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SCIENCE MEDICINES HEALTH

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Withdrawal of application to change the marketing authorisation for Adcetris (brentuximab vedotin)

Takeda Pharma A/S withdrew its application for the use of Adcetris in adults with previously untreated CD30-positive peripheral T-cell lymphoma not otherwise specified (PTCL-NOS).

The company withdrew the application on 23 February 2024.

What is Adcetris and what is it used for?

Adcetris is a cancer medicine used to treat adults with certain lymphomas (cancers of lymphocytes, types of white blood cells) when the cancer cells have a protein called CD30 on their surface (CD30-positive).

In Hodgkin's lymphoma, Adcetris is used:

- together with doxorubicin, vinblastine and dacarbazine (other cancer medicines) in patients whose cancer is advanced (stage III or IV disease) and has not been treated before;
- when the cancer has come back or has not responded to an autologous stem cell transplant (a transplant of the patient's own blood-producing cells);
- if the cancer is likely to come back or get worse after an autologous stem cell transplant;
- when the cancer has come back or has not responded to at least two other therapies and when autologous stem cell transplant or multi-agent chemotherapy (a combination of cancer medicines) cannot be used.

In non-Hodgkin's lymphoma, Adcetris is used for:

- systemic anaplastic large cell lymphoma (sALCL, a cancer of lymphocytes called T cells) when the cancer has never been treated before; Adcetris is used together with cyclophosphamide, doxorubicin and prednisone. It is also used when the cancer has come back or when other treatments have not worked;
- cutaneous T-cell lymphoma (CTCL), a lymphoma of T cells that initially affects the skin, in patients who have received at least one previous treatment.

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Adcetris has been authorised in the EU since October 2012. It contains the active substance brentuximab vedotin and is available as a powder that is made into a solution for infusion (drip) given into a vein.

Further information on Adcetris's current uses can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/adcetris.

What change had the company applied for?

The company applied to extend the use of Adcetris to adults with CD30-positive peripheral T-cell lymphoma not otherwise specified (PTCL-NOS), when the cancer has not been treated before. Adcetris was intended to be used in combination with cyclophosphamide, doxorubicin and prednisone.

Adcetris was designated an 'orphan medicine' (a medicine used in rare diseases) for [peripheral T cell lymphoma](#) 21 August 2019.

How does Adcetris work?

The active substance in Adcetris, brentuximab vedotin, is made up of a monoclonal antibody (a type of protein) that attaches to CD30 and is linked to monomethyl auristatin E, a cytotoxic (cell-killing) molecule. The monoclonal antibody delivers monomethyl auristatin E to the CD30-positive cancer cells. The cytotoxic molecule then enters the cancer cells and prevents them from dividing, causing the cancer cells to die.

What did the company present to support its application?

The company submitted additional data from a main study involving 452 patients with CD30-positive PTCL who received either Adcetris with cyclophosphamide, doxorubicin and prednisone (Adcetris plus CHP) or a combination of cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP), a standard treatment. The study looked at how long patients with different subtypes of PTCL lived without their disease getting worse.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the initial information from the company and had prepared questions for the company.

What did the Agency recommend at that time?

Based on the review of the information, at the time of the withdrawal, the Agency's opinion was that the company had not provided enough information to support the application for a change to the marketing authorisation of Adcetris to include treatment of CD30-positive PTCL-NOS.

The main study involved patients with different types of CD30-positive PTCL; there were too few patients with PTCL-NOS. These patients were not evenly distributed between the two treatment groups and the characteristics of the patients in both groups were not similar. It was also unclear whether results seen in other types of PTCL could be applied to those with PTCL-NOS. Therefore, the Agency considered that there were uncertainties regarding the effectiveness of Adcetris in patients with PTCL-NOS.

What were the reasons given by the company for withdrawing the application?

In its [letter](#) notifying the Agency of the withdrawal of application, the company stated that it withdrew its application because the Agency considered that the data provided were not sufficient to support the extension of indication for Adcetris to include adults with previously untreated CD30-positive PTCL-NOS.

Does this withdrawal affect patients in clinical trials?

There are no consequences for patients in clinical trials using Adcetris.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.

What is happening with Adcetris for the treatment of other diseases?

There are no consequences on the use of Adcetris in its authorised uses.