22 May 2025
EMA/CHMP/134194/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Itovebi

inavolisib

On 22 May 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 Itovebi, intended for the treatment of adults with *PIK3CA*-mutated, oestrogen receptor (ER)-positive, HER2-negative locally advanced and metastatic breast cancer.

The applicant for this medicinal product is Roche Registration GmbH.

Itovebi will be available as 3 mg and 9 mg film-coated tablets. The active substance of Itovebi is inavolisib (ATC code: not yet assigned). Inavolisib is a phosphatidylinositol 3-kinase (PI3K) inhibitor. It inhibits the activity of downstream targets in the PI3K signalling pathway, including Akt, resulting in reduced cellular proliferation and apoptosis in *PIK3CA*-mutated breast cancer cell lines.

The benefits of Itovebi, in combination with palbociclib and fulvestrant, are prolonged progression-free survival and overall survival, as shown in a phase 3 randomised, double blind, placebo-controlled study in adults with *PIK3CA*-mutated, HR-positive, HER2-negative, locally advanced or metastatic breast cancer. The most common side effects with Itovebi include hyperglycaemia, stomatitis, diarrhoea, thrombocytopenia, fatigue, anaemia, nausea, decreased appetite, rash, headache, decreased weight, vomiting and urinary tract infection.

The full indication is:

> Itovebi, in combination with palbociclib and fulvestrant, is indicated for the treatment of adult patients with *PIK3CA*-mutated, oestrogen receptor (ER)-positive, HER2-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment (see section 5.1).
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> Patients previously treated with a CDK 4/6 inhibitor in the (neo)adjuvant setting should have had an interval of at least 12 months between termination of CDK 4/6 inhibitor treatment and the detection of recurrence.
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> In pre/perimenopausal women and in men, endocrine therapy should be combined with a

[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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luteinising hormone-releasing hormone (LHRH) agonist.

Treatment with Itovebi should be initiated 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.