9 February 2015
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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 multiple myeloma

First publication	30 June 2009
Rev.1: sponsor's name change	8 November 2011
Rev.2: withdrawal from the Community Register	9 February 2015

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.

Please note that this product was withdrawn from the Community Register of designated Orphan Medicinal Products in July 2014 on request of the Sponsor.

On 12 June 2009, orphan designation (EU/3/09/642) was granted by the European Commission to Centocor B.V., the Netherlands, for chimeric-anti-interleukin-6 monoclonal antibody for the treatment of multiple myeloma.

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

What is multiple myeloma?

Multiple myeloma is a cancer of a type of white blood cells called plasma cells. Plasma cells are found in the bone marrow, the spongy tissue inside the large bones in the body. In multiple myeloma the division of plasma cells becomes out of control, resulting in abnormal, immature plasma cells multiplying and filling up the bone marrow. This interferes with production of normal white blood cells, red blood cells and platelets (components that help the blood to clot), leading to complications such as anaemia (low red blood cell counts), bone pain and fractures, raised blood calcium levels and kidney disease.

Multiple myeloma is a life-threatening disease that leads to poor long-term survival.

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

At the time of designation, multiple myeloma affected approximately 2.2 in 10,000 people in the European Union (EU). This was equivalent to a total of around 111,000 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 submission of the application for orphan designation, several medicines were already authorised for multiple myeloma in the EU. The main treatment for multiple myeloma is chemotherapy (medicines to treat cancer) usually combined with steroids (medicines used to reduce the activity of the immune system). Treatment with radiotherapy (using radiation to kill cancer cells) can be very useful in treating pain and weakened bones. Interferon alfa, a protein normally produced by the body during viral infections, can sometimes be used in combination with chemotherapy.

The sponsor has provided sufficient information to show that chimeric-anti-interleukin-6 monoclonal antibody might be of significant benefit for patients with multiple myeloma because it works in a different way to existing treatments, and may be used in combination with other medicines to improve their effectiveness. 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?

Chimeric-anti-interleukin-6 monoclonal antibody is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a specific structure (an antigen) called interleukin-6 (IL-6). IL-6 is a protein in the immune system (the body's natural defences) that plays a role in the growth, survival and spread of cancerous plasma cells in multiple myeloma. By attaching to IL-6, the monoclonal antibody is expected to block the protein's activity, slowing down the growth and spread of the cancer.

What is the stage of development of this medicine?

The effects of chimeric-anti-interleukin-6 monoclonal antibody have been evaluated in experimental models.

At the time of submission of the application for orphan designation, clinical trials in patients with multiple myeloma were ongoing.

At the time of submission, this medicine was not authorised anywhere in the EU for multiple myeloma. Orphan designation of this medicine had been granted in the United States of America for multiple myeloma.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 5 May 2009 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 (EU 27), Norway, Iceland and Liechtenstein.
At the time of designation, this represented a population of 502,800,000 (Eurostat 2008).

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 multiple myeloma
Bulgarian	Химериччно анти-интерлевкин-6 моноклонално антитяло	Лечение на мултиплен миелом
Czech	Chimérní kombinovaná myší-lidská monoklonální protilátka proti interleukinu 6	Léčba mnohočetného myelomu
Danish	Kimærisk anti-interleukin 6 monoklonalt antistof	Behandling af multipelt myelom
Dutch	Chimeer anti-interleukine 6 monoklonaal antilichaam	Behandeling van multipel myeloom
Estonian	Kimäärne anti-interleukiin 6 monoklonaalne antikeha	Multiibelse müeloomi ravi
Finnish	Kimeerinen anti-interleukiini 6:n monoklonaalinen vasta-aine	Multippeli myelooman hoito
French	Anticorps chimère anti-interleukine-6	Traitement du myélome multiple
German	Chimärer monoklonaler anti-Interleukin-6 Antikörper	Behandlung des multiplen Myeloms
Greek	αντι Ιντερλευκινη-6 χιμαιρικό (άνθρωπος-ποντίκι) μονοκλωνικό αντίσωμα	Θεραπευτική αγωγή πολλαπλού μυελώματος
Hungarian	Chimera anti-interleukin 6, monoklonális antitest	Myeloma multiplex kezelése
Italian	Anticorpo monoclonale chimerico anti-interleuchina 6	Trattamento del mieloma multiplo
Latvian	Himēriska anti-interleikīna-6 monoklonālas antivielas	Multiplās mielomas ārstēšana
Lithuanian	Chimerinis monokloninis antikūnas prieš interleukiną-6	Dauginės mielomos gydymas
Maltese	Anti-korp monoklonali kimeriku kontra l-interleukin tat-tip 6	Kura tal-mjeloma multipla
Polish	Chimeryczne przeciwciało monoklonalne przeciw interleukinie 6	Leczenie szpiczaka mnogiego
Portuguese	Anticorpo monoclonal quimérico, antagonista da interleucina 6	Tratamento do mieloma múltiplo
Romanian	Anticorp monoclonal anti-interleukină 6 chimeric	Tratamentul mielomului multiplu
Slovak	Chimérická myšia-ľudská monoklonálna protilátka proti interleukínu 6	Liečba mnohopočetného myelómu
Slovenian	Himerno humanizirano mišje monoklonsko protitelo proti interleukinu 6	Zdravljenje multiplega mieloma
Spanish	Anticuerpo monoclonal quimérico anti-interleukina 6	Tratamiento del mieloma múltiple

[1] At the time of designation

Language	Active ingredient	Indication
Swedish	Chimär anti-interleukin 6 monoklonal antikropp	Behandling av multipelt myelom
Norwegian	Kimerisk anti-interleukin 6 monoklonalt antistoff	Behandling av myelomatose
Icelandic	Músa-manna and-interleukín 6 einstofna blendings (chimeric) mótefni	Meðferð við mergfrumuæxli