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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Iodine (131I) chimeric IgG monoclonal antibody cG250 for the treatment of renal cell carcinoma

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Rev.1: administrative update	8 January 2003
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Rev.4: withdrawal from the Community Register	6 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.	

Please note that this product was withdrawn from the Community Register of designated Orphan Medicinal Products in April 2014 on request of the Sponsor.

On 19 March 2002, orphan designation (EU/3/02/095) was granted by the European Commission to Wilex AG, Germany, for iodine (^{131}I) chimeric IgG monoclonal antibody cG250 for the treatment of renal cell carcinoma.

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.

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

At the time of designation, renal cell carninoma affected approximately 3.1 in 10,000 people in the European Union (EU). This was equivalent to a total of 118,000 people*, and was 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 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). The primary therapies for advanced cancer are biologic agents, such as interleukin-2 (IL-2) and interferon-α (IFN-α). Other anticancer agents had also been authorised in the Community for treatment of renal cell carcinoma at the time of submission of the application for orphan designation. Iodine (^{131}I)-cG250 might be of potential significant benefit for the treatment of renal cell carcinoma, particularly as it might offer a new way to kill cancer cells.

How is this medicine expected to work?

Iodine (^{131}I)-cG250 reacts with an antigen, which is expressed by the most frequent type of renal cell carcinomas. The radioactivity is directed to the tumour cells and induces toxicity to tumour cells.

What is the stage of development of this medicine?

The effects of iodine (^{131}I)-cG250 have been evaluated in experimental models.

At the time of submission of the application for orphan designation, clinical trials were ongoing.

Iodine (^{131}I)-cG250 had not been marketed anywhere worldwide for renal cell carcinoma, at the time of submission.

Orphan drug status had been granted by the United States Food and Drug Administration (FDA) ^{131}I-labelled cG250 monoclonal antibodies to treat renal cell carcinoma.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 23 January 2002 recommending the granting of this designation.

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*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 380,600,000 (Eurostat 2002).

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	Iodine (^{131}I) chimeric IgG monoclonal antibody cG250	Treatment of renal cell carcinoma
Danish	Jod (^{131}I) kimerisk IgG monoclonalt antistof cG250	Behandling af renal celle carcinom
Dutch	Iodine (^{131}I) chimerisch IgG monoclonaal cG250	Behandeling van renaal cel carcinoma
Finnish	Jodilla (^{131}I) kimeerinen IgG monoklonaalinen vasta-aine cG250	Munuaissyövän hoito
French	Anticorps IgG monoclonal chimérique cG250 marqué à l'iode (^{131}I)	Traitement du carcinome rénal
German	Iod (^{131}I) chimärer IgG monoklonaler Antikörper cG250	Behandlung des Nierenzellkarzinoms
Greek	Ιώδιο (^{131}I) χιμαιρικό μονοκλωνικό IgG αντίσωμα G250-c	Θεραπεία καρκινώματος νεφρικού παρεγχύματος
Italian	Iodo (^{131}I) anticorpo monoclonale IgG chimerico cG250	Trattamento del carcinoma renale
Portuguese	Iodo (^{131}I) anticorpo IgG monoclonal quimérico	Tratamento do carcinoma renal
Spanish	Yodo (^{131}I) anticuerpo IgG monoclonal quimérico cG250	Tratamiento del carcinoma de células renales
Swedish	Jod (^{131}I) chimär IgG monoklonal antikropp cG250	Behandling av njurcellscarcinom

[1] At the time of designation