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Public Summary SwissPAR dated 6 March 2024

Elrexfio® (active substance: elranatamab)

Temporary authorisation in Switzerland: 5 September 2023

Solution for injection for the treatment of adults with relapsed or refractory multiple myeloma

About the medicinal product

The medicinal product Elrexfio, containing the active substance elranatamab, is used for the treatment of advanced multiple myeloma ("bone marrow cancer") in adults whose multiple myeloma (MM) has not responded or is no longer responding to drugs in the 3 standard therapeutic classes, and who have demonstrated disease progression after the last treatment.

MM is a rare form of cancer that accounts for around 1-2% of all cancers. The frequency of new cases of MM increases with age. Two thirds of new sufferers are aged over 65. The disease is characterised by excessive replication of plasma cells, which are a type of white blood cell responsible for producing antibodies in the body's defence system (immune system). In MM, the plasma cells multiply in an uncontrolled way in the bone marrow and occasionally in other organs as well. This prevents the normal formation of blood cells and can destroy, or disrupt the function of, bones and other organs.

Elrexfio was authorised temporarily in connection with "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. Currently, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Israel (MOH), Canada (HC), Singapore (HSA), Switzerland (Swissmedic), and the United Kingdom (MHRA) are represented in Project Orbis.

Mode of action

Elranatamab is an antibody (an immunologically active protein) that binds both to the tumour cell, via the so-called B cell maturation antigen (BCMA), and the CD3 receptor (binding site) on the T cells (cells of the immune system). As a result, elranatamab links the cancer cells with the T cells, in turn activating the T cells, which are then able to kill the multiple myeloma cells.

Administration

Elrexfio is a prescription-only medicine.

Elrexfio is available as a solution for injection in a vial containing a dose of either 44 mg per 1.1 mL or 76 mg per 1.9 mL, and the dosage is increased gradually up to the treatment dose. Elrexfio is injected under the skin,

Elrexfio should be administered only under the supervision of a healthcare professional with experience of treatment of the potential severe side effects. At the start of treatment with Elrexfio, and also at a later stage of the treatment if necessary, inpatient monitoring is needed for at least 48 hours after administration.

Efficacy

The efficacy of Elrexfio was investigated in a single-arm study without a control group in patients with relapsed (recurrent) or refractory (treatment-resistant) multiple myeloma (MM).

Historically, patients with relapsed or refractory MM who have already received treatment with the 3 standard therapeutic classes have had a poor prognosis. The overall response rate (ORR)[1] used to be approx. 30%. The median[2] progression-free survival (PFS)[3] was approx. 3 to 6 months and overall survival (OS) approx. 6 to 12 months.

With Elrexfio, the study population achieved an ORR of up to 57%. A reliable evaluation of PFS and OS was not yet possible at the time of authorisation based on the data available. However, the studies had not yet been concluded and further data in this regard are expected as part of the temporary authorisation procedure.

Precautions, undesirable effects, & risks

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

The most common undesirable effects include cytopenia[4], infections, cytokine release syndrome (CRS)[5], and adverse neurological reactions. All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

Since multiple myeloma is a rare, life-threatening disease, Elrexfio has been authorised

[1] ORR (objective response rate) is defined as the percentage of patients who respond to the treatment.

[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.

[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] Cytopenia: reduction in the number of cells in the blood.

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

as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Patients with relapsed or refractory and heavily pretreated MM have a poor prognosis. MM patients treated with Elrexfio demonstrated a high response rate of up to 57%. In addition to the 3 standard therapeutic classes, other anti-BCMA therapies are now available to treat advanced MM, particularly CAR T-cell therapy. Even where the MM had progressed again following such a prior anti-BCMA therapy, a good response rate of 30% was achieved after administration of Elrexfio.

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Taking the risks and precautions into account, and based on the available data, Swissmedic has temporarily authorised the medicinal product Elrexfio, containing the active substance elranatamab, in Switzerland (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 authorisation if the benefit-risk assessment of the results remains positive.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Elrexfio®

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.