

Radium-223 dichloride (Xofigo®) for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease

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In patients with advanced castration-resistant prostate cancer (CRPC), symptomatic bone metastases are frequently present. Xofigo® is a radiopharmaceutical that contains the active substance radium-223 dichloride, which targets bone tissue and bone metastases. The EMA licensed the agent for the treatment of adults with CRPC, symptomatic bone metastases and no known visceral metastases in November 2013, the FDA licensed Xofigo® for the same indication already in May 2013.

In a phase III trial, radium-223 was compared to placebo in 921 patients who either had progressed on docetaxel or were docetaxel-naïve (i.e. they were either not eligible or chose not to receive it). The primary endpoint was overall survival (OS). Secondary endpoints included time to first symptomatic skeletal event, time to increase in total ALP/PSA levels or quality of life. For patients treated with radium-223, OS was extended by 3.6 months compared with the control group. Secondary endpoints improved in the intervention group compared with placebo, as well as quality of life. In terms of safety, the most frequent adverse events were bone pain, nausea, anaemia and diarrhoea in both groups.

With the licensing of radium-223, treatment options for patients with mCRPC are increased. The questions of how to best sequence or combine radium-223 with other already licensed agents such as docetaxel, cabazitaxel, abiraterone acetate, enzalutamide or mitoxantrone has not yet been answered satisfactorily. Moreover, clarification is needed on optimised dosing for radium-223. Therefore, further clinical trials are needed.

The full English version is available

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