European Medicines Agency
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 G17(9) gastrin-diphtheria toxoid conjugate for the treatment of gastric cancer

On 28 January 2003, orphan designation (EU/3/02/130) was granted by the European Commission to Orion Clinical Services Limited, United Kingdom, for G17(9) gastrin-diphtheria toxoid conjugate for the treatment of gastric cancer.
The sponsorship was transferred to Kendle International Ltd, United Kingdom, in December 2004 and subsequently to Cato Europe GmbH, Germany, in March 2009.

What is gastric cancer?
Cancer that begins in the stomach is called gastric cancer. The stomach is part of the digestive system. In most cases, the cancer cells originate from the lining of the stomach (mucosa). Cancers originating from the mucosa are called adenocarcinomas. Although today there are fewer new patients with gastric cancer every year compared to the past, gastric cancer remains one of the main causes of cancer. Gastric cancer is life-threatening.

What is the estimated number of patients affected by the condition*?
At the time of designation, gastric cancer affected approximately 2 in 10,000 people in the European Union (EU)*. This is equivalent to a total of around 75,000 people, and is below the threshold for orphan designation, which is 5 people in 10,000. This is based on the information provided by the sponsor and knowledge of the Committee for Orphan Medicinal Products (COMP).

What treatments are available?
The choice of the treatment of gastric cancers depends on several factors, including the stage of the disease. Treatments may include surgery, radiation therapy, and drug therapy. Medicinal products were authorised for use in gastric cancer in the European Union. Due to its new mode of action, G17(9) gastrin-diphtheria toxoid conjugate may be of potential significant benefit for patients affected by the condition. The benefit of G17(9) gastrin-diphtheria toxoid conjugate will have to be confirmed at the time of marketing authorisation. This will be necessary to maintain the orphan status.

How is this medicine expected to work?
Gastrin is a hormone that is normally produced by the body. Gastrin stimulates the stomach to produce gastric secretions. Gastrin also makes certain digestive system cancers grow faster. G17(9) gastrin-diphtheria toxoid conjugate is designed to stimulate the body to make antibodies against gastrin. Antibodies are proteins which specifically recognise and block certain substances. Antibodies against gastrin are expected to specifically link to this hormone, thus blocking its activity. This would consequently slow down the growth of gastric cancer.

*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.

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What is the stage of development of this medicine?
At the time of submission of the application for orphan designation, clinical trials in patients with gastric cancer were ongoing.

At the time of submission, the medicinal product was not marketed anywhere worldwide for gastric cancer. Orphan designation of G17(9) gastrin-diphtheria toxoid conjugate was granted in the United States and in Australia in gastric cancer.

According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 13 December 2002 a positive opinion recommending the grant of the above-mentioned designation.

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Opinions on orphan medicinal product designations are based on the following three criteria:
- the seriousness of the condition;
- the existence of alternative methods of diagnosis, prevention or treatment;
- either the rarity of the condition (affecting not more than 5 in 10,000 people in the Community) or insufficient returns on investment.

Designated orphan medicinal products are products that are still under investigation and are considered for orphan designation on the basis of potential activity. An orphan designation is not a marketing authorisation. As a consequence, demonstration of quality, safety and efficacy is necessary before a product can be granted a marketing authorisation.

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