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SATELLITE SYMPOSIUM, BAUS ANNUAL CONFERENCE

Recognise, react and refer: optimising outcomes in metastatic castration-resistant prostate cancer (mCRPC)

07.45–08.45, Tuesday 27 June 2017, Lomond Auditorium, SECC, Glasgow

Chair:

Professor Alan McNeill,
Consultant Urological Surgeon, Lothian University Hospitals NHS Trust, Edinburgh

Speakers:

Professor Noel Clarke,
Consultant Urologist, The Christie NHS Foundation Trust, Manchester

Professor Rob Jones,
Senior Lecturer and Honorary Consultant in Medical Oncology, University of Glasgow, Glasgow

07.45–07.50
Chair's introduction, Professor Alan McNeill

07.50–08.10
Recognising progression in mCRPC patients, Professor Noel Clarke

08.10–08.35
Radium-223 dichloride ▼: appropriate patient selection for optimal outcomes, Professor Rob Jones

08.35–08.45
Recognise, react and refer: a collaborative MDT approach, panel discussion

This symposium will use interactive keypad voting

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 MBq radium-223 dichloride at the reference date). Each mL of solution contains 1100 kBq 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 2.35 mmol (54 mg) 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.

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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. Tel: 01635 563500, Fax: 01635 563703, Email: pvuk@bayer.com

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