



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Xofigo

Radium-223 chloride

On 19 September 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Xofigo, 1000 kBq/mL, solution for injection, intended for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases. The applicant for this medicinal product is Bayer Pharma AG. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Xofigo is radium-223 chloride, a therapeutic pharmaceutical (ATC Code: V10XX03) that mimics calcium and preferentially targets bone, thereby relaying high linear energy from alpha radiation emitters generated during its radioactive decay to adjacent cells which is claimed to affect bone turnover (inhibition of osteoclast differentiation and osteoblast activity) and to be cytotoxic to cancer cells of bone metastases.

The benefits with Xofigo are its ability to improve survival and to delay skeletal-related events (such as pathological fractures, spinal cord compression and use of radiation to relieve symptoms or surgery to treat complications). The most common side effects are diarrhoea, nausea, vomiting and thrombocytopenia.

A pharmacovigilance plan for Xofigo will be implemented as part of the marketing authorisation.

The approved indication is: "Xofigo is indicated for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases". It is proposed that 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.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Xofigo and therefore recommends the granting of the marketing authorisation.