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Questions and answers

Questions and answers on the outcome of an application for Xgeva to be used in patients with castration-resistant prostate cancer at high risk of spreading to the bones

On 24 October 2013, the Committee for Medicinal Products for Human Use (CHMP) finalised its assessment of an application to extend the use of Xgeva to include the treatment of patients with 'castration-resistant' prostate cancer at high risk of spreading to the bones. The CHMP was of the opinion that the benefits of Xgeva had not been shown to outweigh its risks in these patients.

What is Xgeva?

Xgeva is a medicine used to prevent bone complications in adults with a solid tumour that has spread to the bone. These complications include fractures (breaks in the bone), spinal compression (when the spinal cord is compressed by the bone), or complications requiring radiotherapy (treatment with radiation) or surgery.

Xgeva contains the active substance denosumab and is given as an injection under the skin.

What was Xgeva expected to be used for?

The company applied for Xgeva to be used in patients with castration-resistant prostate cancer at high risk of spreading to the bones. Castration-resistant prostate cancer is cancer of the prostate (a gland of the male reproductive system) that continues to worsen despite medical or surgical castration (treatments that stop the production of male hormones). In many men with castration-resistant prostate cancer the cancer will eventually spread to the bones and Xgeva was expected to help delay or prevent this spread and so improve outcomes in these patients.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7129
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

What did the company present to support its application?

The company presented data from a main study of 1,432 men with castration-resistant prostate cancer at increased risk of bone metastases who were treated with either Xgeva or placebo (a dummy treatment). The main measure of effectiveness in the study was how long the patients lived without the cancer spreading to the bones.

What was the conclusion of the CHMP?

During its evaluation of the application, the CHMP concluded that the effect of Xgeva in delaying the spread of castration-resistant prostate cancer to the bones was small: in the main study after more than two years of treatment, Xgeva reduced the cases where the cancer spread to the bones by about 5 percentage points (47% of Xgeva patients versus 52% of placebo patients). Although the company identified a subgroup of patients where the effect of Xgeva seemed to be somewhat higher, the CHMP was of the view that the 10% reduction after 1½ years of treatment that was seen in this subgroup might have been an overestimation and may not outweigh its known risks. It was therefore not possible to conclude that the benefits of Xgeva in delaying the spread of castration-resistant prostate cancer would outweigh the risks.

As a result of the CHMP provisional opinion, the company decided not to pursue its application to extend the use of the medicine. The CHMP's evaluation did, however, lead to some minor updates in the product information for Xgeva.

What are the consequences for patients in clinical trials?

The company informed the CHMP that it was consulting on next steps concerning patients that are still receiving Xgeva in the main study. Patients in the study who have any question should speak to their doctor.

Further information about Xgeva can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports