EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 May 2014
EMA/232003/2014
EMEA/H/C/000560
EMEA/H/C/000561

Questions and answers

Withdrawal of the applications for a change to the marketing authorisation of Protelos/Osseor (strontium ranelate)

On 21 March 2014, Les Laboratoires Servier officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its applications to extend the indication of Protelos/Osseor to include the treatment of osteoarthritis of the knee and hip.

What is Protelos/Osseor?

Protelos and Osseor are identical medicines that contain the active substance strontium ranelate. They are available as sachets containing strontium ranelate (2 g) as granules to be made up into a suspension to be taken by mouth.

Protelos/Osseor has been authorised since September 2004. It is currently used to treat severe osteoporosis (a disease that makes bones fragile) in post-menopausal women and men who have a high risk of fracture.

What was Protelos/Osseor expected to be used for?

Protelos/Osseor was also expected to be used to treat osteoarthritis (a long-term disease that damages joints and makes them stiff and painful) in the knee and hip.

How is Protelos/Osseor expected to work?

In osteoarthritis, the cartilage, a smooth layer that lines the joints and helps them to move easily, is gradually lost, and the bone underneath becomes damaged and exposed. This causes pain and

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

stiffness when the joint moves. Strontium ranelate, the active substance in Protelos/Osseor, is expected to stimulate formation of new cartilage and reduce bone breakdown.

What did the company present to support its applications?

The applicant presented data from one main study involving 1,683 patients with osteoarthritis of the knee. In this study, strontium ranelate 1 or 2 g was compared with placebo (a dummy treatment). The main measure of effectiveness was the effect in slowing the loss of cartilage from the joint as measured by X-rays after 3 years of treatment.

How far into the evaluation were the applications when they were withdrawn?

The applications were withdrawn after the CHMP had evaluated the documentation provided by the company and formulated lists of questions. After the CHMP had assessed the company's responses to the last round of questions, there were still some unresolved issues.

What was the recommendation of the CHMP at that time?

Based on the review of the data and the company's response to the CHMP lists of questions, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Protelos/Osseor could not have been approved for the treatment of osteoarthritis.

The CHMP noted that the size of the benefit seen in the study was small and the long-term benefit unclear, whereas the medicine had an established risk of serious side effects. In addition, the Committee had some concerns about the way in which the loss of cartilage had been evaluated. Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Protelos/Osseor in the treatment of osteoarthritis did not outweigh its risks.

What were the reasons given by the company for withdrawing the applications?

In its letter notifying the Agency of the withdrawal of the applications, the company stated that the withdrawal was due to the fact that the data so far available were insufficient to address the CHMP's concerns.

The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that there are no consequences for any ongoing clinical trials with Protelos/Osseor.

What is happening with Protelos/Osseor for the treatment of osteoporosis?

There are no consequences on the use of Protelos/Osseor in its authorised indications.

The full European Public Assessment Report for Protelos/Osseor can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.