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

Document Date: London, 26 May 2003
EMEA/COMP/2410/02/Rev 1

COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

PUBLIC SUMMARY OF POSITIVE OPINION FOR ORPHAN DESIGNATION OF iodine (^{131}I) anti-nucleohistone H1 chimeric biotinylated monoclonal antibody for the treatment of glioma

On 13 November 2002, orphan designation (EU/3/02/119) was granted by the European Commission to Interface International Consultancy Limited, United Kingdom, for iodine (^{131}I) anti-nucleohistone H1 chimeric biotinylated monoclonal antibody for the treatment of glioma.

What are gliomas?
Tumours that begin in brain tissue are known as primary brain tumours. Primary brain tumours are classified by the type of tissue from which they originate. The most common brain tumours are gliomas, which begin in the glial (supportive) tissue.
Due to their location, gliomas represent a potentially debilitating and life-threatening condition. Patients affected by gliomas can suffer from medical problems to the nervous system, depending on where in the brain the tumour develops.

What are the methods of treatment available?
Treatment for gliomas depends on a number of factors and may include surgery, radiotherapy or chemotherapy as well as symptomatic treatments. Symptomatic treatments include certain steroid hormones (corticosteroids) to control the effects of raised pressure within the skull, and medication to help control seizures, as required. Methods of treatment of glioma were authorised at the time of submission of the application for orphan designation. Iodine (^{131}I) anti-nucleohistone H1 chimeric biotinylated monoclonal antibody might be of potential significant benefit for the treatment of gliomas, particularly as it is expected to work differently compared to existing treatments.

What is the estimated number of patients affected by the condition*?
According to the information provided by the sponsor, gliomas were considered to affect about 30,000 patients in the European Union.

How is this medicinal product expected to act?
The product is a radioactive element (iodine 131) attached to an antibody. 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. In the case of this antibody, the target is a protein (nucleohistone) which is generally found inside the cells. However, where cells are rapidly dying, as in the centre of a tumour, this protein is also found outside the cells. Thus, this antibody is expected to accumulate in the tumour, so that the beta rays produced by the attached iodine 131 will kill the tumour cells. The product is administered directly into the tumour tissue.

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 gliomas were ongoing.

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Iodine (^{131}I) anti-nucleohistone H1 chimeric biotinylated monoclonal antibody was not marketed anywhere worldwide for gliomas, at the time of submission. Orphan designation of this medicinal product was granted in the United States for the treatment of glioblastoma multiforme and anaplastic astrocytoma on 12 February 1999.

According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 9 October 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 were 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.