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Summary report on authorisation dated 20 May 2025

Itovebi® (active substance: inavolisib)

Authorisation in Switzerland: 31 January 2025

Film-coated tablets for the treatment of adults with *PIK3CA*-mutated, HR-positive, HER2-negative, locally advanced or metastatic breast cancer in combination with palbociclib and fulvestrant

About the medicinal product

Itovebi contains the active substance inavolisib.

It is used to treat adult women with a specific form of breast cancer that is hormone receptor-positive (HR-positive) and HER2-negative (negative in relation to human epidermal growth factor receptor 2). Itovebi is used if the breast cancer has a mutation in the *PIK3CA* gene and has progressed during, or within 12 months of the completion of, adjuvant endocrine therapy (a supportive form of hormone therapy), or has spread to other parts of the body (locally advanced or metastatic).

Itovebi is administered in combination with two other cancer drugs, palbociclib and fulvestrant.

Worldwide, breast cancer is the leading cause of cancer-related deaths in women. The most common form of breast cancer is hormone receptor-positive (HR+) and HER2-negative (HER2-) breast cancer. Approximately 70% of all breast cancers are of this type.

Itovebi was authorised as part of "Project Orbis". Project Orbis is a programme for promising cancer treatments coordinated by the FDA, the US regulatory authority. It provides a framework for the concurrent submission and review of cancer medicines by several international partner authorities in various countries. The ultimate aim is to give patients faster access to innovative cancer treatments. In addition to the FDA, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Israel (MOH), Canada (HC), Singapore (HSA), Switzerland (Swissmedic), and the United Kingdom (MHRA) are currently represented in Project Orbis.

Mode of action

Inavolisib, the active substance in Itovebi, blocks the effect of the protein p110 alpha, an enzyme encoded by the *PIK3CA* gene. Mutations in the *PIK3CA* gene can lead to an increase in the activity of this protein and thereby promote the growth of cancer cells. By inhibiting p110 alpha, Itovebi helps to slow tumour growth and reduce progression of the cancer.

Use

Itovebi, containing the active substance inavolisib, is a prescription-only medicine.

It is available as film-coated tablets in dosage strengths of 3 mg and 9 mg. The recommended dose is 9 mg once daily, taken with or without food. If severe side effects occur, the doctor can reduce the dose to 6 mg or 3 mg daily.
Itovebi is used in combination with palbociclib and fulvestrant.

The treatment with Itovebi is continued until the disease progresses or until unacceptable side effects occur.

Efficacy

The efficacy of Itovebi was investigated in the INAVO120 study with 325 female patients with *PIK3CA*-mutated, HR+, HER2-, locally advanced or metastatic breast cancer.

The patients received either Itovebi in combination with palbociclib and fulvestrant or a placebo (dummy drug) plus palbociclib and fulvestrant. The primary endpoint of the study was progression-free survival (PFS)[1], which was assessed by the investigators (study doctors).

The treatment with Itovebi in combination with palbociclib and fulvestrant showed a statistically significant improvement in median[2] PFS of 15 months compared to the placebo group with a median PFS of 7.3 months.

The hazard ratio was 0.43, which means that Itovebi reduced the risk of disease progression by 57%.

Precautions, undesirable effects, and risks

Itovebi must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects that occurred during the treatment with Itovebi included hyperglycaemia (excessively high blood sugar) (63.3%), diarrhoea (57.6%), stomatitis (mouth sores) (52.5%), nausea (44.2%), tiredness (42.4%), anaemia (low red blood cell count) (33.7%), thrombocytopenia (low platelet count) (33.7%), loss of appetite (29.9%), vomiting (29%) and rash (27.2%).

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

[1] Progression-free survival (PFS): Period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

[2] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always less than the median, the other half are always greater.

Why the medicinal product has been authorised

Despite the numerous available treatment options, advanced breast cancer remains an incurable disease. There is an urgent medical need for new treatment options that improve patient survival and possess tolerable side effects.

The pivotal study INAVO120 showed a prolonged progression-free survival after Itovebi was administered in combination with palbociclib and fulvestrant in the investigated group of female breast cancer patients with HR+ and HER2- tumours with *PIK3CA* mutation.

Taking all the risks and precautions into account, and based on the available data, the benefits of Itovebi outweigh the risks. Swissmedic has therefore authorised the medicinal product Itovebi, containing the active substance inavolisib, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Itovebi®

Information for patients (package leaflet): Information for patients Itovebi®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.