Lunch Symposium – Bayer AG
Sunday, October 14, 13:00–14:20, Hall X

Session Title

5 years and 50,000 patients: confidence through experience with radium-223▼

Chairperson:
Stefano Fanti

Programme

13:00–13:10	**What's in a number?** Putting radium-223 into perspective	Stefano Fanti, Italy
13:10–14:10	**Meet the patients: stories from the 50,000** Use of radium-223 in mCRPC: an interactive multi-disciplinary discussion	Joe O'Sullivan, UK Inge van Oort, the Netherlands Marcel Janssen, the Netherlands
14:10–14:20	**Looking to the future** Key take aways	Stefano Fanti, Italy

▼ **This medicinal product is subject to additional monitoring**.
Adverse events should be reported. Please report any suspected adverse reaction to Bundesinstitut für Arzneimittel und Medizinprodukte, Website: www.bfarm.de

Xofigo 1100 kBq/mL solution for injection Active ingredient: radium Ra 223 dichloride, Refer to full Summary of Product Characteristics before prescribing.
Composition: *Active ingredient*: Each ml solution for injection contains 1100 kBq radium Ra 223 dichloride (radium-223 dichloride), 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 10%. **Indication:** Xofigo monotherapy or in combination with luteinising hormone releasing hormone (LHRH) analogue is indicated for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC), symptomatic bone metastases and no known visceral metastases, in progression after at least two prior lines of systemic therapy for mCRPC (other than LHRH analogues), or ineligible for any available systemic mCRPC treatment. Xofigo should be administered only by persons authorised to handle radiopharmaceuticals in designated clinical settings. **Contraindications:** Xofigo is contraindicated in combination with abiraterone acetate and prednisone/prednisolone. **Warnings and Precautions:** The safety and efficacy of Xofigo in combination with cancer therapies other than LHRH analogues have not been established; an increased risk of mortality and fractures is possible. The combination of radium-223 with other systemic cancer therapies other than LHRH analogues is not recommended. The use of Xofigo is not recommended for treatment of adults with CRPC and only asymptomatic bone metastases. In adults with CRPC and mildly symptomatic bone metastases the benefit of treatment should be carefully assessed to outweigh the risks considering that high osteoblastic activity is likely to be required for treatment benefit. In clinical studies, patients with fewer than 6 bone metastases had an increased risk of fractures and did not have a statistically significant survival benefit. A pre-specified subgroup analysis also showed that overall survival was not significantly improved in patients with a total ALP < 220 U/L. Therefore, in patients with a low level of osteoblastic bone metastases treatment with radium-223 is not recommended. 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. Before the first administration, the absolute neutrophil count (ANC) should be ≥ 1.5 x 10^9/l, the platelet count ≥ 100 x 10^9/l and haemoglobin ≥ 10.0 g/dl. Before subsequent administrations, the ANC should be ≥ 1.0 x 10^9/l and the platelet count ≥ 50 x 10^9/l. 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 (*extent of disease 4,* EOD4; "superscan"), should be treated with caution as an increased incidence of haematological adverse reactions such as neutropenia and thrombocytopenia has been observed. To patients with Crohn's disease and ulcerative colitis Xofigo should only be administered 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. Xofigo increases the risk of bone fractures, especially in patients with medical history of osteoporosis and in patients with < 6 bone metastases. Prior to starting radium-223 bone status and baseline risk of fractures of patients (e.g. osteoporosis, less than 6 bone metastases, medication increasing fracture risk, low body mass index) should be carefully assessed, and closely monitored for at least 24 months. Preventive measures should be considered before starting or resuming treatment with Xofigo. In patients with a high baseline risk of fracture, the benefit of treatment should be carefully assessed to outweigh the risk. 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 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, bone fracture; *Common*: neutropenia, pancytopenia, leukopenia, injection site reactions; *Uncommon*: lymphopenia, osteoporosis.
On prescription only.
Marketing Authorisation Holder: Bayer AG. 51368 Leverkusen. Germany.
Date of Revision of the underlying Prescribing Information: *September / October 2018*