



COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

**PUBLIC SUMMARY OF
POSITIVE OPINION FOR ORPHAN DESIGNATION
OF
oregovomab
for the treatment of ovarian cancer**

On 30 July 2002, orphan designation (EU/3/02/109) was granted by the European Commission to Dorian Regulatory Affairs, The Netherlands, for oregovomab for the treatment of ovarian cancer. The sponsorship was transferred to ViRexx International Corp. Limited, Ireland, in May 2007.

What is ovarian cancer?

Tumours that begin in the ovaries are known as ovarian tumours. Ovarian tumours which have potential to grow rapidly and infiltrate surrounding healthy tissues are called ovarian cancers. Due to the absence of symptoms in early stages of the disease the majority of the patients are diagnosed when the tumours have spread locally or to distant parts of the body and cannot be entirely removed. Ovarian cancer is a life-threatening condition.

What are the methods of treatment available?

Several anticancer medicinal products were authorised for the condition in the Community at the time of submission of the application for orphan designation. Although a significant percentage of patients respond to the initial chemotherapy, most ovarian cancers grow again and respond moderately or poorly to subsequent chemotherapy. Satisfactory argumentation has been submitted by the sponsor to justify the assumption that oregovomab might be of potential significant benefit for the treatment of ovarian cancer, particularly based on the novel mechanism of action.

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

According to the information provided by the sponsor, ovarian cancer was considered to affect about 86,000 persons in the European Union.

How is this medicinal product expected to act?

Oregovomab is an antibody, which is a protein used by the immune system of the body. Oregovomab binds to a protein released by ovarian cancer tissue. This binding stimulates an immune response of the organism against the cancer cells, which might cause the immune system to recognise and kill cancer cells.

What is the stage of development of this medicinal product?

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

Oregovomab has been designated as an orphan medicinal product in the United States for treatment of ovarian cancers and had not been marketed anywhere worldwide for ovarian cancer, at the time of submission.

According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 27 June 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.

For more information:

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