



European Medicines Agency  
Pre-authorisation Evaluation of Medicines for Human Use

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*Please note that this product was withdrawn from the Community Register of designated Orphan Medicinal Products in July 2008 on request of the sponsor.*

## **COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS**

### **PUBLIC SUMMARY OF POSITIVE OPINION FOR ORPHAN DESIGNATION OF human monoclonal antibody against HLA-DR for the treatment of Hodgkin's lymphoma**

On 16 June 2005, orphan designation (EU/3/05/291) was granted by the European Commission to GPC Biotech AG, Germany, for human monoclonal antibody against HLA-DR for the treatment of Hodgkin's lymphoma.

#### **What is Hodgkin's lymphoma?**

Hodgkin's lymphoma is a type of cancer that develops in the lymphatic system. The lymphatic system is part of the body's immune system: the body's natural defence against infection and disease. It is a complex system made up of organs such as bone marrow (the spongy tissue inside the large bones in the body), the thymus and the spleen, and a network of lymph nodes throughout the body that are connected by lymphatic vessels. Because lymphatic tissue is found throughout the body, Hodgkin's lymphoma can begin in almost any part of the body and spread to almost any tissue or organ in the body. Normally, the proliferation of lymphatic cells takes place in a controlled manner but, in Hodgkin's lymphoma, this process gets out of control and the cells continue to divide, developing into a tumour. Hodgkin's lymphoma can occur in both adults and children; however, treatment for adults may be different from treatment for children. Hodgkin's lymphoma can usually be cured if found and treated early. However, despite the available treatments, Hodgkin lymphoma remains a serious and life-threatening condition in certain patients.

#### **What are the methods of treatment available?**

Three different types of standard treatment are available and used: chemotherapy (using drugs to kill cancer cells), radiotherapy (using high-energy x-rays or other types of high-energy rays to kill cancer cells) and surgery (removing all possible cancer tissue in an operation). Bone marrow transplantation is also used. Several treatments had been authorised at the time of submission of the application for orphan drug designation.

Human monoclonal antibody against HLA-DR could be of potential significant benefit for the treatment of Hodgkin's lymphoma because it might act in a different way than other types of treatment. This assumption will have to be confirmed at the time of marketing authorisation. This will be necessary to maintain the orphan status.

**What is the estimated number of patients affected by the condition\*?**

Based on the information provided by the sponsor and previous knowledge of the Committee, Hodgkin's lymphoma was considered to affect approximately 1 in 10,000 persons in the European Union, which, at the time of designation, corresponded to about 46,000 persons.

**How is this medicinal product expected to act?**

Antibodies are proteins in the body that target and bind specific structures on the surface of foreign bodies, such as bacteria or cancer cells. Human monoclonal antibody against HLA-DR is an antibody that recognises a specific area of human leucocyte antigen-DR (HLA-DR), which is a protein present in the surface of some cells in the body. In experimental conditions it has been shown that when the antibody binds HLA-DR, it triggers the death of some malignant cells, and amongst them Hodgkin's lymphoma cells.

**What is the stage of development of this medicinal product?**

The effects of human monoclonal antibody against HLA-DR were evaluated in experimental models.

The medicinal product was not authorised anywhere worldwide for Hodgkin's lymphoma or designated as orphan medicinal product elsewhere for this condition, at the time of submission.

According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 12 May 2005 a positive opinion recommending the grant of the above-mentioned designation.

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Opinions on orphan medicinal products designations are based on the following cumulative criteria: (i) the seriousness of the condition, (ii) the existence or not of alternative methods of diagnosis, prevention or treatment and (iii) either the rarity of the condition (considered to affect not more than five in ten thousand persons in the Community) or the insufficient return of development investments.

Designated orphan medicinal products are still investigational products which were considered for designation on the basis of potential activity. An orphan designation is not a marketing authorisation. As a consequence, demonstration of the quality, safety and efficacy will be necessary before this product can be granted a marketing authorisation.

**For more information:**

Sponsor's contact details:

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\* Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed based on data from the European Union (EU 25), Norway, Iceland and Lichtenstein. This represents a population of 459,700,000 (Eurostat 2004). This estimate is based on available information and calculations presented by the sponsor at the time of the application.

Patients' associations contact points:

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**Leukaemia Care**

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**Translations of the active ingredient and indication in all EU languages  
and Norwegian and Icelandic**

<b>Language</b>	<b>Active Ingredient</b>	<b>Indication</b>
English	Human Monoclonal Antibody against HLA-DR	Treatment of Hodgkin's lymphoma
Czech	Lidská monoklonální protilátka proti HLA-DR	Léčba Hodgkinova lymfomu
Danish	Humant monoklonalt antistof mod HLA-DR	Behandling af Hodgkin lymfom
Dutch	Humaan monoklonaal antilichaam tegen HLA-DR	Behandeling van Hodgkin lymfoom
Estonian	HLA-DR vastane inimese monoklonaalne antikeha	Hodgkini lümfoomi ravi
Finnish	Humanisoitu monoklonaalinen HLA-DR-vasta-aine	Hodgkinin lymfooman hoito
French	Anticorps monoclonal humain contre HLA-DR	Traitement du lymphome de Hodgkin
German	Humaner monoklonaler Antikörper gegen HLA-DR	Behandlung des Hodgkin-Lymphoms
Greek	Ανθρώπινο μονοκλωνικό αντίσωμα κατά HLA-DR	Θεραπεία του λεμφώματος Hodgkin
Hungarian	HLA-DR elleni humán monoklonális ellenanyag	Hodgkin lymphoma kezelése
Italian	Anticorpo monoclonale umano contro l'HLA-DR	Trattamento del linfoma di Hodgkin
Latvian	Cilvēka monoklonālās antivielas pret HLA-DR	Hodžkina limfomas ārstēšana
Lithuanian	Žmogaus monokloninis antikūnas prieš ŽLA-DR	Hodžkino limfomos gydymas
Polish	ludzkie przeciwciało monoklonalne przeciwko HLA-DR	Leczenie chłoniaka Hodgkina (ziarnicy złośliwej)
Portuguese	Anticorpo monoclonal humano contra o HLA-DR	Tratamento do linfoma de Hodgkin
Slovak	Ľudské monoklonné protilátky proti HLA-DR	Liečba lymfómu Hodgkinovho typu
Slovenian	Človeška monoklonska protitelesa proti HLA-DR	Zdravljenje Hodgkinovega limfoma
Spanish	Anticuerpo monoclonal humano contra HLA-DR	Tratamiento del linfoma de Hodgkin
Swedish	Human monoklonal antikropp mot HLA-DR	Behandling av Hodgkin lymfom
Norwegian	Humant monoklonalt antistoff mot HLA-DR	Behandling av Hodgkin-lymfom
Icelandic	Einstofna mótefni úr mönnum gegn HLA-DR mótefnavökum	Meðferð við Hodgkins sjúkdómi