get any side effects, talk to your 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 to store LysaKare

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
LysaKare should be stored below 25°C.
You will not have to store this medicine. The correct storage, use and disposal of this medicine are under the responsibility of the specialist in appropriate premises. You will receive LysaKare in a controlled clinical setting.
The following information is intended for the healthcare specialist charged with your care.
Do not use this medicine:
- if you notice the solution is cloudy or has deposits.
- if overwrap has been previously opened or damaged.
- if the infusion bag is damaged or leaking

6. Contents of the pack and other information

What LysaKare contains
- The active substances are arginine and lysine.
  Each infusion bag contains 25 g of L-arginine hydrochloride and 25 g of L-lysine hydrochloride.
- The other ingredient is water for injections.

What LysaKare looks like and contents of the pack
LysaKare is a clear and colourless solution for infusion, supplied in a single use flexible plastic bag.
Each infusion bag contains 1 L LysaKare of solution.

Marketing Authorisation Holder
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8-10 Rue Henri Sainte-Claire Deville
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Manufacturer
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This leaflet was last revised in {**month YYYY**}.

Other sources of information

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