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Tepkinly® (active substance: epcoritamab)

Temporary authorisation in Switzerland: 15 February 2024

Concentrate for solution for injection for monotherapy of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after 2 or more lines of systemic therapy

About the medicinal product

Tepkinly, containing the active substance epcoritamab, is used to treat adults with a specific type of cancer called "diffuse large B-cell lymphoma" (DLBCL).

DLBCL is a malignant disorder of the lymphatic system[1] that originates from mature B lymphocytes (white blood cells). It is an aggressive and rapidly growing form of non-Hodgkin lymphoma (NHL).

Tepkinly is used to treat recurrent (relapsed) or refractory[2] DLBCL. Patients have previously received at least 2 lines of systemic[3] therapy, including a CD20-targeted antibody therapy. The DLBCL also continued to progress despite previous specific CAR T-cell therapy[4] or the patients were unsuitable for this treatment.

Since DLBCL is a rare and life-threatening disease, the medicine has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Mode of action

The active substance epcoritamab is a "bispecific monoclonal antibody" (an immunologically effective protein). Epcoritamab binds both to the tumour cells, by binding to the CD20 receptor (binding site) on the surface of B cells, and to the CD3 receptor on the surface of T cells (cells of the immune system). By binding simultaneously to CD20 on

[1] Lymphatic system: The lymphatic system includes all the lymph pathways in the body plus the lymphatic organs, including the lymph nodes, the spleen, the lymphatic tissues in the gastrointestinal tract and throat, and the thymus gland.

[2] In the context of cancer, refractory means that the cancer does not respond to the treatment and fails to regress, or even progresses, despite the treatment.

[3] 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.

[4] CAR T-cell therapy is a specific immunotherapy for cancer in which the patients' own immune cells are taken and modified using gene technology so that they recognise cancer cells and specifically destroy them. The modified CAR T cells are administered to the patient via an infusion.

B cells and CD3 on T cells, there is direct contact between the tumour cells and T cells, leading to replication and activation of the T cells. Specific proteins that play a key role in immune defence are excreted as a result.

Thanks to this mechanism of action, the immune system can kill the target B cells, thereby inhibiting the growth of the cancer.

Administration

Tepkinly, containing the active substance epcoritamab, is a prescription-only medicine.

Tepkinly is available as a concentrate for solution for injection containing 4 mg epcoritamab in 0.8 mL solution. It is injected subcutaneously, i.e. under the skin,

The dose is administered according to a specific schedule. During the first 3 treatment cycles, the medication is administered weekly. In the following 6 cycles, administration is reduced to every 2 weeks. From the tenth cycle and for all subsequent cycles, Tepkinly is only administered once a month.

Treatment with Tepkinly is initiated and monitored by a healthcare professional with experience in the administration of cancer treatments. It is administered in a setting with appropriate medical facilities for treating possible severe reactions.

Efficacy

The efficacy of Tepkinly in patients with DLBCL was evaluated on the basis of the pivotal EPCORE NHL-1 trial.

The trial participants had previously received at least 2 lines of systemic therapy, including a CD20-targeted antibody therapy and a CAR T therapy, or these therapies were not possible.

An objective response rate (ORR)[5] of 56% was observed and the median[6] survival was 14.7 months.

[5] Objective response rate: the ORR is defined as the percentage of patients who respond to the treatment.

[6] 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.

Precautions, undesirable effects, & risks

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

Tepkinly may cause serious or life-threatening reactions such as cytokine release syndrome (CRS)[7] and neurological side effects, including immune effector cell-associated neurotoxicity syndrome (ICANS)[8].

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

Why the medicinal product has been authorised

The EPCORE NHL-1 trial showed that patients with relapsed or refractory DLBCL who received Tepkinly benefited from the treatment. Tepkinly can delay progression of DLBCL.

The efficacy of Tepkinly in patients who had previously received at least 2 lines of systemic therapy and CAR T-cell therapy, or in whom these therapies was not possible, is therefore very promising. However, additional data are required, including for further parameters, to confirm the results.

The medicinal product Tepkinly was 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 authorisation without special conditions 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 Tepkinly®

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.

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

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