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Warning about use of prostate cancer medicine Xofigo in combination with Zytiga and prednisone or prednisolone

Ongoing clinical trial shows an increased risk of death and fractures

The European Medicines Agency (EMA) is investigating an increased risk of death and fractures reported in an ongoing clinical trial with the prostate cancer medicine Xofigo (radium-223 dichloride).

The clinical trial is comparing Xofigo with placebo (a dummy treatment), both given in combination with Zytiga (abiraterone acetate) and prednisone/prednisolone. It includes prostate cancer patients with no symptoms or only mild symptoms, such as pain. Xofigo is currently authorised for use in patients whose prostate cancer has spread to the bones and is causing symptoms.

A preliminary analysis by an independent committee responsible for overseeing the trial reported a rate of death of 27% (109 out of 401 patients) for the Xofigo combination compared with 20% (82 out of 405 patients) for the placebo combination. Fractures also occurred more frequently with the Xofigo combination than the placebo combination (24% versus 7%).

Patients in this study are no longer treated with Xofigo and all the patients involved are being monitored closely.

EMA will review the full results of this study as well as other available data to evaluate their impact on the authorised use of Xofigo.

While a full investigation is ongoing, doctors are asked not to use Xofigo in combination with Zytiga and prednisone/prednisolone to treat metastatic castration-resistant prostate cancer patients.

Patients who are currently being treated with Xofigo and have any questions about their treatment should contact their doctor.

More about the medicine

Xofigo is used to treat adult men with cancer of the prostate (a gland of the male reproductive system). It is authorised for use when medical or surgical castration (stopping the production of male hormones in the body using medicines or surgery) does not work, and when the cancer has spread to

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the bones and is causing symptoms such as pain but is not known to have spread to other internal organs.

The ongoing study of Xofigo in combination with Zytiga and prednisone/prednisolone included patients with castration-resistant prostate cancer that has spread mainly to the bones, who have no symptoms or only mild symptoms and who have not been treated with chemotherapy.

Xofigo was authorised in the European Union in November 2013. More information on Xofigo can be found here.

More about the procedure

The review of Xofigo has been initiated at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendations will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt an opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.