European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

London, 16 March 2005
EMEA/COMP/17/04

COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

PUBLIC SUMMARY OF NEGATIVE OPINION FOR ORPHAN DESIGNATION OF histamine dihydrochloride for the treatment of malignant melanoma

On 14 January 2004, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on orphan designation of histamine dihydrochloride for the treatment of malignant melanoma. A negative decision was granted by the European Commission on 24 August 2004.

The sponsor applied for orphan designation on the basis of the severity and rarity of the condition, as well as an assumption of potential benefit despite currently available methods of treatment.

The negative opinion is based on the following elements:

- the sponsor has not provided sufficient justification for the exclusion of thin melanomas from the condition which is the scope of the application (melanomas of <0.75 mm in depth considered by the sponsor to be cured at time of diagnosis)
- the sponsor has not established that malignant melanoma affects not more than 5 in 10,000 persons in the Community at the time the application was made.

Requests for designation as orphan medicinal products are made for investigational products. Absence of orphan designation does not preclude the development of this product, in particular through clinical trials, and subsequently the possibility of obtaining a marketing authorisation if quality, safety and efficacy are demonstrated.

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*Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed based on data from the European Union (EU 25), Norway, Iceland and Lichtenstein. This represents a population of 459,700,000 (Eurostat 2004). This estimate is based on available information and calculations presented by the sponsor at the time of the application