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 recombinant glycoprotein gp350 of Epstein-Barr virus for the prevention of post-transplantation lympho-proliferative disorders

On 22 October 2002, orphan designation (EU/3/02/118) was granted by the European Commission to Henogen S.A., Belgium, for the recombinant glycoprotein gp350 of Epstein-Barr virus for the prevention of post-transplantation lympho-proliferative disorders.

What are the post-transplantation lympho-proliferative disorders?
The lymphatic system consists of the tissues and organs that produce, store, and carry white blood cells that fight infection and other diseases. Cancer (malignant) cells that arise from the lymphatic system in patients after a transplant of an organ, may cause a condition which is called "post-transplantation lympho-proliferative disorders" (PTLD). PTLD is a life-threatening condition similar to other cancers arising in the lymphatic system (lymphomas). Organ transplant requires the administration of drugs that inhibit the immune response, to prevent rejection of transplanted organs, and this may contribute to the development of the disease. Also, a virus called Epstein-Barr virus (EBV), may trigger the rapid multiplication of the cells of the lymphatic system, and this may cause that the cells become malignant in patients in whom the immune response has been inhibited.

What are the methods of prevention available?
There is no medicinal product specifically authorised in the European Union for prevention of the condition. Reduction of the treatment that inhibits the immune system allows it to react and fight against the EBV infection, and prevent lymphocyte proliferation. However, this exposes the patient to a risk of rejection of the transplanted organ.

What is the estimated number of patients at risk of developing the condition*?
According to the information provided by the sponsor, the number of patients eligible for prevention of PTLD was estimated to approximately 87,000 persons in the European Union.

How is this medicinal product expected to act?
The EBV vaccine proposed would allow patients to build immunity against EBV before transplantation. By consequence patients transplanted and receiving immunosuppressive therapy would be less vulnerable to such EBV infections and therefore less at risk of developing PTLD.

What is the stage of development of this medicinal product?
The effects of recombinant glycoprotein gp350 of Epstein-Barr virus have been evaluated in experimental models.

At the time of submission of the application for orphan designation, clinical trials had been initiated.

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Recombinant glycoprotein gp350 of Epstein-Barr virus had not been marketed anywhere worldwide for prevention of PTLD or designated as orphan medicinal product elsewhere for this condition, 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 12 September 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 affect 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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*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.