



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

4 August 2010  
EMA/COMP/110198/2010  
Committee for Orphan Medicinal Products

## Public summary of opinion on orphan designation

### Gastrin 17C diphtheria toxoid conjugate for the treatment of pancreatic cancer

On 3 February 2010, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on the orphan designation application for gastrin 17C diphtheria toxoid conjugate for the treatment of pancreatic cancer. A negative decision was granted by the European Commission on 16 July 2010.

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

The negative opinion was based on the following reason:

The sponsor had not provided sufficient evidence to justify a claim that gastrin 17C diphtheria toxoid conjugate might have been of significant benefit for patients with pancreatic cancer. The justification provided by the sponsor was mainly based on data obtained with a related product, as well as on other pharmacological data that the sponsor had extrapolated to the product. The Committee did not agree that these data could be extrapolated. The COMP therefore concluded that there was not sufficient information to show that the product for which designation was applied might have had a clinically relevant advantage compared with existing treatments, nor that the product might have represented a major contribution to patient care. This justification was necessary because other satisfactory methods of treatment for pancreatic cancer had already been authorised in the European Union.

Requests for designation as an orphan medicinal product are made for investigational products. Absence of orphan designation does not preclude the development of this product, including its use in clinical trials. A marketing authorisation can still be obtained if quality, safety and efficacy are demonstrated.



## **For more information:**

Sponsor's contact details:

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