8 November 2011
EMA/COMP/1193/2003 Rev.1
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Chimeric-anti-interleukin-6 monoclonal antibody for the treatment of renal cell carcinoma

Please note that this product was withdrawn from the Community Register of designated Orphan Medicinal Products in September 2011 on request of the Sponsor.

On 30 June 2003, orphan designation (EU/3/03/148) was granted by the European Commission to Centocor B.V, The Netherlands, for chimeric-anti-interleukin-6 monoclonal antibody for the treatment of renal cell carcinoma.

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

What is renal cell carcinoma?

Renal cell carcinoma (also called cancer of the kidney or renal adenocarcinoma) is a disease in which cancer (malignant) cells are found in certain tissues of the kidney. Inside each kidney are tiny tubules that filter and clean the blood, taking out waste products, and making urine. Renal cell carcinoma is a cancer of the lining of the tubules in the kidney. Renal cell carcinoma accounts for approximately 85% of all kidney cancers. Signs of cancer are difficult to detect in early stages of the disease, and about half of the patients are diagnosed when the disease has spread around the kidney or to distant parts of the body. Surgery is a common treatment of renal cell cancer, and allows taking out the cancer in an operation, although the cancer may appear again. Renal cell carcinoma is life-threatening.

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

At the time of designation, renal cell carcinoma affected approximately 3 in 10,000 people in the European Union (EU)*. This is equivalent to a total of around 113,000 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).

*Disclaimer: The number of patients affected by the condition is estimated and assessed for the purpose of the designation, for a European Community population of 377,000,000 (Eurostat 2001) and may differ from the true number of patients affected by the condition. This estimate is based on available information and calculations presented by the sponsor at the time of the application.

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What treatments are available?

There are treatments for most patients with renal cell cancer. These may include surgery (taking out the cancer in an operation), chemotherapy (using drugs to kill cancer cells), radiation therapy (using high-dose x-rays or other high-energy rays to kill cancer cells), hormone therapy (using hormones to stop cancer cells from growing), and biological therapy (using the body's immune system to fight cancer). Biologic agents, such as interleukin-2 and interferon-α, are primary therapies for advanced cancer. Other anticancer agents were also authorised in the Community for treatment of renal cell carcinoma at the time of submission of the application for orphan designation. Chimeric-anti-interleukin-6 monoclonal antibody might be of potential significant benefit for the treatment of renal cell carcinoma, particularly as it might offer a new way to inhibit tumour growth. This assumption remains to be proven. This will be necessary to maintain the orphan status.

How is this medicine expected to work?

Antibodies are proteins which specifically recognise and attach themselves to certain foreign substances, such as proteins found on the surface of cancer cells or bacteria. Certain antibodies are called chimeric because they are composed of parts that were first found in different species of living organisms. In the case of the chimeric-anti-interleukin-6 monoclonal antibody, the species are mouse, and human. The term "monoclonal" means that the antibody is produced using cells that have identical genes, so each one producing exactly the same antibody molecules. Chimeric-anti-interleukin-6 monoclonal antibody targets a protein called interleukin-6 (IL-6). Interleukin-6 is involved in many processes in the human body. There is preliminary evidence that blocking the action of interleukin-6 may also block cancer cells proliferation. Thus, chimeric-anti-interleukin-6 monoclonal antibody might block the growth of renal cell carcinoma.

What is the stage of development of this medicine?

The evaluation of the effects of chimeric-anti-interleukin-6 monoclonal antibody in experimental models is ongoing.

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

Chimeric-anti-interleukin-6 monoclonal antibody was not marketed anywhere worldwide for renal cancer or designated as orphan medicinal product elsewhere for this condition, at the time of submission of the application to the EMEA.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 8 May 2003 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 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 renal cell carcinoma
Danish	Kimerisk anti-interleukin-6 monoclonalt antistof	Behandling af renalcellecarcinom
Dutch	Chimeer anti-interleukine-6 monoclonaal antilichaam	Behandeling van renaal celcarcinoom
Finnish	Kimeerinen monoklonaalinen anti-IL-6 vasta-aine	Munuaissolukarsinooman hoito
French	anticorps chimère anti-interleukine-6	Traitement du carcinome rénal
German	Chimärer anti-Iinterleukin-6 monoklonaler Antikörper	Behandlung des Nierenzellkarzinoms
Greek	Χιμαιρικό μονοκλωνικό αντίσωμα έναντι Ιντερλευκίνης -6	Θεραπεία του νεφροκυτταρικού καρκινώματος
Italian	Anticorpo monoclinale chimerico anti-interleuchina-6	Trattamento di carcinoma a cellule renali
Portuguese	Anticorpo monoclonal quimérico anti-interleucina 6	Tratamento do carcinoma de células renais
Spanish	Anticuerpo monoclonal quimérico anti-interleucina 6	Tratamiento del carcinoma de células renales
Swedish	Chimär anti-interleukin 6 monoklon antikropp	Behandling av njurcellskarcinom

[1] At the time of designation