18 September 2025
EMA/CHMP/299126/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lynkuet

elinzanetant

On 18 September 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lynkuet, intended for the treatment of moderate to severe vasomotor symptoms (hot flushes). The applicant for this medicinal product is Bayer AG.

Lynkuet is a gynaecological product (ATC code: G02CX07) available as 60 mg soft capsules. The active substance of Lynkuet is elinzanetant, a non-hormonal, selective, neurokinin 1 (NK-1) and 3 (NK-3) receptor antagonist. By blocking NK-1 and NK-3 receptors signalling, elinzanetant is postulated to normalise neuronal activity involved in thermo- and sleep regulation in the hypothalamus.

The main benefit of Lynkuet is a reduction in the frequency of moderate to severe vasomotor symptoms, as demonstrated in three randomised, double-blind, placebo-controlled phase 3 studies: two in postmenopausal women and one in adult women with, or at high risk for developing, hormone-receptor-positive breast cancer and who are experiencing vasomotor symptoms caused by adjuvant endocrine therapy. Other demonstrated benefits are improvements in sleep disturbances and menopausal quality of life. The most common side effects with Lynkuet for both indications include fatigue, somnolence, headache, diarrhoea and muscle spasms while depression was additionally identified only in women with vasomotor symptoms caused by AET related to breast cancer. Use during pregnancy is contraindicated.

The full indication is:

> Lynkuet is indicated for the treatment of moderate to severe vasomotor symptoms (VMS):
>
> - associated with menopause (see section 5.1)
> - caused by adjuvant endocrine therapy (AET) related to breast cancer (see section 5.1).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website 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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