Advanced Accelerator Applications
A Novartis Company

UKI NETS

INVITATION

Dear colleague,

On behalf of the UK and Ireland Neuroendocrine Tumour Society (UKI NETS) and Advanced Accelerator Applications (AAA), a Novartis company, we have the pleasure in inviting you to an AAA-sponsored satellite symposium, **'An evidence-based approach for the management of GEP-NETs with PRRT'**, to be held virtually at **1:00pm** on **Monday, 6th December 2021,** as part of the **UKI NETS 19th Annual Conference.**

Join Dr Alia Munir for a presentation of two patient cases and the latest data from the NETTER-1 trial for Lutathera®▼ ([^{177}Lu]Lu-oxodotreotide). This will be followed by an expert faculty discussion with Dr Francis Sundram, Dr Sebastian Cummins and Dr Alia Munir, chaired by Dr Mairéad McNamara – during this session, you can submit your questions on the management of patients with gastroenteropancreatic neuroendocrine tumours (GEP-NETs) and the right time for treatment with Lutathera®.

The full programme is below.

This AAA-sponsored satellite symposium is approved by the UKI NETS Executive and is part of the UKI NETS 19th Annual Conference.

Click here to register
UKI NETS 19th Annual Conference Online - Registration

We look forward to you joining us on Monday, 6th December.

Kind regards

Dr Mairéad McNamara
Symposium Chair

Professor John Newell-Price
Chair of UKI NETS

This symposium is for healthcare professionals only.

This meeting has been organised and funded by Advanced Accelerator Applications, a Novartis company.
Advanced Accelerator Applications products will be discussed at this meeting.
Prescribing information can be found at the end of this document.
AAA-Lu177-UK-1371 | November 2021

Advanced Accelerator Applications
A Novartis Company

UKI NETS

A sponsored satellite symposium from Advanced Accelerator Applications at the UKI NETS 19th Annual Conference

13:00, MONDAY 6th DECEMBER 2021

You are cordially invited to attend:

An evidence-based approach for the management of GEP-NETs with PRRT

PROGRAMME

Chair: Dr Mairéad McNamara

13:00 **Welcome and introduction**

Dr Mairéad McNamara
Senior Lecturer/Honorary Consultant in Medical Oncology, University of Manchester/ The Christie NHS Foundation Trust, Manchester

13:03 **NETTER-1 update and case presentations**

Dr Alia Munir
Consultant Endocrinologist, Sheffield Teaching Hospitals NHS Foundation Trust

13:30 **Panel discussion and Q&A**

Chaired by Dr Mairéad McNamara
Dr Alia Munir
Dr Francis Sundram
Consultant in Nuclear Medicine, University Hospital Southampton NHS Foundation Trust
Dr Sebastian Cummins
Consultant Clinical Oncologist, Royal Surrey County Hospital NHS Foundation Trust

13:50 **Close**

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LUTATHERA® PRESCRIBING INFORMATION

Lutathera▼370 MBq/mL solution for infusion.
Lutetium (^{177}Lu) oxodotreotide

Prescribing Information: Lutathera 370 MBq/mL solution for infusion. Lutetium (^{177}Lu) oxodotreotide **Presentation:** Solution for infusion. Clear, colourless to slightly yellow solution. One mL of solution contains 370 MBq of lutetium (^{177}Lu) oxodotreotide at the date and time of calibration. The total amount of radioactivity per single dose vial is 7,400 MBq at the date and time of infusion. **Uses:** Lutathera is indicated for the treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP NETs) in adults. **Administration:** Lutathera should be administered only by persons authorised to handle radiopharmaceuticals in designated clinical settings and after evaluation of the patient by a qualified physician. Before starting treatment with Lutathera, somatostatin receptor imaging (scintigraphy or positron emission tomography [PET]) must confirm the overexpression of these receptors in the tumour tissue with the tumour uptake at least as high as normal liver uptake. Additionally, before each administration and during the treatment, biological tests are required to re assess the patient's condition and adapt the therapeutic protocol if necessary (dose, infusion interval, number of infusions). See SmPC for further details. The recommended treatment regimen of Lutathera in adults consists of 4 infusions of 7,400 MBq each. The recommended interval between each administration is 8 weeks. Management of severe or intolerable adverse drug reactions may require temporary dose interruption, extending dosing interval from 8 weeks up to 16 weeks, dose reduction, or discontinuation of treatment with Lutathera. See SmPC for further details. For renal protection purpose, an amino acid solution must be administered intravenously for 4 hours. See SmPC for further details. Given the fixed volumetric activity of 370 MBq/mL at the date and time of calibration, the volume of the solution is adjusted between 20.5 mL and 25.0 mL in order to provide the required amount of radioactivity at the date and time of infusion. Lutathera must be administered by slow intravenous infusion over approximately 30 minutes, concomitantly with amino acid solution administered by contralateral intravenous infusion. This medicinal product must not be injected as a bolus. Premedication with antiemetics should be injected at least 30 minutes prior to the start of amino acid solution infusion to reach the full antiemetic efficacy of the selected product, according to the respective product information. See SmPC for further details. The recommended infusion method for administration of Lutathera is the gravity method, described in more detail in this section. Treating physicians may use other methods deemed appropriate, including the use of infusion pumps, particularly when dose reduction is required. During the administration the recommended radiation safety precaution measures should be undertaken regardless of the infusion method. Lutathera should be infused directly from its original container. The vial must not be opened or the solution transferred to another container. During the administration, only disposable materials should be used. The medicinal product should be infused through an intravenous catheter placed in the vein exclusively for its infusion. See SmPC for further details of storage, room and equipment requirements, as well as detailed administration procedure. In some circumstances, it might be necessary to temporarily discontinue treatment with Lutathera, adapt the dose after the first administration or discontinue the treatment. **Warnings: Contraindications** include hypersensitivity to the active substance, to any of the excipients, established or suspected pregnancy or when pregnancy has not been excluded, kidney failure with creatinine clearance < 30 mL/min. **Special precautions:** Careful monitoring in hepatic impairment, renal impairment/urinary tract abnormalities, prior chemotherapy, haematological toxicities, bone metastasis, prior oncologic radiometabolic therapies or history of other malignant tumours. It is not recommended to start treatment in the following cases: previous external beam radiotherapy involving more than 25% of the bone marrow, severe heart failure, liver impairment, renal impairment with creatinine clearance < 40 mL/min, severely impaired haematological function, somatostatin receptor negative or mixed visceral lesions according to somatostatin receptor imaging. For each patient, the radiation exposure must be justifiable by the likely benefit. Somatostatin and its analogues competitively bind to somatostatin receptors and may interfere with the efficacy of Lutathera. See SmPC for further details. Late-onset myelodysplastic syndrome (MDS) and acute leukaemia (AL) have been observed after treatment with Lutathera. Aetiology of these therapy-related secondary myeloid neoplasms is unclear. Factors such as age > 70 years, impaired renal function, baseline cytopenias, prior number of therapies, prior exposure to chemotherapeutic agents (specifically alkylating agents), and prior radiotherapy are suggested as potential risks and/or predictive factors for MDS/AL. Crises due to excessive release of hormones or bioactive substances may occur following treatment with Lutathera, therefore observation of patients by overnight hospitalisation should be considered in some cases (e.g. patients with poor pharmacologic control of symptoms). Tumour lysis syndrome has been reported. Patients with a history of renal insufficiency and high tumour burden may be at greater risk and should be treated with increased caution. Patients with hepatic metastasis or pre-existing advanced hepatic impairment may be at increased risk of hepatotoxicity due to radiation exposure. Radioprotection rules and precautions should be followed including special care in the event of extravasation and urinary incontinence. See SmPC for further details. The product contains up to 3.5 mmol sodium and this should be considered in patients on a sodium-controlled diet. For patients with creatinine clearance < 50 mL/min, an increased risk of transient hyperkalemia due to the amino acid solution should also be taken into consideration. In addition, care should be taken co-administering the amino acid solution in patients with severe heart failure (risk of volume overload) and in patients receiving total parenteral nutrition protocols (risk of metabolic acidosis). See SmPC for further details. **Undesirable effects:** Common side effects include bone marrow toxicity with thrombocytopenia, lymphopenia, anaemia or pancytopenia. Nephrotoxicity with haematuria, renal failure, proteinuria. Blood creatinine increased, nausea, vomiting, fatigue, decreased appetite, dizziness, headache, sleep disorders, secondary hypothyroidism, dehydration, influenza-like illness, hyponatraemia, hypomagnesaemia, QT prolonged, hypertension, flushing, hypotension, dyspnoea, abdominal distension, diarrhoea, abdominal pain, constipation, dyspepsia, gastritis, hyperbilirubinaemia, alopecia, injection site reaction, musculoskeletal pain, muscle spasms, acute kidney injury, increased LFTs. **Marketing Authorisation Holder:** Advanced Accelerator Applications 20 rue Diesel 01630 Saint Genis Pouilly France **Marketing Authorisation Number:** EU/1/17/1226/001 **Legal Category:** POM **Price:** £17,875 per vial **Date of preparation of PI:** February 2021. **Promomats Job Bag Number:** AAA-NP-UK-0034-21.

ADVERSE EVENTS SHOULD BE REPORTED
Reporting form and information can be found at
yellowcard.mhra.gov.uk
Adverse events should also be reported to
Advanced Accelerator Applications at:
uk.patientsafety@novartis.com

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