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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Chimeric-anti-interleukin 6 monoclonal antibody for the treatment of Castleman's disease

First publication	29 July 2008
Rev.1: sponsor's name change	8 November 2011
Rev.2: information about Marketing Authorisation	26 June 2014

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 30 November 2007, orphan designation (EU/3/07/508) was granted by the European Commission to Centocor, B.V., The Netherlands, for chimeric-anti-interleukin 6 monoclonal antibody for the treatment of Castleman's disease.

Centocor B.V. changed its name to Janssen Biologisc B.V. in July 2011.

What is Castleman's disease?

Castleman's disease is a disorder of the lymphatic system (lymph nodes and lymphatic vessels, where, among other things, fluids and cells of the immune system circulate). In affected patients, for an unknown reason, cells in lymphoid tissue start proliferating causing primarily abnormally large lymph nodes, often with benign tumours. In a majority of cases, the disease is located to only one lymph node, but in some cases the disease is systemic (affects the entire body) and affects several lymph nodes as well as other organs in the body. Affected patients have an increased risk of infections, kidney failure and certain cancers. Castleman's disease is chronically debilitating and life threatening, especially for patients with more than one affected lymph node.

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

At the time of designation, Castleman's disease affected less than 1 in 10,000 people in the European Union (EU). This was equivalent to a total of fewer than 50,000 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?

There are no medicinal products authorised for the treatment of Castleman's disease in the Community. In some mild cases of the disease, affected lymph nodes can be removed surgically. However, in most cases, only symptomatic treatment is available.

How is this medicine expected to work?

Chimeric-anti-interleukin 6 monoclonal antibody is a protein molecule designed to bind and neutralise a compound called interleukin 6 in the body. Interleukin 6 belongs to a family of compounds called cytokines, which mediate processes in the immune system. It has been shown that interleukin 6 itself promotes growth and survival of cells. It is thought that chimeric-anti-interleukin 6 monoclonal antibody will inhibit interleukin 6 from binding to its receptor on the lymphatic cells and thus inhibiting the excessive growth of these cells in affected patients.

What is the stage of development of this medicine?

The effects of Chimeric-anti-interleukin 6 monoclonal antibody were evaluated in experimental models.

At the time of submission of the application for orphan designation, clinical trials in patients with Castleman's disease were ongoing.

Chimeric-anti-interleukin 6 monoclonal antibody was not authorised anywhere worldwide for the treatment of Castleman's disease, at the time of submission.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 10 October 2007 recommending the granting of this designation.

Update: chimeric-anti-interleukin 6 monoclonal antibody (Sylvant) has been authorised in the EU since 22 May 2014 for the treatment of adult patients with multicentric Castleman's disease (MCD who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

More information on Sylvant can be found in the European public assessment report (EPAR) on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports

*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.
At the time of designation, this represented a population of 500,300,000 (Eurostat 2007).

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 languages[1], Norwegian and Icelandic

Language	Active Ingredient	Indication
English	Chimeric-anti-interleukin-6 monoclonal antibody	Treatment of Castleman's disease
Bulgarian	Химеричнo анти-интерлевкин-6 моноклонално антитяло	Лечение на болестта на Кастелман
Czech	Chimérní kombinovaná myší-lidská monoklonální protilátka proti interleukinu 6	Léčba Castlemanovy choroby
Danish	Kimærisk anti-interleukin 6 monoklonalt antistof	Behandling af Castlemans sygdom
Dutch	Chimeer anti-interleukine 6 monoklonaal antilichaam	Behandeling van de ziekte van Castleman
Estonian	Kimäärne anti-interleukiin 6 monoklonaalne antikeha	Castelman'i tõve ravi
Finnish	Kimeerinen anti-interleukiini 6:n monoklonaalinen vasta-aine	Castlemanin taudin hoito
French	Anticorps chimère anti-interleukine-6	Traitement de la maladie de Castleman
German	Chimärer monoklonaler anti-Interleukin-6 Antikörper	Behandlung der Castleman-Krankheit
Greek	αντι Ιντερλευκινη-6 χιμαιρικό (άνθρωπος-ποντίκι) μονοκλωνικό αντίσωμα	Θεραπεία της νόσου του Castleman
Hungarian	Chimera anti-interleukin 6, monoklonális antitest	Castleman-betegség kezelése
Italian	Anticorpo monoclonale chimerico anti-interleuchina 6	Trattamento della malattia di Castleman
Latvian	Himēriska anti-interleikīna-6 monoklonālas antivielas	Kāslmena sindroma ārstēšana
Lithuanian	Chimerinis monokloninis antikūnas prieš interleukiną-6	Castleman'o ligos gydymas
Maltese	Anti-korp monoklonali kimeriku kontra l-*interleukin* tat-tip 6	Kura tal-marda ta' Castleman
Polish	Chimeryczne przeciwciało monoklonalne przeciw interleukinie 6	Leczenie choroby Castlemana
Portuguese	Anticorpo monoclonal quimérico, antagonista da interleucina 6	Tratamento da doença de Castleman
Romanian	Anticorp monoclonal anti-interleukină 6 chimeric	Tratamentul bolii lui Castelman
Slovak	Chimérická myšia-ľudská monoklonálna protilátka proti interleukínu 6	Liečba Castelmanovej choroby

[1] At the time of designation

Language	Active Ingredient	Indication
Slovenian	Himerno humanizirano mišje monoklonsko protitelo proti interleukinu 6	Zdravljenje Castlemanove bolezni
Spanish	Anticuerpo monoclonal quimérico anti-interleukina 6	Tratamiento de la enfermedad de Castleman
Swedish	Chimär anti-interleukin 6 monoklonal antikropp	Behandling av Castlemans sjukdom
Norwegian	Kimerisk anti-interleukin 6 monoklonalt antistoff	Behandling av Castlemans sykdom
Icelandic	Músa-manna and-interleukín 6 einstofna blendings (chimeric) mótefni	Meðferð við Castleman sjúkdómi