



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 June 2019
EMA/353961/2019
EMA/H/C/004465

Refusal of the marketing authorisation for Evenity (romosozumab)

The European Medicines Agency has recommended the refusal of the marketing authorisation for Evenity, a medicine intended for the treatment of osteoporosis.

The Agency issued its opinion on 27 June 2019. The company that applied for authorisation, UCB Pharma S.A., may ask for re-examination of the opinion within 15 days of receiving the opinion.

What is Evenity and what was it intended to be used for?

Evenity was developed as a medicine for the treatment of osteoporosis (a disease that makes bones fragile) in women who have been through the menopause and men at increased risk of bone fractures. Evenity contains the active substance romosozumab and was to be available as an injection to be given under the skin once a month for a year.

How does Evenity work?

The active substance in Evenity, romosozumab, is a monoclonal antibody (a type of protein) that attaches to a specific target in the body called sclerostin. Sclerostin is a natural substance that plays an important role in regulating formation and breakdown of bone. By attaching to sclerostin and blocking its action, romosozumab increases the formation of new bone tissue, and reduces the breakdown of existing bone. This helps strengthen bones and reduce the risk of fractures.

What did the company present to support its application?

The company presented data on the quality, safety and effectiveness of Evenity, including two main studies involving over 11,000 postmenopausal women with osteoporosis and one main study involving 252 men with osteoporosis. In one of these studies, involving women considered at high risk of fracture, the medicine was compared with another osteoporosis medicine, alendronate, and in the other two studies it was compared with placebo (a dummy treatment). The main measure of effectiveness in all the studies was the number of new fractures that developed in the bones of the spine (vertebrae).

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



What were the main reasons for refusing the marketing authorisation?

The Agency was concerned because the results suggested that patients given Evenity had an increased risk of serious effects on the heart or circulatory system, such as heart attacks or strokes. In addition, when all the data were looked at together, there were more deaths in patients aged over 75 years given the medicine. As it was unclear why the medicine appeared to increase the risk of heart and circulatory problems, and there was no obvious group of patients in whom the risk of these was lower, measures to reduce the risk could not readily be put in place.

With respect to its beneficial effects, Evenity was effective in reducing the risk of fracture in patients with severe osteoporosis, although the benefit was not so convincing in patients with less severe disease.

Under the circumstances, the Agency's opinion was that the benefits of Evenity did not outweigh its risks and it recommended refusing marketing authorisation.

Does this refusal affect patients in clinical trials?

The company informed the Agency that there is no impact on patients in current clinical trials with Evenity.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.