EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 October 2022
EMA/806878/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Eladynos

abaloparatide

On 13 October 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Eladynos, intended for the treatment of osteoporosis in postmenopausal women at increased risk of fracture. The applicant for this medicinal product is Radius Health Ireland Ltd.

Eladynos will be available as a 80 µg/dose solution for subcutaneous injection. The active substance of Eladynos is abaloparatide, a parathyroid hormone medicinal product (ATC code: H05AA04). Abaloparatide increases new bone formation on trabecular and cortical bone surfaces by stimulating osteoblastic activity.

The benefits of Eladynos are its ability to increase bone mineral density in the lumbar spine and hip and to reduce new vertebral fractures compared to placebo, as observed in a comparative Phase 3, randomized, double-blind, placebo-controlled, multi-centre, international study. The most common side effects are hypercalciuria, dizziness, back pain, nausea, headache, arthralgia, hypertension, injection site reactions and palpitations.

The full indication is:

Treatment of osteoporosis in postmenopausal women at increased risk of fracture.

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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