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Summary report on authorisation dated 5 December 2025

Jemperli® (active substance: dostarlimab)

Indication extension in Switzerland: 13 March 2025

Concentrate for solution for infusion for the treatment of adults with recurrent or advanced endometrial cancer

About the medicinal product

Jemperli is a cancer treatment containing the active substance dostarlimab.

Jemperli was authorised on 17 February 2022 as monotherapy for the treatment of adults with mismatch repair deficient (dMMR)[1] / microsatellite instability-high (MSI-H)[2] recurrent or advanced endometrial cancer (cancer of the lining of the uterus) that had previously been treated with other medicinal products which were not sufficiently effective (second-line treatment).

On 22 December 2023, Jemperli was also approved for first-line treatment in combination with chemotherapy based on carboplatin and paclitaxel for the treatment of adult patients with recurrent or advanced dMMR / MSI-H endometrial cancer who are at high risk of disease recurrence.

Around 25% of patients with endometrial cancer have mismatch repair deficient / microsatellite instability-high (dMMR/MSI-H) tumours, while the rest have mismatch repair proficient / microsatellite stable (MMRp/MSS) tumours.

The present indication extension means that Jemperli can now also be used in combination with chemotherapy based on carboplatin and paclitaxel for the treatment of all adult patients with recurrent or advanced endometrial cancer, including those with MMRp/MSS tumours, who are at high risk of disease recurrence.

[1] DNA mismatch repair: Mismatch repair (MMR) is a natural mechanism of the body for identifying and correcting (DNA repair proteins) mismatches in the synthesis of DNA (carrier of genetic information in the cells).

[2] Microsatellite instability: Impaired DNA mismatch repair results in the accumulation of mutations that can be identified, by comparison with healthy tissue, as a microsatellite instability (MSI).

Mode of action

The active substance dostarlimab is a monoclonal antibody (immunologically active protein) that binds to a specific protein known as PD-1 (programmed cell death receptor-1) and thereby prevents it from binding to the PD-ligand (programmed cell death-ligand). As a result, the immune response inhibited by the tumour is reduced or eliminated, enabling the body's own immune system to better fight the tumour and delay or stop its growth.

Administration

Jemperli is a prescription-only medicine supplied as a concentrate for solution for infusion that is injected into the veins.

Jemperli is used in combination with chemotherapy based on carboplatin and paclitaxel.

The recommended dosage is 500 mg dostarlimab as combination therapy administered as a 30-minute infusion every three weeks for six cycles, followed by 1,000 mg as monotherapy every six weeks for all cycles thereafter.

Efficacy

The efficacy of Jemperli was investigated in the RUBY study. This study investigated Jemperli in combination with chemotherapy based on carboplatin and paclitaxel versus placebo plus the same chemotherapy in patients with primary advanced or recurrent endometrial cancer.

Patients were randomised (assigned arbitrarily) at a ratio of 1:1. A total of 494 patients with dMMR/MSI-H and MMRp/MSS tumours were enrolled in the study.

The results showed that the the combination of Jemperli (dostarlimab) and chemotherapy significantly reduced the risk of the disease progressing.

Median progress-free survival (PFS)[3] was 11.8 months in the Jemperli arm versus 7.9 months in the placebo arm across the entire population (dMMR/MSI-H and MMRp/MSS tumours). An extension in overall survival (OS)[4] was also observed: 44.6 months with Jemperli versus 28.2 months with placebo.

Precautions, undesirable effects, & risks

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

The most common undesirable effects (affecting more than 10% of patients) were a low red blood cell count (anaemia), reduced thyroid gland activity, loss of appetite, cough, nausea, diarrhoea, constipation, vomiting, increased liver enzyme levels (elevated transaminases), itching, skin rash, joint pain, tiredness and fever.

Jemperli can also trigger what are known as immune-related adverse events. These are caused by overactivation of the immune system. All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

[3] 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.

[4] Overall survival (OS): The period between the start of treatment and the death of the patient.

If Jemperli is administered in combination with other medicinal products (carboplatin and paclitaxel), the Information for healthcare professionals for each of the preparations in the combination therapy should be consulted before the start of treatment.

Why the medicinal product has been authorised

The frequency of endometrial cancers has increased in recent decades. It is often diagnosed at an early stage, when it is still curable. But if the endometrial cancer recurs, or if metastases form, it continues to be a fatal illness.

The RUBY study showed that patients with recurrent or advanced endometrial cancer who are at high risk of disease recurrence benefit from treatment with Jemperli in combination with carboplatin and paclitaxel. The combination therapy resulted in a significantly longer PFS and OS compared to chemotherapy on its own in the entire population (dMMR/MSI-H and MMRp/MSS tumours), with patients with dMMR/MSI-H tumours deriving greater benefit than those with MMRp/MSS tumours. The side effects that were observed are acceptable and manageable in the context of advanced endometrial cancer.

Based on all the available data, the benefits of Jemperli outweigh the risks. Swissmedic has therefore approved the indication extension for Jemperli as combination therapy with carboplatin and paclitaxel for the first-line treatment of patients with recurrent or advanced endometrial cancer who are at high risk of disease recurrence.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Jemperli®

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.

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