



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Yttrium (⁹⁰Y) antiferritin polyclonal antibodies for the treatment of Hodgkin lymphoma

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Rev.1: sponsor's change of address	29 May 2007
Rev.2: sponsor's name change	5 June 2013
Disclaimer Please note that revisions to the Public Summary of Opinion are purely administrative updates. Therefore, the scientific content of the document reflects the outcome of the Committee for Orphan Medicinal Products (COMP) at the time of designation and is not updated after first publication.	

On 2 October 2003, orphan designation (EU/3/03/162) was granted by the European Commission to Monoclonal Antibodies Therapeutics (MAT), France, for Yttrium (⁹⁰Y) antiferritin polyclonal antibodies for the treatment of Hodgkin lymphoma.

In January 2013, Monoclonal Antibodies Therapeutics (MAT) changed name to Mablife.

What is Hodgkin lymphoma?

Hodgkin 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 than 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 is the estimated number of patients affected by the condition?

At the time of designation, Hodgkin lymphoma affected approximately 1.2 in 10,000 people in the European Union (EU). This was equivalent to a total of around 46,000 people*, and is below the ceiling for orphan designation, which is 5 people in 10,000. This is based on the information provided by the sponsor and the knowledge of the Committee for Orphan Medicinal Products (COMP).

What treatments are 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.

Yttrium (^{90}Y) antiferritin polyclonal antibodies could be of potential significant benefit for the treatment of Hodgkin lymphoma, because they may 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.

How is this medicine expected to work?

Yttrium (^{90}Y) antiferritin polyclonal antibodies are a complex formed by specific antibodies linked to the radioactive form of a chemical called Yttrium. An antibody is a protein that targets and links specific shapes on the surface of foreign bodies, such as bacteria or cancer cells. Yttrium (^{90}Y), is a chemical element, which can give off radiation. The antiferritin polyclonal antibodies are thought to recognise the tissues where Hodgkin lymphoma cells are. This might then trigger the body's immune system to attack the cancer cells. In addition, Yttrium (^{90}Y) can give off radiation, which can damage and kill nearby cells, especially those that are dividing, such as cancer cells.

What is the stage of development of this medicine?

At the time of submission of the application for orphan designation, no clinical trials in patients with Hodgkin lymphoma were initiated.

Yttrium (^{90}Y) antiferritin polyclonal antibodies was not marketed anywhere worldwide for the Hodgkin lymphoma or designated as orphan medicinal product elsewhere for this condition, at the time of submission.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 30 July 2003 recommending the granting of this designation.

*Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed on the basis of data from the European Union.
At the time of designation, this represented a population of 382,800,000 (Eurostat 2003).

Opinions on orphan medicinal product designations are based on the following three criteria:

- the seriousness of the condition;
- the existence of alternative methods of diagnosis, prevention or treatment;
- either the rarity of the condition (affecting not more than 5 in 10,000 people in the EU) or insufficient returns on investment.

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

For more information

Sponsor's contact details:

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For contact details of patients' organisations whose activities are targeted at rare diseases see:

- [Orphanet](#), a database containing information on rare diseases which includes a directory of patients' organisations registered in Europe.
- [European Organisation for Rare Diseases \(EURORDIS\)](#), a non-governmental alliance of patient organisations and individuals active in the field of rare diseases.

Translations of the active ingredient and indication in all official EU languages¹

Language	Active Ingredient	Indication
English	Yttrium (⁹⁰ Y) antiferritin polyclonal antibodies	Treatment of Hodgkin lymphoma
Danish	Yttrium (⁹⁰ Y) antiferritin polyklonale antistoffer	Behandling af Hodgkin lymfom
Dutch	Yttrium (⁹⁰ Y) antiferritine polyklonale antilichamen	Behandeling van Hodgkin lymfoom
Finnish	Yttrium(⁹⁰ Y) antiferritiiniset polyklonaaliset vasta-aineet	Hodgkin lymfooman hoito
French	Anticorps polyclonaux anti-ferritine marqués à l'Yttrium (⁹⁰ Y)	Traitement du lymphome de Hodgkin
German	Yttrium (⁹⁰ Y) polyklonale Antiferritin-Antikörper	Behandlung des Hodgkin-Lymphoms
Greek	Υττριο (⁹⁰ Y) – πολυκλωνικά αντισώματα αντιφερριτίνης	Θεραπεία του λεμφώματος Hodgkin
Italian	Anticorpi policlonali antiferritina all'itrio (⁹⁰ Y)	Trattamento del linfoma di Hodgkin
Portuguese	Anticorpos policlonais Ítrio (⁹⁰ Y) - antiferritina	Tratamento do linfoma de Hodgkin
Spanish	Anticuerpos policlonales antiferritina con itrio (⁹⁰ Y)	Tratamiento del linfoma de Hodgkin
Swedish	Yttrium (⁹⁰ Y) antiferritin polyklonalaantikroppar	Behandling av Hodgkin lymfom

¹ At the time of designation