

Expert Forum for Advanced Prostate Cancer

AGENDA

TUESDAY 27-THURSDAY 29 JUNE 2017 GOVERNOR'S HALL, ST THOMAS' HOSPITAL, LONDON

The programme is developed and endorsed by the Steering Committee:

Professor Valerie Lewington, Consultant Nuclear Medicine Physician, Guy's and St Thomas' NHS Foundation Trust, London, UK

Dr Chris Parker, Consultant Clinical Oncologist, The Royal Marsden NHS Foundation Trust, London, UK

Dr John Logue, Consultant Clinical Oncologist, The Christie NHS Foundation Trust. Manchester. UK

Dr Jon Kindblom, Oncologist, Sahlgrenska University Hospital, Gothenburg, Sweden

TUESDAY 27 JUNE 2017

19.00 Welcome dinner

MED1	NESDAY 28 JUNE 2017	
09.00	Welcome to day 1	<u>Chairs</u> Valerie Lewington Sarah Rudman
09.15	Setting the scene: the current treatment paradigm in metastatic castrate-resistant prostate cancer (mCRPC)	ТВС
10.00	Imaging in mCRPC	Nina Tunariu
10.45	Break	
11.00	Treating oligometastatic disease	Alison Tree
11.30	STAMPEDE update	Nick James
12.15	Lunch	
13.30	Latest developments in mCRPC treatment	Nick James
14.15	Personalised medicine/subgroups in mCRPC	Gerhardt Attard
14.45	Break	
15.00	Debate series: hot topics in mCRPC — Delegates to submit hot topic-related questions for the expert panel prior to the meeting	Led by Nick James Gerhardt Attard Valerie Lewington John Logue Sarah Rudman Nina Tunariu
16:15	Summary of day 1 and close	Valerie Lewington Sarah Rudman
19.00	Dinner	

THURSDAY 29 JUNE 2017			
09.00	Welcome to day 2	<u>Chairs</u> Valerie Lewington Simon Hughes	
09.10	Radium-223 dichloride▼ treatment considerations	John Logue Jon Kindblom	
09.45	mCRPC treatments and quality of life considerations	Jon Kindblom	
10.15	Interactive case study session — Delegates to present challenging cases for expert panel advice	Valerie Lewington Simon Hughes Chris Parker Sarah Rudman	
11.00	Break		
11.15	Interactive case study session (continued)	Valerie Lewington Simon Hughes Chris Parker Sarah Rudman	
12.15	Introducing new therapies into the treatment pathway: cross-functional working	John Logue Valerie Lewington	
12.45	Meeting review and summary	Valerie Lewington Simon Hughes	
13.00	Lunch		
13.45	Departures		

▼ Xofigo® 1100 kBq/mL solution for injection (radium-223 dichloride) Prescribing Information (Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: Each vial contains 6 mL of solution (6.6 MBg radium-223 dichloride at the reference date). Each mL of solution contains 1100 kBg radium Ra 223 dichloride (radium-223 dichloride), corresponding to 0.58 ng radium-223 at the reference date. Indication(s): Treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases. Posology & method of administration: Xofigo should be administered only by persons authorised to handle radiopharmaceuticals in designated clinical settings, and after evaluation of the patient by a qualified physician. Xofigo is for intravenous use and must be administered by slow injection (generally up to 1 minute). The intravenous access line or cannula must be flushed with isotonic sodium chloride 9 mg/mL (0.9%) solution for injection before and after injection of Xofigo. Adults: The dose regimen of Xofigo is an activity of 55 kBq per kg body weight, given at 4 week intervals for 6 injections. Hepatic impairment: No dose adjustment is considered necessary in patients with hepatic impairment. Renal impairment: No dose adjustment is considered necessary in patients with renal impairment. Elderly patients: No dose adjustment is considered necessary in elderly patients. Children & adolescents: There is no relevant use of this medicinal product in the paediatric population for prostate cancer. Contra-indications: None known. Warnings & precautions: Bone marrow suppression, notably thrombocytopenia, neutropenia, leukopenia and pancytopenia, have been reported in patients treated with Xofigo, Haematological evaluation of patients must be performed at baseline and prior to every dose of Xofigo. In case there is no recovery in values for absolute neutrophil count (ANC), platelets and haemoglobin within 6 weeks after the last administration of Xofigo despite receiving standard of care, further treatment with Xofigo should only be continued after a careful benefit/risk evaluation. Patients with evidence of compromised bone marrow should be treated with caution. Safety and efficacy of Xofigo have not been studied in patients with Crohn's disease and ulcerative colitis. Due to faecal excretion of Xofigo, radiation may lead to aggravation of acute inflammatory bowel disease. Therefore, Xofigo should only be administered after a careful benefit-risk assessment in these patients. In patients with untreated imminent or established spinal cord compression, treatment with standard of care, as clinically indicated, should be completed before starting or resuming treatment with Xofigo. In patients with bone fractures, orthopaedic stabilisation of fractures should be performed before starting or resuming treatment with Xofigo. In patients treated with bisphosphonates and Xofigo, an increased risk of development of osteonecrosis of the jaw (ONJ) cannot be

excluded. Xofigo contributes to a patient's overall long-term cumulative radiation exposure which may be associated with an increased risk of cancer and hereditary defects. In particular, the risk for osteosarcoma, myelodysplastic syndrome and leukaemias may be increased. This medicinal product can contain up to 2.35mmol (54mg) sodium per dose, depending on the required volume, and must be taken into consideration by patients on a controlled sodium diet. Interactions: No clinical interaction studies have been performed. Interactions with calcium and phosphate cannot be excluded. Safety and efficacy of concomitant chemotherapy with Xofigo have not been established. Fertility, pregnancy & lactation: Xofigo is not indicated in women. Results from animal studies, indicate there is a potential risk that radiation from Xofigo could cause adverse effects on fertility. Male patients should seek advice on conservation of sperm prior to treatment. Due to potential effects on spermatogenesis associated with radiation, men should be advised to use effective contraceptive methods during and up to 6 months after treatment with Xofigo. Effects on ability to drive and use machines: There is no evidence, nor is it expected, that Xofigo will affect the ability to drive or use machines. Undesirable effects: Very common: Thrombocytopenia, diarrhoea, vomiting, nausea. Common: Neutropenia, pancytopenia, leukopenia and injection site reactions. Uncommon: Lymphopenia. Serious: Thrombocytopenia and neutropenia. Prescribers should consult the SmPC in relation to other side effects. Overdose: No specific antidote. In the event of an inadvertent overdose, general supportive measures, including monitoring for potential haematological and gastrointestinal toxicity should be undertaken. Incompatibilities: Do not mix with other medicinal products. Special Precautions for Storage: Store in accordance with national regulation on radioactive materials. Legal Category: POM. Package Quantities & Basic NHS Costs: Single vial pack £4040. MA Number(s): EU/1/13/873/001. Further information available from: Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA United Kingdom. Telephone: 01635 563000. Date of preparation: January 2016. Xofigo® is a trademark of the Bayer Group

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 Bayer plc.
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