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Ordspono (*odronextamab*)

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

What is Ordspono and what is it used for?

Ordspono is a cancer medicine for treating adults with follicular lymphoma or diffuse large B-cell lymphoma (DLBCL), two types of blood cancer. Ordspono is used when the cancer has returned (relapsed) or not responded (refractory) after at least two previous therapies that affect the whole body (systemic therapies).

Ordspono contains the active substance odronextamab.

How is Ordspono used?

Ordspono can only be obtained with a prescription, and treatment must be monitored by a healthcare professional experienced in the treatment of cancer. It should be given in a setting with appropriate medical support to manage severe reactions due to cytokine release syndrome (a potentially life-threatening condition that causes fever, vomiting, shortness of breath, headache and low blood pressure).

Ordspono is given as an infusion (drip) into a vein. Treatment starts with four 21-day cycles. In the first cycle, infusions are given on days 1, 2, 8, 9, 15 and 16 at increasing doses; in cycles 2 to 4, infusions are given on days 1, 8 and 15. Ordspono is then given every 2 or 4 weeks, depending on how the patient responds to treatment. Treatment should continue until the disease gets worse or the patient experiences unacceptable side effects.

To reduce the risk of developing cytokine release syndrome and infusion-related reactions, patients are given medicines before and after certain Ordspono infusions for the first 2 cycles, and beyond if needed.

The doctor may delay doses if certain side effects occur or stop treatment altogether for certain severe side effects.

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

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How does Ordspono work?

Follicular lymphoma and DLBCL are cancers that affect B cells, a type of white blood cell. The active substance in Ordspono, odronextamab, is an antibody (a type of protein) which is described as 'bispecific' because it recognises and attaches to two targets simultaneously: CD20, a protein on the surface of B cells (including the cancer cells), and CD3, a protein on the surface of T cells (cells of the immune system). By attaching to CD20 and CD3 proteins, Ordspono brings the cancer cells and T cells together. This activates the T cells which then kill the cancer cells, helping to control the disease.

What benefits of Ordspono have been shown in studies?

Ordspono was tested in a main study involving patients with different types of lymphoma, including 128 patients with follicular lymphoma and 127 patients with DLBCL, whose cancer had returned or not responded after at least two previous treatments. Ordspono was not compared with any other treatment.

The study showed that around 80% of patients with follicular lymphoma had a response to treatment: about 73% (94 out of 128) had a complete response (no signs of cancer) and 7% (9 out of 128) had a partial response after 52 weeks of treatment. The responses were maintained for an average of 23 months. Of the patients with DLBCL about 52% responded to treatment: about 31% (40 out of 127) had a complete response and 20% (26 out of 127) had a partial response after 36 weeks of treatment. The responses were maintained for 11 months on average.

What are the risks associated with Ordspono?

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

The most common side effects with Ordspono (which may affect more than 1 in 5 people) include cytokine release syndrome, neutropenia ((low levels of neutrophils, a type of white blood cell that fights infection), fever, anaemia (low levels of red blood cells), thrombocytopenia (low levels of blood platelets), diarrhoea and COVID-19.

The most common serious side effects include cytokine release syndrome (which may affect more than 1 in 10 people), as well as pneumonia (lung infection), COVID-19 and fever, which may affect up to 1 in 10 people.

Why is Ordspono authorised in the EU?

At the time of approval, there were limited treatment options for patients with follicular lymphoma or DLBCL whose cancer had returned or not responded after at least two systemic therapies. In studies most patients had a response to treatment, which was either complete or partial. Although the medicine was not compared with other treatments, these results are considered highly relevant for these patients. In terms of safety, the side effects with Ordspono are similar to those seen with other medicines of the same class. Although serious side effects can occur, measures will be in place to help manage these risks. The European Medicines Agency therefore decided that Ordspono's benefits are greater than its risks and it can be authorised for use in the EU.

Ordspono has been given conditional authorisation. This means that it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The Agency considers that the benefit of having the medicine available earlier outweighs any risks associated with using it while awaiting further evidence.

The company must provide further data on Ordspono. It must submit data on the effectiveness and safety of the medicine in patients with relapsed or refractory follicular lymphoma or DLBCL compared with that of other therapies for treating these cancers. Every year, the Agency will review any new information that becomes available.

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

The company that markets Ordspono will provide an alert card to patients receiving the medicine with important information on the risk of cytokine release syndrome and neurological toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS, a neurological disorder with symptoms that include problems with speech and writing, confusion and altered consciousness). The card will include instructions on when to seek urgent attention from a healthcare provider or seek emergency help.

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

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

Other information about Ordspono

Ordspono received a conditional marketing authorisation valid throughout the EU on 22 August 2024.

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

This overview was last updated in 08-2024.