swissmedic

Public Summary SwissPAR dated 30 June 2023

Lunsumio® (active substance: mosunetuzumab)

Temporary authorisation in Switzerland: 9 February 2023

Medicinal product (concentrate for solution for infusion) for the treatment of adults with relapsed or refractory follicular lymphoma (r/r FL).

About the medicine

The medicinal product Lunsumio, containing the active substance mosunetuzumab, is used to treat adults with relapsed (recurrent) or refractory[1] follicular lymphoma (r/r FL).

Patients had previously undergone at least two lines of systemic[2] therapy to which they had not responded//which were unsuccessful.

r/r FL is a malignant cancer affecting mainly the parts of the body with a large amount of lymphatic tissue[3].

Since r/r FL is a rare, life-threatening disease, Lunsumio has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Lunsumio was authorised under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in another country with comparable medicinal product control. In this case, Swissmedic takes into consideration the results of checks carried out by the foreign regulatory agency, provided certain requirements are fulfilled. These involve checks on the quality, efficacy, and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland.

The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

In deciding whether to authorise Lunsumio in Switzerland, Swissmedic has accepted parts of the assessment and approval decision of the European authority (EMA).

Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Public Summary SwissPAR, Swissmedic refers to the

[1] Refractory: In relation to cancer, refractory means that the cancer is resistant to treatment and does not recede or may even progress, despite treatment.

[2] Systemic therapy: In contrast to local therapy (treatment at the site of the disorder), systemic therapy involves treatment of the entire body to eliminate a disorder.

[3] Lymphatic tissue: Lymphatic tissue (e.g. the spleen, lymph nodes or bone marrow) is where lymphocytes, which are a subgroup of leukocytes (white blood cells), differentiate and multiply.

Assessment Report and the short report issued by the reference authority: (www.ema.europa.eu)

Mode of action

In follicular lymphoma, B cells that have undergone malignant changes reproduce in an uncontrolled fashion. Mosunetuzumab is an antibody (an immunologically active protein) that binds both to the tumour cell, via the bond to the CD20 receptor (binding site) on the B cells, and to the CD3 receptor on the T cells (cells of the immune system). As a result, mosunetuzumab links the cancer cells with the T cells, in turn activating the T cells, which are then able to kill the target B cells.

Indication

Lunsumio, containing the active substance mosunetuzumab, is a prescription-only medicine available as a vial containing 1 mg of the active substance in 1 ml or 30 mg of the active substance in 30 ml.

Lunsumio is injected into the veins. The dosage is adjusted gradually. A treatment cycle lasts 21 days. Lunsumio should be used for 8 cycles.

Treatment with Lunsumio is initiated and monitored by a healthcare professional with experience in the administration of cancer treatments. It must be administered in a setting with appropriate medical facilities for treating possible severe reactions. Inpatient monitoring is needed at the start of treatment, and also at a later stage of the treatment if required.

Prior to treatment with Lunsumio, preliminary treatment (premedication) is given to reduce the risk of these severe reactions.

Efficacy

The efficacy of Lunsumio in patients with relapsed or refractory follicular lymphoma was evaluated on the basis of the pivotal GO29781 trial. The patients had previously received at least two lines of systemic therapy, including another monoclonal antibody that binds to the CD20 receptor of the B cells, and another medicine directed primarily at the genetic material of cells.

The interim evaluation showed that 80% of the patients had responded to the therapy (objective response rate), and in 60% the disease was no longer detectable (complete remission).

Precautions, undesirable effects & risks

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

Lunsumio may cause serious or life-threatening reactions such as cytokine release syndrome (CRS[4]) and neurological toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS)[5].

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

[4] CRS: Cytokine release syndrome is a systemic inflammatory response to the massive secretion of cytokines (proteins), which activate the white blood cells.

[5] ICANS: Immune effector cell-associated neurotoxicity syndrome is a complex of diverse neurological symptoms of varying intensity, such as impaired consciousness.

Why the medicinal product has been authorised

r/r follicular lymphoma is incurable with the currently available treatments. Patients with r/r FL who have already received two lines of therapy have a high need for new therapies with acceptable side effects.

The efficacy of Lunsumio in patients who have previously received at least 2 lines of systemic therapy is promising on the basis of the complete remission rate (60%). However, additional data are required, including for further parameters, to confirm the results. A further trial is currently ongoing to confirm the benefit.

The medicinal product Lunsumio was therefore authorised temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials were available or had been concluded at the time of authorisation. The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Lunsumio

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 Public Summary SwissPAR.

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.