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), we are pleased to invite you to a satellite symposium entitled **Complex GEP-NET cases and PRRT** at **14:00–15:40** on **Wednesday, 2nd December 2020**, to be held virtually as part of the **UKI NETS 18th National Conference Online.**

Our expert faculty will discuss a series of complex cases that we face in the management of patients with gastroenteropancreatic neuroendocrine tumours (GEP-NETs) and discuss 'When is the right time for treatment with Lutathera®▼(lutetium (^{177}Lu) oxodotreotide)?'

Please see the programme agenda below for full details of the presentations and our faculty.

The satellite symposium is approved by the UKI NETS Executive and is part of the UKI NETS National Conference Online.

TO JOIN *Please register for the UKI NETS 18th National Conference Online here:* ukinets.org

We look forward to you joining us on 2nd December.

Kind regards

John Ramage
Symposium Chair

John Newell-Price
Chair, 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-0594 | November 2020

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UKI NETS

Advanced Accelerator Applications (AAA)-sponsored symposium
Wednesday, 2nd December 2020, 14:00–15:40

You are cordially invited to attend:

Complex GEP-NET cases and PRRT

PROGRAMME

Chair:
Professor John Ramage

14:00	**Welcome and introduction** *Professor John Ramage*
14:05	**Lutathera®▼(lutetium (^{177}Lu) oxodotreotide): Efficacy, tolerability and quality of life** *Dr Shaunak Navalkissoor*
14:20	**PRRT and other NET treatments in patients with borderline renal function and haematology profile** *Professor Nick Reed*
14:35	**PRRT in patients with liver disease and mesenteric fibrosis** *Professor Mark Pritchard*
14:45	**Timing of PRRT in carcinoid heart disease** *Dr Raj Srirajaskanthan*
14:55	**When is the right time for Lutathera?** *Professor Val Lewington*
15:10	**Panel discussion and Q&A** *Chaired by Professor John Ramage*
15:40	Close

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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 (177Lu) 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 (tumour uptake score ≥ 2). Additionally, before each administration and during the treatment, 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 which could be extended up to 16 weeks in case of dose modifying toxicity (DMT). For renal protection purpose, an amino acid solution must be administered intravenously. 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 (separate intravenous catheter and initiated 30 minutes prior to Lutathera). This medicinal product must not be injected as a bolus. Premedication with antiemetics should be injected 30 minutes before the start of amino acid solution infusion. The recommended infusion method for administration of Lutathera is the gravity method. During the administration, the recommended precaution measures should be undertaken. 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 < 50 mL/min, impaired haematological function, somatostatin receptor negative or mixed visceral lesions. For each patient, the radiation exposure must be justifiable by the likely benefit. Concomitant use of cold somatostatin analogues may be needed for disease symptoms control. Administration of long-acting somatostatin analogues should be avoided within 30 days prior to the administration. Late-onset myelodysplastic syndrome (MDS) and acute leukaemia (AL) have been observed after treatment with Lutathera. 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. 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. 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. **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:** April 2020

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Advanced Accelerator Applications at: uk.patientsafety@novartis.com

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