Advanced Accelerator Applications

A Novartis Company

UKI NETS

INVITATION

Dear Colleague,

On behalf of UKI NETS and Advanced Accelerator Applications, we have the pleasure in inviting you to a satellite symposium entitled **"Precision Diagnosis and Optimized Treatment in GEP-NETs"**, to be held at **MacDonald Burlington Hotel on Sunday the 1st of December 2019 at 5:00pm.**

Themes of the meeting include Patient Journey to Diagnosis, the Practical Role of imaging in GEP-NETs, treatment options for PanNETs, treatment outcomes and QoL in GEP-NETs, and medical case presentations. A full programme agenda is attached.

Imaging Equipment Limited will be funding and managing this event.
Imaging Equipment Limited is a subsidiary of Advance Accelerator Applications, a Novartis company.

The satellite symposium is approved by the UKI NETS Executive and is part of the UKI NETS conference, which continues the following day.

This is an invitation only event which will be held in a private room.
We have password protected our meeting on Eventbrite, please register on **https://ukinetsinvite2019.eventbrite.co.uk** using password **December**

Where travel distance or time creates a requirement accommodation, please apply to **marketing@imagingequipment.co.uk**

Looking forward to seeing you on 1st December.

Kind regards

Martyn Caplin
Satellite Chairman

John Newell-Price
Chairman, UKI NETS

Advanced Accelerator Applications

A Novartis Company

SUNDAY 1ST DECEMBER 2019

You are cordially invited to attend

PRECISION DIAGNOSIS & OPTIMIZED TREATMENT IN GEP-NETs

MACDONALD BURLINGTON HOTEL, BURLINGTON ARCADE,
126 NEW STREET, BIRMINGHAM B2 4JQ
TEL: +44 344 879 9019

PROGRAMME

Chairs	Professors John Newell-Price & Martyn Caplin
16.30	Registration and refreshments
17.00	Welcome & Introduction *Professor John Newell-Price*
17.05	Patient Journey to Diagnosis *Nikie Jervis*
17.20	The Practical Role of imaging in GEP-NETs *Dr Rajaventhan Srirajaskanthan*
17.40	Round Table Discussion *Professor Martyn Caplin* *Professor Sobhan Vinjamuri* *Dr Rajaventhan Srirajaskanthan* *Nikie Jervis*
18.00	Tea and coffee break
18.20	Treatment options for PanNETs; what's different? *Dr Prakash Manoharan*
18.45	Treatment Outcomes and QoL in GEP-NETs *Professor John Ramage*
19.00	Round Table Discussion *Professor John Ramage* *Dr Prakash Manoharan* *Professor Juan Valle* *Professor Jonathan Wadsley* *Dr Tahir Shah* *Elizabeth Quaglia*
19.20	Case Presentations *Interactive session including panel discussion* *Dr Christos Toumpanakis* *Panel:* *Professor John Newell-Price* *Professor Martyn Caplin* *Professor Nick Reed* *Professor Jonathan Wadsley* *Professor Sobhan Vinjamuri* *Mr Tom Armstrong* *Elizabeth Quaglia*
20.05	Summary and close *Professor Martyn Caplin*
20.15	Dinner

UKI NETS

AAA-Lu177-UK-0136. Date of Preparation: October 2019

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 (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. **General 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 should be taken where patients have renal or urinary tract morphological abnormalities, urinary incontinence, mild to moderate chronic kidney disease with creatinine clearance ≥ 50 mL/min, haematologic toxicity greater or equal to grade 2 (CTCAE) before treatment other than lymphopenia, bone metastasis or have had previous chemotherapy. Late-onset myelodisplastic 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. Crises due to excessive release of hormones or bioactive substances may occur and overnight hospitalisation should be considered for vulnerable patients. Radioprotection rules should be followed including special care in the event of extravasation and urinary incontinence, see SmPC for full details or radio protective measures. 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, QT prolonged, hypertension, flushing, hypotension, dyspnoea, abdominal distension, diarrhoea, abdominal pain, constipation, dyspepsia, gastritis, hyperbilirubinaemia, alopecia, 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:** October 2017

Prescribing Information; SomaKit TOC 40 micrograms kit for radiopharmaceutical preparation.

Presentation; Each vial of powder contains 40 micrograms of edotreotide. The radionuclide is not part of the kit. **Uses**: The medicinal product is for diagnostic use only. After radiolabelling with gallium (^{68}Ga) chloride solution, the solution of gallium (^{68}Ga) edotreotide obtained is indicated for Positron Emission Tomography (PET) imaging of somatostatin receptor overexpression in adult patients with confirmed or suspected well-differentiated gastro-enteropancreatic neuroendocrine tumours (GEP-NET) for localizing primary tumours and their metastases. **Administration**; The medicinal product should only be administered by trained healthcare professionals with technical expertise in using and handling nuclear medicine diagnostic agents and only in a designated nuclear medicine facility. The recommended activity for an adult weighing 70 kg is 100 to 200 MBq, administered by direct slow intravenous injection. The activity should be adapted to patient characteristics, the type of PET camera used and acquisition mode. The safety and efficacy of gallium (^{68}Ga) edotreotide has not been studied in patients with renal or hepatic impairment or paediatric populations where the effective dose might be different, see SmPC for further information. SomaKit TOC is for intravenous use and for single use only. The medicinal product should be radiolabelled before administration to the patient. The patient should be well hydrated before the start of the examination and urged to void as often as possible, during the first hours after examination in order to reduce radiation. The activity of gallium (^{68}Ga) edotreotide has to be measured with an activimeter immediately prior to injection. The injection of gallium (^{68}Ga) edotreotide must be administered intravenously in order to avoid local extravasation resulting in inadvertent radiation to the patient and imaging artefacts. For instructions on extemporaneous preparation of the medicinal product before administration, see SmPC. **Contraindications and warnings**; Known hypersensitivity to the active substance or any of the excipients contraindicates. If hypersensitivity or anaphylactic reactions occur, the administration of the medicinal product must be discontinued immediately and intravenous treatment initiated, if necessary. To enable immediate action in emergencies, the necessary medicinal products and equipment such as endotracheal tube must be immediately available. For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable. Careful consideration of the benefit risk ratio is required in patients with renal or hepatic impairment since increased radiation exposure is possible. For PET image interpretation refer to SmPC. It is preferable to perform imaging with gallium (^{68}Ga) edotreotide the day(s) before the next administration of a somatostatin analogue. After the procedure close contact with infants and pregnant women should be restricted during for 8 hours. Content of sodium may in some cases be greater than 1 mmol and this should be taken into account in patient on low sodium diet. Accidental extravasation may cause local irritation. In cases of extravasation, the injection must be stopped, the site of injection must be changed and the affected area should be irrigated with sodium chloride solution. **General Warnings**: Radiopharmaceuticals should be received, used and administered only by authorized persons in designated clinical settings. Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken. See SmPC for further handling information to minimize risk of contamination of the medicinal product and irradiation of the operators. **Undesirable effects** No adverse reactions related to gallium (^{68}Ga) edotreotide have been reported. Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is about 4.5 mSv when the maximal recommended activity of 200 MBq is administered, these adverse reactions are expected to occur with a low probability. **Marketing Authorisation Holder**; Advanced Accelerator Applications 20 rue Diesel 01630 Saint Genis Pouilly France **Marketing Authorisation Number** EU/1/16/1141/001 **Legal Category**; Medicinal Product for diagnostic use **Package Quantity and Cost**; Package Kit for radiopharmaceutical preparation containing: - Powder for solution for injection: the vial contains a white lyophilised powder. - Reaction buffer: the vial contains a clear, colourless solution. For radiolabelling with gallium (^{68}Ga) chloride solution Price £995 **Date of Preparation of PI**; November 2018

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:
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pv@imagingequipment.co.uk
Fax +334 50 99 3634

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