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 negative opinion for orphan designation of ibritumomab tiuxetan for use with ^{90}Yttrium for the treatment of B-cell non-Hodgkin's lymphoma

On 20 March 2001 the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on orphan designation of ibritumomab tiuxetan for use with ^{90}Yttrium in the treatment of B-cell non-Hodgkin's lymphoma. A negative decision was adopted by the European Commission on 1 February 2002.

The sponsor, Schering AG, Germany, applied for orphan designation of ibritumomab tiuxetan for use with ^{90}Yttrium for treatment of patients with CD20+ indolent B-cell non-Hodgkin`s lymphoma. This application was based on the severity and rarity of the condition, as well as on assumption of potential significant benefit despite currently available methods of treatment.

The negative opinion was based on the following grounds:

- For the purpose of designation as orphan medicinal product, limiting the indication to the subset proposed was not acceptable as an effect in a broader population (including aggressive B-cell non-Hodgkin`s lymphoma) had not been excluded.
- It had not been established that B-cell non-Hodgkin´s lymphoma (including both indolent and aggressive forms) affect not more than 5 in 10,000 persons in the Community.

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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