



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

London, 14 October 2009
Doc.Ref.: EMEA/COMP/475406/2009

Committee for Orphan Medicinal Products

Public summary of positive opinion for orphan designation of recombinant antibody construct against human CD30 and CD16A for the treatment of Hodgkin's lymphoma

On 9 October 2009, orphan designation (EU/3/09/673) was granted by the European Commission to Affimed Therapeutics AG, Germany, for recombinant antibody construct against human CD30 and CD16A for the treatment of Hodgkin's lymphoma.

What is Hodgkin's lymphoma?

Hodgkin's lymphoma is a type of cancer of the lymphatic system, a network of vessels that transport lymph from tissues through the lymph nodes and into the bloodstream. Because the lymphatic system is found throughout the body, the cancer can begin in almost any part of the body.

In Hodgkin's lymphoma, the lymphatic cancer cells multiply too quickly and live for too long, so there are too many of them in a lymph node. Sometimes these cells spread through the lymphatic system to other lymph nodes and they may also enter the bloodstream which carries them to various organs, forming new tumours. When the disease progresses, patients may develop serious infections and sepsis (generalised spreading of infection through the blood).

Many people with Hodgkin's lymphoma can be cured if the disease is found and treated early. However, despite the available treatments, Hodgkin's lymphoma remains a serious and life-threatening disease in some patients because of its complications.

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

At the time of designation, Hodgkin's lymphoma affected approximately 1 in 10,000 people in the European Union (EU)*. This is equivalent to a total of 50,000 people, and is below the threshold for orphan designation, which is 5 people in 10,000. This is based on the information provided by the sponsor and knowledge of the Committee for Orphan Medicinal Products (COMP).

What treatments are available?

At the time of designation, several medicines were authorised for the treatment of Hodgkin's lymphoma in the EU. The main treatments for Hodgkin's lymphoma included chemotherapy (medicines to treat cancer) and radiotherapy (treatment with radiation). Autologous bone marrow transplantation was also used when patients had not responded to treatment or when the disease had come back after treatment. This is a complex procedure where the bone marrow of the patient is destroyed and replaced with healthy bone marrow previously obtained from the same patient. The sponsor has provided sufficient information to show that recombinant antibody construct against human CD30 and CD16A might be of significant benefit for patients with Hodgkin's lymphoma because it works in a different way to existing treatments. Early studies indicate that it might represent an alternative way to treat Hodgkin's lymphoma, in particular in patients who cannot receive or do not

*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 (EU 27), Norway, Iceland and Liechtenstein. This represents a population of 504,800,000 (Eurostat 2009).

respond to standard chemotherapy. These assumptions will need to be confirmed at the time of marketing authorisation, in order to maintain the orphan status.

How is this medicine expected to work?

Recombinant antibody construct against human CD30 and CD16A is a protein that is made up of two antibody-like components, each of which is designed to recognise and attach to a specific structure (antigen):

- CD30, a receptor that is found in large amounts on the surface of Hodgkin's lymphoma cells;
- CD16A, a receptor that is found on the surface of cells of the immune system (the body's natural defences) called natural killer cells and macrophages.

This medicine is expected to attach simultaneously to Hodgkin's lymphoma cells through CD30, and natural killer cells and macrophages through CD16A. By attaching to CD16A, this medicine is expected to stimulate the natural killer cells and macrophages to kill the Hodgkin's lymphoma cells to which they are attached.

What is the stage of development of this medicine?

The effects of recombinant antibody construct against human CD30 and CD16A have been evaluated in experimental models.

At the time of submission of the application for orphan designation, no clinical trials in patients with Hodgkin's lymphoma had been started.

At the time of submission, this medicine was not authorised anywhere in the EU for Hodgkin's lymphoma or designated as an orphan medicinal product elsewhere for this condition.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 8 July 2009 recommending the granting of this designation.

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 Community) 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:

Affimed Therapeutics AG

Im Neuenheimer Feld 582

69120 Heidelberg

Germany

Telephone: +49 6221 65309 20

Telefax: +49 6221 65307 77

E-mail: info@affimed.com

Patient associations' contact points:

Ligue Nationale Contre le Cancer

14 Rue Corvisart

75013 Paris

France

Telephone: +33 (0)1 53 55 24 00

Telefax: +33 (0)1 43 36 91 10

E-mail: ligue@ligue-cancer.net

European Cancer Patient Coalition

ECPC Office

Am Rothenanger 1b

85521 Riemerling

Germany

Telephone: +49 89 628 36 807

Telefax: +49 89 628 36 808

E-mail: info@ecpc-online.org

Macmillan Cancer Support

3 Bath Place

Rivington Street

London EC2A 3JR

United Kingdom

Telephone: +44 (0) 20 7696 9003

Telefax: +44 (0)20 7696 9002

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

Language	Active ingredient	Indication
English	Recombinant antibody construct against human CD30 and CD16A	Treatment of Hodgkin lymphoma
Bulgarian	Рекомбинантен анти тяло елемент срещу човешки CD30 и CD16A	Лечение на лимфом на Ходжкин
Czech	Rekombinantní protilátka antiCD20 a antiCD16A	Léčba Hodgkinova lymfomu
Danish	Rekombinant antistofderivatmod humant CD30 og CD16A	Behandling af Hodgkin lymfom
Dutch	Recombinant antilichaamderivaat gericht tegen humaan CD30 en CD16A	Behandeling van Hodgkin lymfoom
Estonian	Inimese CD 30 ja CD 16A vastu konstrueeritud rekombinantne antikeha	Hodgkini lümfoomi ravi
Finnish	Rekombinantti vasta-aineen johdannainen ihmisen CD30:a ja CD16A:a vastaan	Hodgkinin lymfooman hoito
French	Anticorps recombinant dirigé contre les antigènes CD30 et CD16A humains	Traitement du lymphome de Hodgkin
German	Rekombinantes Antikörperkonstrukt gegen humanes CD30- und CD16A-Antigen	Behandlung des Hodgkin-Lymphoms
Greek	Ανασυνδυασμένο παράγωγο αντισώματος έναντι των ανθρώπινων CD30 και CD16A	Θεραπεία του λεμφώματος Hodgkin
Hungarian	Humán CD30- és CD16A-ellenes rekombináns antitest-készítmény	Hodgkin lymphoma kezelése
Italian	Derivato di anticorpo ricombinante anti-CD30 e CD16A umani	Trattamento del linfoma di Hodgkin
Latvian	Rekombinants antivielu veidojums pret cilvēka CD30 un CD16A antigēniem	Hodžkina limfomas ārstēšana
Lithuanian	Rekombinantinis antikūnas sukurtas prieš žmogaus CD30 ir CD16A	Hodžkino limfomos gydymas
Maltese	Antikorp rikombinanti maħdum kontra CD30 u CD16A uman	Kura tal-linfoma ta' Hodgkin
Polish	Rekombinowane przeciwciało przeciwko ludzkim antygenom CD 30 i CD 16A	Leczenie chłoniaka Hodgkina (ziarnicy złośliwej)
Portuguese	Anticorpo recombinante contra os antígenos humanos CD30 e CD16A	Tratamento do linfoma de Hodgkin
Romanian	Anticorp recombinant uman anti CD30 și CD16A	Tratamentul limfomului Hodgkin
Slovak	Rekombinantný protilátkový konštrukt proti ľudskému CD30 a CD16A	Liečba lymfómu Hodgkinovho typu
Slovenian	Rekombinantni konstrukt protiteles proti človeškima antigenoma CD30 in CD16A	Zdravljenje Hodgkinovega limfoma
Spanish	Complejo de anticuerpo recombinante contra los antígenos humanos CD30 y CD16A	Tratamiento del linfoma de Hodgkin
Swedish	Rekombinant antikroppsderivat riktat mot humant CD30 och CD16A	Behandling av Hodgkin lymfom
Norwegian	Rekombinant antistoffderivat rettet mot CD30 og CD16A	Behandling av Hodgkin-lymfom

Icelandic	Raðbrigða mótefni gegn manna CD30 og CD16A	Meðferð við Hodgkins sjúkdómi
-----------	--	-------------------------------