13 November 2025
EMA/CHMP/354855/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Inluriyo

imlunestrant

On 13 November 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 Inluriyo, intended for the treatment of adults with locally advanced or metastatic breast cancer with an activating ESR1-mutation.

The applicant for this medicinal product is Eli Lilly Nederland B.V.

Inluriyo will be available as 200 mg film-coated tablets. The active substance of Inluriyo is imlunestrant, an anti-oestrogen endocrine therapy (ATC code: not yet assigned). Imlunestrant is an antagonist and degrader of wild-type and mutant oestrogen receptor α (ERα), leading to inhibition of oestrogen receptor-dependent gene transcription and cellular proliferation in ER-positive breast cancer cells.

The benefit of Inluriyo monotherapy is an improved progression-free survival (PFS) compared with fulvestrant or exemestane in adults with ER-positive, HER2-negative locally advanced or metastatic breast cancer with an activating ESR1-mutation who had disease progression following prior treatment with an endocrine based regimen, as shown in a phase 3, randomised, open-label study. The most common side effects with Inluriyo monotherapy include increased liver enzymes, fatigue, diarrhoea, nausea and vomiting.

The full indication is:

> Inluriyo is indicated as monotherapy for the treatment of adult patients with oestrogen receptor (ER)-positive, HER2-negative, locally advanced or metastatic breast cancer with an activating ESR1-mutation, who have disease progression following prior treatment with an endocrine based regimen (for biomarker-based patient selection, see section 4.2).
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> In pre- or perimenopausal women, or men, Inluriyo should be combined with a luteinising hormone-releasing hormone (LHRH) agonist.

[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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Treatment with Inluriyo should be initiated and supervised by physicians experienced in the use of cancer treatments.

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.