17 October 2019
EMA/546072/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Evenity

romosozumab

On 17 October 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion following a re-examination procedure, recommending the granting of a marketing authorisation for the medicinal product Evenity, intended for the treatment of severe postmenopausal osteoporosis. The applicant for this medicinal product is UCB Pharma S.A.

Evenity will be available as a solution for injection (105 mg). The active substance of Evenity is romosozumab, a treatment for metabolic bone diseases affecting bone structure and mineralisation (ATC code: M05BX06). It works by inhibiting the action of sclerostin, a signalling protein in bone metabolism, thereby increasing bone formation and decreasing bone resorption.

The benefits with Evenity are its ability to decrease the number of osteoporotic fractures, including vertebral and non-vertebral fractures, in postmenopausal women with severe osteoporosis and at high risk of fractures. The most common side effects are nasopharyngitis and arthralgia; serious cardiovascular events are an important identified risk.

The full indication is: “Treatment of severe osteoporosis in postmenopausal women at high risk of fracture (see section 5.1)”. It is proposed that Evenity treatment be initiated and supervised by specialist physicians experienced in the treatment of osteoporosis.

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

[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

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