The European Agency for the Evaluation of Medicinal Products
Pre-authorisation Evaluation of Medicines for Human Use

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COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

PUBLIC SUMMARY OF POSITIVE OPINION FOR ORPHAN DESIGNATION OF chimeric IgG monoclonal antibody cG250 for the treatment of renal cell carcinoma

On 19 March 2002, orphan designation (EU/3/02/094) was granted by the European Commission to Wilex AG, Germany, for 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.

What are the methods of treatment 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. Autologous tumour vaccine 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.

What is the estimated number of patients affected by the condition*?
According to the information provided by the sponsor, renal cell carcinoma was considered to affect about 117,000 persons in the European Union.

How is this medicinal product expected to act?
The antibody cG250 reacts with an antigen, which is expressed by the most frequent type of renal cell carcinomas. This antigen-antibody reaction induces toxicity to the tumour cells.

What is the stage of development of this medicinal product?
The effects of cG250 have been evaluated in experimental models. At the time of submission of the application for orphan designation, clinical trials were ongoing.

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The chimeric monoclonal antibody cG250 had not been marketed anywhere worldwide for renal cell carcinoma, at the time of submission. Orphan drug status has been granted by the United States Food and Drug Administration (FDA) for the cG250 monoclonal antibody to treat renal cell carcinoma.

According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 23 January 2002 a positive opinion recommending the grant of the above mentioned designation.

Opinions on orphan medicinal products designations are based on the following cumulative criteria: (i) the seriousness of the condition, (ii) the existence or not of alternative methods of diagnosis, prevention or treatment and (iii) either the rarity of the condition (considered to be affecting not more than five in ten thousand persons in the Community) or the insufficient return of development investments.

Designated orphan medicinal products are still investigational products, which have been considered for designation on the basis of potential activity. An orphan designation is not a marketing authorisation. As a consequence, demonstration of the quality, safety and efficacy will be necessary before this product can be granted a marketing authorisation.

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*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.