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Tepkinly (*epcoritamab*)

An overview of Tepkinly and why it is authorised in the EU

What is Tepkinly and what is it used for?

Tepkinly is a cancer medicine used to treat adults with a blood cancer called diffuse large B-cell lymphoma (DLBCL) whose cancer has returned (relapsed) or stopped responding (refractory) after at least two previous treatments.

DLBCL is rare, and Tepkinly was designated an 'orphan medicine' (a medicine used in rare diseases) on 24 February 2022. Further information on the orphan designation can be found on the EMA website.

Tepkinly contains the active substance epcoritamab.

How is Tepkinly used?

Tepkinly can only be obtained with a prescription and treatment must be started and supervised by a doctor experienced in treating cancer, in a location with appropriate medical support to manage severe side effects such as cytokine release syndrome (CRS, a potentially life-threatening condition that causes fever, vomiting, shortness of breath, headache and low blood pressure).

Tepkinly is given as an injection under the skin, in cycles of 28 days. Treatment starts with injections on days 1, 8 and 15 at increasing doses (so-called step-up dosing). After step-up dosing, patients are given the full dose on certain days of each cycle. Treatment can continue until the disease gets worse or the patient experiences unacceptable side effects.

Several medicines are given before Tepkinly to reduce the risk of CRS. Patients should also be closely monitored for serious side effects like CRS and immune effector cell-associated neurotoxicity syndrome (ICANS, a neurological disorder with symptoms including problems with speech and writing, confusion and depressed level of consciousness), especially after receiving the full dose for the first time.

For more information about using Tepkinly, see the package leaflet or contact your doctor or pharmacist.

How does Tepkinly work?

DLBCL is a cancer that affects B cells, a type of white blood cell. The active substance in Tepkinly, epcoritamab, is an antibody (a type of protein) that recognises and attaches to two targets simultaneously: CD20, a protein that is present on the surface of B cells (including the cancer cells),

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and CD3, a protein found on the surface of healthy T cells (cells in the immune system). By attaching to CD20 and CD3 proteins, Tepkinly brings the cancer cells and T cells together. This encourages the T cells to destroy the cancer cells and helps control the disease.

What benefits of Tepkinly have been shown in studies?

The benefits of Tepkinly were evaluated in a study involving 157 adults with DLBCL or a related lymphoma whose cancer had returned or was not responding after at least two other treatments. In this study, Tepkinly was given for an average of four months and was not compared with other medicines or placebo (dummy treatment). Of the patients with DLBCL, 62% (86 out of 139) had either a complete response (no sign of cancer) or a partial response to Tepkinly; they maintained these responses for an average of around 16 months.

What are the risks associated with Tepkinly?

For the full list of side effects and restrictions with Tepkinly, see the package leaflet.

The most common side effects with Tepkinly (which may affect more than 1 in 5 people) include CRS, tiredness, neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), injection site reactions, pain in muscles and bones, abdominal (belly) pain, fever, nausea (feeling sick) and diarrhoea.

The most common serious side effects (which may affect more than 3 in 10 people) was CRS.

Why is Tepkinly authorised in the EU?

Patients with DLBCL whose cancer has returned or not responded after at least two previous treatments have limited treatment options. Treatment with Tepkinly was shown to provide a clinically meaningful and durable response. Although serious side effects, particularly CRS and ICANS, can occur, they were considered manageable with appropriate measures. The European Medicines Agency therefore decided that Tepkinly's benefits are greater than its risks and it can be authorised for use in the EU.

Tepkinly has been given 'conditional authorisation'. This means that the European Medicines Agency decided that the benefits of Tepkinly are greater than its risks, but the company will have to provide additional evidence after authorisation.

Conditional authorisation is granted on the basis of less comprehensive data than are normally required. It is granted for medicines that fulfil an unmet medical need to treat serious diseases and when the benefits of having them available earlier outweigh any risks associated with using the medicines while waiting for further evidence. Every year, the Agency will review any new information that becomes available until data become comprehensive, and this overview will be updated as necessary.

Since Tepkinly was given conditional authorisation, at the time of authorisation the company marketing Tepkinly was required to provide updated results from the main study. The company was also required to provide results from a study comparing Tepkinly with another immunochemotherapy in patients with relapsed or refractory DLBCL.

What measures are being taken to ensure the safe and effective use of Tepkinly?

The company that markets Tepkinly will provide patients with an alert card to inform them about the risks of the serious side effects CRS and ICANS and to give instructions on when to contact their doctor if they experience symptoms. The company will also provide the final results of a study with Tepkinly to confirm the safety and benefit of the recommended dose.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Tepkinly have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Tepkinly are continuously monitored. Suspected side effects reported with Tepkinly are carefully evaluated and any necessary action taken to protect patients.

Other information about Tepkinly

Tepkinly received a conditional marketing authorisation valid throughout the EU on 22 September 2023.

Further information on Tepkinly can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/tepkinly.

This overview was last updated in 09-2023.