Lunch Symposium - Bayer
Sunday, October 22, 2017, 13:00-14:15

Session Title

Four years of radium Ra 223 dichloride▼ on the market: what have we learned?

Programme

13:00 - 13:20 Joe O'Sullivan (UK): Learning from trials and experience in mCRPC

13:20 - 13:30 Val Lewington (UK): Lesson 1: who to treat, when, and why

13:30 - 13:40 All faculty (Chair: Joe O'Sullivan, UK): Panel discussion

13:40 - 13:55 Yong Du (UK): Lesson 2: 10 key steps to improve your service

13:55 - 14:05 Wouter Vogel (The Netherlands): Lesson 3: our journey to becoming an expert centre

14:05 - 14:15 All faculty (Chair: Joe O'Sullivan, UK): Panel discussion

< ▼ **This medicinal product is subject to additional monitoring**. Adverse events should be reported. Please report any suspected adverse reaction to Bundesamt für Sicherheit im Gesundheitswesen, Website: http://www.basg.gv.at/. Please refer to your local prescribing information when using radium-223 dichloride (Xofigo). >

Xofigo 1100 kBq/mL solution for injection (Refer to full Summary of Product Characteristics before prescribing.)
Composition: *Active ingredient*: radium Ra 223 dichloride (radium-223 dichloride, 1100 kBq/ml, corresponding to 0.58 ng radium-223 at the reference date). Each vial contains 6 mL of solution (6.6 MBq radium-223 dichloride at the reference date). *Excipients:* Water for injections, sodium citrate, sodium chloride, hydrochloric acid, dilute. **Indication:** Treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases. Xofigo should be administered only by persons authorised to handle radiopharmaceuticals in designated clinical settings. **Contraindications:** There are no known contraindications. **Warnings and Precautions:** Bone marrow suppression, notably thrombocytopenia, neutropenia, leukopenia and pancytopenia, have been reported. Haematological evaluation of patients must be performed at baseline and prior to every dose. In case there is no recovery in values for absolute neutrophil count (ANC) 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 careful benefit/risk evaluation. Patients with evidence of compromised bone marrow reserve e.g. following prior cytotoxic chemotherapy and/or radiation treatment (EBRT) or patients with advanced diffuse infiltration of the bone (EOD4; "superscan"), should be treated with caution as an increased incidence of haematological adverse reactions such as neutropenia and thrombocytopenia has been observed. Limited available data indicates that patients receiving chemotherapy after Xofigo had a similar haematological profile compared to patients receiving chemotherapy after placebo. Crohn's disease and ulcerative colitis: due to the faecal excretion of Xofigo, radiation may lead to aggravation of acute inflammatory bowel disease, therefore Xofigo should only be administered to these patients after a careful benefit-risk assessment. 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. In the phase III study, cases of ONJ have been reported in 0.67% patients (4/600) in the Xofigo arm compared to 0.33% patients (1/301) in the placebo arm. However, all patients with ONJ were also exposed to prior or concomitant bisphosphonates and prior chemotherapy. Xofigo contributes to a patient's overall long-term cumulative radiation exposure and therefore, may be associated with an increased risk of cancer and hereditary defects. No cases of Xofigo-induced cancer have been reported in clinical trials in follow-up of up to three years. Depending on the volume administered, this medicinal product can contain up to 2.35 mmol (54 mg) sodium per dose. **Undesirable effects:** *Very common*: thrombocytopenia, diarrhoea, vomiting, nausea; *Common*: neutropenia, pancytopenia, leukopenia, injection site reactions; *Uncommon*: lymphopenia.
On prescription only.
Marketing Authorisation Holder: Bayer AG. 51368 Leverkusen. Germany.
Date of Revision of the underlying Prescribing Information: *August 2017*